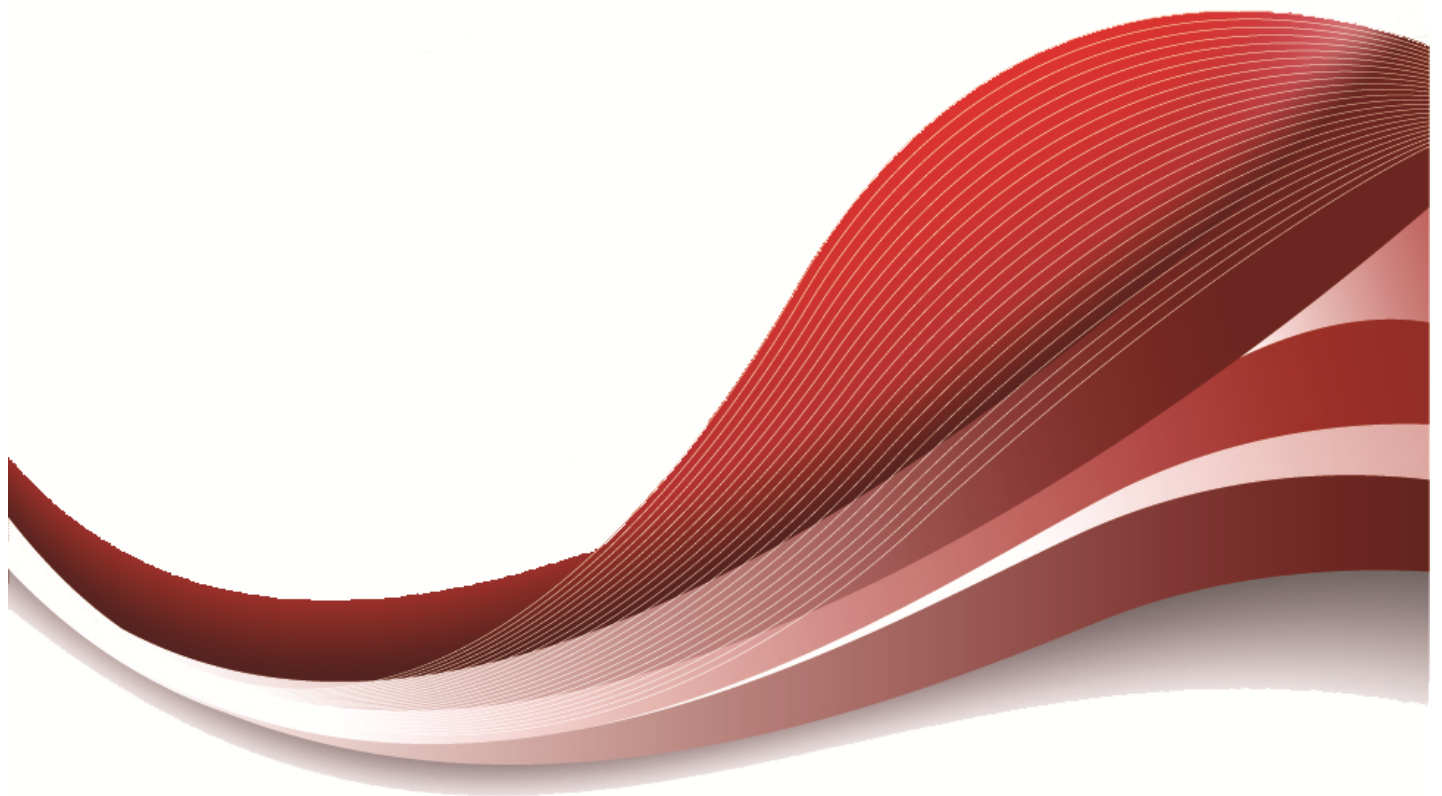


HIOSSEN, INC.

THE PHYSICIANS PAYMENTS SUNSHINE LAW



This brochure is intended to provide a brief education summary of the Sunshine Law's key provisions.

*All Information was taken from AdvaMed

What is the Physician Payments Sunshine Act?

The Sunshine Act was signed into law in 2010, as part of the Affordable Care Act. The Sunshine Act requires manufacturers and some distributors of medical devices, drugs, biologicals and medical suppliers to track and report certain payments made (including transfer of value) to physicians and teaching hospitals.

In addition, the Sunshine Act requires manufacturers and Group Purchasing Organizations (GPO) to report any ownership and investment interests that a physician and their immediate family may have.

Why was the Sunshine Act Enacted?

The Sunshine Act is to provide patients with transparent information about the relationship(s) their health care provider(s) have with medical device, drug, biologicals manufacturers. The Sunshine Act does not prohibit or restrict industry-physician collaboration or interaction, but it does require tracking and reporting of payments (including transfer of value) resulting from these interactions.

