

I Like the Way You Work It... Creating Effective Compliance Programs

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Presented By:

UT Southwestern Medical Center Office of Compliance and Audit Services

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Office of Institutional Compliance and Audit Services



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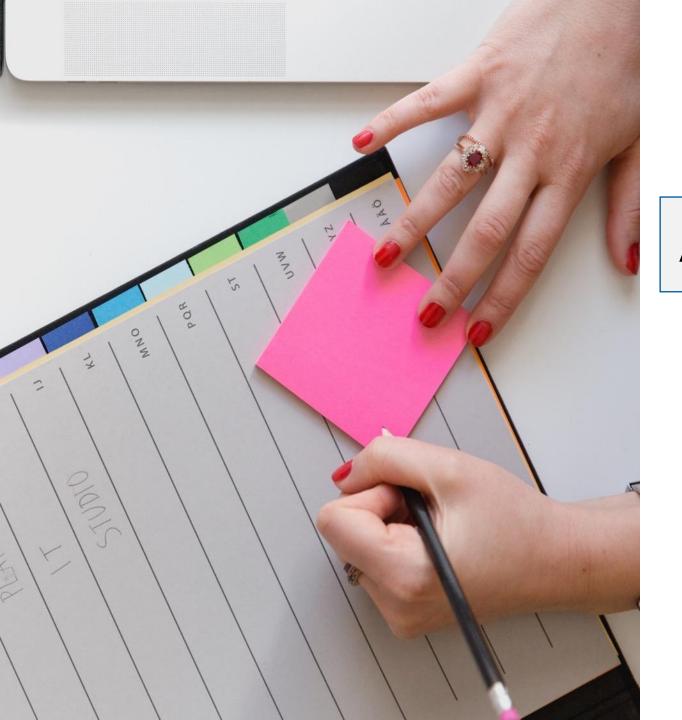
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OBJECTIVES

- Identify key elements of a compliance program tailored to organizational needs.
- Develop strategies for continuous monitoring, development of effective KPIs and regular program updates.
- Foster a culture of integrity through targeted employee training and engagement.





AGENDA

- I. Who Are We
- II. When Compliance Programs Are Ineffective
- III. 7 Elements of an Effective Compliance Program
- IV. Measuring Compliance Program Effectiveness
- V. Auditing & Monitoring
- VI. Building Effective Key Performance Indicators
- VII. Training & Employee Engagement
- VIII.Resources

KNOW THE AUDIENCE

- HEALTH SYSTEMS
- ACADEMIC MEDICAL CENTERS
- PHYSICIAN PRACTICES
- HEALTH CARE PLANS
- NURSING FACILITIES
- OTHER

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105,000 hospital patients, 370,000 ER cases, 3 million outpatient visits

2700+ clinical and

research faculty with \$500 Million in research funding

Integrate biomedical research with clinical care & education



2 hospitals & 80+ clinics

Medical Care in 80 specialities





School of Health Professions & School of Public Health

6 Nobel Laureates



UT Southwestern Medical Center is a premier Academic Medical Institution operating in and around Dallas, Texas.

ABOUT UTSW

OFFICE OF INSTITUTIONAL COMPLIANCE & AUDIT SERVICES

Expect to encounter willing partners, ready to provide support, with awareness of potential risks and knowledge of best practices to maintain compliant business units.





WHEN COMPLIANCE PROGRAMS ARE INEFFECTIVE...

US women's national soccer team captain says players are 'angry' and want immediate changes following misconduct investigation

Over 300 Alleged Sexual Abuse Victims Sue Columbia University—Claim Ex-**Gynecologist Richard Hadden** Is 'Most Prolific' Predator In N.Y. History

U.S. gymnasts testify about abuse by Larry Nassar: "We have been failed"

What did Michigan State know about Larry Nassar's abuse?

IS IT JUST ABOUT CHECKING THE BOX...



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COMPLIANCE CAN NEVER BE ABOUT JUST CHECKING THE BOX...

