A Veeva White Paper

Embracing the Sunshine Act

An Opportunity for Customer Centricity.

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Executive Summary

It's Finally Here!

As of August 1, 2013 the Physician Payment Sunshine Act requires life sciences companies to track and report payments, gifts, travel, and other honoraria to healthcare professionals (HCPs) and health care organizations (HCOs). The aim of the Sunshine Act is to highlight potential conflicts of interest by allowing the public to look up financial transactions that have taken place. For both life sciences companies and physicians, public disclosure can significantly affect brand and personal reputation.

A significant challenge for life sciences companies will come when they must send their first data submission reports to the Centers for Medicare and Medicaid Services (CMS). The reports must be made before March 31, 2014, and on the 90th day of each calendar year thereafter. Transactions exceeding an aggregate total of $100 annually to doctors of medicine and osteopathy, dentists, podiatrists, optometrists, chiropractors, and teaching hospitals must be reported in order avoid fines of up to $1,150,000 annually. The reports will be publicly available on September 20, 2014 and June 30 in future years. For many life sciences companies, this adds to an existing burden of state aggregate spend compliance. States including California, Massachusetts, Vermont, and West Virginia already have laws that require pharmaceutical and medical device manufacturers to report various types of spending.

The fundamental obstacle presented by federal or state aggregate spend regulations is one of data capture and management. In order to track and document payments to HCPs and HCOs, life sciences companies have had to collect thousands of records from a myriad of disparate systems. These internal and outsourced vendors systems are rarely well integrated and typically do not leverage a common customer identifier, resulting in expensive reconciliation efforts.

According to an Industry Standard Research (ISR) report titled "The Sunshine Act and Clinical Research" (March 2013), there is a lack of awareness about this new legislation among physicians. Over one third report they are "not at all familiar" with the Sunshine Act. Once aware, 74 percent say that incorrect information could be personally and professionally damaging. Physicians must be diligent in ensuring the data reported is accurate and also be prepared to dispute inconsistencies. All of this comes with added costs to their practices, ranging from confusion about which medical education programs can be excluded to increased administrative burden.

This whitepaper outlines physicians' perceptions and concerns about the Sunshine Act and presents key opportunities to engage with physicians in a more customer-centric way by employing new processes and technologies designed to address these issues.

10 Reasons Why Physicians Are Concerned About The Sunshine Act

Who Are Considered Covered Recipients?

Covered recipients include all current licensed doctors of medicine and osteopathy, dentists, podiatrists, optometrists, and chiropractors. Medical residents can be excluded, but must be correctly identified. Nurse practitioners and physician assistants are excluded but life sciences companies need to be aware that if an item is passed through to a physician, the associated physician's information must be reported.

My identity could be Stolen

Physician Concern #1
My identity could be stolen

Physicians are worried about the extent of the information being reported due to fear of identity theft through data breaches or broad public disclosures. On behalf of physicians, the American Medical Association (AMA) has urged CMS to limit mandatory reporting of the scope of the data.

Opportunity

While identify theft cannot be completely prevented, life sciences companies can reduce the risk by ensuring that only relevant data is included in the reports. Physicians can also help themselves by flagging sensitive data for correction during a 45-day review and correction period prior to CMS posting the information publicly.

Why Is The National Provider Identifier (NPI) Important?

The 10-digit National Provider Identifier (NPI) number, which uniquely identifies a physician, is required as part of the Sunshine Act reporting record. CMS requires life sciences companies to use good faith efforts to obtain an NPI — this includes requesting it from the physician directly if it cannot be obtained from the National Plan and Provider Enumeration System (NPPES) database. However, the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services (HHS) has voiced concern about accuracy, going so far as to issue a report on "Improvements Needed to Ensure Provider Enumeration and Medicare Enrollment Data Are Accurate, Complete, and Consistent." The report cites multiple failings in the reliability of the data contained in the NPPES database.

