

Conflict of Interest Compliance

November 16-18, 2020

2020 Healthcare Enforcement Compliance Conference

0

Overview

In this session, we plan to cover the current regulatory environment, the components of an effective COI Program, and lessons learned for assessment and improvement.



- Current Regulatory Environment
- Recent changes to the Sunshine Act
- Conflict of Interest in the Headlines
- Stakeholder Implications

- Clearly Defined COI Governance Structure
- Appropriate Staffing and Resources
- Creation and Implementation of Policies and Procedures
- Robust Training and Communications
- Consistent Audit and Monitoring
- Open Lines of Communication

- Maturity Model Roadmap for a best-in-class COI Program

1

Regulatory and Enforcement Activity

2

Current Regulatory Environment

These rules and guidances serve as an overview for Conflict of Interest programs.

PHS Regulations

- **42 CFR Part 50, Subpart F** | Requires disclosure of significant financial interests related to research¹
- **45 CFR Part 94** | Applicable to institutions with PHS agreed contracts²

FDA Regulations

- **21 CFR Part 54** | Requires disclosure of certain financial interests of investigator³

Physician Payments Sunshine Act

- **Affordable Care Act – Section 6002** | Requires applicable manufacturers of drugs, biologicals or medical supplies covered by Medicare, Medicaid or CHIP to report annually certain payments or transfers of value provided to physicians or teaching hospitals⁴

Internal Revenue Services (IRS)

- **Non-Profit Corporations - 501(c)(3)** | Organization must be organized and operated exclusively for exempt purposes and none of its earnings may inure to any private shareholder or individual⁵
- **Non-Profit Board Disclosures - Form 990** | Requires organizations to report certain employees' conflicts of interest⁶

State Ethics Laws

- **State Ethics Laws** | Many states are governed by their State Ethics Commission to encourage ethics in government activities⁷

Other Guidance

- **Association of American Medical Colleges (AAMC)** | Offers the "Forum on COI in Academe" which may be joined upon request⁸
- **Office for Human Research Protection** | Guidance to determine if COI affects the rights or wellness of human subjects⁹
- **AdvaMed Code of Ethics** | Guidance for medical technology companies¹⁰

1. <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgndiv=5&view=text&node=42:1.0.1.4.23&idno=42#sp42.1.50.f>

2. <https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=992817854207767214895b1fa023755d&rgndiv=5&view=text&node=45:1.0.1.1.51&idno=45>

3. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=54>

4. <https://www.cms.gov/OpenPayments/Downloads/AllforAffordable-Care-Act-Section-6002-Final-Rule.pdf>

5. <https://www.irs.gov/charities-non-profits/charitable-organizations/exemption-requirements-501c3-organizations>

6. <https://www.irs.gov/pub/irs-pdf/i990.pdf>

7. <https://www.ncsl.org/research/ethics/50-state-chart-state-ethics-commissions-jurisdiction.aspx>

8. <https://www.aamc.org/professional-development/affinity-groups/foi>

9. <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.htm>

10. <https://www.advaamed.org/issues/code-ethics/code-ethics>

3

3

CMS Open Payments

Newly Added Covered Recipients – Effective January 1, 2021

In addition to those currently identified as “covered recipients,” the definition expanded to include five new provider types:

- * Physician assistants
- * Nurse practitioners
- * Clinical nurse specialists
- * Certified registered nurse anesthetists & anesthesiologist assistants
- * Certified nurse midwives

Data collected in 2021 will be submitted to CMS and published in 2022

11. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index>

COI in the Headlines

Researchers in the medical community have been failing to disclose financial Conflicts of Interest.

U.S. Reaches Settlement on Undisclosed Chinese Funding of Scientists | December 19, 2019

Deal with Michigan institute reveals new government tactic to fight China's talent-recruitment efforts

<https://www.wsj.com/articles/u-s-reaches-settlement-on-undisclosed-chinese-funding-of-scientists-11576801714>

Fifty-four scientists have lost their jobs as a result of NIH probe into foreign ties

By Jeffrey Mervis | Jun. 12, 2020 , 6:00 PM

<https://www.sciencemag.org/news/2020/06/fifty-four-scientists-have-lost-their-jobs-result-nih-probe-foreign-ties>

◆ WSJ NEWS EXCLUSIVE | WORLD

How China Targets Scientists via Global Network of Recruiting Stations | August 20, 2020

New study details inner workings of talent recruitment programs linked to misconduct

<https://www.wsj.com/articles/how-china-targets-scientists-via-global-network-of-recruiting-stations-11597915803>

Moffitt Cancer Center details links of fired scientists to Chinese talent programs

By Jeffrey Mervis | Jan. 19, 2020 , 10:30 AM

<https://www.sciencemag.org/news/2020/01/moffitt-cancer-center-details-links-fired-scientists-chinese-talent-programs>

Deception by Professor Costs Lehigh \$200K As Yet Another University Settles an FCA Case

August 20, 2020

<https://compliancecosmos.org/deception-professor-costs-lehigh-200k-yet-another-university-settles-fca-case>

Stakeholders

Conflicts of interest impacts organizations in various ways and in different areas. A few key areas for consideration are noted below.

-  Researchers should consider and comply with Public Health Services (PHS) COI regulations
-  Committees (e.g. Pharmacy and Therapeutics Committees) with purchasing and contracting responsibilities should be alert to possible vendor conflicts
-  Providers may favor medications or devices manufactured by organizations in which they have a financial or other relationship
-  Individuals at various levels may have purchasing authority or make other contractual decisions on behalf of the organization
-  Board members may be faced with business decisions impacting fiduciary duties

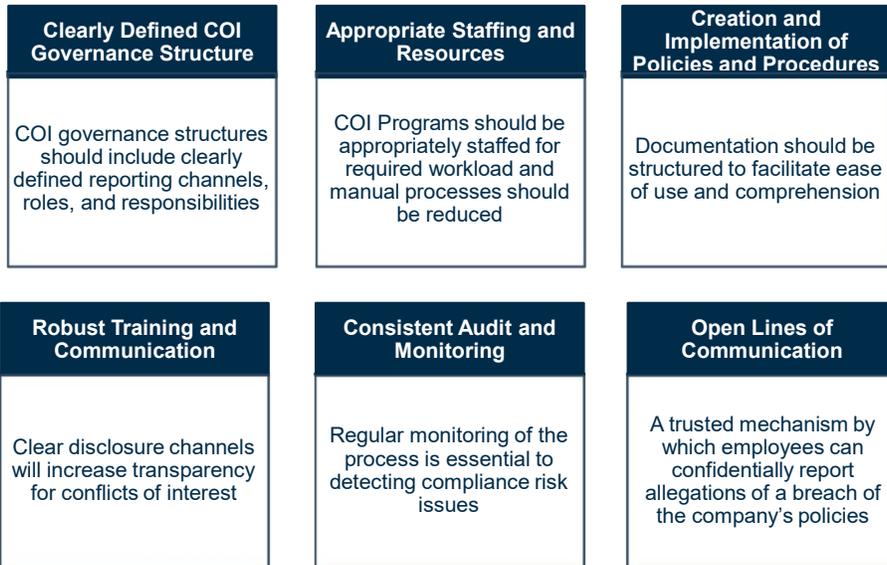
6

6

Components of an Effective COI Program

7

Key COI Program Assessment Areas



8

8

Polling Question 1

In what areas of your COI Program do you anticipate the most risk?