Who is Required to Report?

Manufacturers of medical devices, drugs, biologicals, and medical supplies operating in the United States, including certain wholesalers/distributors and certain entities under common ownership (5% or more) with a Manufacturer (collectively, "Manufacturers") must submit Transparency Reports annually to CMS on payments/transfers of value given to Physicians and Teaching Hospitals.

- ▶ Group Purchasing Organizations (GPOs) and Manufacturers must report ownership and investment interests held by Physicians or their Immediate Family Members and any Payments/Transfers of Value to Physician Owner/Investors.

Which Recipients of Payments or Transfers of Value Must be Reported?

Payments and transfers of value made by Manufacturers to Physicians and Teaching Hospitals must be reported.

Payments made to Physicians and Teaching Hospitals through a third party or those made to a third party at the request of or on behalf of a Physician or Teaching Hospital are reported and include the name of the third party.

- ▶ The Sunshine Law applies to all of the following types of doctors, as long as they hold a current license to practice in the United States:
 - Doctors of Medicine
 - Doctors of Osteopathy

- Fellows
- Dentists
- Podiatrists
- Optometrists
- Chiropractors

These doctors are subject to the law regardless of whether or not they are enrolled in Medicare, Medicaid or CHIP.

- ▶ Residents and Allied Health professionals are excluded from the requirement (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic).

What Must be Reported?

Payments, transfers of value, and ownership/investment interests.

Payments and transfers of value must be reported when an item is worth \$10 or more and, if items are worth less than \$10 when the sum of all items given to a particular recipient over a year exceeds \$100.

Manufacturers are required to report :

- (a) Direct payments and transfers of value
- (b) Indirect payments and transfers of value
- (c) Payments and transfers of value that are made to a third party at the request of or on behalf of a physician.

Ownership and investment interests held by Physicians or their immediate family members, in GPOs and Manufacturers

- The dollar amount invested and the value and terms of the ownership or investment interest (excluding interests in publicly traded securities or mutual funds).
- Any payments/transfers of value provided to the Physician owner or investor

What Details Must be Included in the Report About the Payment/Transfer of Value?

- ▶ Manufacturer or GPO name
- ▶ Name and business address of the Physician
- ▶ Specialty, NPI, and State Professional License Number
- ▶ Dollar value and date of the payment/transfer of value
- ▶ Form of payment/transfer of value (e.g., cash/cash equivalent; in-kind items/services; stock, stock option, or any other ownership interest; and dividend, profit, or other return on investment);
- ▶ Nature of payment/transfer of value –one of 16 pre-defined categories (*see What are the Nature of Payment Categories that must be used to describe Payments and Transfers of Value?*)
- ▶ Device product name, therapeutic area or product category related to the payment/transfer of value
- ▶ Context - (optional) brief description of the context of the payment/transfer of value

- ▶ Name of entity that received the payment/transfer of value, if not provided to the Physician directly
- ▶ Whether the payment/transfer of value was provided to a Physician holding ownership/investment interests in the Manufacturer
- ▶ Whether the Physician or an immediate family member holds the ownership/investment interest

- ▶ Less than \$10 when the total value for the year is less than or equal to \$100. (This amount to be adjusted beginning 2014 with the consumer price index.)
- ▶ Educational materials that directly benefit patients or are intended for patient use
- ▶ Discounts and rebates
- ▶ In-kind items for the provision of charity care
- ▶ Product samples (including coupons and vouchers) where there is an agreement in writing that the products will be provided to patients
- ▶ Evaluation/demonstration units – of 90 days or less average daily use
- ▶ Items and services provided under a contractual warranty, service or maintenance agreement
- ▶ Received by the Physician as a patient (e.g., product samples, coupons, or vouchers or as a subject in a research study)
- ▶ For the provision of healthcare services provided to a Manufacturer’s employees or their family (e.g., on-site clinic)
- ▶ For licensed nonmedical professional services (e.g., a physician-attorney paid only for legal services)
- ▶ For services with respect to a civil or criminal action or administrative proceeding (e.g., as an expert witness)

What are the Nature of Payment Categories that Must be Used to Describe Payments and Transfers of Value?

The payment/transfer of value must be categorized as one of the following:

- | | |
|---|---|
| • Compensation for serving as faculty or as a speaker for an accredited or certified CME program | • Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CME program |
| • Compensation for services other than consulting, including serving as faculty at an event other than a Continuing Medical Education (CME) program | • Travel and lodging (including specifying the destination) |
| • Ownership or investment interest (current/prospective) | • Space rental or facility fees (Teaching Hospital only) |
| • Education | • Charitable contribution |
| • Honoraria | • Royalty or license |
| • Gift | • Research |
| • Food and beverage | • Grant |
| • Consulting fee | • Entertainment |

How will Research Payments be Handled?