My information could be incorrectly reported

Physician Concern #2
My information could be incorrectly reported

CMS has urged health care providers to closely review their NPPES data to ensure it is correct. Inaccuracies can occur with the NPI and the associated profile information tracked in the NPPES database, including: name (first, last, middle), mailing address, primary practice address (and secondary if applicable), specialty, and any applicable state license numbers. Given the potential for error, physicians may be wary of the identification and payment tracking systems life sciences companies are using.

Opportunity

Getting the correct NPI for a physician is very important. Other common elements such as customer name, address, and phone number can vary across payment data sources due to incorrect data entry or misspellings. Information may also be outdated due to a recent move or name change, and the ubiquity of certain first and last names (e.g., John Smith) complicates the process of gathering such data. This makes it difficult to tie back and aggregate transactions to the correct physicians. Life sciences companies should not rely solely the NPPES database but consider using a third party data source or service that can help obtain and verify the quality of data. This could help to reassure physicians that they have been identified correctly and that life sciences companies have procedures and applications to ensure accurate reporting.

What Transactions And Activities Are Recorded?

Life sciences companies must report transactions in great detail, and are required to include items such as amount, date, form, and nature of payment or other transfer of value. “Nature of payment” encompasses a wide range of activities, each with its own reporting nuances. For example, reportable transactions can include providing consulting fees, honoraria, gifts, food and beverage, entertainment, travel and lodging (including the specified destinations), contributing funding toward research (with many of related justifications), charitable contributions, having physicians serve as faculty or speakers at events, and more.

My payments received could be incorrectly reported

Physician Concern #3
My payments received could be incorrectly reported

Physicians will want to ensure that payments are being correctly attributed and include the source and accurate value of payments. They will also want to engage in a dialogue and supply information to life sciences companies so that these organizations can provide the appropriate context for research funding, grants, or other payments.

Opportunity

Large enterprise life sciences organizations have invested heavily in on-premise master data management (MDM) platforms and tools to create customer master solutions that would not only reflect aggregate spend to meet state laws and the Sunshine Act, but also deliver operating efficiencies and provide better insights across customer interactions. Significant ongoing costs also include the purchase of outside data sources to supplement their own data sets. Small to medium-sized life sciences companies, on the other hand, have never been able to afford the time and costs of customizing and integrating systems to create a true customer master. Instead, they continue to track information manually or outsource their aggregate spend tracking needs.

Furthermore, many MDM platforms fall short in addressing the high rate of change in physician details. Although sales representatives often capture the latest information following their physician visits through their customer relationship management

(CRM) applications, the updates are often inconsistently reflected due to ad-hoc or incomplete integration with their customer master solution.

More complex payments and transfers involving clinical trials and grants require a compliant content management platform with a built-in workflow engine. Life sciences companies need this capability in order to support the routing and approval of forms to correctly identify and aggregate these payments and to keep all activities audited in case of inquiries or disputes.

Modern cloud-based customer master and regulatory content management systems are now available to dramatically improve the accuracy and efficiency of reports, built to scale with the size and needs of organizations large and small. The ability to consistently produce accurate reports will reduce the number of disputes and alleviate many of physicians' greatest concerns around the Sunshine Act.

What Special Rules Apply To Continuing Education Programs (CME)?

In most states, physicians enroll in continuing medical education courses in order to to maintain their licenses. The Accreditation Council for Continuing Medical Education estimates that drug and device companies sponsor nearly a third of this medical training. According to a survey released September 2012 by the CME Coalition, a lobbying group for the continuing medical education (CME) community, 95 percent of physicians said CME was moderately to very important to their ability to keep up with the latest in patient treatments. Seventy five percent of the physicians surveyed said that if the Sunshine Act's reporting requirements included accredited, commercially supported CME, this would have some effect on their decision to participate in certified CME activities produced with industry funding. Fortunately, the CMS made adjustments before the final act went into effect, which limited the reporting requirements for CME, provided that certain conditions are met.

My education options could be limited

Physician Concern #4
My education options could be limited

Physicians, patients, and other healthcare stakeholders recognize this change in the CME reporting as an important step for keeping medical professionals abreast of the latest treatments available for their patients. But widespread concerns remain in the medical community.

Opportunity

Life sciences companies have an opportunity to gain physician trust and loyalty by clearly outlining how specific CME programs being offered to the physician will be reported.

