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IS YOUR DATA WORKING FOR OR AGAINST YOU?

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Life sciences executives, take heed. Now more than ever, it is time to examine your data and make sure it is working for you and not against you. The stakes are especially high, given recent Corporate Integrity Agreements (CIAs), accompanied by large government settlements, for companies in the pharmaceutical industry. In fiscal year 2014 alone, approximately $3.3 billion was returned to the federal government or private persons as a result of healthcare fraud.[1] The Department of Justice opened 924 new criminal health care fraud investigations and 782 new civil health care fraud investigations in 2014. Alarmingly, many of these cases—hinging on companies having data but not taking appropriate action—have led to costly settlements, and increased government oversight and enforcement through CIAs.

The gravity of the situation for life sciences companies is fueled in part by the Open Payments program, which went into effect in 2013. Through Open Payments, the Affordable Care Act requires companies to submit annual reports about payments made to practicing physicians and teaching hospitals. The reports are then made public by the Centers for Medicare & Medicaid Services (CMS). According to the CMS website, between August 2013 and December 2014, 1,617 companies reported 15.7 million payments, valued at $9.9 billion. With the increased transparency, government entities and other watchdog organizations can analyze this data, and flag concerns such as False Claims Act or federal Anti-Kickback Statute violations.

> "The HHS-OIG continues to use data mining, predictive analytics, trend evaluation, and modeling approaches to better analyze and target the oversight of HHS programs."
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> THE DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE DEPARTMENT OF JUSTICE HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM ANNUAL REPORT FOR FISCAL YEAR 2014

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[1] The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2014

GETTING A HANDLE ON YOUR DATA

For most life sciences companies, the risk implications of their data have long flown under the radar. These companies produce vast amounts of data related to interactions with external healthcare professionals and institutions; and other customers, including but not limited to: product promotion; samples; speaker programs; advisory boards; clinical investigations; and other research and publication activities. And let's not forget meals and other travel expenses associated with such interactions. For all of these activities, the large amounts of data are often collected in disparate source information systems. Simply put, life sciences companies need to get better at keeping inventory of and analyzing this data so they can better monitor and address risks as they arise, as opposed to having these risks turn into full-blown issues investigated by the government. The government has the advantage of relators who can point to particular issues. Companies have the challenge of being able to identify issues on their own, without a relator driven road map. Data can be the road map for companies to preemptively identify issues and address them.

Despite what's at stake, a surprising number of life sciences companies are not asking the right questions about their data. They may not even know what the full inventory of their data is, or be aware of what needs to happen with that data. The good news is that an effective data management program is not rocket science. In fact, it is fairly straightforward and involves three basic steps.

ARE YOU ASKING THE RIGHT QUESTIONS ABOUT YOUR DATA?

- Where is the data housed?
- Is there any data that is being overlooked?
- Who owns the data?
- What are the associated risks?
- Is the data being audited or monitored?
- How are the results of any data analytics being used?
- Are there written standards covering data management?

3 STEPS TO EFFECTIVE DATA MANAGEMENT

1. First, establish a solid understanding of the data that might lead to risk. This begins with a thorough comprehension of the universe of data you are collecting and how it is being collected, stored and used. For example, life sciences companies often collect data in numerous databases, such as sales force automation tools, third-party expense tracking systems, speaker programs databases, clinical trial management systems and possibly numerous others.

   Moreover, the more therapeutic areas and products your company profile covers, the more opportunities there are for disparity and potential compliance landmines. If the documentation is sloppy or conveys that the activity is not done in accordance with relevant standards, it can incriminate your company. If there is no evidence of monitoring for such risks, or even of mining data to evaluate for such risks, it can signal an ineffective compliance program.