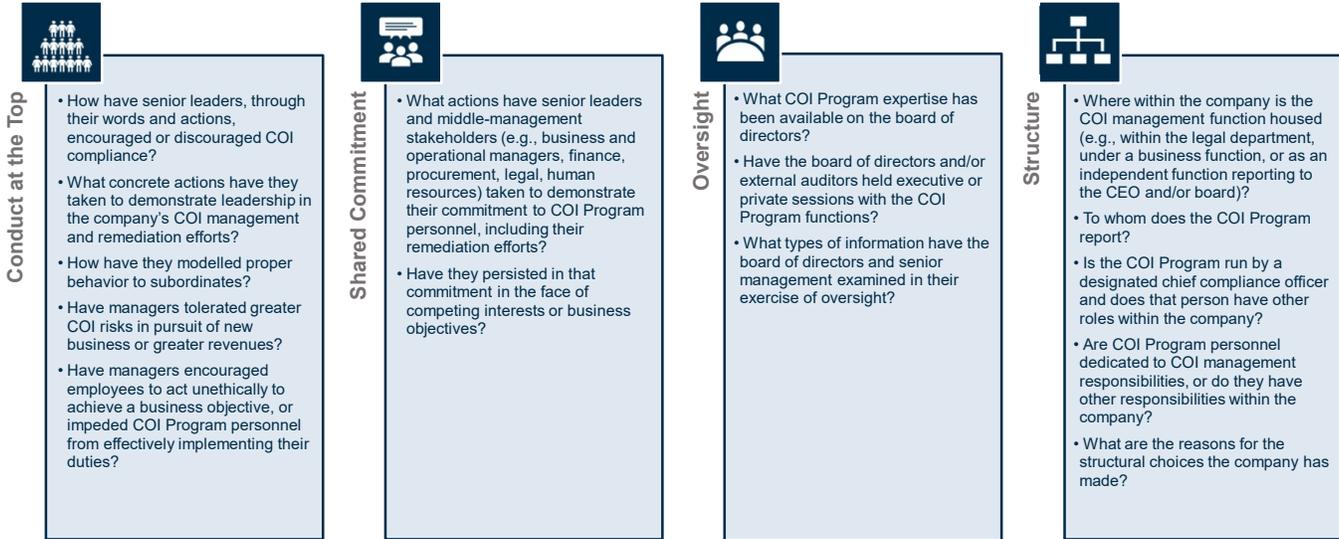
- A. Clearly Defined COI Governance Structure
- B. Appropriate Staffing and Resources
- C. Creation and Implementation of Policies and Procedures
- D. Robust Training and Communications
- E. Consistent Audit and Monitoring
- F. Open Lines of Communication

9

9

Clearly Defined COI Governance Structure

An effective COI Program will have established corporate governance mechanisms that can effectively identify and manage Conflicts of Interest.



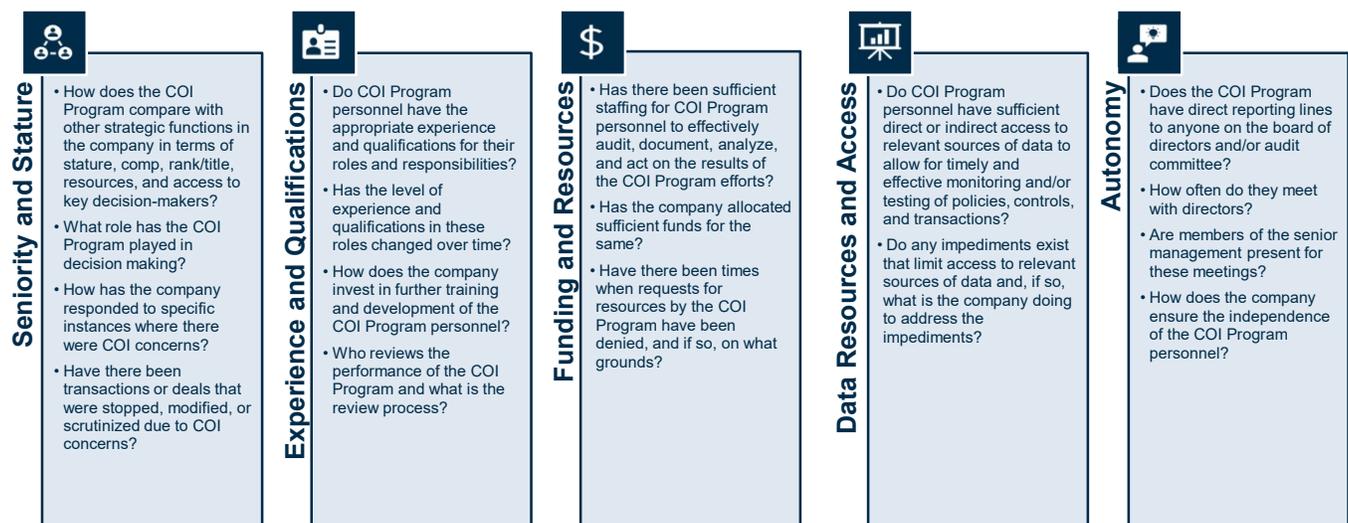
Source: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

10

10

Appropriate Staffing and Resources

The effectiveness of a COI Program requires a high-level commitment by company leadership to implement a culture of compliance from the middle and the top.



Source: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

11

11

Polling Question 2

Does your institution have specific caps or flags on the amount of compensation one can earn from outside activities?

