



Time crunch.

Life science companies must start tracking payments to physicians and teaching hospitals. Here are four actions they should be taking to comply on time.

Executives at life science companies have known for some time that the final rule implementing the Physician Payment Sunshine Act¹ (“Sunshine Act”) would have a significant impact on their operations. The rule requires medical device and drug companies to start tracking payments and “transfers of value” – such as gifts, honoraria, and ownership interests – to physicians and teaching hospitals.

Companies must track these payments starting August 1, 2013, so they have very little time to prepare their processes and systems for compliance.² How well prepared are companies to meet the deadline? The answer varies considerably among pharmaceutical, medical device, and medical supply companies. The larger drug and medical device companies are generally further along the process, spurred on by the variety of similar laws enacted in U.S. states and in foreign countries as well as voluntary international industry codes.

Larger companies will likely need to modify their mature systems and processes to accommodate, for instance, the newly expanded Sunshine Act requirements around research payments. As a recent [Deloitte Consulting LLP survey](#) found, several larger companies are starting to leverage IT systems, data, and processes to comply with similar disclosure laws in other countries, resulting in greater efficiencies and cost savings.³

However, smaller companies with fewer resources generally have much more work to do across their organizations to prepare. They often deal with more basic questions such as:

- What kind of changes to systems, tools, applications, processes, and data will we need to make?
- We already report to state regulators, so what additional information do we need to report?
- What kind of business rules should we put into place?
- How much training should we provide our employees?

Based on our experience in helping companies prepare their business processes and systems for compliance, we have identified four areas where companies can take action as they prepare to begin collecting the necessary data by August 1.

Empower decision makers

As companies initially cope with the many moving parts of the Sunshine Act, they should create and empower a cross-functional compliance team. This team should include a few high-ranking stakeholders, who not only have the ability to make decisions about a range of issues, from data management and quality to technology investments, but who can also rapidly deploy resources. The team should design a plan and structure for collecting information, and determine what tools and applications are needed to facilitate compliance. It should also monitor company progress toward compliance and be able to quickly and effectively address challenges as they arise. Without an empowered team in place, compliance efforts will likely take longer than expected – possibly beyond the deadline.

While companies can establish a dedicated team that deals only with the Sunshine Act, in our experience, the team is much more effective when it becomes part of an existing governance structure, such as a company’s compliance department. However, while many medium-sized to larger companies have the necessary framework in place to incorporate such a team into their established compliance departments, some smaller companies may not have a compliance department. In these cases, a high-level executive, such as the chief financial officer (CFO) or general counsel, can double as the chief compliance officer (CCO).

But even as part of an established governance structure, a dedicated Sunshine Act team may not have sufficient authority to make the calls on key issues, such as approving large investments or addressing technical challenges. It will need to look higher, perhaps to the CFO, CCO, or another executive to help with those significant decisions. This means organizations should establish accountability within the governance structure for such a team.

¹ The Sunshine Act is part of the Patient Protection and Affordable Care Act, which was signed into law March 2010 by President Obama.

² The data collected between August 1 and December 31, 2013 must be submitted to the Centers for Medicare and Medicaid (CMS) by March 31, 2014. 78 Fed. Reg. 9458 (Feb. 8, 2013).

³ Global HCP Transparency Study: Regulatory disclosure challenges and program guidance for life science companies, Deloitte Consulting LLP, 2013, deloitte.com/globaltransparencystudy

Make smarter tradeoffs

A company's policy decisions can cast long shadows over Sunshine Act compliance. A few simple adjustments to existing policies can greatly simplify compliance reporting, but those very changes often have ramifications to the business itself, including its operations, internal controls, and systems. This means company leaders should clearly understand the tradeoffs they decide to make.

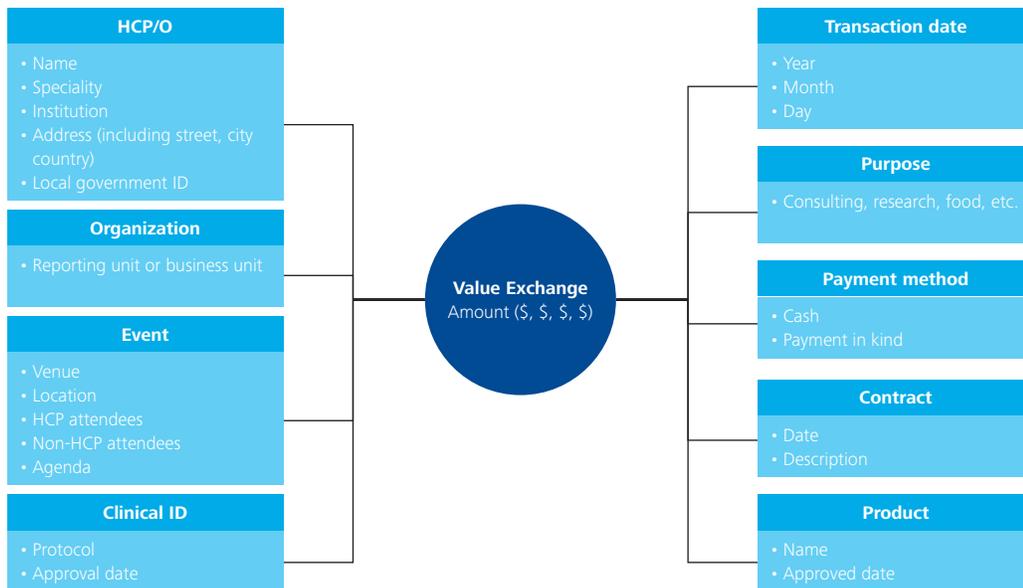
For example, consider a company that rents a room to host a dinner for a dozen physicians and also provides promotional items. Under this scenario, the company must report the costs of the meal, the promotional item, and room rental in three different categories for each physician who attends the event. These types of common activities can add a layer of complexity to compliance efforts. However, in an effort to reduce the reporting

