



**THE MODERN COMPLIANCE OFFICE:**  
TACKLING PRESENT-DAY CHALLENGES  
AND REFRESHING PRACTICES

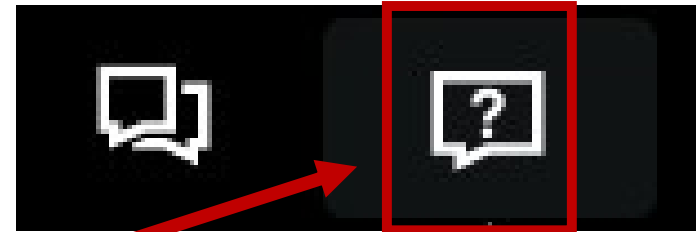
**SAI360**

 STRATEGIC MANAGEMENT SERVICES

# QUESTIONS OR FEEDBACK?

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# QUESTIONS OR FEEDBACK?

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# SAI360

RISK FROM EVERY ANGLE

SAI360 is giving companies a new perspective on risk management. By integrating Governance, Risk, Compliance software and Ethics & Compliance Learning resources. SAI360 can broaden your risk horizon and increase your ability to identify, manage, and mitigate risk.

**See risk from every angle.**

# ABOUT STRATEGIC MANAGEMENT

Strategic Management is a pioneer in helping the health care industry with timely and innovative regulatory compliance solutions. As the only consulting company focused exclusively on the health care compliance industry, we differentiate ourselves by our expertise, qualifications and people.

Since 1992, Strategic Management has assisted thousands of health care organizations with regulatory and operational compliance and privacy services.

## How we help our clients:

- ✓ Conducting effectiveness assessments and gap analyses of their compliance or privacy program
- ✓ Developing and implementing a new compliance and/or privacy program
- ✓ Acting in an interim or designated Compliance and/or Privacy Officer role
- ✓ Auditing billing, coding and claims processes
- ✓ Supporting clients under a CIA as Compliance Expert to the Board, assisting with the implementation report and on-going CIA requirement or as an IRO
- ✓ Ongoing and at-hire sanction and exclusion screening against Federal and state data

# PRESENTERS

**Richard P. Kusserow, Former DHHS  
Inspector General**

Strategic Management Founder and CEO



**Jillian Concepcion, MPA, CHC, CHPC**

Strategic Management COO





# AGENDA

- Evolution of the traditional Compliance Office
- Current day Compliance Office
- Compliance Officer's education/experience
- Navigating modern challenges
  - Remote staff
  - Talent retention
  - Budget
- Rebuilding the compliance culture
- Questions & Answers

# TRADITIONAL COMPLIANCE OFFICE EVOLUTION

WHERE IT BEGAN



# COMPLIANCE OFFICE

## TRADITIONAL

- **Compliance Officer**
  - Mid-Level reporting
- **Focus on the seven elements**
- **Silo or little integration**

## TRENDING TO

- **Chief Compliance Officer**
  - C-Suite / Executive management
  - Reports to the Board
- **Mission evolved due to numerous factors:**
  - Increasing regulatory demands (HIPAA, enforcement)
  - Maturing standards (GCPG, DOJ Guidelines, OIG CIAs)
  - Expanding business needs: technology, mergers/acquisition
- **Responsibilities have moved beyond the seven elements**
  - Privacy
  - Risk
  - Audit
  - M&A