- A. Yes, Cap
- B. Yes, Flag
- C. Yes, Both Cap and Flag
- D. No

12

12

Creation and Implementation of Policies and Procedures

A well-designed COI Program has policies and procedures that create ethical norms, foster a culture of COI disclosure, and address and reduce risks.

 <p>Design</p> <ul style="list-style-type: none"> • What is the company's process for designing and implementing new policies and procedures and updating existing policies and procedures, and has that process changed over time? • Who has been involved in the design of policies and procedures? • Have business units been consulted prior to rolling them out? 	 <p>Comprehensiveness</p> <ul style="list-style-type: none"> • What efforts has the company made to monitor and implement policies and procedures that reflect and deal with the spectrum of risks it faces, including changes to the legal and regulatory landscape? 	 <p>Accessibility</p> <ul style="list-style-type: none"> • How has the company communicated its policies and procedures to all employees and relevant third parties? • If the company has foreign subsidiaries, are there linguistic or other barriers to foreign employees' access? • Have the policies and procedures been published in a searchable format for easy reference? • Does the company track access to various policies and procedures to understand what policies are attracting more attention from relevant employees? 	 <p>Responsibility for Operational Integration</p> <ul style="list-style-type: none"> • Who has been responsible for integrating policies and procedures? • Have they been rolled out in a way that ensures employees' understanding of the policies? • In what specific ways are COI Program policies and procedures reinforced through the company's internal control systems? 	 <p>Gatekeepers</p> <ul style="list-style-type: none"> • What, if any, guidance and training has been provided to key gatekeepers in the control processes (e.g., those with approval authority)? • Do they know when and how to escalate concerns?
--	--	---	--	---

Source: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

13

13

Robust Training and Communication

Periodic training for employees is essential to an effective COI Program. The company should relay information tailored to the audience's size, sophistication, or subject matter expertise.



Risk-Based Training

- What training have employees in relevant control functions received?
- Has the company provided tailored training for high-risk and control employees, including training that addresses risks?
- Have supervisory employees received different or supplementary training?
- What analysis has the company undertaken to determine who should be trained and on what subjects?



Form/Content/Effectiveness of Training

- Is the training provided online or in-person (or both), and what is the company's rationale for its choice?
- Has the training addressed lessons learned from prior COI incidents?
- In-person, is there a process by which employees can ask questions arising out of the trainings?
- How has the company measured the effectiveness of the training?
- Has the company evaluated the extent to which the training has an impact on employee behavior or operations?



Availability of Guidance

- What resources have been available to employees to provide guidance relating to COI Program policies?
- How has the company assessed whether its employees know when to seek advice and whether they would be willing to do so?

Source: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

14

14

Polling Question 3

Does your institution cap or flag the number of outside relationships/interests one can engage in with regard to conflict of commitment concerns?

- A. Yes, Flag**
- B. Yes, Cap**
- C. Yes, Both Cap and Flag**
- D. No**

15

15

Consistent Audit and Monitoring

For a well-designed COI Program, companies should engage in meaningful efforts to review their COI Programs and ensure they are not outdated.

 <p>Internal Audit</p> <ul style="list-style-type: none"> • What is the process for determining where and how frequently internal audit (or an external review) will undertake an audit, and what is the rationale behind that process? • How are audits carried out? • What types of audits would have identified issues? • Did those audits occur and what were the findings? • What types of relevant audit findings and remediation progress have been reported to management and the board on a regular basis? • How have management and the board followed up? 	 <p>Control Testing</p> <ul style="list-style-type: none"> • Has the company reviewed and audited its COI Program? • More generally, what testing of controls, collection and analysis of COI data, and interviews of employees and third parties does the company undertake? • How are the results reported and action items tracked? 	 <p>Evolving Updates</p> <ul style="list-style-type: none"> • How often has the company updated and revised COI policies, procedures, and practices? • Has the company undertaken a gap analysis to determine if particular areas of risk are not sufficiently addressed in its policies, controls, or training? • What steps has the company taken to determine whether policies/procedures/practices make sense for business segments/subsidiaries? 	 <p>Culture of COI Disclosure</p> <ul style="list-style-type: none"> • How often and how does the company measure its culture of COI disclosure? • Does the company seek input from all levels of employees to determine whether they perceive senior and middle management's commitment to the COI disclosure process? • What steps has the company taken in response to its measurement of the COI disclosure culture?
--	---	--	---

Source: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

16

16

Open Lines of Communication

An effective COI Program should have an efficient and trusted mechanism by which employees can anonymously or confidentially report concerns or seek consultation.

 <p>Effectiveness of the Reporting Mechanism</p> <ul style="list-style-type: none"> • Does the company have an anonymous reporting mechanism and, if not, why not? • How is the reporting mechanism publicized to the company's employees and other third parties? Has it been used? • Does the company take measures to test whether employees are aware of the hotline and feel comfortable using it? 	 <p>Properly Scoped Investigations by Qualified Personnel</p> <ul style="list-style-type: none"> • How does the company determine which complaints or red flags merit further investigation? • How does the company ensure that investigations are properly scoped? • What steps does the company take to ensure investigations are independent, objective, appropriately conducted, and properly documented? • How does the company determine who should conduct an investigation, and who makes that determination? 	 <p>Investigation Response</p> <ul style="list-style-type: none"> • Does the company apply timing metrics to ensure responsiveness? • Does the company have a process for monitoring the outcome of investigations and ensuring accountability for the response to any findings or recommendations? 	 <p>Resources and Tracking of Results</p> <ul style="list-style-type: none"> • Are the reporting and investigating mechanisms sufficiently funded? • How has the company collected, tracked, analyzed, and used information from its reporting mechanisms? • Does the company periodically analyze the reports or investigation findings for red flags for COI Program weaknesses? • Does the company periodically test the effectiveness of the hotline, for example by tracking a report from start to finish?
--	---	---	--

