With corporate integrity agreements (CIAs) broadening in scope and strong pressure from federal regulators to create clearer separation between commercial (promotional) and medical (nonpromotional) activities, many life sciences organizations are starting to take a closer look at the structure, processes, and controls embedded within their medical affairs functions.

Companies need to move quickly to identify gaps in their medical affairs compliance frameworks.

The ongoing trend towards healthcare convergence has seen the mandate of medical affairs functions broaden to include a wider range of healthcare professional activities, which, in turn, have increased the risk of noncompliance. And the risk will only grow as restrictions on physician detailing tighten.

Our experience suggests that many pharmaceutical, medical device, and biotech executives may be surprised by the gaps they find in their medical affairs compliance frameworks; they will want to move quickly to close them.

1. Coming into scope

The fact that the medical affairs function has come under increased scrutiny should come as no surprise to anyone in the life sciences sector. Over the past few years, we have seen regulators sharpen their focus on the promotional activity between life sciences organizations and healthcare providers. Yet while the focus of this attention has largely been aimed towards the sales and marketing functions up to this point, we are increasingly seeing the scope of CIAs broaden to include virtually any interaction that may occur between healthcare professionals and the commercial functions of life sciences organizations.

At the same time, we have also seen a dramatic expansion of the mandate of most medical affairs functions to include new responsibilities, such as medical science liaison activities, healthcare professional contracting, and health economics and outcomes research—all activities that could in some way unduly influence drug prescribing or violate anti-kickback statutes.
Not there yet

Many organizations are starting to recognize the risk. This is not only because they face significant fines and regulatory scrutiny if they are found to be lacking, but because interactions between the sales force and healthcare professionals have become more restricted. As a result, medical affairs is quickly becoming one of the few remaining access points to reach physician audiences.

Our experience suggests that many life sciences organizations may have good reason for concern. Over the past few years, we have conducted numerous gap assessments for clients across the life sciences sector and have found that few—if any—are fully compliant.

Balancing business value and compliance

Closing the gaps and achieving consistency will not be easy. The reality is that there is no blueprint for creating a good medical affairs function; each organization is unique and, therefore, requires an equally unique compliance and control framework.

Over the past few years, we have seen the emergence of clear leading practices within the sector that provide practical guidelines for structuring, managing, and monitoring the medical affairs function.

Based on our experience, we believe there are four key steps that all life sciences organizations should now be undertaking to help ensure they have the right medical affairs compliance and control environments for the future.

1. Review existing documentation and training around medical affairs policies, procedures, and practices
2. Identify any gaps in the medical affairs structure, functions, current practices, systems, and internal controls versus industry-leading practices
3. Assess and prioritize departmental risks in order to facilitate the allocation of resources and remediation across the department
4. Identify and execute gap resolutions and operational effectiveness initiatives to enhance internal controls.

Case study: Reducing risk in medical affairs

When a top five global pharmaceutical manufacturer wanted to improve its medical affairs compliance, they called on KPMG LLP (KPMG) to help identify potential problems and create a program of remediation.

Leveraging deep experience in the sector and practical insight into the changing regulatory environment, KPMG conducted a thorough assessment of the organization’s procedures, practices, and activities to provide executives with a clear picture of their risks and challenges.

Based on these insights, KPMG was able to help the client improve its compliance position and reduce its regulatory risk through a series of remediation actions, activities, and recommendations.
An objective view

Likely the biggest challenge facing life sciences organizations, however, will be achieving objective views of their current control environments. Few organizations have the resources (or the appetite) to spend time uncovering problems; most do not even know what “good” looks like.

As a leading provider of regulatory compliance services to the life sciences sector, we have worked with a number of organizations to help identify potential compliance gaps in the structure, functions, practices, policies, and governance systems of a wide range of medical affairs functions. Simply put, we know what “good” looks like, and we know what it takes to create a program that is not just passable but proactive and sustainable for the future.

The bottom line is that—whether you know it or not—there is significant risk growing within medical affairs functions that actively interact with Healthcare Providers. Given the increasing regulatory and public scrutiny now being placed on the life sciences sector, executives would be well advised to close these gaps before they lead to regulatory action.

Related links

For more perspective on the convergent marketplace in the United States and in other countries, please see:

**Deep dive into data: An aggregate spend compliance assessment that works** – Life sciences companies and providers depend on each other, especially in regard to the accuracy of aggregate spend reporting data. This brief shows how a proactive compliance program can help reduce risk and bring efficiencies to the organization beyond the scope of aggregate spend.

**Growing the pipeline, growing the bottom line – Shifts in pharmaceutical R&D innovation** – This report looks at the great research challenge through the eyes of senior R&D executives from some of the world’s leading pharmaceutical companies.

**Are life sciences companies trying to address 21st century challenges with 20th century business models?** – The time is right for life sciences organizations to focus on moving up the maturity ladder from a suboptimized model to one that is highly integrated. This point of view provides information on the trend to global business services (GBS) as well as the 10 practices where GBS leaders should place their focus.

**Cost Transparency in Healthcare** – This KPMG Global Healthcare Center of Excellence issue brief summarizes the current state of cost transparency efforts and considerations that health plans need to make in providing cost transparency tools to the consumer.

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These days, it seems everyone is talking about healthcare transformation. However, “transformation” really only focuses on a subset of what is currently happening in the U.S. healthcare ecosystem and does not adequately address what is happening more broadly at a systemic level.

At KPMG, we believe that life sciences companies, health plans, and providers should be thinking beyond transformation and focusing more on healthcare “convergence” and the broader implications of operating in a more collaborative and integrated U.S. healthcare delivery model. While transformation of current operations is likely going to be a business requirement, the real question for forward-looking organizations is what role they plan to play in a new and more converged health system.