Companies need to move from a manual to an automated system that accounts for an evolving regulatory environment, ensures accuracy and consistency, and mitigates risk.

IMS Health's **REBECCA FISHER** talks about what companies should do to address state and federal reporting requirements of transactions with physicians.

Since 2006, more than 20 states have introduced legislation requiring pharmaceutical and device manufacturers to disclose various financial transactions or exchanges of financial value to healthcare providers and affiliated healthcare organizations. Similar legislation has recently been enacted at the federal level.

THE IMPACT

What will be the impact of the federal legislation requiring companies to disclose financial transactions with providers?

FISHER. The federal legislation is not going to hugely impact pharmaceutical companies. The PhRMA guidelines cover a lot of this already. The biggest change is how companies maintain and manage all of the information and provide reports that are accurate and consistent, given differences in requirements by state and federal legislation. The impact will be most significant on the device side.

If you look at the state legislation and at the individual state's requirements, the states have not been focused on medical devices, but rather on pharmaceuticals. On the pharma side, there has been much more focus and internal policies around tracking of gifts and spend for the past few years because of OIG and the PhRMA code, as well as some state reporting requirements. But the impact for the life-sciences industry as a whole is that reporting will now be required in all 50 states, which means quite a bit more information to identify, align, aggregate, and maintain.

Device manufacturers are now auditing their systems for readiness, ensuring organizational alignment is in place, and refining policies and processes to support the legislation. This is new for them; historically, they never had to report their payments.

STATES VS. FEDERAL

How does the federal legislation differ from what some states require?

FISHER. There are a couple of differences. The states are much more varied in what they want reported. The federal legislation captures the majority of what the states, in general, are requesting. In some states, the reporting threshold is quite low, whereas in others it is higher. The federal legislation has an even higher monetary reporting threshold.

THE FEDERAL EFFORT

The healthcare reform bill passed by Congress — and signed by President Barack Obama — in March incorporates provisions of the Physician Payment Sunshine Act, which seeks to establish a nationwide standard requiring pharmaceutical and medical-device manufacturers to report to the U.S. Department of Health and Human Services information regarding their payments to physicians. This information, which will identify the recipient, amount, and nature of each payment, will be posted on a publicly available, online database six months after the first report is due.

The final version of the reporting requirement excludes the honoraria that are typically paid to physicians for participating in scientific surveys and marketing research from the reporting requirements, and this amended language is contained in the newly enacted bill.

The PPSA was drafted originally in 2007 by Senators Max Baucus (D- Montana) and Charles Grassley (R- Iowa).

CHANGES TO THE ORGANIZATION

What technology will be needed for these reporting requirements?

FISHER. For pharma and device companies, internally, the marketing and the sales side of the organization is only one small piece. There are places within the company that one does not generally think of where a transaction or some type of honoraria has commenced.

From an internal organizational alignment perspective, this means that a complete diagnostic of systems and departments needs to take place to ensure that all transactions are captured and matched correctly. This entails rigor around policy and procedures to groups and departments that haven't necessarily had much experience in the past with this type of compliance monitoring and reporting.

This is the foundation for aligning and managing this organizational change because it's more deeply defined than just the sales and marketing side of the business, where we normally think it all occurs.

The first step is to review your systems and determine ways you can manage these systems effectively. The systems need to be able to aggregate and match not only the transactional information to that professional but also ensure that professional is matched correctly to the transaction as well.

In other words, make sure you have the right honorarium being matched to the right prescriber or the right healthcare professional or organization. You will need an application that can streamline many of the processes and that moves away from a manual effort as much as possible because you will be creating these reports several times a year to satisfy these different reporting requirements.

To mitigate risk and ensure confidence that reports will satisfy both internal policy and future anticipated changes, the ideal would be to have a system and process that accounts for an evolving regulatory environment, while at the same time ensuring accuracy and consistency across reports and over time. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

CAREER Highlights

Rebecca Fisher is Director of IMS Health's Commercial Research, where she oversees all primary research assets, including Healthcare Relational Services (HCRS), a reference set comprised of healthcare organizations and professionals and their affiliations. Additionally, she leads launch and business planning activities for IMS's Commercial Research Product Line, which includes aggregate spend compliance services.

Before joining IMS Health, Ms. Fisher worked in the pharmaceutical industry for more than 15 years in marketing as a brand lead on a range of products as well as strategy for products in development.

Ms. Fisher holds an MBA from Fairleigh Dickinson University.

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