burden, company executives may decide to hold dinners only at locations that do not charge a rental fee or they may decide that the company will no longer provide promotional items to physicians. These seemingly simple policy changes could result in the company's sales team becoming concerned about the impact to the sales strategy, leading to further discussions about the costs of such policies versus their benefits.

As a host of unintended consequences and challenges arise, employees will likely need guidance in these situations. That is why it is important for companies to empower an individual or committee to provide clear and consistent policy statements to help steer the company along a smoother path.

Common data elements for global transparency reporting

While different jurisdictions have different compliance requirements and nuances, certain data requirements are generally common to all, which can help ease compliance concerns. The illustration below shows 10 standard data elements that companies can collect for the U.S. government, states, and other countries. However, the Sunshine Act also requires companies to supply certain unique data elements, such as state license numbers.



Clean up your data

Companies typically maintain master data files for vendors and customers. Some companies may keep vendor and customer data as separate files, while others may combine them into a single large file. However, as these files have grown through the years, many companies may not have implemented processes and procedures to keep the data current and accurate. As a result, these files might hold duplicate, incomplete, or inaccurate information, such as mis-spelled names. This problem can be compounded when other departments within an organization, such as sales and marketing, maintain their own data files. If a company is unable to reconcile, aggregate, and report up-to-date and accurate data, compliance with the Sunshine Act becomes that much more difficult.

As companies face such challenges, they need to review their vendor and customer data for accuracy and, where necessary, clean it up. Companies have several options to help them achieve this, including outsourcing this process to a vendor or performing the task in-house, which could strain a company's resources and time.

Larger companies with more resources and larger budgets are likely to consider a wider range of options. Smaller companies with fewer means could take a simpler route. For example, they could consider building and maintaining a master data list in a spreadsheet that is stored in a secure file. However, these are high-level decisions that will likely need to be made by a dedicated cross-functional team empowered to establish such policies after considering their broader implications to the business.

Automate with a human touch

In the current environment, new regulatory requirements generally mean new technology requirements. With the right infrastructure and automated systems in place to track, analyze, and report the required data, Sunshine Act compliance can be much easier to achieve. This can be especially valuable for companies that may have previously kept paper receipts and logged information into spreadsheets as they complied with previously enacted state laws. Given the scope and range of the Sunshine Act, companies appear to have little choice, but to automate tracking processes and tasks.

Beyond accounts payable and even travel and expense systems that many companies might have in place, executives may be surprised to learn that a number of systems across their organizations already house the data they seek. Consequently, they should map, assemble, consolidate, and reconcile relevant data across the different systems and processes (in the event tracking in some departments is done outside of a system), which can then be transmitted to a centralized data repository. A reporting tool on top of the data repository can then extract the needed information to comply with the Sunshine Act.

But even the most effective IT systems may fall short in matching the payment to a recipient. Companies still need to maintain quality control and vet information, before it is reported. That is why it is important for the company to review and examine the information it intends to report to verify its completeness and accuracy. It is important not to lose sight of the human element, when seeking regulatory compliance.

Beyond the Sunshine Act

Companies need to make decisions quickly and may need to make significant investments across a range of areas – including data, governance, processes and policies, and technology – if they want to meet the August 1 deadline. This means companies should thoroughly understand the requirements as stated in the final rule; identify and assess gaps in their infrastructure and processes; create a plan to achieve their tracking and reporting responsibilities; and manage change as they go through the process of collecting, validating, and reporting spend data.

Another essential part of this effort will be to educate employees about the legal requirements, responsibilities, policies, and expectations for achieving compliance. Companies should also start considering the process of communicating and disseminating the reported data to physicians and other required health care professionals. It may be helpful to educate them on the reporting requirements and anticipate potential questions and concerns.

As executives prepare their organizations, they also should keep in mind that this is more than a compliance exercise. The data they collect and analyze can also provide valuable insights into their business practices. Using data analytics and predictive modeling, companies could, for example, understand why they're spending so much in one area or even identify waste, fraud, and abuse in other areas. These tools can also help companies to enhance their operational compliance, internal controls, and overall effectiveness.

In the end, companies can use the process and system improvements they implement, including greater integration, automation, and standardization, to track and report their payments and make smarter spending and budgeting decisions across their organizations. As a result, companies should be better prepared to not only handle future compliance regulations, but improve business performance.



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