- Investigations often fail from the very beginning.
- In the earlier examples, reports were made, the Hotline was used, but no evidence of investigation coordination, interviews or final reports could be produced.
- It's important to have appropriate subject matter experts for each allegation to adjudicate those issues (independent factfinders that aren't biased). This is a critical element of an effective compliance program.
- Getting the allegation to the right place is the first critical step in conducting effective and robust investigations.

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WHERE IS THE GUIDANCE COMING FROM...

- Federal Sentencing Guidelines
- Department of Health Human Services (DHHS) Office of Inspector General's (OIG) publication of the "Compliance Program Guidance for Hospitals", "Supplemental Compliance Program Guidance for Hospitals" and "General Compliance Program Guidance"
- U.S. Department of Justice (DOJ) Criminal Division Fraud Section "Evaluation of Corporate Compliance Programs"
- Yates Memo
- The Affordable Care Act (ACA) mandates the establishment of compliance programs for all Medicare and Medicaid participating providers









WHAT DO THE REGULATORS SAY ABOUT EFFECTIVENESS

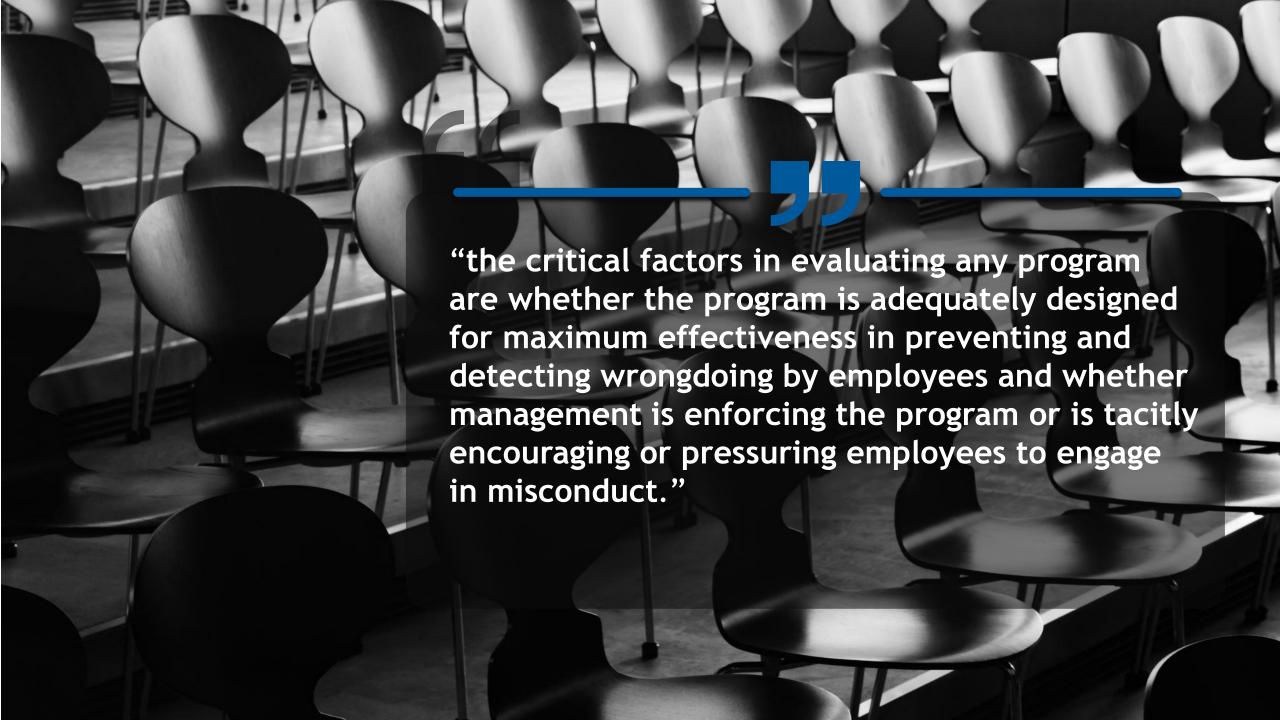
- The 1991 Federal Sentencing Guidelines (FSG) provided incentives for organizations to create "effective" compliance programs, which included sentencing credit for organizations that demonstrate that they have implemented an effective compliance program.
- The 2004 FSG amendments added further clarification into what constitutes an effective compliance program, including anonymous reporting, effective training, and ongoing risk assessments.
- June 1, 2020, the Criminal Division of the U.S. Department of Justice (DOJ) released updated guidance to its prosecutors on how to evaluate the design, implementation, and effective operation of corporate compliance programs in determining whether, and to what extent, the DOJ considers a corporation's compliance program to have been effective at the time of the offense and to be effective at the time of a charging decision or resolution.
 - ✓ The guidance updates a prior version issued on April 30, 2019.



