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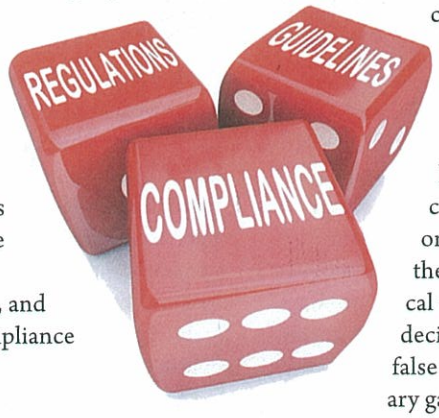
Pharma Compliance 101

CFOs need counsel and advice to cover many types of compliance issues

Most people know that the health care industry is awash in regulations, leading to ever-greater expansion of the field known broadly as "compliance." Few, however, know precisely when to recognize business activity that may trigger compliance issues.

Since many internal corporate compliance officers report up to the chief financial officer, CFOs need to be capable of recognizing scenarios that require compliance advice and counseling. This article highlights several of the largest of these regulatory pitfalls.

Many compliance issues can be grouped into three categories: those that arise from interactions with consumers, those that arise by virtue of product development, and more generalized compliance issues.



1. Broadly speaking, many compliance issues arise at the point of interaction between the company, typically a pharmaceutical company or medical device manufacturer, and their customers. Such customers include the ultimate consumer — you and me — and also physicians, hospitals, purchasers, and other intermediaries between the manufacturers of drug and device products and the patients benefitting from them. Point-of-interaction regulatory issues arise through:

- The dissemination of educational, promotional, and advertising materials, including physician, managed care, and direct-to-consumer pieces
- Labeling and recalls
- The structuring and implementation of health care provider speaker programs and speaker training
- The dissemination of product samples
- Grants for medical education programs, consumer programs, and research, including investigator-initiated studies
- Legislative and industry code transparency requirements in the U.S. as well as internationally

The purpose of these regulations is to ensure health care providers and consumers are not misled or manipulated, so that they make the best medical decisions rather than decisions that can implicate false claims, personal pecuniary gain, or other improper practices or motives.

2. Issues arising as a result of health care companies' needing to run a gauntlet of approvals to bring products to market rest on a regulatory framework requiring products' risks and benefits be weighed and documented through the approval process. These compliance situations include:

- State requirements for licensure of manufacturers and distributors of prescription drugs and devices
- Patient assistance and co-pay reduction programs to provide free or reduced-price medications
- Industry-sponsored research and company-sponsored medical literature
- Advisory boards
- Market research studies

3. The final category of compliance issues facing the health care industry arises in the context of more generalized internal risk management. These are often similar, in many respects, to compliance issues affecting non-health-care-industry companies. Included within this category are:

- The procurement of insurance, product liability issues, and general risk-management initiatives
- Internal corporate compliance audits and investigations
- Negotiation of various contracts, particularly for marketing, sales, or managed care

In today's changing political and regulatory climate, it is safe to say that the above categories are not all-encompassing and certainly do not include tomorrow's compliance issues.

Most corporations are committed to doing business ethically, in full compliance with all laws and regulations. Missteps can lead to regulatory enforcement actions, damage to corporate and executive reputations, lost business, and loss of employment. Care needs to be taken to ensure that health care companies are aware and have resources they can turn to when they perceive themselves as being in over their heads. ✣

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