# EXPANSION OF RESPONSIBILITIES

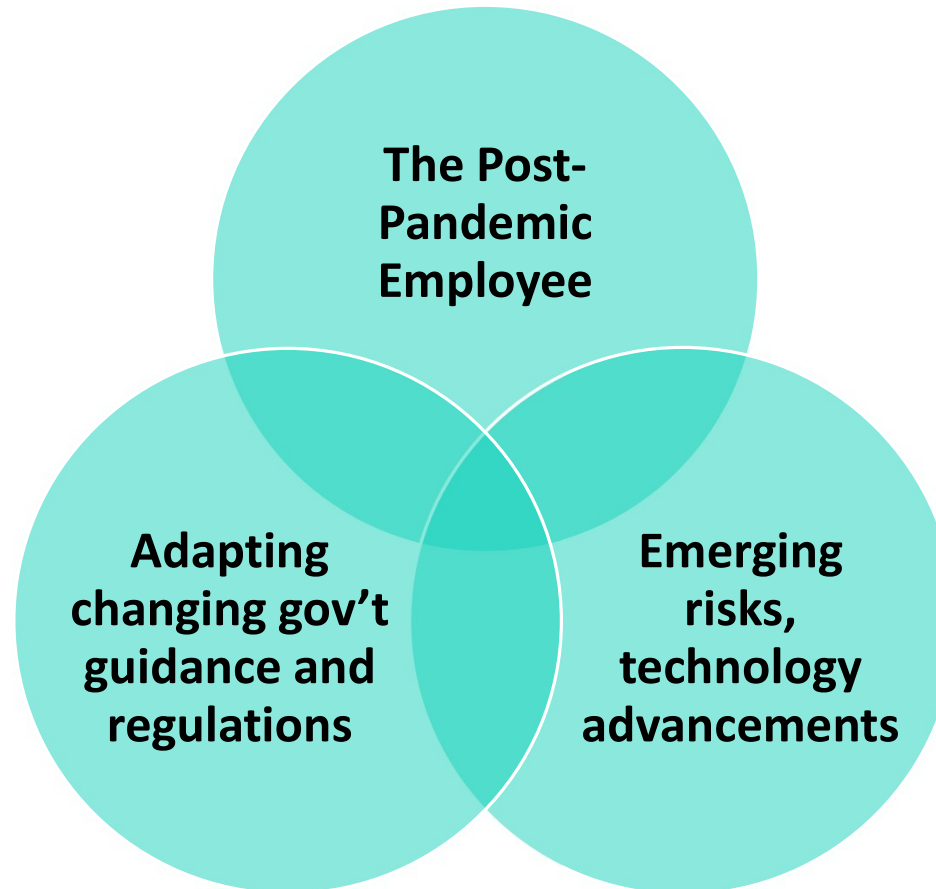
## Compliance Office work is diverse, requiring collaboration with other organization's departments

- ✓ **The Seven Elements**
- ✓ **Regulatory/Legal Compliance:** FAG, AKS/Stark Laws, Affordable Care Act, Data Privacy, False Claims
- ✓ **Risk Assessment:** evaluating impact of regulatory changes, assessing the potential consequences of non-compliance, and identifying areas where the company may be vulnerable
- ✓ **Reporting/Documentation:** informing internal and external stakeholders, external auditors, investigators and government agencies
- ✓ **Continuous Improvement:** improving the compliance programs and processes continuously. They adapt to changes in regulations, industry best practices, and emerging risks to enhance the company's compliance posture
- ✓ **Crisis Management:** managing the situation, coordinating responses, and minimizing damage to the company's reputation and bottom line

COMPLIANCE OFFICE TODAY

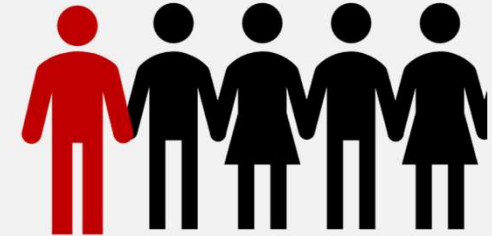
WHERE IT IS GOING

# INFLUENCING FACTORS



# COMPLIANCE STAFF SHORTAGE

- Bureau of Labor Statistics reported job U.S. openings were at 11 million and growing
- There has been widespread staffing shortages impacting compliance programs
- People leave to obtain increased salaries, benefits, more free time, and working remotely
- Employee gap crisis has led to major competition in the hiring of skilled and experienced staff
- Six out of ten organizations reported increasing reliance contracted services to fill staffing gaps



It is estimated **that one out of five workers may quit** their job in the coming year

