

NAVIGATING THE COMPLIANCE MAZE

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Compliance Officer: Role and Qualifications

Is your program preventive or reactionary? Does the program exist because of a regulation or as a part of a culture that believes in doing the right thing all the time? Is the program viewed as an expense or an investment? According to Bissey⁽¹⁾, knowing the answers to these questions will help you match the traits of a Compliance Officer (CO) to the beliefs and culture of an organization. Establishing the reporting structure and basic responsibilities before recruitment will pave the way for a strong foundation and successful transition for both the organization and the employee.

Let us begin by reviewing the role and reporting relationship of the Compliance Officer (CO). Guidance offered by the Office of Inspector General (OIG) indicates, "The compliance department should be led by a well-qualified compliance officer, who is a member of senior management, and should be supported by a compliance committee."⁽²⁾

In the Cambridge English Dictionary, the definition of well qualified is having suitable experience or formal qualifications.⁽³⁾ That definition does not provide any additional clarification and leaves the organization the task of establishing qualifications to guide their selection process.

The healthcare regulatory environment is complex and complicated therefore hiring someone without healthcare knowledge may be difficult but depending on the individual, this may still be a viable option. Finding someone with experience in healthcare compliance will be even more challenging. The role of a Compliance Officer is fairly new and means there is not an abundant supply of individuals with experience. Those who possess experience are likely working in larger organizations and recruiting them to smaller rural areas may prove to be difficult.

If you find the right person but they lack the compliance experience necessary it will be extremely important that you provide the resources necessary to ensure his/her success. It is unlikely that the organization will have someone on staff with compliance experience so on-the-job training or mentoring may not be an option. Educational resources are available and may include sending the CO to healthcare compliance-related conferences, the Health Care Compliance Association Basic Compliance Academy or hiring consultants to orient and provide ongoing support.

A successful CO should have public speaking skills and the ability to build relationships that will foster a culture of reporting. The person needs to be able to perform investigations and mitigate harm so the need to interact diplomatically is important. Issues and concerns need handled carefully, compliance officers should know when to hit the panic button and how to deal with non-urgent situations.⁽⁴⁾ Not everything is a crisis and knowing the difference is a necessary skill.

In an on-line article for *Inside Counsel*, Kelly and Folsom metaphorically compare Sir Ernest Shackleton who successfully lead polar explorations over rough terrain to the regulatory landscapes that companies must traverse today.⁽⁵⁾ Through his leadership, Sir Ernest Shackleton was able to keep his crew engaged in their work and moving forward even though they faced a multitude of dangers. "Despite the daunting legal and regulatory landscape today, chief compliance officers must do the same".⁽⁶⁾

They suggest that the traits of a good compliance officer should include:

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| 1) Integrity | 6) Leadership |
| 2) Courage | 7) Business Judgement |
| 3) Presence | 8) Teamwork |
| 4) Strong analytical ability and understanding of laws and regulations | 9) Proactivity |
| 5) Attention to detail and a global vision | 10) Reactivity ⁽⁷⁾ |

Determining the level at which the CO functions will need to be determined. A compliance officer as a member of the C-Suite has been controversial. However, this level empowers the CO to communicate at a senior level, pursue an effective compliance agenda, receive adequate resources, and provides autonomy.⁽⁸⁾

A reporting relationship directly to the CEO and the governing board further protects their independence. A review of language in multiple corporate integrity agreements indicates that the CO should not be general counsel or the chief financial officer nor should they be subordinate to these individuals.⁽⁹⁾ This structure allows the CO to be neutral, provides for a level of checks and balances, and minimizes the potential for them to experience undue influence and pressure to act in a certain way.

Another consideration is the reporting structure for the other roles assigned to the compliance officer. In many cases, the compliance officer may have additional duties such as the Risk Manager or Quality Director. If this "additional duty" leaves them subordinate to another senior leader, the CFO or legal counsel they may feel pressured or may feel intimidated to act a specific way in their compliance officer role.

Once you have determined the role and reporting structure of the CO, you will need to identify responsibilities of the position. This may vary with each organization but in theory, will contain many of the same tasks. According to the OIG 1998 Program Guidance for Hospitals, his or her primary responsibility should be to oversee and monitor the implementation of the compliance program. Other duties may include:

- Reporting regularly to the governing board, the CEO and the compliance committee
- Periodically reviewing and revising the program
- Developing and implementing a compliance training program
- Ensuring that all staff including independent contractors are aware of the requirements of the program
- Coordinating with Human Resources to ensure that appropriate background checks and exclusion screenings are completed
- Coordinating auditing and monitoring activities
- Independently investigating compliance matters and
- Developing policies and programs for reporting without fear of retaliation⁽¹⁰⁾

Establishing roles, reporting structure and responsibilities will serve as a guideline during the recruitment process. Once hired, the expectations will be clear and provide for a successful transition for the both the new employee and the organization.

HealthTechS3's Compliance Consulting Services are intended to be educational in nature and are not intended to identify potential compliance violations. The Compliance Consulting Services may include advice and recommendations, but the ultimate responsibility for decisions regarding Client's compliance program and related processes, policies and procedures, including without limitation, the decision to further investigate, consult original source materials or notify qualified healthcare regulatory counsel for specific guidance remains with Client as the owner and operator of its business.

- (1) Bissey, B. (2015). Hiring the Right Compliance and Ethics Officer. Available from <http://www.pharmacompliancemonitor.com/hiring-the-right-compliance-and-ethics-officer/8905/>
- (2) 70 Federal Register 4874 (January 31, 2005). Available from <http://oig.hhs.gov/fraud/docs/complianceguidance/012705HospSupplementalGuidance.pdf>
- (3) Cambridge Dictionaries Online. Available from <http://dictionary.cambridge.org/dictionary/english/well-qualified>
- (4) See Bissey
- (5) Kelly, A. & Folsom, S. (2013). 10 traits of a good chief compliance officer: Lessons from polar exploration. Available from <http://www.insidecounsel.com/2013/11/22/10-traits-of-a-good-chief-compliance-officer-lesso>
- (6) See above (p.2)
- (7) See above (p. 2)
- (8) Volkov, M. (n.d.). Empowering the Chief Compliance Officer: A Recipe for Effective Compliances. Available at <https://www.lexisnexis.com/communities/corporatecounselnewsletter/b/newsletter/archive/2013/07/17/empowering-the-chief-compliance-officer-a-recipe-for-effective-compliances.aspx>
- (9) HHS OIG Website: Corporate Integrity Agreements. Available at <http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp>
- (10) 63 Federal Register 8993 (February 23, 1998). Available at <http://oig.hhs.gov/authorities/docs/cpghosp.pdf>

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