

**DON'T GET BURNED BY THE SUNSHINE ACT**

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# Scrutinizing Physician Compensation

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## Introduction

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The Physician Payments Sunshine Act (now known simply as the Sunshine Act) requires pharmaceutical companies, medical device manufacturers, biotechnology organizations and medical supply companies (collectively referred to in the Act as “life sciences companies”) to track nearly all payments and other transfers of value made to physicians and academic medical centers. The Sunshine Act is the latest expansion of the federal government’s ongoing scrutiny of physician relationships with life sciences companies.

While recognizing that life sciences companies legitimately rely on physician expertise to develop, evaluate, market, and train providers on the proper use of their products, the government worries physicians are being improperly influenced in making referrals for these products. **Historically, the government has relied on well-publicized, high-dollar enforcement actions as a deterrent to pay-for-referral schemes. Now, with the Sunshine Act, the government has a new weapon in its arsenal: public transparency in financial relationships between physicians and life sciences companies.**

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## Overview of the Open Payments Program

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Under the authority of the Sunshine Act, the Centers for Medicare & Medicaid Services (CMS) has established the Open Payments program. While many companies have maintained internal mechanisms to track their aggregate spend on healthcare providers (or HCPs), all life sciences companies now must post to a CMS-sponsored portal all direct and indirect payments or other transfers of value made to physicians and academic medical centers. This includes cash, cash equivalents, in-kind items or services, stock options or ownership interests, dividends, profits, and other returns on investment.

In addition to consulting fees and similar payments for thought leadership or key opinion leader activities, services on advisory boards, presentation of educational programs, or meeting attendance, the reporting requirement also extends to gifts, entertainment, food and beverage, travel, textbooks, clinical research, and journal reprints. The very narrow exceptions to the reporting requirement are payments or items valued under \$10 (unless more than \$100/year in the aggregate), educational materials intended for patient use, manufacturer discounts and rebates, and product samples.

## Initial Open Payments Reporting Results

Since September 30, 2014, the information reported through the Open Payments portal for the period August 1, 2013, through December 31, 2013, (known as the Initial Reporting Period) has been publicly available through a [searchable database](#). Today, anyone with internet access can search for payment records by name of physician, teaching hospital, or the life sciences company making the payment.

Each record lists the payer, the recipient, the amount of the payment (including the value of goods or services provided), and its purpose (e.g., consulting or speaking fees, research grants, travel reimbursement, meals). CMS plans to enhance functionality to allow searches on additional criteria (e.g., by specialty or by type of payment) in the future.

According to a [CMS fact sheet](#), nearly 1,400 organizations reported unique identifiable payments totaling \$1.3 billion made to approximately 360,000 physicians and 900 teaching hospitals during the Initial Reporting Period. Another 1.7 million payments totaling \$2.2 billion were reported but have not yet been tied to a specific recipient. CMS has directed many life sciences companies to provide more detailed information, and the agency will supplement the database as more payments are identified.

Prior to making the payment information publicly available, CMS allowed pre-registered physicians and teaching hospitals to review the payments attributed to them. Approximately 26,000 physicians and 400 hospitals took advantage of this opportunity. From this group, CMS received challenges to approximately 13,000 payments. **About three-quarters of those challenges remain unresolved and are not included in the data made available September 30.**

In light of this, physicians should register at the [CMS Enterprise Portal](#) to review calendar year 2014 reported payments before they are made publicly available in June 2015. There have been several reports of payments having been attributed to the wrong physician and of payment amounts having been inaccurately reported by the life science company making the report.

