



Maintaining Compliance With Limited Resources

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The need for a company to have a strong corporate compliance program is directly related to the risk of a government enforcement action: the greater the degree of government regulation, the greater the risk and need for compliance. For example, a large publicly traded pharmaceutical company will need a sizable in-house compliance staff to monitor the health of the compliance program on a daily basis. But with privately-held, leaner or less regulated companies, a smaller staff and regular check-ups are in order.

A few years ago, many companies used the basic “Seven Elements” of a compliance program, taken from the government’s April, 2003 Guidance for Pharmaceutical Manufacturers, as a blueprint in designing their own compliance programs. The seven elements include a chief compliance officer and committee; written standards of conduct; strong communication channels and an anonymous hotline; internal monitoring and auditing; prompt corrective action; and an established disciplinary process. Within a short period of time an unofficial “eighth” element was established — formal risk assessments.

As compliance officers soon realized, though, having an *effective* compliance program requires not only implementation of the basic elements, but ongoing evaluation, improvement and refinement of each compliance program component. However, since there is no “one size fits all” compliance program, the deployment of resources will vary according to the size and complexity of the organization and its regulatory environment.

For companies without a large in-house compliance staff, it’s critical to manage limited resources efficiently, but in a way that still ensures an *effective* compliance program. When it isn’t possible or practical to add headcount to the compliance staff or divert existing resources from ongoing long-term needs to short-term compliance projects, companies should develop an outsourcing plan that addresses a compliance program’s needs and periodic requirements, such as:

- Training programs
- Targeted risk assessments and audits
- Testing of processes and internal controls
- Conducting internal investigations of alleged wrongdoing.

Although hiring an experienced law firm is essential for internal investigations where maintaining attorney-client privilege is crucial, the privilege may be just as important in other areas, such as during an audit where many problems are often first detected. Every organization’s compliance needs are different, but the proper managing of limited resources in this important area can make or break it for a company.

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In the Field

Jose Sierra joins L&S as partner & leads new corporate compliance practice

L&S’s new partner José Sierra advises and represents clients under government investigation, litigates business disputes, and counsels companies on compliance. Prior to joining Laredo & Smith, Mr. Sierra was a principal at Fish & Richardson. He will lead Laredo & Smith’s new corporate compliance practice, drawing on his background as chief compliance and ethics officer for two pharmaceutical companies. Mr. Sierra also spent a dozen years as an Assistant U.S. Attorney in Newark, NJ and served as clerk to the Honorable Reynaldo G. Garza in the U.S. Court of Appeals, Fifth Circuit.

“Is Confidentiality Really Forever, Even if the Client Dies or Ceases to Exist?”

was published in the spring issue of *Litigation* (v.40:3), the journal of the Litigation Section of the American Bar Association. In this article, Laredo & Smith Partner Marc Laredo and Anne Klinefelter, director of the law library and professor of law at the University of North Carolina, explore how long we can reasonably expect the attorney-client privilege to protect clients.

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