



Frequently Asked Questions about the Sunshine Act

What is the Sunshine Act?

The National Physician Payment Transparency Program (Open Payments), a.k.a. Sunshine Act, is a section of the Patient Protection and Affordable Care Act of 2010 that requires pharmaceutical and medical device companies to report to the federal government certain payments and other transfers of value that they make to US physicians and teaching hospitals. The Sunshine Act also requires impacted companies to report any physician ownership or investment interests.

Which healthcare professionals qualify as a “US physician” for reporting purposes?

The term “US physician” includes only the following types of healthcare professionals:

- Medical Doctors (MD)
- Doctors of Optometry (OD)
- Doctors of Osteopathy (DO)
- Doctors of Dental Surgery and Doctors of Dental Medicine (DDS, DMD)
- Doctors of Podiatry (DPM)
- Doctors of Chiropractic Medicine (DC)

Payments and other transfers of value need to be reported only for those US physicians who are currently licensed to practice in the United States.

Which institutions qualify as a “teaching hospital” for reporting purposes?

The Centers for Medicare and Medicaid Services (CMS) maintains a list of teaching hospitals. Institutions are included on the CMS list if they received a payment in the prior calendar year under one of the defined Medicare direct Graduate Medical Education or Independent Medical Education programs.

What types of payments and other transfers of value must be reported under the Sunshine Act?

Under the Sunshine Act, impacted companies must report payments and other transfers of value made to US physicians and teaching hospitals. This includes the cost of meals provided to US physicians, as well as payments made to US physicians or teaching hospitals as part of a contracted service such as speaker programs, advisory boards, consulting, and clinical trials. In addition to meals and payments, other transfers of value provided to a US physician or teaching hospital, including, but not limited to, travel, educational items that do not directly benefit patients, stocks and grants must be reported. Expenses covered or reimbursed by a pharmaceutical or medical device manufacturer, such as hotel and travel arrangements, also are reportable.

What research-related payments and other transfers of value must be reported?

All research-related payments and other transfers of value to US physicians and teaching hospitals must be reported to CMS. Under the Sunshine Act, a payment or other transfer of value made in connection with an activity that meets the definition of research and that is subject to a written agreement, a research protocol or both should be included in the total amount of the research payment. Reporting must include both cash payments and the value of in-kind support, such as ancillary supplies and equipment provided by the reporting company for purposes of conducting a clinical trial. Pursuant to the Sunshine Act's implementing regulations, research-related payments will be reported separately from other payments and must include the name and address of the individual or entity paid, information regarding each physician principal investigator, and the total amount of the research payments.

What types of ownership or investment interests must be reported?

Pharmaceutical and medical device manufacturers must report information concerning ownership and investment interests held by physicians or their immediate family members and payments or other transfers of value to such physician owners or investors. The report must include the dollar amount invested and the value and terms of the ownership or investment interest, and any payment provided to the physician owner or investor. Stock options received as compensation are not an ownership or investment interest until they are exercised.

What if my state already has disclosure laws or prohibitions? Does the Sunshine Act preempt those?

The Sunshine Act reporting requirements preempt (or override) state laws and regulations that require disclosure or reporting of the same information required to be reported on the federal level, unless a state requires this information for reasons other than transparency. Additionally, states are permitted to require reporting of information that is different from the scope of the information reported to the federal government. Thus, different information relating to payments and transfers of value to physicians and teaching hospitals and information about payments to health care providers that are not physicians or teaching hospitals may still be reportable at the individual state level, generally based on where the health care provider is licensed or practices. In addition, the Sunshine Act does not prohibit activities or interactions and thus leaves untouched any prohibitions under state laws.

What level of detail will the Sunshine Act report have?

The following information must be reported for each payment or other transfer of value:

- Name
- Business address
- Physician specialty
- National provider identifier
- State license number
- Value of the payment or transfer of value
- Name of the related device
- A description of the form of payment (e.g., cash, in-kind items or services, stock)
- Date of payment or transfer of value
- Nature of payment or transfer of value (e.g., consulting, food, travel, education)
- Clinical Research: Principle Investigator

When will the first payments be reported to CMS? When will CMS disclose the information it has received?