Total_Amount_of_Payment_USDollars	Date_of_Payment	Number_of_Payments_Included_in_Total_Amount	Form_of_Payment_or_Transfer_of_Value	Nature_of_Payment_or_Transfer_of_Value
\$7,495.19	09/16/2013		1 Cash or cash equivalent	Travel and Lodging
\$1,472.44	08/07/2013		5 Cash or cash equivalent	Food and Beverage
\$15,258.60	08/07/2013		2 Cash or cash equivalent	Consulting Fee
\$2,709.89	08/07/2013		1 Cash or cash equivalent	Travel and Lodging
\$2,565.35	12/19/2013		1 Cash or cash equivalent	Travel and Lodging
\$195.63	10/25/2013		1 In-kind items and services	Charitable Contribution
\$163.64	10/04/2013		1 In-kind items and services	Charitable Contribution
\$86.00	11/15/2013		1 In-kind items and services	Gift
\$219.50	10/25/2013		1 In-kind items and services	Charitable Contribution
\$128.00	11/14/2013		1 In-kind items and services	Gift
\$75.00	11/14/2013		1 Cash or cash equivalent	Gift
\$1,250.46	12/26/2013		1 In-kind items and services	Charitable Contribution
\$86.00	12/20/2013		1 In-kind items and services	Gift
\$128.00	12/04/2013		1 In-kind items and services	Gift
\$529.11	12/04/2013		1 In-kind items and services	Charitable Contribution
\$144.72	12/04/2013		1 In-kind items and services	Charitable Contribution

## Getting Burned: The Impact of the Sunshine Act on Life Sciences Companies

Since the Sunshine Act only requires transparency of payment information, it does not involve any mechanism to evaluate the appropriateness of the payments. For this reason, its implications are causing significant change within the life sciences industry. Some companies have imposed new limits on payments for certain services. For example, GlaxoSmithKline (GSK) has decided to no longer make any payments for drug promotion to physicians who are not bona fide GSK employees. This approach, however, is not a viable strategy for many life sciences companies that must rely on the clinical expertise of independent physicians in developing and marketing their products.

It is imperative that these companies make sufficient efforts to ensure they are compensating physicians at fair market value (FMV)<sup>1</sup> for services rendered, and that such arrangements can be supported as commercially reasonable.<sup>2</sup> Without the use of an independent third party or the development of a clear, objective methodology to set appropriate physician compensation, a company risks significant liability under federal and state fraud and abuse laws.<sup>3</sup>

The significance of FMV is demonstrated by recent settlement agreements (known as Corporate Integrity Agreements, or CIAs) between life sciences companies and the Office of Inspector General (OIG). For example, Pfizer entered into a CIA following a \$2.3 billion

settlement involving off-label promotional practices of certain pharmaceuticals. The Pfizer CIA specifically required that educational and promotional speakers be paid consistent with FMV.

Further, a recent case highlights the risk that excessive payments will lead to criminal prosecution. The Department of Justice announced in February 2015 that an Illinois physician had pleaded guilty to receiving illegal kickbacks totaling nearly \$600,000 from two pharmaceutical companies in exchange for regularly prescribing a certain anti-psychotic drug.

Finally, as more payment data is reported and released, patients may have a negative perception of physicians who receive substantial payments from life sciences companies, even if for legitimate purposes. In these cases, documentation of FMV compensation could minimize the repercussions surrounding such arrangements.



<sup>1</sup> The IRS has defined fair market value as: "The price at which the property or service would change hands between a willing buyer and a willing seller, neither being under a compulsion to buy or sell and both having reasonable knowledge of the relevant facts." Treas. Reg. § 20.2031-1(b) (2005); Rev. Rul. 59-60, 1959-1 C.B.237. This is consistent with the Stark Law definition of fair market value: "The value in arm's-length transactions, consistent with the general market value" where "general market value" is defined as the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party at the time of the service agreement. Usually, the fair market price is the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals. See 42 C.F.R. § 411.351 (2011).

<sup>2</sup> Per CMS, "an arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential designated health services (DHS) referrals." 63 Fed. Reg. 1700 (Jan. 9, 1998).

<sup>3</sup> Failure to timely, accurately or completely report the required information is subject to a civil monetary penalty of not less than \$1,000, but not more than \$10,000 for each payment or other transfer of value or ownership or investment not properly reported, not to exceed \$150,000 in an annual submission. Failure to knowingly report results in higher penalties. See 42 C.F.R. § 403.912 (2013).

