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The Business Benefits of Sunshine Spend Compliance

by Thomas Hannigan

By now most in the Life Sciences industry have heard about the Physicians Payments Sunshine Act, legislation passed within the Patient Protection and Affordable Care Act of 2010. This legislation, more commonly referred to as “the Sunshine Act”, attempts to introduce transparency around “any transfers of value” between pharmaceutical and medical device manufacturers, and the health care practitioners that they seek to influence. While there is much understood about the information required for reporting, the final regulations have not yet been published so most companies are casting a wide net in order to capture everything that could potentially be considered a reportable activity. Since reporting does not begin until 2013 most are expecting to spend 2012 finalizing what to integrate and include in the reporting.

On March 23, 2010 President Obama signed into law the **Patient Protection and Affordable Care Act of 2010**. Two sections directly impact drug marketing.

- ✓ Prescription Drug Sample Transparency Act
- ✓ Physician Payment Sunshine Provision



Covered Entities:
Prescribers & Teaching
Hospitals

What gets Reported:
Transfers of Value > \$10 or
\$100 in total for the year

What count as a "Transfer of Value"?

- Food & Travel
- Entertainment
- Honoraria
- Education
- Speaking Fees
- Research Funding
- Grants
- Consulting Fees
- Ownership interest
- Royalties
- Licensing fees
- Dividends / Profits / Stock
- Charitable Contributions
- Direct Compensation for Medical Education faculty or speakers

Timeline for Compliance



What makes Sunshine different?

For those already working in the State Compliance reporting space, Sunshine did not seem to be a major departure from the activities that were already occurring. Companies had solutions in place to collect spend transaction data, integrate it and tie it to a specific individual in order to generate the required data formats to send to the regulating bodies. Even though it was only for a dozen or so states and the data was not being posted online unless there was a Corporate Integrity Agreement in place, the process was generally working.

Fast forward 12 months and those working on Compliance reporting initiatives began to see that Sunshine was bigger than initially expected.

- **Additional Manufacturers Included** - The Federal Sunshine reporting requirements include manufacturers such as Medical Device and Medical Supply companies, many of whom did not consider themselves covered by state reporting requirements.

- **Additional Covered Entities** – State reporting initiatives focused mainly on promotional activities for pharmaceutical manufacturers. Sunshine looks to provide transparency around the entire influence value chain, which includes clinical as well as promotional activities. As companies look to understand the external partners that are part of this ecosystem many have found there are dozens, and in some cases hundreds of external partners that now need to track and provide transactional data for reporting.
- **There is a lot of manual effort occurring** – We find that State Compliance reporting is generally being handled by a small group of individuals in the compliance department with support from individuals in other business and technology groups. Typically the compliance team is spending time integrating data from various sources and manually handling any data duplication or quality issues. As Sunshine expands to include all practitioners from all states these manual tasks must be automated.
- **Data governance & stewardship is non-existent** – In many Life Sciences organizations there is still not an enterprise view of information. Silos exist within Sales, Marketing, Medical Affairs and Clinical teams so governance and stewardship for the information supporting those business teams is fragmented and no conducive to compliance grade data.
- **Visibility is much higher** – It is safe to say that organizations are producing state reports today that are not 100% complete or correct. Duplication exists in the data and some transactions do not make their way into the reports. A study by ProPublica, an independent, non-profit newsroom that produces investigative journalism in the public interest, found that pharmaceutical manufacturers reporting spend under a Corporate Integrity Agreement had posted totals online that did not match what they had reported to the states. Since the data collected for Sunshine reporting will all be posted online physicians and consumers will certainly expect that data to be correct.
- **Support is not something we are doing today** – Once spend transaction data has been posted online for all the world to see, companies should expect to be contacted by health care practitioners. There will be disputes around dates and value provided, to whom it was provided (think fathers and sons practicing at the same address) as well as a general misunderstanding around the dollars appearing in the reports (“how come I got an allocation for the meeting room and the projector?”). For Sunshine, organizations will need to develop processes to support this investigation and remediation of spend related transaction data.

So where is the Benefit?

Life Sciences organizations have typically been very functionally focused, with sporadic sharing across business units only when required. The concept of “Customer Relationship Management”, or CRM has always been a tough sell to the industry because it required the integration and sharing of information across a disparate set of internal and external departments and partners. True CRM is an expensive proposition that requires senior level agreement on the benefits and approach, something many pharmaceuticals manufacturers never attained.

The good news coming from Sunshine planning and development is that the expense of integrating information across these disparate business domains needs to occur for compliance and is being funded from enterprise budgets. Forward thinking organizations can take advantage of this integration to create a true single view of an individual, practice or institution in order to better understand where

investments are being made and how those investments are driving better outcomes for patients and shareholders. While the indirect sales model of pharmaceutical and medical device products does not lend itself to CRM the way it does for financial services and retail firms, there is clear benefit in being able to have a more complete view of activities related to a specific individual or organization, and the associated costs of those activities. With changing commercial models and more focus on outcomes and benefits, this integrated view of activities only becomes more valuable.

So what should companies do?

While working with clients on spend compliance reporting initiatives we have identified five things that companies should consider while planning their compliance reporting projects for 2012.

- **Take a “customer-centric” view** – As with other CRM initiatives it helps to take a view of activities that occur through the eyes of the customer, or in this case the health care professional, hospital or managed care organization. Looking across the organization to find these touch-points is the first step. Company’s should not stop at the compliance related activities, but spend the incremental extra effort to ensure all activities are discovered. This will help complete the picture and mitigate the risk of additional activities being added to the reporting requirements.
- **Strengthen data management capabilities** – Sunshine compliance reporting is all about attributing a transfer of value to the right person or institution. Manual de-duplicating of information will not scale to support federal reporting so this is the time to invest in fully functioning Master Data Management (MDM) capabilities to ensure an enterprise scale approach to cleansing, standardizing, validating and matching master (i.e. Individuals, organizations) and reference data (i.e. spend types, reason codes)
- **Ensure Enterprise Governance and Stewardship are in place** – Companies quickly find that having senior executives at the table for compliance reporting discussions highlights the disparate approaches and processes around managing data. Having all parties at the table and designing a formal approach to governing information as a valuable enterprise asset will provide benefits outside of compliance reporting.
- **Define business metrics** – While it is generally true that data becomes more valuable to the enterprise as it is integrated with other information it does not mean that integrating and sharing all data with all people is the right thing to do. Early on in the process it is important to define the business metrics that are meaningful and measurable, and that can drive specific action, and make sure those can be supported in this new integrated environment. For example if it is useful to let a field sales professional know when a physician in his territory has called to dispute spend related data, that should be incorporated into the overall flow of information.
- **Think about the support model early** – Initial discussions with companies have led us to believe that the support model is not getting enough attention. It is certain that individuals will have questions or issues with the data that is reported so there needs to be a clear process around reviewing data, fixing issues, auditing results, posting updated reports and communicating status to health care professionals. Since that process will be critical it is important to define and implement that model long before the data is posted.
- **Optimize Processes** – While in the discovery phase of compliance reporting projects, organizations often learn about inefficiencies in existing processes. Meetings and Event Planning, as well as Grants and Charitable contributions management are two examples we

have come across. Organizations have processes in place to manage these types of activities but they are often rife with overrides and exceptions. Take the opportunity to tighten those processes and ensure the right technology is in place to capture data that can be audited if need be.

As companies kick off their Sunshine compliance integration and reporting activities in 2012 we feel that it is critical to focus on the long-term benefits to the organization and ensure that the proper steps are taken to provide the full business benefit of this initiative.

About the Author

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