2. Once you have inventoried your data, ensure that your data management structure is appropriate. There needs to be a clearly documented hierarchy of rules governing your data management. Do you have written standards covering:
   - How data is collected How long it is retained
   - Who has user rights, and
   - Who is responsible for the data

3. Finally, understand who is reviewing the data and how they are analyzing it:
   - What is being revealed, and what is your organization doing with this information?
   - What are the ongoing auditing and monitoring issues?
   - Do you have processes to make sure these issues are escalated as needed?
   - How well are you leveraging your analytics as input for ongoing risk assessments?

TIPS FOR SUCCESS

Start with the data, not the risk. A lot of companies begin with their interpretation of what is risky, and then go out and look for data related to that belief. While that can be effective in isolated cases of risk, it is far more effective over the long term to let the analysis of the data inform your risk assessment process.

Examine multiple data systems. True data analytics occurs when data from two or more source systems or databases are analyzed together. While many companies might appreciate that definition, most are still not in a position to conduct such analytics, due to a myriad of reasons, not the least of which are a lack of human resources and an explicit plan to do so. As a result, too often companies are still only able to simply examine data one database at a time. An issue that might look fine in one system can take on a different risk profile when examined next to another database.

For example, analyzing a sales representative's performance and the number of medical information requests submitted by that sales representative over the same time period might reveal some information that leads to some concerns about risky behavior. For instance, what if the sales representative has lowest number of medical information requests but is the top seller during the same time period? Is that sales representative answering more questions than he/she should, venturing into off-label discussions or inappropriately promoting in any other way. Alternatively, is this representative operating in a compliant fashion and is operating his/her business in a way that is optimizing the promotional impact that needs to be learned and shared throughout the organization as a better practice?

Loop data back to the organization. The findings based on your data analytics can benefit the entire organization by providing insight into the associated risks, and provide support for decision-making. Analytics should be disseminated to the relevant functions and departments, especially the critical commercial, medical and research functions. In the example above, the sales organization will want to dig deeper into better understanding if such a sales representative is violating policy by answering too many questions that should otherwise be referred to medical information, or if he/she has uncovered an appropriate and effective way of handling objections that minimize the need for such requests at all. Medical information will also want to understand the relationship that sales representative has with the respective medical liaison to assess for risk and opportunity as well.

As the data analytics team examines data and begins to identify risks, it needs to also share this information with the organization's various assurance groups in order to paint a comprehensive picture of its risks. For example, if certain regions are consistently troubled by excessive spending, perhaps next year's internal audit plan might include a closer look at spending in those areas?

Automate, automate, automate. Consider how technology can help make your compliance program more efficient and cost-effective, in terms of work flow, data collection, analysis and reporting. So many compliance-related activities involve recurring processes (i.e., annual training plans, auditing processes, risk assessment processes, hotline calls, investigations, corrective and preventive action plans, etc.), which present great opportunities for companies to leverage technology. This is especially true given the need for companies to demonstrate that they have a sustainable and effective compliance program. For example, there are numerous automated governance, risk and compliance tools available that allow you to perform many different types of repeating tasks, including loading annual employee training records; establishing required training topics, such as policies and procedures, compliance agreements and codes of conduct; setting deadlines; generating reminder emails; contacting recipients if they fail to respond; and automatically triggering follow-up actions. These tools allow executives and their teams to spend their time performing more value-added, mission-critical activities, instead of performing excessive administrative tasks.

DATA COMPLIANCE IN A DIGITAL AGE

Getting a handle on your data management is critical to helping your organization effectively manage risk in the digital age. However, a consistent challenge remains in that many companies still view compliance as a cost center, not a cost-savings center that is worthy of prudent investment. These short-sighted companies likely are not investing sufficient attention or resources

A savvy and evolving program should keep close tabs on the data that is being collected, its purpose, and how it is being used. In addition, effective programs should stay on top of data management and help determine how to slice, dice and analyze it to assess risk—whether as part of an audit or as part of an ongoing monitoring program.

- Here is another awfully good reason: All of your data is potential evidence in a future case against you. Now is the time to take a more proactive approach to data risk and comprehensively track, manage and monitor all of your company's relevant data. It can be your road map to risk mitigation and business enhancement.

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