

THE PHYSICIAN PAYMENTS SUNSHINE LAW

A teaching hospital guide to industry transparency reporting requirements.

What is the Physician Payments Sunshine Act?

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act (the "Sunshine Law") requires manufacturers, including certain distributors, of medical devices, drugs, biologicals, and medical supplies to track and report certain payments made to and transfers of value provided to physicians and teaching hospitals.

Teaching Hospitals are defined as hospitals that received payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. CMS will publish a list on annual basis of hospitals which it considers to be teaching hospitals.

Why was the Sunshine Law Enacted?

The main purpose of the Sunshine Law is to provide patients with enhanced transparency into the relationships their health care providers have with life science manufacturers, including medical technology companies. It's important to note that the Sunshine Law does not restrict industry-physician collaboration or interactions, or prohibit payments or transfers of value. Rather, it requires tracking and reporting of payments and transfers of value that result from these interactions.

Where can I find more information?

The Official CMS Website for the Sunshine Law, also referred to as the National Physician Payment Transparency Program: OPEN PAYMENTS:

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

Information from the AMA:

<http://www.ama-assn.org/ama/pub/advocacy/topics/sunshine-act-and-physician-financial-transparency-reports.page>

Please visit DJO's Sunshine site at

<http://djoglobal.com/compliance/sunshine>



What is the Compliance Timeline on the Sunshine Law Requirements?

- Aug. 1, 2013: Manufacturers and GPOs are required to begin collecting information about payments, transfers of value, and ownership interests.
- Mar. 31, 2014: First manufacturer / GPO report is due. This report must cover August – December 2013 payments/transfers of value and ownership interests. Subsequent reports will cover an entire calendar year and be due the 90th day of the following year.
- Aug. 2014 (in subsequent years, during the month of May): 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.

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.

- Teaching Hospital List - published by CMS on its Open Payments website, identifies all teaching hospitals subject to Manufacturer & GPO reporting (www.goo.gl/OxdrE)
- 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 Osteopathy; Dentists; Podiatrists; Optometrists; and Chiropractors.

- Residents are excluded from the requirement (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic).
- Third Party Entity recipients of a Payment / Transfer of Value made "at the request of" or in the name of a Physician or Teaching Hospital, must be reported in the name of the physician and the recipient.

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; and
- (c) payments and transfers of value that are made to a third party at the request of or on behalf of a Teaching Hospital.
 - 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 next column)
- 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; and
- Whether the Physician or an Immediate Family Member holds the Ownership/Investment Interest;

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:

- Consulting fee;
- Compensation for serving as faculty or as a speaker for an accredited or certified CE program;
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CE program;
- Compensation for services other than consulting, including serving as faculty at an event other than a Continuing Education (CE) program;
- Honoraria;
- Gift;
- Entertainment;
- Food and beverage;
- Travel & lodging (including specifying the destination);
- Education;
- Research;
- Charitable Contribution;
- Royalty or License;
- Ownership or Investment Interest (Current Prospective);
- Grant; and
- Space rental or facility fees (Teaching Hospital only).

Can Teaching Hospitals Review the Data and Make Corrections, if necessary?

Before information is publicly posted, a Teaching Hospital will have 45 days to Review submitted data and Initiate Disputes once access to its 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.

Teaching Hospitals are also able to seek correction or contest reports for two years after access has been provided to a report with disputed information.

If a Non-Physician Employee of a Teaching Hospital Receives a Transfer of Value, would that transfer of value need to be reported as a transfer of value to the Teaching Hospital?

- Generally, no, these would not need to be reported (e.g., a meal).
- Non-physician employees of a Teaching Hospital are not covered recipients for the purposes of Open Payments. Accordingly, payments or other transfers of value made to these non-physician employees generally do not need to be reported.
- Transfers of Value to Non-Physician Employees would need to be reported if:
 - the payments were made to the non-physician employees at the request of or designated by the Manufacturer on behalf of a covered recipient Physician or Teaching Hospital [pursuant to 42 C.F.R. §403.904(a) and (c)(10)]
 - they were in fact Indirect Payments to a covered recipient Physician or Teaching Hospital being made through the non-physician employee [as defined at §403.902];
- Indirect payments or other transfers of value occur when an applicable manufacturer or GPO requires, instructs, directs or otherwise causes a third party to provide the payment or other transfer of value, in whole or in part, to a covered recipient.
- ex: a Manufacturer providing equipment to a non-physician employee of a Teaching Hospital that is intended to benefit the Teaching Hospital is considered an indirect payment to the Teaching Hospital.
- See CMS FAQ8272 at: <http://goo.gl/djGUqe>

Are payments from a Manufacturer to a Teaching Hospital in order to purchase products or materials considered reportable under Open Payments?

- Yes. There is no reporting exclusion for payments made to covered recipients for the purpose of purchasing products or materials.
- See CMS FAQ8374 at: <http://goo.gl/lu51dP>

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. The Secretary of HHS will also be required to submit a report to Congress on an annual basis.

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 & principal investigators.

- Some of these details may qualify for delayed publication to the public CMS website if the following conditions are met:
 - (1) The payment or transfer of value was made under a product research or development agreement, which must include either a written agreement or a research protocol; and
 - (2) The payment or transfer of value was made in connection with either:
 - (a) Research on or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply; or
 - (b) Clinical investigations regarding a new drug, device, biological, or medical supply.
- Clinical investigations (Phases I - IV clinical research for drugs & biologicals, and approval trials for devices) related to new applications of existing products do not qualify for delayed publication.
- Payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of "clinical investigation."
- Information about payments and other transfers of value that are delayed from publication must be made publicly available on the first publication date after the earlier of either:
 - (a) the approval, licensure or clearance by the FDA of the covered drug, device, biological or medical supply; or
 - (b) 4 calendar years after the date of payment or other transfer of value.

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 be imposed against a Manufacturer or GPO is \$1,150,000 per year.

What Payments/Transfers of Value are excluded from reporting?

Payments /Transfers of Value that are:

- for Speaking at a Continuing Education Program if 3 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; and
 - 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)
- 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 such as patient education materials and anatomical models, but excluding journal articles and textbooks.
- 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)

Value of Industry-Provider Collaborations

Collaboration and interactions between medical technology companies and health care providers are essential to advancing new, safe and effective medical technologies that benefit patients. AdvaMed recognizes that this goal must be balanced against the obligation

of health care providers to make independent decisions regarding the care and treatment of their patients. AdvaMed and its member medical technology companies are committed to transparency with patients about interactions between providers and industry.

HOW CAN TEACHING HOSPITALS WORK TOGETHER WITH MEDICAL TECHNOLOGY COMPANIES TO PROMOTE COMPLIANCE?

AdvaMed and its members support the transparency goal of the Sunshine Law to ensure that physicians and teaching hospitals continue to make independent decisions regarding the health care and treatment of patients and the development and improvement of medical technology. Teaching hospitals can work with us to promote strong standards in all interactions with industry. Medtech companies can assist teaching hospitals in educating their health care professionals and patients about the requirements of the Sunshine Law. Important elements to remember include:

- Industry collaboration with teaching hospitals and health care 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 teaching hospitals and health care 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 that 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.

Many AdvaMed member companies have certified to compliance with the AdvaMed Code of Ethics on Interactions with Health Care Professionals which also supports ethical collaborations. It is by driving ethical collaborations that we help protect patients. To see the companies that have certified to the Code, visit:



www.advamed.org/CodeCertification