## Applying "Sunscreen": Establishing an Internal Pre-Approval Process

To manage and mitigate the regulatory and reputational risks associated with physician payments, a life sciences company should develop and implement a standard pre-approval process to be completed before any such payment is made. This process should be based on an objective, consistent methodology that produces defensible conclusions and is supported by formal documentation.

### Step One: Define the Service

The first step in the process is to define the specific services for which a physician will be compensated. This includes detailing the precise qualifications required for the position (such as education, experience, and expertise), the nature of the duties to be performed (including the separation of clinical and administrative functions), and the expected time or burden associated with the services. The ultimate goal of this step is to eliminate any ambiguity in the proposed scope of work and delineate the explicit experience required for the identified service.

### Step Two: Document the Need

The second step in the process is generating and maintaining documentation showing a genuine business need to engage a physician to provide the proposed services. Specific items to address include, but are not limited to:

- The justifiable business purpose of the arrangement, *i.e.*, how it meets an essential need of the company.
- The qualifications and time demanded to adequately perform the services.
- The expected outcome and benefit to the organization from the services.
- The safeguards that are in place to ensure the company receives real value from the physician services (*e.g.*, written agreement, time sheets, performance evaluation).

## Internal Pre-Approval Process



### Step Three: Validate Fair Market Value

The final step in the internal pre-approval process is validating the compensation to be paid to the physician is FMV for the services provided. With the information identified in Steps One and Two, a company can then set appropriate compensation based on adjustments to relevant market data and other factors used to determine FMV. To demonstrate independence, a life sciences company could consider utilizing an independent appraiser in designing its standard compensation methodology.

Typically, payments to physicians for the identified services utilize a tiered stratification model which facilitates decision-making based upon a fixed set of criteria. This approach gives life sciences companies a tool to objectively determine physician compensation, which ultimately leads to classification into a predetermined tier based on the details of the arrangement. Many life sciences compensation models are broken into four tiers; with the highest tier compensation indicating the most advanced knowledge and experience (generally for an international audience), followed by national, regional, and local-level classifications.

This approach allows a company to use the same model for similar physician engagements, classifying each arrangement into a certain tier on a case-by-case basis, and then compensating the physician based on the tier's accompanying payment amount. Life sciences companies should thoroughly evaluate each proposed arrangement and set compensation levels accordingly, with standard hours and/or limits, regardless of whether they choose to utilize an internal methodology or a stratification tool created by an external appraiser.

While the tiered model is an effective tool to determine physician compensation in many scenarios, situations may arise in which the circumstances warrant paying a physician an amount outside of the predetermined level for the appropriate tier. Such exceptions may be necessitated by the highly specialized requirements of the position or other unusual elements of the arrangement.

In these cases, life sciences companies may seek a formal FMV "exception opinion" report. Such a report would include case-specific analyses of the facts and circumstances of the proposed arrangement, resulting in a conclusion of FMV rather than classification into the predetermined tiers of a stratification model. And, with the publicity surrounding physician payments in the life sciences industry due to the release of Open Payments data, exception opinion reports provided by external

appraisers also may help mitigate reputational damage by providing documented support and context for the terms of the arrangement.

Exception opinions are usually exclusive to the physician and the compensation arrangement in question, and are not applicable to other scenarios as with the tiered model. Because exception opinions provide stronger regulatory support for the determined compensation amount, a life sciences company should consider seeking an exception opinion

on higher-risk arrangements to ensure proper examination of all related facts and circumstances. For example, a company may build into its model the directive to obtain such an opinion for any proposed arrangement over a certain dollar figure.



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## PYA Valuation Services for Life Sciences Companies

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PYA has extensive valuation experience in the healthcare and life sciences sectors, offering valuation opinions on a wide range of services and financial arrangements. From stratification models used to evaluate multiple compensation arrangements across various medical specialties to analysis of individual arrangements, PYA's consulting team uses its knowledge of healthcare and its valuation expertise to design a valuation approach that is specific to our client's facts and circumstances.

In every case, we begin with the most current and comprehensive market data available and utilize our specialized knowledge and extensive expertise to identify and evaluate a multitude of other factors which determine fair market value.

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