# IN-, OUT-, & CO-SOURCING

- **Insourcing** or in-house staffing, is obtaining or supplementing staffing needs by drawing upon resources temporarily from other programs and operations.
- **Outsourcing** is a common and growing practice among companies that involves transferring non-core functions to outside providers (e.g., hotline, sanction screening, training programs, evaluations/audits/investigations, etc.). Smaller organizations unable to support a W-2 Compliance Officer may outsource the entire program to outside experts to cut labor costs, including salaries, overhead, benefits, equipment, and technology
- **Co-Sourcing** is an option that is halfway between insourcing and outsourcing, in that it brings needed professionals with the expertise to perform specialized tasks under direction of the Compliance Office, often under on-call agreements. This means the organization is not hiring a vendor but a co-worker

# COMPLIANCE OFFICER'S EDUCATION & EXPERIENCE

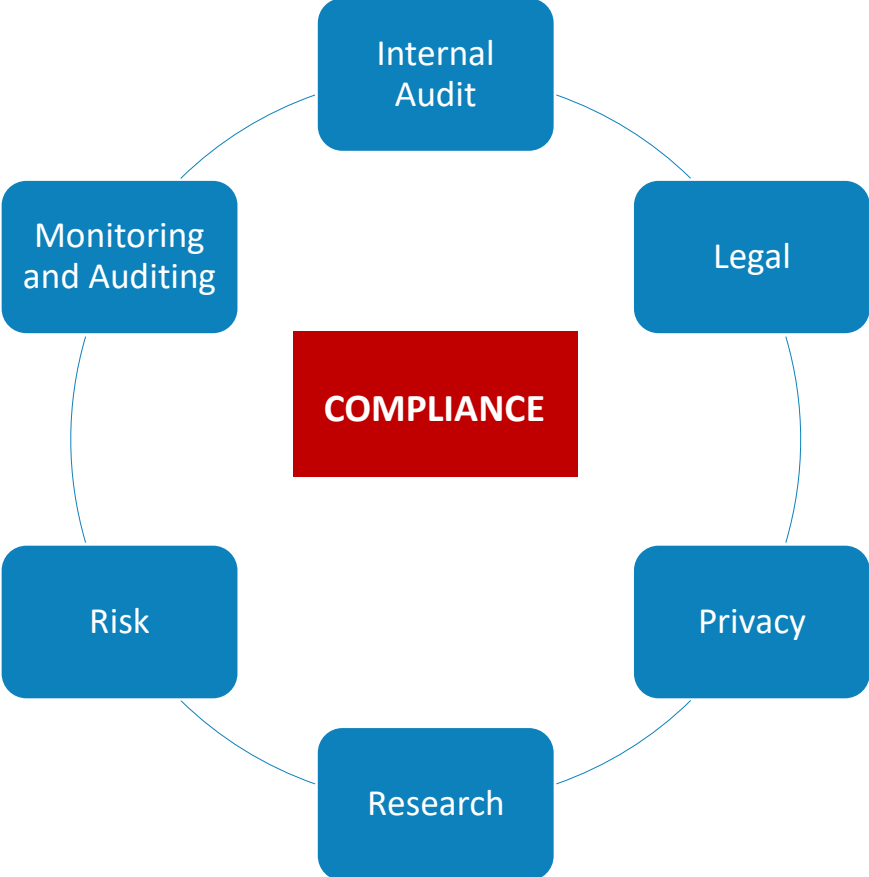
UNDERSTANDING MORE  
THAN COMPLIANCE

# TODAY'S COMPLIANCE OFFICER

- Doing more with less budget, staff
- Compliance professionals need to adjust their focus and prioritize resources and time in response to evolving priorities and risks.
- National Compliance Benchmark Surveys over the years evidenced an increasing accretion of duties
  - 36% of respondents reported an increase in duties and workload
  - 8 out of 10 Compliance Programs now include HIPAA Privacy
  - Half of Compliance Offices include responsibility for Internal Audit
  - More than a third reported Compliance Officer responsible for HIPAA and Cyber Security
  - About a quarter of organizations reported Compliance and Legal under the same roof
  - Over one third reported having responsibility for research compliance
  - Many Compliance Officers are taking on miscellaneous duties that distract from core mission



