



What is the Sunshine Act?

Beginning August 1, 2013, the Physician Payments Sunshine Act (the “Sunshine Act”), which is part of the Affordable Care Act, requires manufacturers of drugs, medical devices, and biologicals that participate in U.S. federal healthcare programs to track and then report certain payments and items of value given to U.S. physicians and U.S. teaching hospitals (defined as “Covered Recipients”).

The Sunshine Act requires that manufacturers collect this information on a yearly basis and then report it to Centers for Medicare & Medicaid Services (“CMS”) by the 90th day of each subsequent year.

Since the inception of this Act, Mission Pharmacal Company has been in compliance with the federal reporting requirements under such Act.

Who are “Covered Recipients” under the Sunshine Act?

Manufacturers are required to report payments and transfers of value made to “Covered Recipients.” The term Covered Recipients refers to U.S. physicians and teaching hospitals.

The Sunshine Act defines a “physician” as any of the following types of professionals who are legally authorized to practice:

- Doctor of Medicine
- Doctor of Osteopathy
- Doctor of Dentistry
- Doctor of Dental Surgery
- Doctor of Podiatry
- Doctor of Optometry
- Doctor of Chiropractic Medicine

Medical residents, nurse practitioners, and office staff are NOT currently included in the definition of Covered Recipients. However, the SUPPORT Act of 2018 has included the following list of health professionals to be added and reported on beginning in 2022:

- Physician assistants
- Nurse practitioners
- Clinical nurse specialists
- Certified registered nurse anesthetists
- Certified nurse midwives

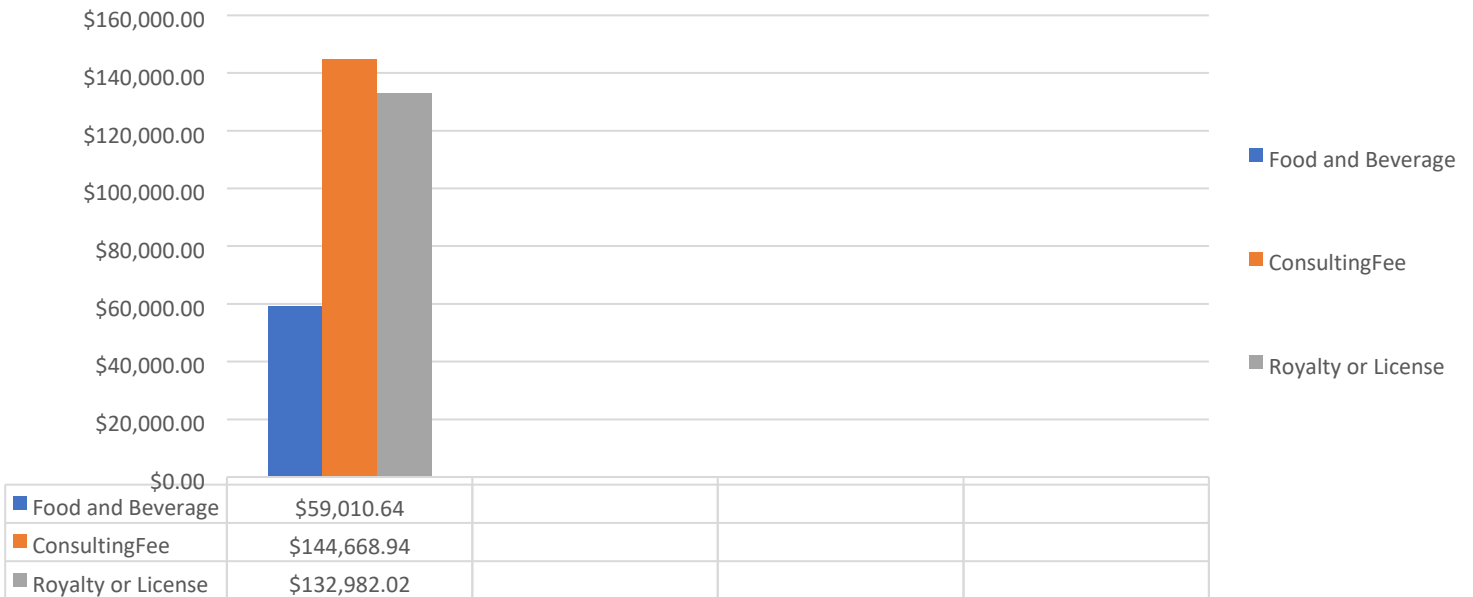
CMS will annually publish a list of hospitals that meet the definition of a teaching hospital for Sunshine Act reporting purposes.