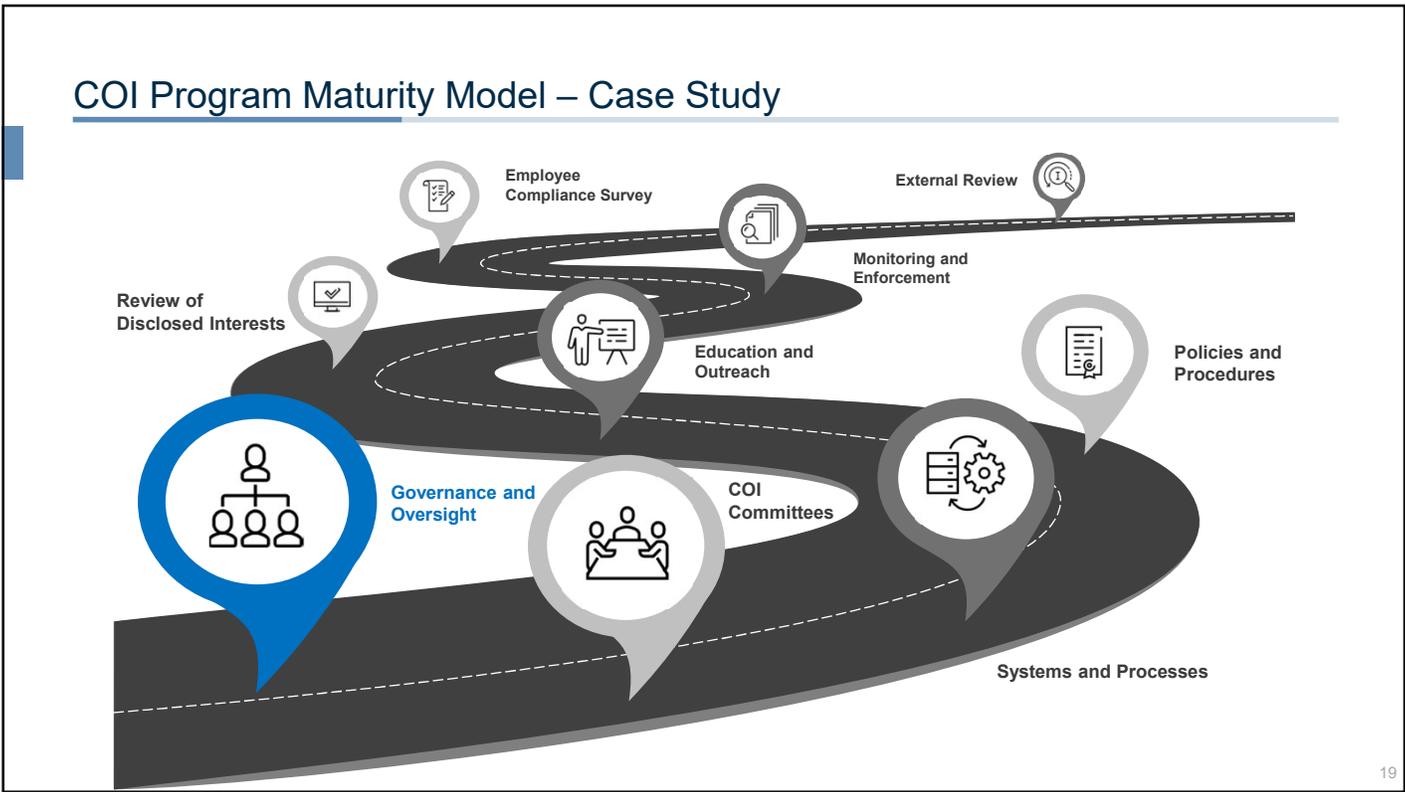
Source: <https://www.justice.gov/criminal-fraud/page/file/937501/download>