# COMPLIANCE EXTENDS INTO OTHER AREAS



# INTERNAL AUDIT

- Internal Auditor (IA) is appointed by and reports directly to the Board, including executive sessions
- Independently evaluates internal controls, processes & operations for legal/regulatory compliance
- Helps the maintenance of accurate and timely financial reporting and data collection
- Provides independent/objective assurance that risks are being managed to acceptable levels
- Focuses on risks that management has addressed through internal controls, including compliance risks
- Provides assurance over risks regarding the reliability and integrity of financial and operational
- Adheres to standards set forth by the AICPA and IIA
- Employs a systematic, disciplined approach in evaluating and analyzing risk management
- Responsible for identifying risks within the business
- Often works with and in support of external auditors
- Focuses on set for operational effectiveness and efficiency for reliable financial reporting
- Checks on whether operations are being carried in compliance with policy, procedures, internal controls
- Monitors and evaluates the internal control environment as to its adequacy, efficiency and effectiveness

# INTERNAL AUDIT VS. COMPLIANCE

- While compliance and IA are like two sides of the same coin, they play very different roles
- Growth of the Compliance Office function has blurred the lines between it and IA
- They often occupy similar space, leading to tension, rivalry, and competition for resources
- Both share common work characteristics that they must be objective, ethical, and independent
- Both independently and objectively analyze, review, evaluate, report, and recommend improvements
- Roles overlap, especially with regards to ongoing auditing of high-risk areas to ensure program compliance
- How these functions operate varies considerably among organizations
- IA focuses on risk management, Compliance Officer focuses on regulatory, legal, and reputational risks
- IA evaluates adequacy/effectiveness of internal controls in meeting laws, rules, and policies
- Compliance Offices ensure potential violations of the Code, policies, rules, and regulations are addressed
- Compliance ensures processes to resolve and/or mitigate potential and/or real compliance risks identified
- Compliance is primarily concerned with regulatory risk and therefore the scope of operations
- Compliance examines a policy, process and procedure to determine if laws/regulations are being followed
- Compliance Office focuses on complying with applicable laws, rules and regulations, Codes, and policies

# COMPLIANCE AND LEGAL COUNSEL

- Compliance and Legal Counsel under the same roof is not a best practice and strains resources
- It is not prohibited by law, but DOJ and OIG believe it undercuts Compliance Program Effectiveness
- OIG Corporate Integrity Agreements prohibit such an arrangement
- OIG General Compliance Program Guidance makes it clear they see it as a bad practice
- Considered as potential conflict of interest between the two roles
- In many cases DOJ/OIG have found Legal Counsel placing matters under privilege rather than disclosing them
- Such arrangements can lead to employee confusion as to roles
- Though similar in protecting against wrongdoing, their missions and functions varies considerably
- Legal Counsel attorneys are bound to give the Upjohn Warning to employees
- Best practice is to ensure a separation of functions with Compliance reporting to the CEO

# PRIVACY COMPLIANCE

- Most Compliance Officers have the HIPAA Privacy Officer added to their responsibilities
- HIPAA Privacy Compliance unlike Corporate Compliance operates under detailed mandated standard
- HIPAA Privacy Programs can be as demanding as Corporate Compliance
- For the Compliance Officer to also be the Privacy Officer stretches the ability to do both properly
- Many have a certified Privacy Officer reporting to the Compliance Officer
- For some it is outsourcing the Privacy Officer to a certified expert on a part time basis
- Whereas HIPAA Privacy is a natural fit with Corporate Compliance, HIPAA Security Officer is not
- HIPAA Security fits with Cyber Security and because of its technical nature should be aligned to IT

