

Law 124-R01

Essential Compliance - The Role and Value of Ethics and Compliance Functions (Winter Session 2024)

Instructor: Lisa Estrada

Email: Lisa.Estrada@scionhealth.com

Instructor: Mary Shirley

Email: Mary@GreatWomenInCompliance.com

Office Hours: By Appointment (please email to schedule)

Class Schedule: January 4, 5, 6, 10, 11 (class time is 7:30-10:30 p.m. Eastern with the exception of Saturday January 6 when class time will be 1:00-4:00 p.m. Eastern)

Location: Virtual (link to be provided)

Course Description:

This course provides an in-depth examination of the role and value of ethics and compliance functions within organizations. The course will focus on the pillars of a compliance program and analyze how these elements fall within the context of international and domestic legislation. Special emphasis will be placed on key statutes such as the US Anti-Kickback Statute, False Claims Act, Stark Law, The Foreign Corrupt Practices Act and the UK Bribery Act, providing students with an understanding of the regulatory landscape and key compliance risk areas for companies operating both domestically and internationally.

.....

Discussion #1 (January 4, 2024)

The Role of an Ethics and Compliance Function

- Analyze the role of an Ethics and Compliance Function
- Understand What's Involved in Building an Ethical and Compliant Culture
- Evaluate the impact of ethical and compliance failures on organizations
- Discuss Wells Fargo Cross-Selling Scandal Case Study

Required Pre-Read:

1. The Starbucks Standards of Business
Conduct <https://livingourvalues.starbucks.com/en-us/>
2. Complex Compliance Investigations, Veronica Root Martinez, Columbia Law Review, March 2020, available at <https://columbialawreview.org/wp-content/uploads/2020/03/Martinez-Complex-Compliance-Investigations.pdf>

Additional Suggested Reading

1. A Better Approach to Avoiding Misconduct, Harvard Business Review, <https://hbr.org/2022/05/a-better-approach-to-avoiding-misconduct>
2. Department of Justice Albermarle FCPA Settlement, <https://www.justice.gov/opa/pr/albermarle-pay-over-218m-resolve-foreign-corrupt-practices-act-investigation>

.....

Discussion #2 (January 5, 2024)
Compliance Program Pillars

- Examine the fundamental components of an effective compliance program.

Required Pre-Read:

1. U.S. Department of Justice, Criminal Division, Evaluation of Corporate Compliance Programs, <https://www.justice.gov/d9/pages/attachments/2017/02/08/evaluation-of-corporate-compliance-programs-march-20-2023.pdf>

Additional Suggested Reading

1. <https://oig.hhs.gov/documents/root/162/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf>
2. The Compliance Handbook: A Guide to Operationalizing Your Compliance Program, Thomas Fox, CreateSpace Independent Publishing Platform, 2018

.....

Discussion #3 (January 6, 2024)
Key Compliance and Ethics Risks

- Introduction to Key International and Domestic Laws
 - Anti-Bribery & Corruption Laws (UK Bribery Act, Foreign Corrupt Practices Act)
 - Health Care Fraud and Abuse Laws
 - Antitrust Laws
 - Data Privacy
 - Conflict of Interest
- Understand the challenges of operating within a global regulatory environment
- Discuss Case Studies

Required Pre-Reading:

1. UK Ministry of Justice Guidance, UK Bribery Act, [Bribery Act 2010 guidance - GOV.UK \(www.gov.uk\)](http://www.gov.uk)
2. Department of Justice, Criminal Division, FCPA Resource Guide, <https://www.justice.gov/criminal/criminal-fraud/fcpa-resource-guide>
3. A Roadmap for New Physicians, Avoiding Medicare and Medicaid Fraud and Abuse, https://oig.hhs.gov/documents/physicians-resources/947/roadmap_web_version.pdf

Additional Suggested Reading

1. Understanding Key Aspects of Data Compliance, Tim Freestone, Security and Compliance Blog, available at <https://www.kiteworks.com/regulatory-compliance/data-compliance/>
2. US Department of Justice Evaluation of Corporate Compliance Programs in Criminal Antitrust Investigations, July 2019, available at <https://www.justice.gov/atr/page/file/1182001/download>

.....
**Discussion #4 (January 10, 2024)
Focus on Detecting and Correcting Compliance Failures**

- Soliciting and Investigating Compliance Concerns
- Compliance Failures: Reporting Obligations and Considerations
- Corrective Action
- Corporate Integrity Agreements and Monitorships
- Case Study on Compliance-Legal Balancing Act

Required Pre-Reading:

1. U.S. Department of Justice, Press Release: Novartis Pays over \$642 Million to Settle Allegations of Improper Payments to Patients and Physicians, July 1, 2020, available at <https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians>
2. U.S. Department of Justice, Corporate Integrity Agreement Between the Office of Inspector General of the Department of Health and Human Services and Novartis Corporation (pages 1-43 only), available at https://OIG.hhs.gov/fraud/cia/agreements/Novartis_Corporation_06302020.pdf

Additional Suggested Reading

1. U.S. Department of Justice, Revised Memorandum on Selection of Monitors in Criminal Division Matters, March 1, 2023, available at <https://www.justice.gov/criminal-fraud/file/1100366/download>
2. Navex 2023 Hotline and Incident Management Benchmark Report, <https://www.navex.com/en-us/campaigns/2023-hotline-benchmark-report/>

.....