Will Sales Rep Visits To Physicians Be Impacted?

CME practice visits by pharmaceutical reps are exempt from Sunshine Act reporting. Lunches provided by pharmaceutical representatives may be excluded from physician reporting as long as the transfer of value is less than $10 per person (up to $100 per year). Another ISR report, "Sunshine Act: Pharma Impact – Changes in US Physician Behavior," stated that the Sunshine Act would have a dramatic impact on the ability of pharmaceutical sales representatives to frequently detail physicians, both one-on-one and in a group setting.

My sales representative's visits may have to be curtailed

Physician Concern #5
My sales representative's visits may have to be curtailed

While some physicians field multiple visits daily from pharmaceutical sales representatives, who can wait hours to get a 30-second meeting, many medical practices have already banned such visits because of the associated administrative burden and time requirements. The ISR Report stated that 47 percent of physicians report that they currently participate in a group detail on a weekly basis, but only 30 percent said they plan to continue this practice after the Sunshine Act requirements go into effect.

Opportunity

Even before the Sunshine Act, there was a growing trend of physicians accepting fewer in-person sales representative visits. As a result, life sciences companies have developed alternative channels of communication. For example, eDetailing offers a self-directed way for physicians to educate themselves. Email has also been used to inform no-see or low-see physicians, but it has always come with the risk of non-compliant off-label discussions. A compliant email capability must be part of or tightly integrated with CRM to allow sales representatives to use approved templates and content, with full audit trail and keyword filtering controls. Having up-to-date and accurate emails for each physician is important and there are several reliable data enrichment services that can help. Orchestrated planning using a compliant multichannel application is essential to maintaining good personal relationships with physicians.

Will Drug Sample Distribution Be Reduced?

Free drug samples serve a crucial clinical role. Physicians can learn more about the drug, and patients are more likely to start treatment if they walk out of their doctor's office with the medicine they need. Samples are not reportable under the Sunshine Act, but in 2012 some life sciences companies had already began fulfilling a federal government program called the "Prescription Drug Sample Transparency Provision," which required annual reports on the identity and quantity of all drug samples requested and distributed. This provision is distinct from the Sunshine Act, and the government has not announced any plans to share this information publicly.

My access to samples may be affected

Physician Concern #6
My access to samples may be affected

Pharmaceutical sales representatives who visit physicians in person often provide samples, which are sometimes used by the physician to help people who are struggling financially. Given the atmosphere of public disclosure and scrutiny ushered in by the Sunshine Act, physicians may be conflicted about accepting visits, yet also worry about losing access to samples. Life sciences companies must ensure that they have alternative channels for sample distribution.

Opportunity

Life sciences companies can alleviate physician concerns through a central sample ordering system that can be used by representatives and that same system should also be integrated with a call center, custom portals, or third party solutions which capture sample requests, providing multiple ways of getting samples to physicians.

What Is The Review And Correction Process?

Following the end of a 45-day review and correction period, there will be an additional 15 days to correct data in order to resolve disputes. During this time, updated data may be provided to CMS to finalize data submission. If a dispute cannot be resolved in this time, the parties can continue to work to reach resolution and update the data. It is possible that CMS will continue to move forward with publishing the original and attested data, but CMS will mark this information as disputed. CMS plans to monitor not only the rate of disputes and resolutions, but also any abnormally high number of disputes or unresolved disputes submitted per reporting company.

My data should be verified by me before it is submitted

Physician Concern #7
My data should be verified by me before it is submitted

Since companies are not required to share data with physicians prior to submission to CMS, physicians are concerned that the limited time period for disputing incorrect information may inhibit them from ensuring that the final report is accurate. According to the ISR's "The Sunshine Act and Clinical Research" report (March 2013), 71 percent of physician respondents stated that they expect pharmaceutical companies to inform them of the value of a service or benefit before it is offered to them.

Opportunity

Life sciences companies could choose to share information with physicians before it is published. In order to do so, they would need an automated system offering secure, personalized physician access to the latest content. Collaboration between companies and physicians to preemptively resolve inaccuracies would reduce the number of "in dispute" items noted by the CMS and the public, avoiding negative brand perception.