# RESEARCH COMPLIANCE

- Refers to following the rules, regulations, policies, and standards of conduct that govern research
- Workload depends on amount and range of research activities
- Ensure ethical research in accordance with applicable laws, research practice guidelines, regulations
- Compliance varies according to types of research (human and animal subjects, COI, grants, etc.)
- May involve reviewing research protocols, providing compliance oversight, investigating research misconduct matters, developing/reviewing related policies/guidelines, verifying accreditation processing
- Compliance involves complex/detailed rules, regulations, policies, and standards that governs research
- This is a complicated area with many government agencies mandating standards and rules
- Includes the development, implementation, and operation of research related policies and procedures
- A key compliance responsibility in research fall upon the mandated Independent Review Organizations
- IRBs ensure review research studies comply with applicable regulations, meet commonly accepted ethical standards, follow institutional policies, and adequately protect research participants
- May be best to have a separate Research Compliance Officer or have the Office/Director of Research manage compliance with the Compliance Officer independently verifying the program is meeting its obligations

# RISK MANAGEMENT

- A systematic process to identify, assess, and reduce the likelihood and impact of threats and uncertainties
- Involves risk identification, analysis/assessment, impact evaluation, addressing strategies & monitoring
- Enterprise Risk Management (ERM) ranges across all business activities (e.g., mergers and acquisitions, clinical and medical practices, physical and IT security, Human Resource Management, etc.)
- Many Compliance Offices improperly believe they are responsible for ERM
- Risk management is a shared responsibility across an organization
- Board holds overall ERM responsibility to define, manage, and establish risk tolerances
- Leadership, including the CEO, have responsibility for overall strategic direction for managing risks
- Program Managers are responsible for managing day-to-day risks in their area of operation
- Common for a Chief Risk Officers responsible for identifying, analyzing, and mitigating organization risks
- Compliance can verify and report on ERM is taking place
- Compliance should focus on regulatory compliance part of ERM and should work to be limited to this

# AUDITING AND MONITORING

- Compliance “auditing” and “monitoring” are not the same, they relate to different parties and result types
- Compliance Officer is responsible for ongoing monitoring of the Compliance Program and auditing that monitoring is being conducted by program/department managers
- Program or department managers are responsible for their own ongoing compliance monitoring, which includes: (a) keeping current with changes in rules, (b) regulations, and applicable laws; (c) developing internal controls, policies, and procedures to comply with them; (d) training staff on these rules; and (e) taking active steps in monitoring or verifying compliance with these new guidelines.
- Auditing must be performed by parties independent of the areas being reviewed to (a) verify program managers are meeting their monitoring obligations, (b) validate they are functioning as they were intended, and (c) identify weaknesses in the program that need to be addressed
- Many Compliance Officers have undertaken ongoing monitoring of operational areas that strain resources; and efforts should be made to move it to program managers



# NAVIGATING MODERN CHALLENGES

REMOTE STAFF, TALENT RETENTION,  
BUDGET AND MORE

# MEETING WORKLOAD CHALLENGES

- Analyze current, most important, and urgent tasks/projects against available resources
- Rethink priorities and timeframes on scheduled projects and tasks
- Examine whether Compliance has assumed duties better placed outside the compliance office
- Determine if staff experience and capabilities exist that can be used in other capacities
- Develop a plan of action to prepare and organize your team for the workload ahead
- Assist staff in developing skills for different roles/duties (training, webinars, conferences)
- Consider engaging an on-call consultant to address tasks/projects current staff can't handle
- Decide if any functions or tasks can be outsourced (e.g., hotline, sanction screening, training programs, assessments, internal auditing, etc.)
- Give consideration for engaging interns to help with task work
- Discuss with staff about meeting challenges
- Focus on strategies to boost morale and prevent staff turnover

# REMOTE STAFF

## 2024 SMS/SAI360 COMPLIANCE BENCHMARK SURVEY

- 75% percent of reported that compliance staff work partly or full-time remote.
- Three quarters of Compliance Offices have staff working remotely to one degree or another
- 14% of Compliance Offices report work was 100% remote working

## GENERAL REMOTE WORK TRENDS

- 98% of remote workers desire to work remotely for the rest of their careers.
- 29% of hybrid and remote workers would want a pay raise if forced to return to the office full-time.
- 40% of people wouldn't take a job that doesn't offer flexible work hours or requires them to be present in the office during specific days or times.
- 16% of employees working at the office would take a pay cut to work remotely
- Three out of ten would seek new employment if recalled to the office remotely and 6% would quit