17

17

Lessons Learned for Assessment and Improvement

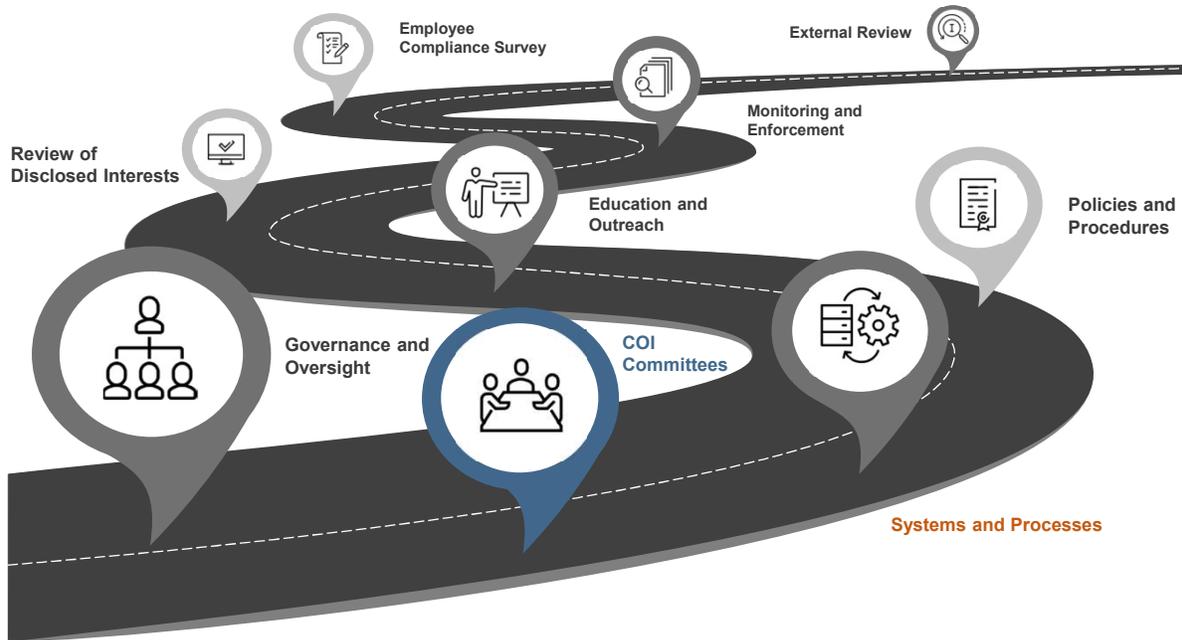
18



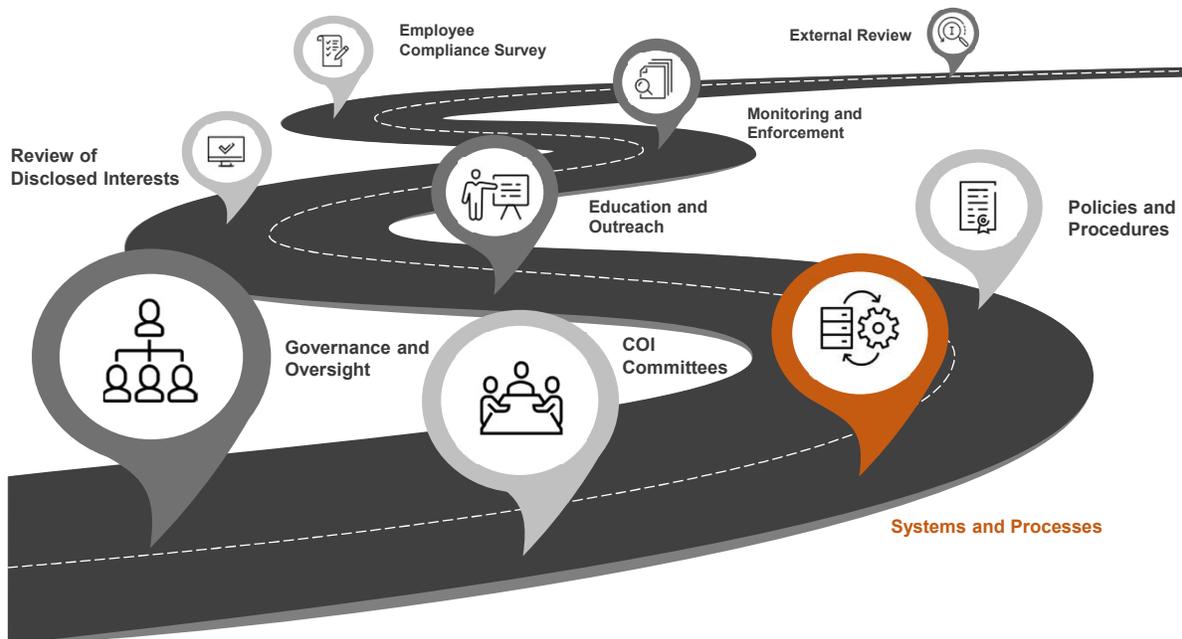
19

19

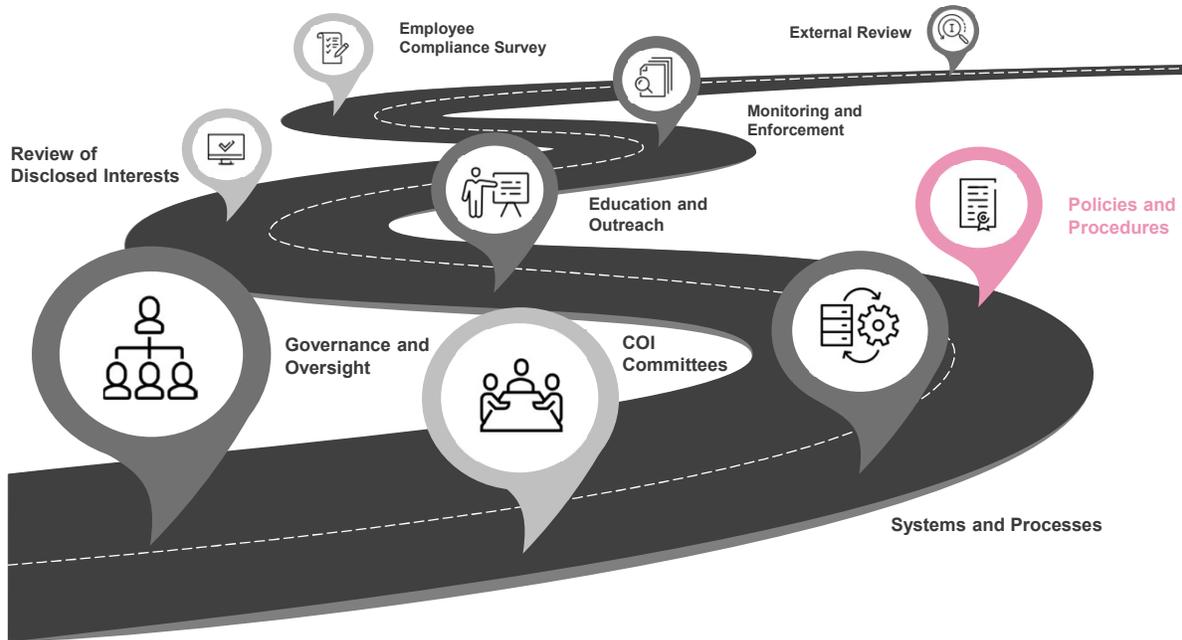
COI Program Maturity Model – Case Study



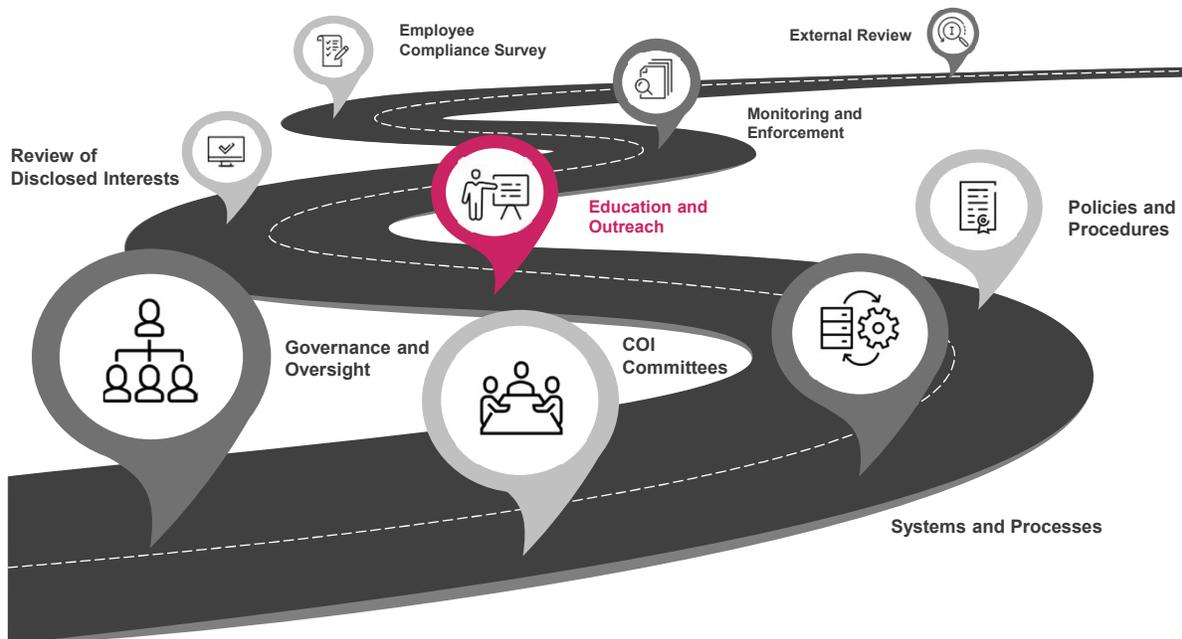
COI Program Maturity Model – Case Study



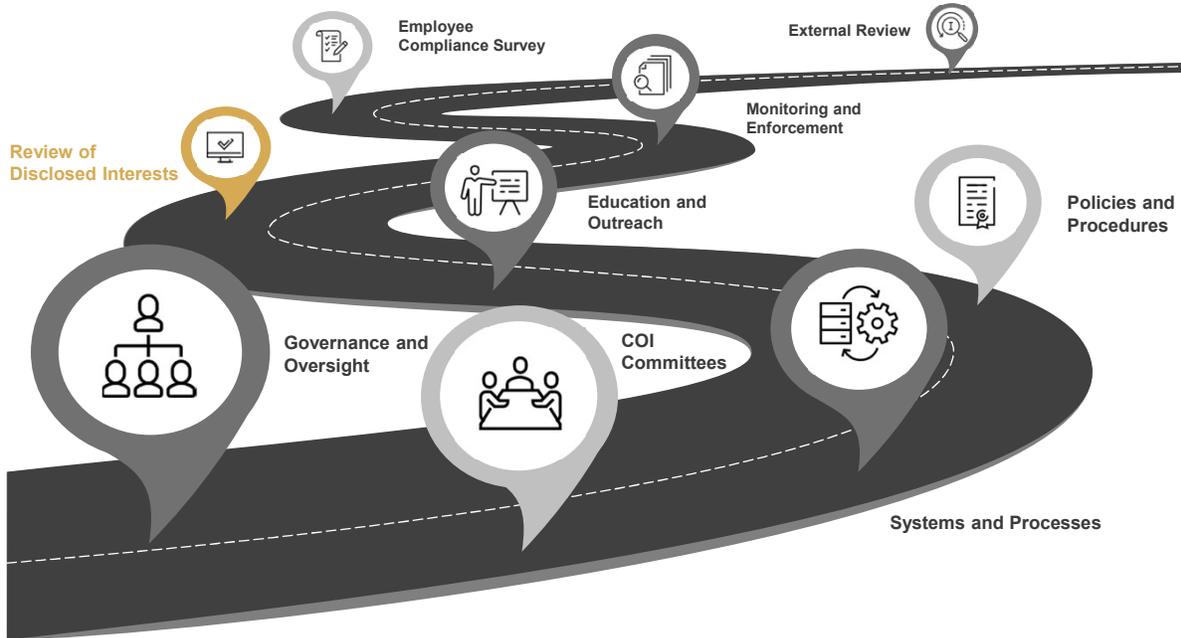
COI Program Maturity Model – Case Study



COI Program Maturity Model – Case Study



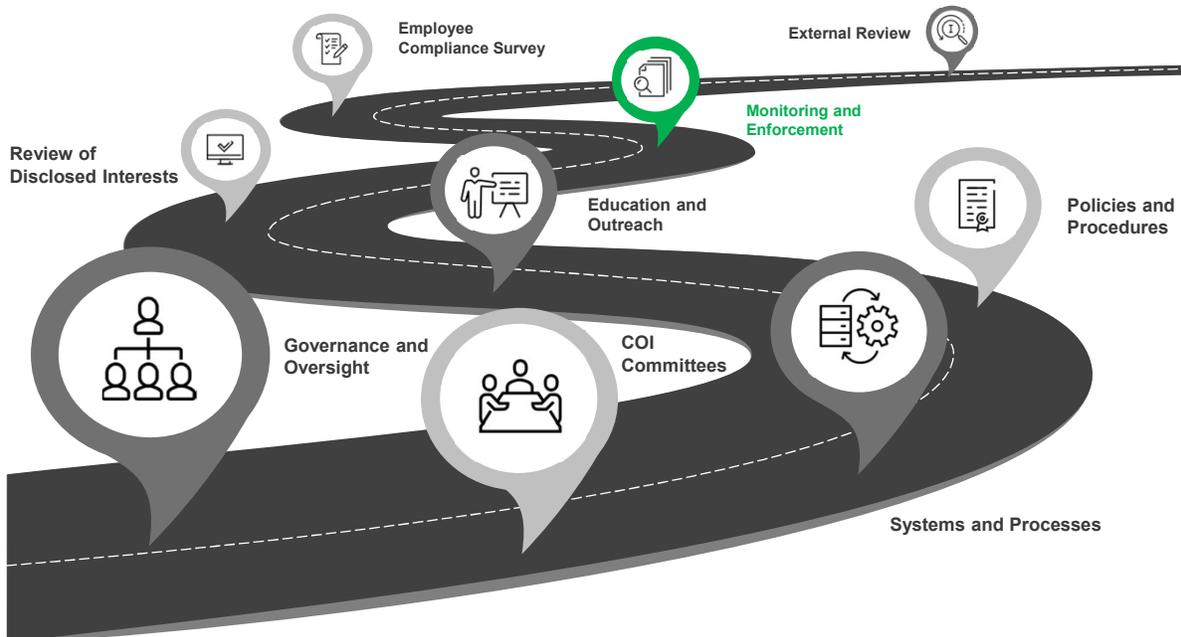