Payments related to research must be reported separately and submitted the year the payment occurs stating the institution name and principal investigators. Some of these details may qualify for delayed publication to the public CMS website.

What Payments/Transfers of Value are Excluded from Reporting?

Payments/transfers of value that are:

- ▶ For speaking at a Continuing Education Program if three conditions are met:
 - 1) Program meets accreditation/certification requirements and standards of ACCME, AOA, AMA, AAFP or ADA CERP
 - 2) The Manufacturer does not select the speaker and does not provide a distinct, identifiable set of individuals to be considered as speakers
 - 3) The Manufacturer does not directly pay the Physician speaker
- ▶ From existing personal relationships (e.g., one spouse who works for a manufacturer giving a gift to their spouse who is a Physician)

Can Physicians Review the Data and Make Corrections, if Necessary?

Before information is publicly posted, a Physician will have 45 days to review submitted data and initiate disputes once access to his/her own data is made available by CMS on a secure online portal. If the dispute is not resolved during this 45 day period, an additional 15 days are provided to come to a resolution.

If the dispute continues, the data will still be posted to the public webpage but will be flagged as “Disputed.” Physicians are also able to seek correction or contest reports for two years after access has been provided to a report with disputed information.

What is the Timing of the Sunshine Act Requirements?

- ▶ **Aug. 1, 2013**
Manufacturers are required to begin collecting information about payments, transfers of value and ownership interests.
- ▶ **Feb. 18, 2014 - Mar. 31, 2014**
*(Phase 1 Data Submission)**
Manufacturers & GPOs are required to submit aggregate 2013 payment data to CMS by March 31, 2014.

► **May 2014 + 30 days or more**

*(Phase 2 Data Submission)**

Manufacturers and GPOs are required to submit detailed 2013 data (covering Aug. - Dec. 2013 payments)

► **Aug. 2014**

Physicians and teaching hospitals may access their own data via secure online portal for review and correction

- 45 Days to Review and Initiate Disputes

-15 Days to Resolve Disputes

► **Sept. 30, 2014**

2013 data published on a public website by CMS. In subsequent years, information will be published on June 30.

**This 2 phased approach only applies in 2014. Subsequent reports will cover an entire calendar year and will be due the 09th day of the following year.*

What are the Penalties for Non-compliance?

Reporting incomplete or inaccurate information has the potential to mislead patients and other stakeholders and damage the reputation of manufacturers, physicians and teaching hospitals.

Depending on the circumstances, non-compliance with the Sunshine Law's reporting requirements could subject a manufacturer to financial penalties ranging from:

(a)\$1,000 to \$10,000 for each payment or transfer of value not reported; and

(b)\$10,000 to \$100,000 for "knowingly" failing to report a payment or transfer of value.

The total maximum penalties which may imposed against a Manufacturer or GPO is \$1,150,000 per year.

What will be Done with the Reported Information?

Most of what is provided in the Transparency Reports will be published annually on a public website that is searchable.

2013 data will be published on Sept. 30, 2014. (In subsequent years, information made public on June 30.)

Also by Sept. 30, 2014 (in subsequent years by June 30), CMS submits reports to states that include a summary of payments made to covered recipients in each state.

April 1, 2015 - CMS submits first annual report to Congress that will include aggregated information submitted during the

previous calendar year (data collected in CY 2013 and submitted March 2014), as well as any enforcement actions taken and any penalties paid.

How has Hiossen prepared for Compliance with the Sunshine Act?

Hiossen has enhanced our existing tracking systems to capture the required payment data beginning on August 1, 2013.

How can I work with Hiossen to promote Ethical Collaboration?

Hiossen supports the transparency goal of the Sunshine Law to ensure that healthcare professionals, like you, continue to make independent decisions regarding the healthcare and treatment of patients and the development and improvement of medical technology. Important elements of the Sunshine Law to remember include:

Industry collaboration with healthcare professionals is necessary to promote the safe and effective use of medical technologies as well as design innovative and advanced technologies.

Your patients and other stakeholders may not understand the benefits of industry collaborations with healthcare professionals and how and why such collaborations may result in bona fide payments and transfers of value and the need to make such payments public.

The specific information that is required to be reported by manufacturers will be publicly available on the internet.

The importance of working with manufacturers to promote the accurate capture, tracking, auditing and monitoring, documentation and reporting of information to ensure maximum compliance with the Sunshine Law, as most of the information will be published by CMS onto a public website.

Where can I find more Information?

The official CMS Website for the Sunshine Law, also referred to as Open Payments:

<http://go.cms.gov/openpayments>

Information from the AMA:

www.ama-assn.org/go/sunshine

Information from AdvaMed:

www.advamed.org/sunshine

Partners for Healthy Dialogues: