

# Embracing the Sunshine Act

## An Opportunity for Customer Centricity.

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

### Table of Contents

<b>Executive Summary</b>	<b>3</b>
It's Finally Here!	3
<b>10 Reasons Why Physicians Are Concerned About The Sunshine Act</b>	<b>4</b>
Who Are Considered Covered Recipients?	4
Physician Concern #1: My identity could be stolen	4
Why Is The National Provider Identifier (NPI) Important	4
Physician Concern #2: My information could be incorrectly reported	4
What Transactions And Activities Are Recorded?	5
Physician Concern #3: My payments received could be incorrectly reported	5
What Special Rules Apply To Continuing Education Programs (CME)?	6
Physician Concern #4: My education options could be limited	6
Will Sales Rep Visits To Physicians Be Impacted?	7
Physician Concern #5: My sales representative's visits may have to be curtailed	7
Will Drug Sample Distribution Be Reduced?	7
Physician Concern #6: My access to samples may be affected	8
What Is The Review And Correction Process?	8
Physician Concern #7: My data should be verified by me before it is submitte	8
What Will The Public See?	9
Physician Concern #8: My reported information may be misleading	9
What Still Needs To Be Put In Place?	9
Physician Concern #9: My administrative expenses will increase	9
What Is At Stake?	10
Physician Concern #10: My reputation and business could be at risk	10
<b>Conclusion</b>	<b>10</b>

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

### Executive Summary

#### It's Finally Here!

Public access to [Open Payments](#) data collected in 2013 will be available as of September 30, 2014. Popularly known as the Physician Payments Sunshine Act, it requires life sciences companies to track and report payments, gifts, travel, and other honoraria to healthcare professionals (HCPs) and healthcare organizations (HCOs). It delivers transparency by allowing the public to look up transactions of value that have taken place. For both life sciences companies and physicians, the public disclosure can significantly affect brand and personal reputation.

Life sciences companies sent their first data submission reports to the Centers for Medicare and Medicaid Services (CMS) before March 31, 2014, and must continue to do so on the 90th day of each future calendar year. Transactions exceeding an aggregate total of \$100 annually to doctors of medicine and osteopathy, dentists, podiatrists, optometrists, chiropractors, and teaching hospitals must be reported to avoid fines of up to \$1,150,000 annually. For many life sciences companies, this added to an existing burden of state aggregate spend compliance. States including California, Massachusetts, Vermont, and West Virginia already had laws that required pharmaceutical and medical device manufacturers to report various types of spending.

The fundamental challenge 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), 74 percent of physicians polled indicated that incorrect information could be personally and professionally damaging. Physicians have had an [opportunity to review their data](#) (ended September 11) to ensure that the data reported is accurate and [disputing inconsistencies](#). All of this has come 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' continuing 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.

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

### 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.

#### *Physician Concern #1* *My identity could be stolen*

Physicians are worried about the extent of the information 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 identity theft cannot be completely prevented, life sciences companies need to continue to reduce the risk by ensuring that only the most up-to-date and relevant data is included in the reports. Physicians were also given an opportunity to help themselves by [flagging sensitive data for correction](#) during the 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 they cannot obtain it 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) had 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."

#### *Physician Concern #2* *My information could be incorrectly reported*

CMS has urged healthcare 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.



**My identity could  
be Stolen**



**My information  
could be incorrectly  
reported**

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

### *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 on 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 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.

### *Physician Concern #3*

#### *My payments received could be incorrectly reported*

Physicians will want to continue 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



**My payments  
received could be  
incorrectly reported**

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

(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 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. The CMS limited the reporting requirements for CME, provided that certain conditions were met, but most recently in July 2014 [submitted a proposal](#) to remove the exemption.

#### *Physician Concern #4*

##### *My education options could be limited*

Physicians, patients, and other healthcare stakeholders recognize that CME is important for keeping medical professionals abreast of the latest treatments available for their patients, so widespread concerns remain in the medical community about the proposal by CMS to remove the exemption.

#### *Opportunity*

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



**My education  
options could  
be limited**

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.



**My sales  
representative's  
visits may have  
to be curtailed**

### Will Sales Rep Visits To Physicians Be Impacted?

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.

#### *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% of physicians report that they currently participate in a group detail on a weekly basis, but only 30 per-cent 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 begun 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.

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

### Physician Concern #6

**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 continue to 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 45-day review and correction period which [ended on September 11th](#), there were an additional 15 days to correct data in order to resolve disputes. During this time, companies could provide updated data to CMS to finalize data submission. If the parties could not resolve a dispute in that time, they would continue to work to reach resolution and update the data. CMS would move forward with publishing the original and attested data, but would 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.

#### *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 inhibited them from ensuring the accuracy of the final report. 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*

In the future, 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.

### Physician Concern #7

**My data should  
be verified by  
me before it  
is submitted**



## Embracing the Sunshine Act. An Opportunity for Customer Centricity.

### Physician Concern #8

**My reported  
information may  
be misleading**

#### 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 30, 2014 and on June 30 in future years.

#### *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 a written contract. However, in the case of industry-funded clinical research, physicians have contracts with life sciences companies or contract research organizations (CRO). These contracts can result in aggregated payments records that reflect huge sums, even if only a fraction represent payment to the physician. For example, the contract can result in a record 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 direct income to the investigator.

#### *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 have used tracking systems they had in place, as they have long 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 continued reporting with the highest level of accuracy requires clean master data and systems that can efficiently reconcile disparate data sources.

#### *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 increase as disputes resulting from inaccurate reporting continue to mount.

### Physician Concern #9

**My administrative  
expenses will  
increase**

## Embracing the Sunshine Act. An Opportunity for Customer Centricity.



**My reputation  
and business  
could be at risk**

### *Opportunity*

Reporting accurate information will help avoid disputes, administrative cost, and strained relationships with physicians. Orchestrated multichannel 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 dis-closed data, life sciences companies and physicians have a lot at stake, both financially and in terms of brand and personal reputation.

#### *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 healthcare 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**

Global 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. One of the most significant upcoming events is the [EFPIA](#) (European Federation of Pharmaceutical Industries and Associations) Disclosure code. Beginning in 2015, life sciences companies in Europe must track transfers of value to HCPs and HCOs, with disclosure [no later than June 30, 2016](#). According to the Deloitte Consulting "[Global HCP Transparency Study](#)", by 2015 more than 70 percent of drug sales will take place in countries with stringent transparency 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 they can confidently share with physicians. By taking advantage of coordinated multichannel sales and marketing, combined with secure regulated content management, companies can turn a challenging act into a customer-centric opportunity, anticipating and responding to physician behavior and concerns.



**Veeva Systems Inc.** is a leader in cloud-based software for the global life sciences industry. Committed to innovation, product excellence, and customer success, Veeva has more than 200 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. Veeva is headquartered in the San Francisco Bay Area, with offices in Europe, Asia, and Latin America. For more information, visit [www.veeva.com](http://www.veeva.com).

For more information  
**Veeva Systems**  
4637 Chabot Drive  
Suite 210  
Pleasanton, CA 94588  
925.452.6500

[veeva.com](http://veeva.com)  
[info@veeva.com](mailto:info@veeva.com)