COI Program Maturity Model – Case Study



24

24

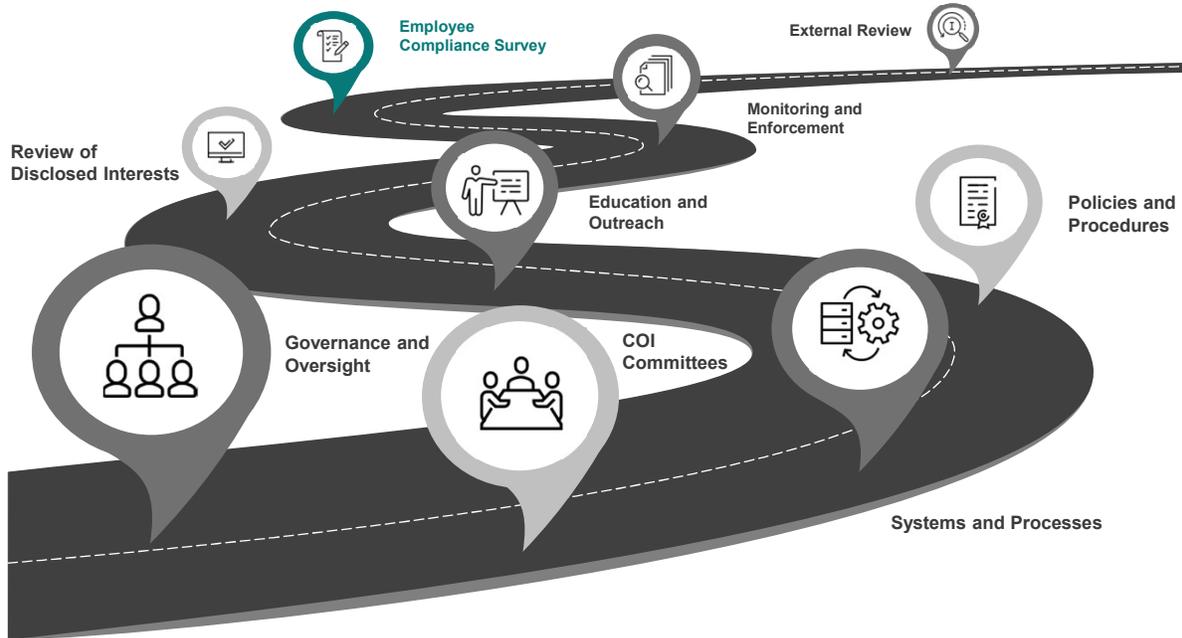
COI Program Maturity Model – Case Study



25

25

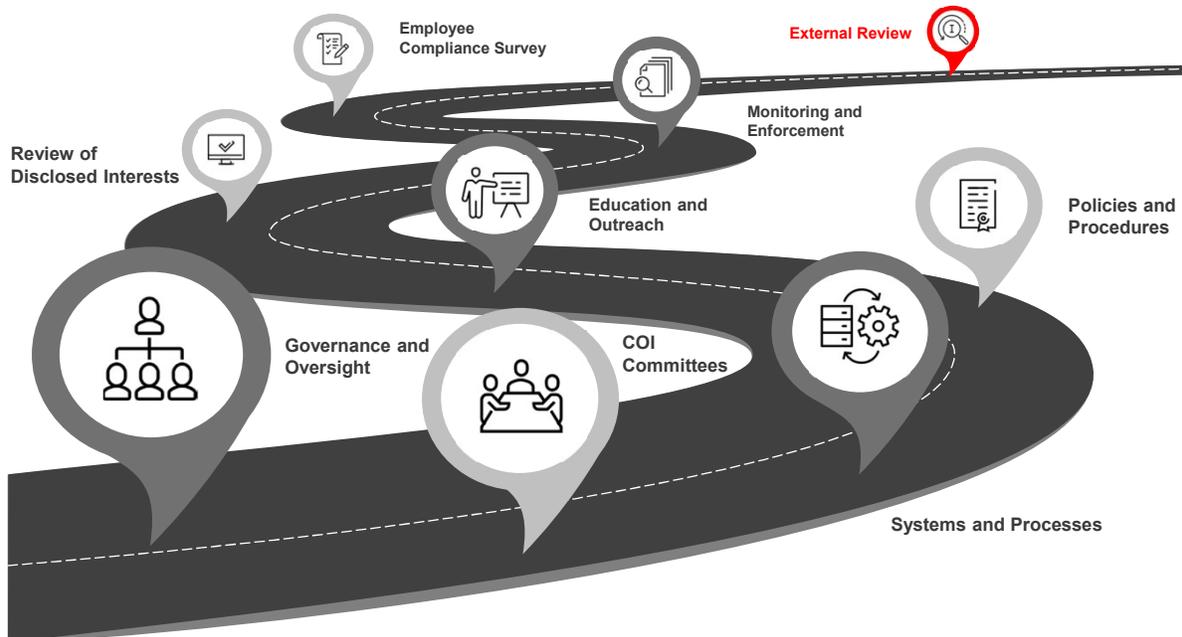
COI Program Maturity Model – Case Study



26

26

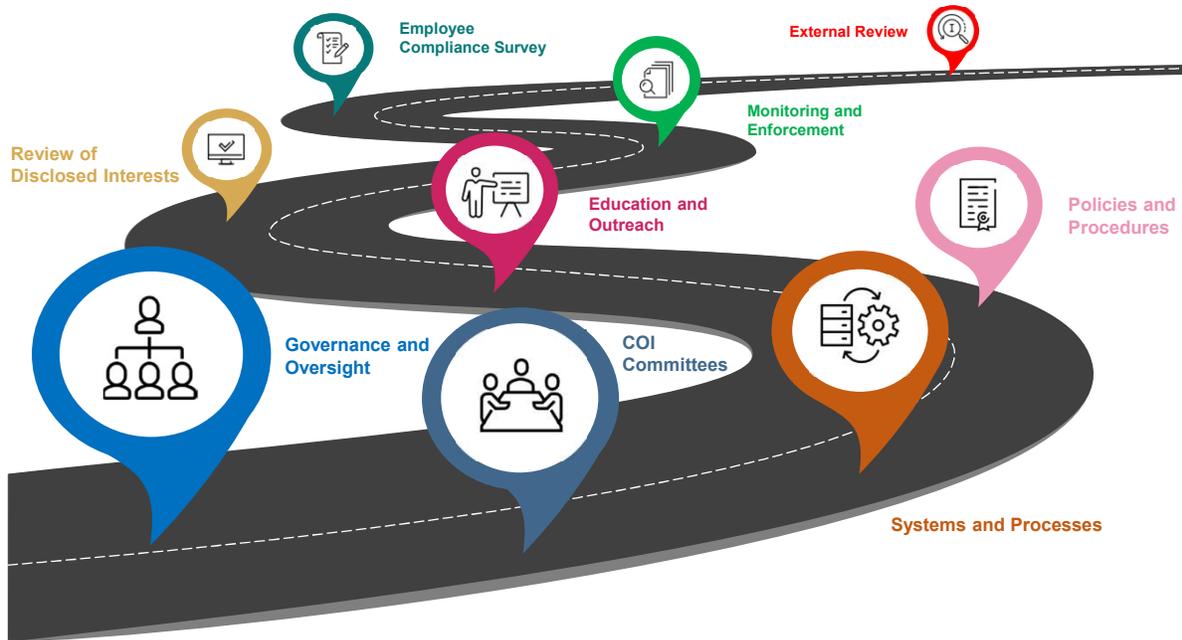
COI Program Maturity Model – Case Study



27

27

COI Program Maturity Model – Case Study



28

28

Bios

29

Deb Berns

Senior Vice President and Chief Compliance Officer, Internal Audit Executive, and Risk Officer

Deb serves as Memorial Sloan Kettering Cancer Center's Senior Vice President, Chief Compliance Officer, Internal Audit Executive, and Risk Officer, overseeing the compliance, privacy, conflict of interest, internal audit, and enterprise risk management functions. Memorial Sloan Kettering – the world's oldest and largest private cancer center – is devoted to exceptional patient care, innovative research, and outstanding educational programs.

