



Nothing But Net – Four Keys to Drafting The Right Compliance Officer

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In recent years, the federal government has adopted what might be viewed as a “take no prisoners” stance when it comes to healthcare fraud and abuse.

The pharmaceutical industry, in particular, has been hit with billions of dollars in fines for fraudulent marketing practices including the promotion of drugs for uses not approved by the Food and Drug Administration, as well as paying physicians kickbacks in exchange for purchasing their product.

The U.S. Department of Health and Human Services Office of the Inspector General has provided the healthcare industry with guidance documents designed to help companies create internal controls to ensure they are in compliance with ever-changing rules and regulations.

Guidance for pharmaceutical manufacturers contains seven elements that are considered fundamental to an effective program – not the least of which is designating a chief compliance officer and compliance committee.

In today’s world, the chief compliance officer is viewed as the gatekeeper of a company’s reputation and finding the right one is critical to a pharmaceutical company’s survival.

Finding the right chief compliance officer goes beyond hiring someone who knows what’s legal and what is not. Here are four items your company should focus on during its search for the right fit.

Someone who understands the complexities of the law

While the enactment of Medicare Part D under the Bush Administration and the Affordable Healthcare Act under the Obama administration have had the most significant impact on the pharmaceutical industry in recent memory, healthcare regulations continue to be in constant flux.

As a result, the successful chief compliance officer must be able to continually navigate through the complicated maze of laws and regulations affecting his or her organization. He or she not only must have a broad understanding of the pharmaceutical space in which they operate, but also possess a detailed understanding of the laws, rules and guidelines on a state and federal level. They must understand the various enforcement initiatives that are taking place and how federal and state agencies, as well as licensure boards, are interpreting those laws, rules and guidelines. Because of this, the chief compliance officer must be a highly detail-oriented individual who stays abreast of these changes on a daily basis.

Someone who is an effective leader

It is imperative that the chief compliance officer be an effective leader who is able to instill in everyone – from top management on down – the company's commitment to compliance. He or she must inspire an understanding that compliance is an important part of the company's culture – a living mantra – that the organization lives by. This can be seen by the actions and examples set forth by the compliance officer. He or she must initiate in-service training, webinars and other methods of continuing education. This is key and it must come in the form of a continuous flow of information from the chief compliance officer.

Someone who can work well with others and instill a culture of corporate compliance

The general consensus among regulatory agencies is that compliance officers should operate separate and apart from a company's general counsel. They want to see compliance officers reporting directly to a company's board of directors. Often this is because GCs try to minimize and insulate compliance problems from the board.

The compliance officer must be comfortable acting independently and be able to bring identified issues to existing channels within an organization for investigation and resolution.

He or she must be able to work with the company's senior management to foster a culture that promotes the prevention and detection of any wrongdoing. The chief compliance officer should not be afraid to confront top management when the need arises and should maintain an open-door policy that allows those in the trenches to know he or she is able and willing to listen to their concerns without fear of retaliation.

Someone who is proactive

Like an old-time police officer who walks the beat, gets to know his community and works to thwart crimes of opportunity, the chief compliance officer should be proactive. This is particularly important because having a proactive compliance program in place can help a company in terms of mitigation should a violation be identified. Regulatory agencies are more inclined to reduce penalties and other forms of punishment if a company is viewed as having been proactive in its compliance efforts.

As enforcement agencies put greater emphasis and monetary resources into combating fraud and abuse, we are seeing an increase in the number of prison sentences and civil fines. As a result, the role of an organization's compliance officer has never been as vitally important as it is today.

The role of a chief compliance officer is complicated and requires someone with a specialized skill set. While everyone at a company should take ownership of its compliance program and perform their jobs with the utmost integrity, having someone in place who can provide expert legal and strategic guidance on the most important issues facing the company is imperative.

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Chris travels the country on behalf of a wide range of health care organizations lecturing on varying topics affecting their particular industries. He is a member of the American Academy of Professional Coders (AAPC) National Legal Advisory Board and Ethics Committee.

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