What Will The Public See?

The data collection and submission report templates required from life sciences companies were finalized in May 2013. The actual Sunshine Act financial transparency data will be made publicly available on September 20, 2014 and on June 30 in future years, most likely via links from the CMS website.

My reported information may be misleading

Physician Concern #8
My reported information may be misleading

The interaction between a physician and a salesperson for a pharmaceutical or medical device company might include education, travel, honoraria, and meals. Most often, these transactions are made without written contract. However, in the case of industry-funded clinical research, physicians have contracts with life sciences company or contract research organizations (CRO). This contract could end up causing an aggregated payments record to be created under the name of a single principal investigator, the physician who leads the conduct of a clinical trial, which includes the salaries of multiple staff members, such as study coordinators and research nurses, as well as the costs of on-site supplies, equipment rental, shipping, and document storage. Without appropriate education, consumers could view all payments as income to the physician.

Opportunity

While it is impossible to control the public reaction to data published by CMS, life sciences companies can help by working with physicians to produce accurate reports and proactive public education. Such efforts will reassure the public that life sciences companies and physicians have a mutual goal of improving patient outcomes.

What Still Needs To Be Put In Place?

Many life sciences organizations may already have tracking systems in place, as they have been responsible for monitoring state aggregate spend compliance. States like California, Massachusetts, Vermont, and West Virginia already had laws that required pharmaceutical and medical device manufacturers to report various types of spending. However, reporting this information with the highest level of accuracy requires clean master data and systems that can efficiently reconcile disparate data sources.

My administrative expenses will increase

Physician Concern #9
My administrative expenses will increase

Physicians say they now are working to find a balance between necessary transparency and what some perceive to be time-consuming and arduous filing requests. The American Medical Association (AMA) has produced a Sunshine Act financial transparency toolkit for its members to help them through the process. The administrative load will only get heavier as disputes resulting from inaccurate reporting surface.

Opportunity

Reporting accurate information would avoid disputes, administrative cost, and strained relationships with physicians. Multichannel orchestrated communication can also ensure that information is well organized and delivered to physicians quickly and compliantly with or without in-person visits.

What Is At Stake?

With concerns ranging from the precision of reporting to public misinterpretation of disclosed data, life sciences companies and physicians have a lot at stake, both financially and in terms of brand and personal reputation.

My reputation and business could be at risk

Physician Concern #10
My reputation and business could be at risk

The ISR report "The Sunshine Act and Clinical Research" (March 2013) indicates that many US Primary Care Physicians are not in favor of the Sunshine Act, and 74 percent of respondents believed that it would negatively impact their practice.

Opportunity

Although life sciences companies may not be able to address all of the concerns that physicians have around the Sunshine Act, they can build a closer relationship with health care professionals by adopting a customer-centric focus. Companies can utilize integrated surveys executed through multiple channels to understand and analyze individual and collective physician concerns. With this information, they will be empowered to proactively address any emerging trend.

Conclusion

Multinational life sciences companies are already aware of the growing number of laws similar to the Sunshine Act being enacted globally. For many, the Sunshine Act is just the beginning. In France, The Bertrand Law (colloquially known as the "French Sunshine Act") was passed in 2011. In early 2013, the Association of the British Pharmaceutical Industry, an organization that represents the interests of the UK biopharmaceutical industry, published its toolkit for companies to assist them in complying with clinical trial transparency requirements. According to the Deloitte Consulting "Global HCP Transparency Study", by 2015 more than 70 percent of drug sales will be in countries with such measures.

Only time will tell whether the Sunshine Act will achieve its desired effect or spawn a set of additional unintended consequences. In the meantime, life sciences companies should utilize modern cloud-based customer master data solutions to efficiently deliver accurate reports that can be confidently shared with physicians. By taking advantage of orchestrated multichannel sales and marketing, combined with secure regulated content management, companies can turn a challenging act into a customer-centric opportunity by anticipating and responding to physician behavior and concerns.

Veeva

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