# MEETING THE CHALLENGE OF REMOTE WORK

- Compliance is largely hands on work that includes meeting, briefing & interviewing people
- Efficiency is a challenge when compliance and operational staff work remote; can be less efficient and effective than in-office staff
- As a result, Compliance Officers/Managers are forced to manage work in new ways
  - Task driven assignments
  - Interviews and meetings are done by phone or video conference
  - Often times more meetings so the Compliance Officer/Manager is aware what staff are working on
  - Building trust between staff and managers
  - Productivity can be difficult to keep track of
  - Access to information
  - Maintain security of information

# TALENT RETENTION

- Create a plan with HR to uses to keep employees and reduce turnover
- Set goals to increase employee engagement, job satisfaction, and pay equity
  - Review benefits; benefits that are no-cost to employer
  - Recognize employees' achievements and promote when possible
  - Encourage open communication between employees, managers, and leaders.
  - Collect feedback for current employees and during exit interviews
  - Track turnover metrics to identify trends
  - Recruit the right employees that match your company culture; be clear on job expectations during the recruiting process
  - Offer flexible work options

# ADDRESSING STAFFING GAPS

- No organization can afford long-term gaps in coverage of compliance leadership
- Replacement of a CO can take six months or longer; too long for a CP without leadership
- Replacement of compliance staff averages 90 days
- Rapid CP degeneration can occur without someone responsibility for day-to-day compliance decisions
- Designating someone internally is not a good option
  - They are unable to address problems properly, timely, effectively
  - They may not have available time if an investigation, breach or audit
  - They are splitting time to address the CP and their other role's responsibilities
- Increasing trend is to engage an Interim Compliance Officer to cover the gap until a new hire is made

# INTERIM COMPLIANCE OFFICER BENEFITS

- Work can be done part-time, and pay is only for the hours worked
- Can maintain Compliance Program continuity while searching for a full-time replacement
- No learning curve on duties and up to date on the ever-changing regulatory environment
- Have prior experience in adapting compliance programs to other organizations
- Able to address new and emerging compliance issues
- Can tackle any work backlogs left by a departing Compliance Officer
- Expertise in compliance in high-risk areas
- Would bring high credibility to executive leadership and board
- No added overhead costs (e.g., FICA, leave, benefits, etc.); possess their own multi-million dollars liability insurance coverage

# DESIGNATED COMPLIANCE OFFICER BENEFITS

- Smaller organizations may be unable to afford a CO and additional compliance staff
- Most OIG and DOJ settlement agreements are with small organizations unable to evidence a compliance program; OIG/DOJ accept no excuse for ignorance in violating laws and regulations
- Having someone perform compliance duties as a secondary responsibility is not effective
- Designated CO agreements can be long running
- OIG finds outsourced designated CO an acceptable option
- Pay is only for tasks and hours worked with other benefits as noted for an Interim Compliance Officer
- It is also common to use the same expert to serve also as the HIPAA Privacy Officer



# BUDGET

- The Compliance Officer needs to sell the program internally
- Adopting a mindset that compliance is everyone's responsibility
- Focus on a sufficient budget that helps the organization become more resilient and compliant and can help preserve their reputation and financial stability
- Building into the budget addressing potential risks, lowering the chance of excessive fines or reputational harm brought on by non-compliance
- Identify operational efficiency with other departments; overlap in software or tools
- A well-designed budget demonstrates a serious commitment to compliance and builds stakeholder confidence in the overall organization

# REBUILDING THE COMPLIANCE CULTURE

ADJUSTING TO THE NEW WORK PARADIGM

# COMPLIANCE CULTURE

- Every employee is responsible for compliance; part of the performance review
- Increase compliance awareness; training, newsletter, breakroom
- Prioritize communication with your employees
  - Connect on a personal level
  - Be available
  - Ensure communication happens across teams.
- Be clear on expectations
- Help employees/teams feel valued; recognize success, share company-wide success
- Schedule time for fun; incorporate team-building activities

# QUESTIONS & ANSWERS

WRAP-UP AND FOLLOW-UP

# QUESTIONS?

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