If an organization can demonstrate that they have implemented an effective compliance program, the severity of an offense can be reduced.

DO THEY GIVE US A FRAMEWORK OR STANDARDS...

- The 2020 guidance outlines three (3) "fundamental questions" a prosecutor should ask:
 - I. "Is the corporation's compliance program well-designed?"
 - II. "Is the program being applied earnestly and in good faith?"
 - In other words, is the program adequately resourced and empowered to function effectively?
 - III. "Does the corporation's compliance program work" in practice?
 - As such, the DOJ guidance is frequently used as a benchmark to determine whether a compliance program is effective.



IS THE COMPLIANCE PROGRAM WELL DESIGNED...

- 5 Areas of Review: What is the company's process for identifying risk?
 - ✓ Review policies and procedures to ensure the company has established processes to prevent and detect misconduct.
 - Established processes to prevent and detect misconduct.
 - ✓ Appropriately tailored training and communication.
 - ✓ Assess whether the company's complaint-handling process includes proactive measures to create a workplace atmosphere that encourages reporting of misconduct without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers.
 - Oversight of third-party partners.

IS THE PROGRAM BEING APPLIED EARNESTLY AND IN GOOD FAITH...

- How the program has been implemented and supported by company leadership.
- The commitment by senior and middle management, the autonomy and resources of the Compliance Department, and the establishment of incentives for compliance and disincentives for non-compliance.
- Ensure that the Compliance Department can act with independence and autonomy when needed.
- The extent to which the company has conveyed to employees that unethical conduct will not be tolerated and will bring swift consequences, regardless of the position or title of the employee who engages in the conduct.
- Determine if the Compliance Department was adequately funded and had enough resources to complete compliance efforts.
 - ✓ "Has there been sufficient staffing for compliance personnel to effectively audit, document, analyze and act on the results of compliance efforts?"

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DOES THE COMPLIANCE PROGRAM WORK IN PRACTICE....

- The DOJ guidance directs prosecutors to consider, among other factors, "whether the corporation has made significant investments in, and improvements to, its corporate compliance program and internal controls systems."
- One hallmark of an effective compliance program is its capacity to improve and evolve along with changes in the business landscape including patients, customers, laws impacting the business, and industry practices overall. Accordingly, prosecutors will consider whether the company has engaged in meaningful efforts to review its compliance program and ensure that it is not stale.

DOES THE COMPLIANCE PROGRAM WORK IN PRACTICE...

- The DOJ advises that prosecutors look at three (3) areas to determine if the Compliance
 Program has grown and evolved to work in practice.
 - ✓ Assess how frequently the company has conducted audits and then implemented management/corrective action in response to audit results.
 - Additionally, the DOJ guidance suggests that a company periodically perform a gap analysis to ensure that policies, procedures, and training properly cover identified risk areas.
 - ✓ Determining if the program works in practice is the existence of a well-functioning investigation process.
 - ✓ An indicator of a compliance program that is working effectively in practice is the extent to which the company conducts a thoughtful root cause analysis of misconduct and timely and appropriately remediate to address the root causes.



