

Monitoring and auditing

Taking aim: The case for targeted internal compliance auditing

By Andy Bender, Noah D. Shannon, and John Yen

In the late 1960's, surgeons replaced traditional knee surgery with a revolutionary procedure called arthroscopy. The new technique avoided incisions by utilizing tiny cameras and instruments introduced through a small opening in the skin to conduct the required procedure. According to Polaris Management Partners, a management consulting firm specializing in risk assessment, the genesis of knee surgery is akin to compliance auditing in the pharmaceutical industry.

"Unfortunately, the healthcare compliance audits currently conducted by some pharmaceutical firms more closely resemble traditional knee surgery than arthroscopy," says Polaris President Andy Bender. According to Bender, who has conducted more than 125 compliance reviews, some pharmaceutical companies have limited insight into their key risk areas. As a result, they struggle to uncover compliance issues using broad-based auditing techniques. Low-risk areas are often addressed with the same resources as high-risk areas and cycle times from issue identification to resolution are often quite long. Bender says these audits can be costly to the organization and may fail to match potential compliance risks with auditing expenditures.

In the article below, Bender and his partners outline the forces that drive the need for improved compliance auditing and propose a new risk assessment approach akin to the advent of arthroscopic knee surgery -- a framework that focuses auditing resources to address the most pressing compliance issues, ensuring that high-risk issues

are identified and addressed quickly while limiting disturbance to the organization.

Why Audit?

Pharmaceutical firms are being knocked back on their heels by a growing number of investigations into sales and marketing practices and rising fines for healthcare compliance violations. In addition to an increasing number of fines and criminal prosecutions, many pharmaceutical companies are still reacting to the HHS Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers published in April 2003.

One clause of the OIG's guidance requires "the use of audits and/or other risk evaluation techniques to monitor compliance, identify risk areas, and assist in the reduction of identified problems." This mandate has caused pharmaceutical firms to scramble, using scattershot auditing approaches to respond to the government's guidance.

Unfortunately, this "boil the ocean" tactic is not the most effective approach. By addressing all potential risk areas in a uniform manner, companies risk overlooking the most pressing issues, addressing minor infractions rather than major abuses. To remedy this, a structured risk assessment framework is recommended.

Activity Area	Description
Educational Grants	Funding provided by pharmaceutical companies in support of independent, scientific, and community-based educational activities.
Promotional Programs	Events coordinated by companies to market their products.
Entertainment & Gifts	Physician-related expenses incurred by pharmaceutical companies related to sales and marketing activities
Consultant Contracts	Agreements between pharmaceutical companies and physicians and/or researchers.
Clinical Grants	Funding provided by pharmaceutical companies in support of medical research.
Discounts and Rebates	Price reporting for pharmaceutical products used to aid government entities in compiling Best Price and AMP information.

The Methodology

Every pharmaceutical firm engages in a variety of activities that may carry healthcare compliance risks, from gifts and entertainment provided to physicians by the sales force to unrestricted grants provided to researchers or educators. In general, the average firm engages in fifteen to twenty types of activities that carry potential healthcare compliance risk. (*The table on the page 7 outlines some of these areas*).

In its simplest form, a company's greatest potential healthcare compliance risk is defined as the intersection of high dollar spending and high compliance exposure. At the other end of the spectrum, low-risk areas are characterized by lower spending and reduced exposure. The challenge is to determine which is which. This is the purpose of the compliance risk assessment methodology.

By measuring the dollar magnitude of a pharmaceutical firm's different activity areas and comparing this against the level of compliance exposure for each area, auditors can generate a compliance risk profile for each area. For example, a firm with a large sales force and limited compliance policies and training for that sales force will likely find the compliance risk profile for sales activities is relatively high. While this is intuitively logical, a structured approach is needed to add rigor and remove bias from the process, ensuring that each activity area is coded with the appropriate risk profile.

To that end, the two key axes of the compliance risk assessment methodology, dollar magnitude and compliance exposure, must be formally defined and made quantifiable. Just as it sounds, dollar magnitude refers to the total dollar spent on a given activity area. Typically, this is synonymous with the budget for any given area. For example, if a firm's

budget for educational grants is \$100 million per year, that figure will be used as the "dollar magnitude" for that area.

This same principle can be applied to nearly all activity areas. However, care must be taken to ensure that budgets are carefully parsed to avoid the inclusion of multiple activity areas in each analysis.

If magnitude cannot be adequately measured with a dollar figure, a workable proxy is "number of transactions," the definition of which will vary by activity type (e.g., number of grants, number of entertainment and gift charges.)

