

Financial Transparency: 'Sunshine Law' Overview

Beginning Aug. 1, manufacturers and certain other entities must begin collecting information about their payments to and other financial relationships with physicians and teaching hospitals. CMS will begin an annual, public release of the data in September 2014, a program known as Open Payments. The program was stipulated by a physician "sunshine law" passed as part of the health care reform law. The aim of Open Payments is to ensure greater transparency about health care providers' financial interests.

Physicians and hospitals have no data-collection responsibility. However, providers will be able to review and, as needed, correct their information before its public release. To help members understand the law's implications for them, the Academy has prepared the following overview.

Related Resources

- [CMS Open Payments site](#)
- [AMA guide to the law](#)
- [AdvaMed guide](#)
- [PhRMA site: Healthy Dialogues](#)

- [Key Dates](#)
- [What Must Be Reported](#)
- [Exclusions](#)
- [Who Must Report](#)
- [Review and Corrections](#)

Key Dates

- **Aug. 1, 2013:** Organizations begin collecting information about payments, transfers of value and ownership interests.
- **March 31, 2014:** First data report is due, covering August to December 2013 payments/transfers of value and ownership interests.
- **August 2014:** Physician/teaching hospitals' review of data; parties will be able to access data via secure online portal. Timeline for review and correction:
 - 45 days to review and initiate disputes (e.g., Sept. 15 deadline)
 - 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.

Subsequent reports

- **March 30 of each year:** Reports for previous calendar year due (e.g., 2014 reports will be due March 30, 2015)
- **May of each year:** Physician/hospital review and correction period

What Must Be Reported

The law requires manufacturers to disclose payments, transfers of value and ownership/investment interests.

Physician payments/transfers

Direct and indirect payments and transfers of value must be reported when:

- An item is worth \$10 or more; or
- The sum of all annual gifts to a particular recipient exceeds \$100 (for items worth less than \$10 each).

Third-party payments/transfers

Manufacturers are also required to report payments and transfers of value made to a third party at the request of or on behalf of a physician.

Note: Speaking or consulting fees that physicians ask be donated to a charitable organization will be reported as directed to the physician.

Ownership and investment interests

Group purchasing organizations and manufacturers must report any and all such interests held by physicians or their immediate family members.

Research payments

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

Manufacturers will be subject to penalties for non-compliance with the law or false reporting.

Report specifics

All reports must include:

- Manufacturer or group purchasing organization name
- Physician's name and business address
- Physician's 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, using one of the following pre-defined categories (NOTE: Some [exclusions](#) apply to CME):
 - Consulting fee
 - 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 CME program
 - Honoraria
 - Gift
 - Entertainment
 - Food and beverage
 - Travel and lodging (including specifying the destination)
 - Education
 - Research
 - Charitable contribution
 - Royalty or license
 - Ownership or investment
 - Interest (current/prospective)
 - Grant
 - Space rental or facility fees (teaching hospital only)
- Device product name, therapeutic area or product category related to the payment/transfer of value
- Optional context – i.e., 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 (e.g., charity)
- Whether the payment/transfer of value was provided to a physician holding ownership/investment interests in the manufacturer and if so, who holds the ownership/investment interest

For investment/ownership interests, reports must also include:

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

Exclusions

The following payments and transfers of value do not have to be reported annually to CMS:

- Payments/transfers of value for speaking at a CME program that meets each of the following three conditions:
 1. Program meets accreditation/ certification requirements and standards of ACCME, AOA, AMA, AAFP or ADA CERP;
 2. Manufacturer does not select the speaker and does not provide a distinct, identifiable set of individuals to be considered as speakers; and
 3. Manufacturer does not directly pay the physician speaker with whom it has an existing personal relationship (e.g., one spouse who works for a manufacturer giving a gift to their spouse who is a physician).
- Those of 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
- Educational materials including handouts, slides and web downloads included as part of tuition or grant for an educational seminar as long as the material does not promote a drug or device
- 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, services, equipment, space)

- a patient (e.g., product samples, coupons or vouchers or as a subject in a research study)
- Payments/value transfers for the provision of health care services provided to a manufacturer's employees or their family (e.g., on-site clinic)
- Payments/value transfers for licensed nonmedical professional services (e.g., a physician-attorney paid only for legal services)
- Payments/value transfers for services with respect to a civil or criminal action or administrative proceeding (e.g., as an expert witness)

Who Must Report

The Sunshine Act applies to two main non-physician entities:

1. 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 percent or more) with a manufacturer (collectively, "Manufacturers");
2. Group purchasing organizations.

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;
- 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.

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

Review and Corrections

Before publicly posting information, CMS will give physicians 45 days to review submitted data and initiate disputes. CMS will host pre-publication data on a secure online portal. If the dispute is not resolved during this 45-day period, physicians will have an additional 15 days to reach a resolution. If the dispute continues, the data will still be posted to the public Web page but flagged as "Disputed." Physicians will be able to seek correction or contest reports for two years after they first get access to reports with disputed information.