The first report is due to CMS by June 30, 2014, and the report will cover payments or other transfers of value made during the period of August 1, 2013 to December 31, 2013. CMS has stated that it will post payments or other transfers of value and ownership or investment interest reports on a public website for the initial implementation year (partial reporting year) no later than September 30, 2014. Thereafter, manufacturers must submit reports to CMS by the 90th day of the calendar year, with CMS publishing the data by June 30 of the same year.

Will CMS provide a mechanism for reviewing and disputing payments and other transfers of value?

Before information is publicly posted, physicians and teaching hospitals will have 45 days to review submitted data and initiate disputes once access to his/her/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 still will be posted to the public webpage but will be flagged as "Disputed." Physicians and teaching hospitals also are able to seek correction or contest reports for two years after access has been provided to a report with disputed information.

I have questions about which payments or transfers of value will be reported – who can help answer my questions?

If you have any questions about the types of payments or transfers of value that ConforMIS is required to report, please contact our Compliance Hotline at 781-270-1415. If you have general questions about the Sunshine Act or the Open Payments Program, the CMS Open Payments Program website is also a good resource, and can be accessed at <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>.

Can companies decline to report?

No. Pharmaceutical and medical device manufacturers must comply fully with the new federal law so there is no ability for you to opt out of the Sunshine Act report if a payment, meal, or other transfer of value is provided to you from August 1, 2013 through any later date.

What about my nurses and office staff?

Under the Sunshine Act, meals provided to nurses and office staff will not be reportable and will not be attributed to physicians. However, some state marketing disclosure laws require disclosure of payments to a broader group of recipients, including non-physician prescribers, nurses and office staff. Often times, this spend is attributed to the physician or other prescriber in the office. For states with these types of disclosure requirements, these payments will not be preempted by the federal law, and thus are still reportable to the state. In addition, the AdvaMed Code of Ethics on Interactions with Health Care Professionals and some state laws prevent or limit meals to health care professionals under certain circumstances.

If I am contracted to perform work for an impacted company, and I direct the company to pay my fee to another entity instead of me personally, how will that be reported under the Sunshine Act?

The fee will be reported under your name and will list the entity paid as the third party recipient on the same line item. In addition, any expenses covered or reimbursed as part of your contract, such as travel and lodging expenses, also are reportable under your name.

What if a payment is made to another recipient, such as a charity, on my behalf or at my request, is it reportable?

Yes. If a payment is made to a charity or other third party on your behalf, or at your request, it is reportable as a transfer of value to you.

Will the payments and transfers of value I receive for international engagements be reported?

Yes. The Sunshine Act requires all payments and transfers of value made to US physicians with active licenses in the United States to be reported, regardless of where the activity took place.

Are there any types of payment that don't need to be reported?

Yes. The following payments and transfers of value are among the exceptions to the reporting requirements:

- **Office staff meals:** In general, meals are reportable only for the physicians who actually partake in the meal. Meals provided to the office staff of the physician typically are not reportable. When the value of physician meals is calculated, the total cost of the meal is divided by the total number of people who ate (including physicians and non-physicians) and only the proportional cost that is attributable to each physician is reported. For example, if a company spends \$200 on a meal for five physicians and five non-physician staff members, the physician meals will be reported at \$20 each and the staff meals will be excluded from Sunshine Act reporting. However, although meals to office staff generally are not reportable under the Sunshine Act, the AdvaMed Code of Ethics on Interactions with Health Care Professionals and some state laws prevent or limit meals to health care professionals under certain circumstances.
- **Meals at conferences and large-scale events:** The Sunshine Act implementing regulations do not require reporting of buffet meals, snacks, soft drinks, or coffee made generally available to all participants at major conferences or other large-scale events.
- **Patient educational materials:** Educational materials and items that directly benefit patients or are intended to be used by or with patients are not reportable. However, textbooks and journal reprints do not fall within the exclusion.
- **Speaker compensation at accredited continuing medical education:** Payments to physicians who serve as speakers at industry-supported independent continuing medical education (CME) generally are not required to be reported, if the event is certified or accredited by ACCME or certain other organizations, the reporting company does not pay the physician directly and does not select or suggest the individuals to be used as speakers.