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The other axis of the analysis, compliance exposure, is sometimes more difficult to gauge. While dollar magnitude is already a quantitative measure, compliance exposure is a set of qualitative factors that must be rendered quantitative through structured analysis. Within the compliance risk assessment framework, compliance exposure refers to the six factors outlined in the table below. These factors are measured for each activity area using a detailed questionnaire that asks the audit team to answer a range of questions for each factor using a five-point scale. The answers to these questions are compiled, weighted, and tabulated, resulting in an overall score for compliance exposure. The higher the compliance exposure score, the more likely an area will pose a significant risk, suggesting the need for a deeper audit and subsequent remediation.

Compliance Exposure

Compliance Exposure Factors	Description
Process	Standard and compliant processes
Documentation	Capture and maintenance of key compliance documentation
Policy	Compliant and enforced standard operating procedures
Training	Up-to-date and accurate compliance training
Technology	A systems infrastructure that supports uniform and compliant processes and auditable data capture
Prior Audit Scores	Tracking of key issues from previous compliance audits

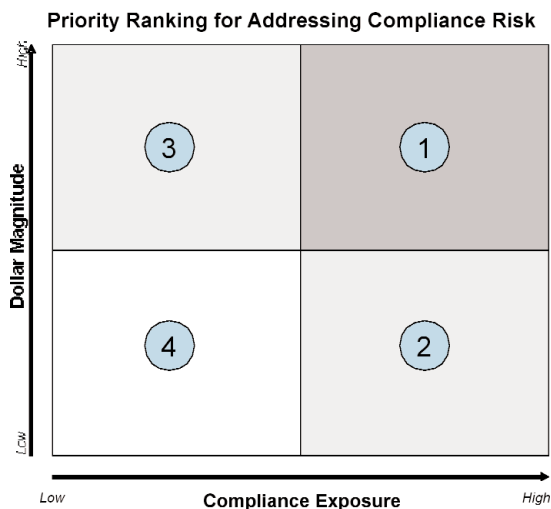
Prioritization

Taken together, an activity area's scores for dollar magnitude and compliance exposure provide insight into that area's compliance risk profile. An area scoring high on both axes should be addressed immediately, receiving resources commensurate with the potential liability. Areas scoring high on compliance exposure but relatively low on dollar magnitude should generally be prioritized second, right after those with High/High ratings. High compliance exposure demands action, even in the absence of high dollar magnitudes. The figure below provides a "rule of thumb" for the prioritization of activity areas by compliance risk. The general framework will apply to most firms, but each organization must also consider these scores through its own lens, factoring in unique organizational and cultural components to refine the results.

Addressing the Issues

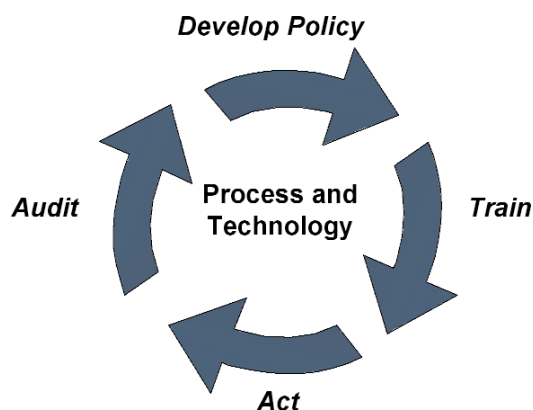
Once the potential compliance risk of each activity area has been prioritized, each must be addressed. This consists of two activities: 1) an in-depth compliance audit, and 2) remediation as necessary. An "in-depth compliance audit" means different things to different firms, but generally there is a set of common steps, including interviewing, document review, and the reporting of findings. A rigorous, structured, and standard methodology for compliance auditing is recommended.

When the audits are completed and the findings compiled and reported, firms must conduct proper remediation, showing a commitment to ongoing healthcare compliance. From the perspective of the OIG and Justice Department, identifying issues and failing to address them can be worse than not



identifying them at all. Again, different firms may take different approaches to addressing identified issues, but a general recommendation is that any action taken should be viewed within the context of the compliance lifecycle (*see below*). Auditing and subsequent issue remediation is not divorced from a firm's overall operations. Instead, these steps should be seen as integral inputs into an ongoing cycle of improvement. Audits lead to findings, which lead to updated policies. These new policies require training to ensure organizational acceptance and action. This action is guided by improved technologies and processes and finally audited to ensure effectiveness. Keeping a holistic perspective is key to making compliance a core organizational function.

The Compliance Lifecycle



Wrap-up

With rising fines and a government mandate, healthcare compliance auditing is now more important than ever. Companies are beginning to recognize this and direct their resources accordingly, but without a structured approach to identifying and addressing issues, companies risk missing the target with their audits. By implementing the compliance risk assessment methodology, firms can more precisely focus their auditing resources, hitting on the high-risk issues and addressing them accordingly. ■

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