General Compliance Program Guidance

November 2023

APPOINT A
COMPLIANCE OFFICER
AND CONSIDER
SEGREGATING THE ROLE
WITH RESPECT TO
COMPLIANCE
FUNCTIONS



CODE OF CONDUCT

ADOPT A CODE OF CONDUCT THAT SETS FORTH THE ENTITY'S GOALS, MISSION AND ETHICAL AND COMPLIANCE REQUIREMENTS

EDUCATE LEADERSHIP
ON THE SEVEN
ELEMENTS OF AN
EFFECTIVE
COMPLIANCE
PROGRAM





INCENTIVIZE RAISING COMPLIANCE CONCERNS



RIGHT-SIZE THE GCPG GUIDANCE FOR THE ORGANIZATION

ADDRESS
COMPLIANCE RISK
AREAS RELEVANT TO
THE ENTITY'S
SPECIFIC
HEALTHCARE
SUBINDUSTRY





TRAIN STAFF ON COMPLIANCE



ENSURE
COMMUNICATION
WITH RESPECT
TO AN ENTITY'S
COMPLIANCE
PROGRAMS



ADD QUALITY AND
PATIENT SAFETY
GOALS TO AN ENTITY'S
COMPLIANCE
PROGRAMS

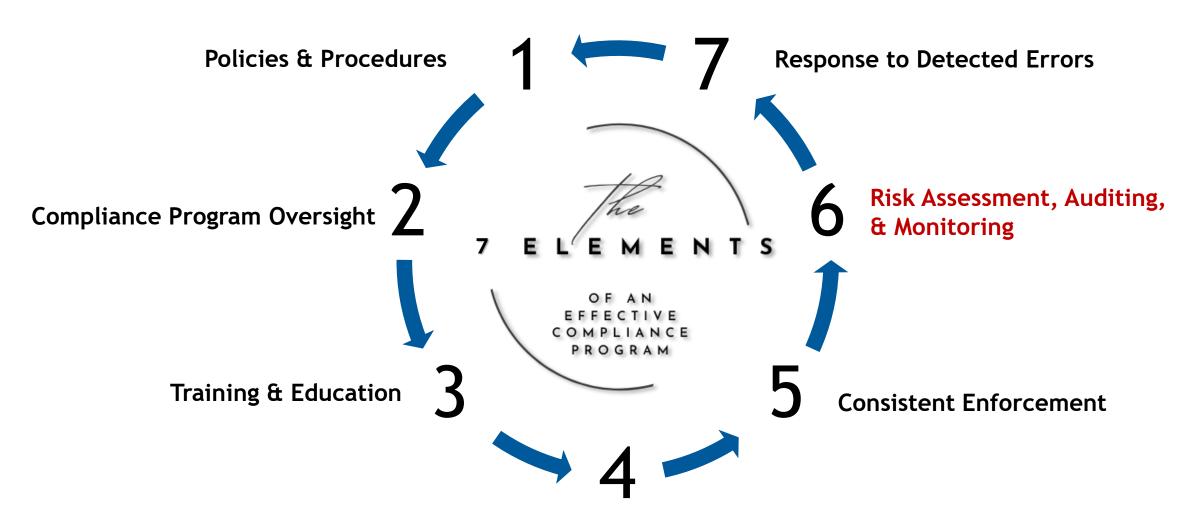


KEY THEMES

- OIG highlights the importance of healthcare regulatory compliance knowledge and familiarity for "new entrants" and entities tangential to the traditional healthcare industry, such as private equity funds and investors, social services organizations and technology companies.
- OIG structures the GCPG as a broad resource for compliance for healthcare industry stakeholders and entities.
- OIG uses the GCPG to stress flexibility and adaptability for compliance programs depending on entity size and organizational needs.
- OIG plans to introduce industry-specific guidance in the future to focus on specific sectors, which also highlights the OIG's emphasis on flexible, adaptable compliance programs depending on an entity's characteristics and needs.
- OIG reiterates its seven fundamental elements of an effective compliance program with some updates to focus on governance, quality and integration.
- OIG directly links compliance to quality and patient safety.



7 ELEMENTS OF AN EFFECTIVE COMPLIANCE PROGRAM



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Open Lines of Communication



4 STEP PROCESS...

- Analyze compliance program documentation (e.g., program governance, policies and procedures, Code of Conduct, meeting minutes, monitoring reports, training materials, etc.).
- Assess the Compliance Department's resources and personnel, appropriateness of organizational structure and reporting relationships, and maturity of methodology employed for training, auditing, corrective action plans, etc.
- Interview key compliance and management personnel to gain insight into the operation, reach, perception, and overall effectiveness compliance program; and
- Reviewed documentation of a sample of activities to evaluate adherence to both practices discussed in interviews and policies and procedures.
 - ✓ Testing should be robust, this is where a lot of CPE evaluations fail.