Discussion #5 (January 11, 2024)

Focus on Preventing Compliance Failures

- Proactive vs Reactive Compliance Programs
- Control Framework and Lines of Defense
- Outreach, Advocacy and Awareness
- Training and Education
- Empowered and Independent Function, Buy-In and Seat at the Table
- Monitoring, Review and Continuous Improvement
- Data Analytics and Behavioral Science as Tools

Required Pre-Reading:

1. Leveraging Coso Across the Three Lines of Defense [3059fc_cc80a9492ca743fd90d517049736c4da.pdf \(coso.org\)](https://www.ciso.org/3059fc_cc80a9492ca743fd90d517049736c4da.pdf) (Pages 1-9 only)

Additional Suggested Reading

1. 65 Hacks & Cheat Codes to Level Up Your Ethics and Compliance Program, Mary Shirley, CCI Press, 2023
 2. Humanizing Rules: Bringing Behavioural Science to Ethics and Compliance Christian Hunt, Wiley, 2023
-

| Due Date | Assignment | Expectation |
|-----------------|---|---|
| Jan. 4, 2024 | Familiarize yourself with the Starbucks Code of Business Standards | Come to Class #1 prepared to discuss the purpose and potential impact of a Code of Conduct, including what you find effective/ineffective about the Starbucks Code. |
| Jan. 4, 2024 | Read the <i>Root Martinez</i> Columbia Law Review article | Come to Class #1 prepared to participate in a deep dive discussion on the Wells Fargo compliance failure |
| Jan. 5, 2024 | Read the US DOJ Evaluation of Corporate Compliance Programs | Come to Class #2 prepared to participate in a discussion on the elements of an effective compliance program as defined by the DOJ |
| Jan. 6, 2024 | Read the UK Ministry of Justice Guidance on the UK Bribery Act and the US DOJ FCPA Resource Guide | Come to Class #3 prepared to participate in a deep dive discussion of Anti-Bribery and Corruption laws |
| Jan. 6, 2024 | Read Roadmap for New Physicians: avoiding Medicare and Medicaid Fraud and Abuse | Come to Class #3 prepared to participate in a deep dive discussion on US Health Care Fraud and Abuse laws |
| Jan. 9, 2024 | Submit your proposed topic and an outline for a 750-1000 word paper on a compliance hot topic | Email your submission to Lisa.Estrada@scion-health.com and Mary@GreatWomenInCompliance.com no later than 11:59 PM Pacific time on 1/9/2024. |
| Jan. 10, 2024 | Read DOJ Press Release re Novartis Settlement and US DOJ-Novartis Corporate Integrity Agreement (pages 1-43 only) | Come to Class #4 prepared to participate in a discussion about the US government's compliance program expectations with respect to detection and correction of compliance failures and the tension those expectations might create between the goals of the legal and compliance functions. |
| Jan. 11, 2024 | Read pages 1-9 of Leveraging COSO Across the Three Lines of Defense | Come to Class #5 prepared to participate in a discussion about successful implementation of internal controls as well as what makes people pay attention to rules and expectations outside of their core roles. |
| Jan. 14, 2024 | Submit your final compliance hot topic paper (750-1000 words) | Email your submission to Lisa.Estrada@scion-health.com and Mary@GreatWomenInCompliance.com |

| | | |
|--|--|---|
| | | no later than 11:59 PM Pacific time on 1/14/2024. |
|--|--|---|

Grading Scale:

Grading will be Pass/Fail based on (1) attendance, (2) class participation, and (3) submission of a “Compliance Hot Topic” paper of publishable quality.

Course Policies:

- Attendance and Participation: Regular attendance is expected, and participation is required to achieve a passing grade.
- Students are expected to complete pre-read assignments and be prepared to discuss.
- Each student (either individually or as part of a group) will be required to lead a compliance case student class discussion).
- Academic Integrity: All work submitted must be your own. Plagiarism or any form of academic dishonesty, including use of generative artificial intelligence will not be tolerated.

Note:

This syllabus is subject to change at the discretion of the instructor. Any changes will be communicated to students in advance.