Compliance Keys
Repeatable Process and Automated Monitoring

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Companies in the pharmaceutical, medical device, diagnostics and biotech industries face increasing government scrutiny while at the same time grappling with a reduction in margins, skilled resources and increased market pressure. This combination has created a perfect storm of regulatory and health care compliance risk, especially as the life sciences industry faces an ever-shifting regulatory landscape.

There has never been a better time for life sciences organizations to consider the development of automated, risk-based approaches to regulatory and health care compliance challenges.

A look at recent costs of non-compliance with government regulations gives an idea of the challenges life sciences organizations face:

- State and federal governments recovered $7.2 billion from the health care industry through settlements in 2012, up from $3.8 billion in 2011. The largest settlement to date was $3 billion in 2012 regarding Department of Justice (DOJ) allegations of off-label promotion and unreported safety issues.
- Increased coordination between government agencies, state and federal: DOJ, Food and Drug Administration, Office of Inspector General (OIG) and Center for Medicare and Medicaid Services.
- Twenty-seven major pharma and device companies are under corporate integrity agreements with the OIG. These agreements are expensive to implement, time consuming and increase scrutiny, whether from the government or competitors.
- The Physician Payments Sunshine Act of 2010 – which went into effect on August 1, 2013, and requires life sciences companies to report annually to the U.S. government regarding payments made to practicing physicians and teaching hospitals – is one indicator that the lens has grown wider, expanding from sales and marketing activities to include research and development (R&D). The data reported is undoubtedly going to raise more questions that may lead to more fines and settlements on a go-forward basis.

Physician payments carry risk primarily in terms of potential inducements and can also, more importantly, raise questions about the justification of activities and the potential for using such activities for off-label promotion. There is also concern about a potential lack of fair balance in product information.

Life sciences manufacturers often perceive R&D interactions and activities with health care professionals/entities (HCP/HCE) to be lower risk than sales and marketing activities. As a result, auditing and monitoring activities for R&D have historically been de-prioritized or non-existent. When in place, they have focused more on good clinical practices or Sarbanes Oxley – not OIG guidance or health care compliance risks. The development and implementation of a risk-based compliance monitoring plan that addresses all of these risks forms the foundation for an R&D compliance program.

It is customary for life sciences organizations to compose risk-based compliance programs to track everything from clinical trials to compensation incentives for sales representatives. Typically, critical data and/or processes to be monitored are identified; a risk assessment is conducted; and a risk-based monitoring plan (including timing, frequency and extent of monitoring activities) is developed. In our example of monitoring physician payments, we would include the following:

Leaders of the Indianapolis office of Navigant (from left): Saul B. Helman MD, Colleen Hittle RAC and Jack Tanselle MBA.

- Tracking all activities that include either the transfer of value between the "applicable manufacturer" and HCP/HCE (e.g. clinical trials, advisory boards) or the transfer of product information (e.g., investigator meeting for clinical trial for a secondary indication, handling of unsolicited product inquiries, promotional speaker programs).
- Providing and tracking training to corporate management about the real and perceived risks associated with physician payment activities (this step cannot be overestimated in the importance of securing "buy-in" from management, sometimes the most challenging aspect of developing an effective compliance monitoring program).
- Teaching and requiring the business units and departments to take ownership of the monitoring of their own business activities, developing a culture of good business with good compliance, and allowing those stakeholders to understand the relevance and value of the data that comes from such monitoring activities.

At Navigant, we view data and metrics as best practice tools for managing regulatory compliance challenges. However, like many aspects of modern life, the processes monitored are ever-recurring and the opportunity exists for vigilance failure and non-standard recording. To bring a measure of standardization to compliance monitoring and derive meaningful data, Navigant believes life sciences companies need standardized processes to implement repeatedly, as well as automated compliance monitoring tools that allow for the greatest efficiencies and output to emerge from such processes.

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