LEVERAGING DATA AND TECHNOLOGY IN THE PROACTIVE ASSESSMENT OF RISK

The process of assessing risk seems to be a fairly straightforward set of tasks – identify, prioritize, and mitigate risks facing an organization. But is it really that simple? The breadth and volume of available data regarding the various activities conducted by companies in the pharmaceutical industry continues to expand and with it comes the opportunity, as well as the obligation, for compliance professionals to act on the information it may contain. In order to best leverage this information, it is key to have a dynamic risk assessment process that organizes available data into a streamlined output prioritizing risks on an ongoing basis. This kind of proactive approach is vital as “without effective management of the compliance risks that really matter, the organization is reactive at best and non-compliant, at worst.”1

Government entities have been making an effort to emphasize and further enforce the importance of a thorough, organized risk assessment process. According to the Office of the Inspector General (OIG) and Department of Health and Human Services (HHS), companies should “conduct risk assessments and identify emerging issues to prioritize work.”2 The Centers for Medicare and Medicaid Services (CMS) is also among the government agencies advocating prioritized risk assessment and have created specific templates that lay out what effective risk management plans entail. For example, two key metrics that CMS places at the center of any qualitative risk analysis include probability (the likelihood that a risk will occur) and impact (the consequence a risk will have if it does occur).3

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1/ Is the Organization’s Compliance Approach Working?, Carol Beaumier, Brian Christensen, and Jim DeLoach, December 2012, Page 30
2/ OIG Strategic Plan 2014-2018, Page 7
3/ CMS Risk Management Plan Template, Pages 4-6
Over the past several years, the OIG has increasingly required a compliance risk assessment as part of either the CIA requirements and/or part of what the IRO might be required to review as part of a systems review and/or a transactions review. In 2009, Pfizer was obligated to perform a Risk Assessment and Mitigation Process that was focused risk at a product level. More recently, Sanofi has entered into a CIA that requires a Compliance Assessment and Risk Evaluation process (C.A.R.E.) which incorporates a baseline risk score for company activities, followed by modulation based on product risk, financial risk and previous risk mitigation steps, reinforcing a more targeted focus of risk mitigation strategies, including targeted compliance auditing and monitoring.

As detailed in the April 2015 publication: Practical Guidance for Health Care Governing Boards on Compliance Oversight, the OIG, AHIA and AHLA lay out some key considerations for Board members (and company executives). A key factor that needs to be considered is “Identifying and Auditing Potential Risk Areas”, a section of this report, which reaffirms “Audits can pinpoint potential risk factors, identify regulatory or compliance problems, or confirm the effectiveness of compliance controls. Audit results that reflect compliance issues or control deficiencies should be accompanied by corrective action plans.”

Ultimately, regardless of the emphasis placed on the process by government entities, effectively assessing risk leads to a competitive advantage for the business. The prioritization of risk allows for informed allocation of resources for compliance efforts, defensibility of targeted auditing and monitoring plans, and the proactive mitigation of risks that could become detrimental to the business if not monitored. A detailed review, understanding, and prioritization of the risks facing a company allows for the development of a customized compliance program focused on the activities that pose the largest risk to the business. As the industry continues to gain a better grasp of the data generated by, and available to, the business, the ability to “leverage cutting-edge technology and data”, as highlighted by the OIG, can prove to be a differentiating strength for any organization.

So what does an effective risk assessment process entail? As the answer will undoubtedly vary across organizations, a thorough analysis and inventory of activities the business conducts and the available data points associated with each is warranted.

4/ http://www.pharmacomplianceforum.org/docs/resources/PfizerCIA.pdf
IDENTIFY

The first step is to identify all activities that pose a potential risk to the organization. This should be a collaborative process across the compliance, regulatory, legal, and commercial functions of the business. Together, with the perspective of each function incorporated, a comprehensive list of activities can be developed. While the ongoing auditing and monitoring of all activities may undoubtedly be beneficial to the organization, time and resource constraints often prohibit such an approach.

THE OIG’S 2015 PUBLICATION PRACTICAL GUIDANCE FOR HEALTH CARE GOVERNING BOARDS ON COMPLIANCE OVERSIGHT REINFORCES THE NEED FOR A COMPREHENSIVE COMPLIANCE ASSESSMENT AND RISK EVALUATION:

“The Board should ensure that management consistently reviews and audits risk areas, as well as develops, implements, and monitors corrective action plans. One of the reasonable steps an organization is expected to take under the Guidelines is “monitoring and auditing to detect criminal conduct.” Audits can pinpoint potential risk factors, identify regulatory or compliance problems, or confirm the effectiveness of compliance controls.”

PRIORITIZE

In order to prioritize time and effort towards monitoring the risk activities most important to the business, information and data must be gathered from a variety of sources. This prioritization could involve several components:

An effective approach might be to initially establish a baseline evaluation of each risk by surveying various individual stakeholders within the organization. Using CMS’ likelihood and impact scale, these stakeholders could establish an initial “risk score” that would provide a baseline prioritization of these activities.

Furthermore, additional data points could be collected for the development of modifiers to provide increased prioritization. For example, the audit history of the activities could be collected such that the risk score of activities with previous audit findings could be increased. Additionally, financial spend data could be collected in order to identify certain activities for which the business was devoting an abnormally high level of resources – thereby warranting an increased risk score. Dependent upon the data available to the organization, these modifiers could take many forms – all reliant on what drives risk within a particular business.

This would result in an adjusted risk weighting for each identified activity that incorporates the input of cross-functional stakeholders as well as the breadth of information/data available within the business.
MITIGATE

With the benefit of the information collected through the assessment process, compliance professionals can then efficiently allocate resources to **mitigate** those activities posing the highest priority risk to the business. Mitigation of risk will involve confirmation that the underlying compliance program effectiveness is present and the company is addressing all seven elements in a comprehensive way. In other words, the governance of activities is in place and effective, the policies and procedures that provide for appropriate compliance controls are present and implemented through effective training, the ability to report concerns and confidential allegations without fear of retaliation. Finally, once all of this is confirmed, compliance auditing and monitoring provide the ultimate mitigation against fundamental risk that exists despite the best efforts of an effective compliance program. Having data to support/defend this allocation of resources for audit planning purposes can prove beneficial when presenting to both internal management and external reviewers. It is readily apparent that “when presenting the merits of a given mitigation effort, data and the patterns it creates are crucial to quantify the risk.”

Effective mitigation of potential risk is necessary to maintain competitive advantage, and with recent increasing government emphasis, an effective, comprehensive, data driven risk assessment process is even more of a priority. Companies have the resources available to formulate thorough assessments by collecting data from a variety of areas — surveys, financial statements, audit records, among numerous other sources. Combining this cross-functional input with the use of technology and structured processes is key to identifying and prioritizing risks in order to create an efficient yet comprehensive compliance program.

 DR. SAUL B. HELMAN MD, GLOBAL CHAIR OF NAVIGANT’S HEALTHCARE AND LIFE SCIENCES PRACTICE REINFORCES:

“Highly regulated industries are constantly exposed to evolving compliance risk. These risks are mitigated in part by establishing and maintaining an effective compliance program. However, fundamental risk will remain, and in the Life Sciences industry, any activity that involves the transfer of value or data into or out of the organization will still have fundamental risk that should be further mitigated through targeted compliance auditing and monitoring. CMS and the OIG have recognized this need as reflected in their publications and enforcements.”

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7/ Selling Risk Mitigation to Executives Requires Data, Polished Presentations, Bill Kenealy, June 2014, Page 2