EFFORT & OUTCOME

- Effort is the time, money, resources and commitment that an organization puts into building and improving a compliance program.
- Outcomes are the impact that our efforts have on our level of compliance.
- As the compliance program matures, the principal measure of effectiveness moves from effort to outcomes. Practice Tip: Always document outcomes.

EXAMPLES POLICIES & PROCEDURES

Effort

- ✓ Do policies and procedures exist for relevant topics and areas?
- ✓ Has a risk assessment been completed to identify the relevant risk areas?
- ✓ Are the policies comprehensive?
- ✓ Are policies understandable and capable of being fully applied?
- ✓ Have the requirements of the policies and procedures been communicated to employees?
- ✓ Have any audits been conducted to monitor compliance with the policies and procedures?

Outcome

- ✓ Have audits revealed fewer errors in the areas where policies have been implemented?
- ✓ Upon testing, are the internal controls established by policies working?
- ✓ When interviewing employees during an audit or review, do they understand what the policies require?

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STEPS OF AN AUDIT



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SAMPLE WORK PLAN

UT Southwestern Medical Center FY 2025 Office of Institutional Compliance Work Plan

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STATUS LEGEND

= Completed

= Not Started

= Deferred / Canceled

#	Compliance Focus Area	Goal / Objective	Program Element	Quarter to be Performed	Status	Estimated Dedicated Hours	
1	I HB	Quarterly assessments of clinical department billing, coding, and clinical documentation with a primary focus on HB.	Auditing & Monitoring	Ongoing	•	1500	
2	РВ	Quarterly assessments of clinical department billing, coding, and clinical documentation with a primary focus on PB.	Auditing & Monitoring	Ongoing	•	1500	
3	PK PK	Follow-up assessment of APP billing, coding, and clinical documentation, with a primary focus on incident-to billing and split/shared billing.	Auditing & Monitoring	Q1	•	200	
4	Operations	Follow-up assessment of the Medicare Outpatient Observation Notice (MOON) process.	Auditing & Monitoring	Q3	•	200	

EVALUATING COMPLIANCE PROGRAM EFFECTIVENESS

- The OIG emphasizes that compliance programs must include ongoing evaluation and monitoring of adherence to compliance policies and procedures.
- Continuous auditing and monitoring helps to demonstrate program effectiveness and identify potential risks early.
- These practices align with the OIG's general recommendation for regular audits, risk assessments, and corrective action plans in effective compliance programs to ensure compliance with laws and regulations.





WHAT ARE KEY PERFORMANCE INDICATORS

 KPIs are measurable values that indicate how effectively a compliance program is achieving its objectives.