Deb is a graduate of the University of Connecticut and received her law degree from the University of New Hampshire Law School. She also received a master's degree in tax law from the New York University School of Law. She started her career at a Hartford-based law firm.

Deb joined The Pillsbury Co. (now part of General Mills) in 1999 and served as employment and benefits counsel until joining Willis Towers Watson in 2002 where she led a compliance team focused on employer retirement plans. She became a Vice President and in-house counsel for CBS Corp. in 2006 before joining United Health Group at the end of 2008. During her decade at UnitedHealth Group, Deb was Chief Privacy Officer, Chief Compliance & Ethics Officer, and oversaw the corporate security, employment and benefit legal functions. She was among a key group of leaders who advised the board on matters related to reputational, business, cyber and other risks.



30

Colleen Curran

Managing Director, Alvarez & Marsal

Colleen Curran is a Managing Director with Alvarez & Marsal's Healthcare Industry Group. Ms. Curran has more than 20 years of experience in the healthcare industry focusing on life science and healthcare regulatory, compliance and consulting. She has significant experience in various roles, including serving as CEO/COO of medical group practices, interim Compliance Officer for large healthcare entities and as a practicing healthcare attorney. Ms. Curran brings expert knowledge of the best practices, regulations and guidelines impacting hospitals and health systems, health plans, providers, life science and device manufacturing companies and government agencies.

Specifically, Ms. Curran has deep expertise in healthcare compliance. She has led compliance and regulatory assessments focused on contracting, credentialing, privacy, compliance effectiveness and clinical research. Her experience encompasses compliance and risk assessments, responding to government inquiries, and managing compliance while under corporate integrity agreements. She also has provided process guidance in the identification, implementation and maintenance of compliance and privacy policies and procedures within organizations.

Ms. Curran has led large process redesign and work flow optimization efforts for health plan, health systems, academic medical centers, Children hospitals and global medical device manufactures. She provided strategic, operational and implementation expertise to support efficient, compliant and effective processes.

Ms. Curran has advised clients on a wide range of business operational and risk issues pertaining to compliance with federal regulatory requirements, meeting corporate integrity agreement requirements, corporate compliance and risk management programs and governance and corporate structure. She has also assisted clients with regulations impacting the research functions within healthcare and life science enterprises. Additionally, she has experience assisting clients with compliance investigations, root cause analysis and responding to federal and state regulatory matters. She has provided counsel on regulatory matters implicating the Stark Act, Anti-kickback Statute, HIPAA and privacy matters and FDA regulations.

Ms. Curran earned her Juris Doctorate (JD) degree, with honors, from Cleveland Marshall College of Law and a Bachelor's degree in psychology from Bowling Green State University. She is an attorney licensed in Ohio and is a member of American Health Lawyers Association (AHLA) and Health Care Compliance Association (HCCA).



31

Julie Hamilton

Healthcare Executive & Consultant

Julie has over 20 years of experience in the healthcare industry specializing in developing, assessing and managing corporate compliance and education programs. Julie has over 10 years of experience serving as Chief Compliance Officer at large academic health care systems and at a comprehensive cancer center. At Deloitte, she worked with clients on assessments of program effectiveness, due diligence of merger and acquisitions and organizational restructuring projects. Prior to joining Deloitte, she served as the Vice President, Chief Compliance Officer at Yale New Haven Health System. In this role, she was responsible for system wide compliance program efforts including coordinating compliance efforts with Yale University School of Medicine. In a prior role at the Seattle Cancer Care Alliance, she served as the Corporate Integrity Officer / Human Protections Administrator. Her approach to compliance and risk is education focused. She has worked to revamp compliance education programs in her previous organizations as well as taken on responsibility for organization wide training and development. In between Compliance Officer roles, she was the owner and Managing Partner of a healthcare compliance consulting business for four (4) years where she worked with many healthcare providers including health systems and physician offices (large and small) to evaluate their compliance, coding and documentation efforts.

This experience has given Julie a thorough understanding of healthcare operations, reimbursement, enterprise risk assessment and mitigation, and compliance program development and implementation particularly within merger and acquisition due diligence, hospital and physician documentation, coding and billing matters, conflicts of interest, research compliance, and hospital-physician financial arrangements. She is particularly interested in assisting compliance programs in assessing their effectiveness as well as modernization efforts.

Julie has an MBA from Creighton University and is a Fellow of the American College of Healthcare Executives (FACHE).



32

Appendix

33

Comprehensive Disclosure Review and Management

Disclosure Review and Management is an essential component of an effective COI Program. The Program reviews disclosures of potential COIs to determine what action is necessary to manage, reduce, or eliminate the COI.



Disclosure Form

- Is the questionnaire thorough and guides discernment of potential conflicts?
- Does the questionnaire walk employees through their business relationships and reveal the potential scenario for a COI?
- Is the disclosure form part of an automated system with an online COI questionnaire? Automation simplifies this process significantly and reduces the possibility of overlooking important disclosures. Unknown and undisclosed conflicts can threaten an institution's tax-exempt status, reputation, research funding, and most importantly, patient safety.



Disclosure Review

- Does review of the Disclosure Form include proper vetting of a variety of risks, especially any possible influence on medical judgment?
- Does the process include evaluating whether any compensation is for bona fide work and whether it reflects fair market value?
- Does the review reveal whether referrals were expected because of any gift or compensation?



Management and Mitigation Plan

- Does the Management and Mitigation Plan prescribe the steps the organization will take to mitigate any bias or appearance of bias?
- Does the plan designate the threshold amount the value of a financial relationship should be reduced to in the case of an individual with a conflict?
- Is every Management and Mitigation Plan approved and signed by the Compliance Officer or other appropriate leader?

Sources: <https://coi.mit.edu/policy/review-evaluation-and-resolution>, [https://www.healthstream.com/resources/blog/blog/2018/06/08/best-practices-for-reducing-conflicts-of-interest-\(coi\)-risk-in-healthcare](https://www.healthstream.com/resources/blog/blog/2018/06/08/best-practices-for-reducing-conflicts-of-interest-(coi)-risk-in-healthcare)

34

34

35