WHY KPIS MATTER



Demonstrate the effectiveness of the compliance program



Identify areas for improvement

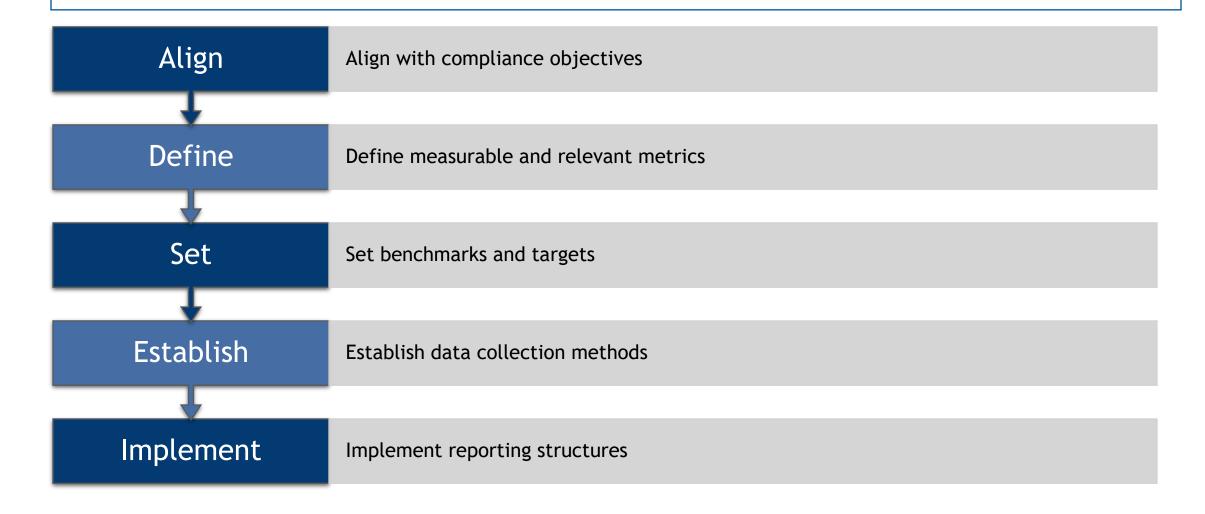


Enhance accountability and transparency



Support regulatory compliance and risk mitigation

STEPS TO DEVELOP COMPLIANCE KPIS



TYPES OF COMPLIANCE KPIS



Process-Based KPIs (e.g., completion of compliance training)



Outcome-Based KPIs (e.g., reduction in compliance violations)



Operational KPIs (e.g., time taken to resolve compliance issues)



EXAMPLES OF COMPLIANCE KPIS

- % of employees completing annual compliance training
- Number of reported compliance concerns per quarter
- Time to resolve compliance investigations
- Audit pass rate for regulatory compliance
- % of policy updates communicated to employees

SETTING BENCHMARKS AND TARGETS

- Compare against industry standards
- Use historical data to set realistic goals
- Adjust benchmarks as compliance needs evolve



DATA COLLECTION AND REPORTING



USE COMPLIANCE
MANAGEMENT SYSTEMS TO
TRACK KPIS



ESTABLISH AUTOMATED REPORTING PROCESSES



REGULARLY REVIEW KPI DATA WITH LEADERSHIP

HOW TO PRESENT KPI DATA

- Dashboards for real-time insights
- Monthly or quarterly reports
- Heat maps for risk assessment
- Trend analysis to show progress



COMPLIANCE METRICS - FY 2025 KPIs

Status Legend:				
	Exceeding Target			
	Meeting Target			
	Off Target			

METRICS	PROGRAM ELEMENT	NOTES	TARGET	STRETCH	Q1	Q2	Q3	04
RESEARCH & ACADEMICS								
Quarterly Audit Completion per FTE	Auditing & Monitoring		2 Audits	3 Audits	- 2			
Consulting / Stakeholder Engagement	Education & Training		1 Quarterly	2 Quarterly	2			
Outreach Activities - Clinical Research	Education & Training		3 Quarterly	4 Quarterly	3			
See and the street - Protecting treesing et	Education & Francis		a square tot ty	4 Quality				
Policy Briefs / Education Resources	Education & Training		3 Quarterly	4 Quarterly	2			
CONTROLLED SUBSTANCE & PHARMACY								
Cases Reviewed for Potential IN - Days to Report	Investigations		1 B. Day	N/A	- 1			
DEA Reportables - # of Events - Rolling	Investigations		<40	<30	0			
% Discrepancies Resolved in 24 Hours	Monitoring & Accountability		95%	100%	99%			
Outreach Activities / Education Resources	Education & Training		1 Quarterly	2 Quarterly	2			
Controlled Substance Training Completion Rate - Within 30 Days of Hire	Education & Training		95%	100%	986			
PRIVACY								
Accounting of Disclosures - Days to Completion	Accountability		30 Days	15 Days	3			
Amendments - Days to Completion	Accountability		60 Days	45 Days	7			
Break the Glass - Days to Completion	Accountability		2 B. Days	1 B. Day	- 1			
Opt-Outs - Business Days to Completion	Accountability		10 B. Days	3 B. Days	3			
Restrictions - Days to Completion	Accountability		30 Days	15 Days	9			
OCR Reportables - # of Events - Rolling	Investigations		-40	-25	49			
Privacy Investigations - Days to Completion	Investigations		60 Days	45 Days	41			
HEALTH SYSTEM								
'S New Providers Audited	Auditing & Monitoring		100%	N/A	68%			
Audit Accuracy - PB / HB	Auditing & Monitoring		90%	95%	986			
Quarterly Audit Completion per FTE	Auditing & Monitoring		2 Audits	3 Audits	2			
Special Projects / Engagements	Auditing & Monitoring		1 Quarterly	2 Quarterly	- 1			
Quarterly Education	Education & Training		2	3	3			
Health System Investigation - Days to Completion	Investigations		60 Days	45 Days	124			
Advisory Request Turnaround Time	Education / Communication		14 Days	7 Days	34			
Patient Assistance Office / Patient Safety Events Turnaround Time	Education / Communication		7 Days	3 Days	47			
COMPLIANCE PROGRAM EFFECTIVENESS								
Monthly Excluded Party Screening of Existing Employees	Auditing & Monitoring		100%	N/A	100%			
Consulting / Stakeholder Special Projects	Auditing & Monitoring		1 Quarterly	2 Quarterly	2			
Annual Training Completion Rate - Within 45 Days of Assignment	Education & Training		95%	100%				
New Hire Training Completion Rate - Within 30 Days of Hire	Education & Training		95%	100%	98%			
Trainings Completed / Reviewed / Updated per Quarter	Education & Training		2 Quarterly	3 Quarterly	5			
Tip Sheets / Educational & Operational Resources	Education & Training		1 Quarterly	2 Quarterly	14			
Compliance Liaison Meetings Participation Rate	Education / Communication		75%	85%	19%			
Compliance Investigation - Days to Completion	Investigations		60 Days	45 Days	12			
Hotline Call Assignments - Days to Triage	Investigations		5 Days	3 Days	3			
Rate of Anonymous Hotline Calls - Quarterly	Lines of Communication		~40%	<30%	22%			
Annual Compliance Survey Response Rate	Lines of Communication		15%	30%				



DEMONSTRATING COMPLIANCE PROGRAM VALUE

- KPIs provide objective evidence of compliance effectiveness
- Help secure leadership buy-in and resource allocation
- Support continuous program improvement and risk mitigation

KEY TAKEAWAYS

- KPIs are essential for measuring and improving compliance
- Clear reporting ensures transparency and accountability
- Continuous evaluation enhances compliance effectiveness





WHY COMPLIANCE TRAINING MATTERS



Ensures adherence to regulations



Reduces legal and financial risks



Fosters a culture of compliance and ethics



Empowers employees to recognize and report concerns

KEY COMPONENTS OF AN EFFECTIVE COMPLIANCE TRAINING PROGRAM

- Clear learning objectives
- Role-specific training
- Interactive and engaging methods
- Regular updates and refreshers
- Measurable outcomes



TYPES OF COMPLIANCE TRAINING



General Compliance Training



Role-Specific Compliance Training



New Employee Education



Annual Refresher Courses



Specialized Training (e.g., HIPAA, Anti-Fraud, Workplace Safety)

EXAMPLE TRAINING TOPICS

- HIPAA and Patient Privacy
- Anti-Kickback and Stark Law
- Fraud, Waste, and Abuse Prevention
- Conflict of Interest Policies
- Reporting and Whistleblower Protections
- Coding and Billing Topics
- Regulatory Updates



ENGAGING EMPLOYEES IN COMPLIANCE TRAINING

- Use real-world case studies and scenarios
- Incorporate interactive e-learning modules
- Host live Q&A sessions with compliance officers
- Provide incentives for course completion
- Gamify training with quizzes and rewards



TRAINING DELIVERY METHODS

Online Learning
Management
Systems (LMS)

In-Person
Workshops and
Seminars

Webinars and Virtual Training

Microlearning (short, focused modules)

Compliance Newsletters and Tipsheets

Compliance Liaison Program

TRACKING AND MEASURING TRAINING EFFECTIVENESS



Track

Track completion rates and quiz scores



Conduct

Conduct employee feedback surveys



Monitor

Monitor compliancerelated incidents



Adjust

Adjust training based on audit results

RESOURCES

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RESOURCES

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