PAYMENT BREAKDOWN

On June 30, 2020, CMS published the Open Payments data for the period between January 1, 2019 – December 31, 2019. This data can be found and searched on the Open Payments website (<https://openpaymentsdata.cms.gov/>).

For the 2019 federal reporting completed by Mission, the following chart provides the areas for which payments were made to physicians:

2019 Natures of Payment



Natures of Payment Definitions

Consulting Fee

Payments made to physicians for advice and expertise on a particular medical product or treatment, typically provided under a written agreement and in response to a particular business need. These payments often vary depending on the experience of the physician being consulting. Examples: Product development – Training – Development of educational materials and disease management programs – Unblinded Market Research.

Compensation for Services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program

Payments made to physicians for speaking, training, and education engagements that are not for continuing education.

Honoraria

Similar to consulting fees, but generally reserved for a one-time, short duration activity. Also distinguishable in that they are generally provided for services which custom prohibits a price from being set.

Gift

A general category, which will often include anything provided to a physician or teaching hospital that does not fit into another category.

Entertainment

This category generally includes payments or transfers of value for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a professional. This category can include things like textbooks and medical journal articles.

Food and Beverage

Food and beverage can include meals, whether paid directly or reimbursed, provided in conjunction with: Consulting services – Training – Educational and other business discussions with physicians.

Travel and Lodging

Travel and lodging, whether paid directly or reimbursed, in conjunction with: Consulting services – Product training.

Education

This category generally includes payments or transfers of value for classes, activities, programs or events that involve the imparting or acquiring of particular knowledge or skills, such as those used for a professional. This category can include things like textbooks and medical journal articles.

Research

Payment for different types of research activities, including enrolling patients into studies of new drugs or devices. Examples: Clinical studies and research that provide valuable scientific and clinical information about the medicines and medical devices that improve patients' lives.

Charitable Contribution

Any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, but only if it is not more specifically described by one of the other nature of payment categories.

Royalty or License

Royalty or other payment based on sales of products that use a physician's intellectual property.

Current or Prospective Ownership or Investment Interest

Ownership or investment interests currently held by physicians and teaching hospitals, as well as ownership interests or investments that physicians and teaching hospitals have not yet exercised.

Compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program

Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program. Example: Indirect payment by a third-party organization to speakers at a nonaccredited educational program, funded by an education grant from Mission.

Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program

Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program. Example: Indirect payment by a third-party organization to speakers at an accredited educational program, funded by an educational grant from Mission.

Grant

Payments to a physician or teaching hospital in support of a specific cause or activity. Examples: Sponsorship of an educational event, patient advocacy event or publication – Sponsorship of fellowships for fellow and resident training – Certified Independent educational activities – Non-certified medical education activities.

Space rental or facility fees (teaching hospital only)

Fees for renting space or facilities, in a teaching hospital, for example. Examples: Booth or exhibit space rental – Facility rental for product training or clinical studies.

CMS has provided a list of their own FAQs which can be found at

<https://www.cms.gov/OpenPayments/Downloads/open-payments-general-faq.pdf>.

Mission has included several FAQs below which questions have often arisen from various vendors and HCPs throughout the years since the inception of the Sunshine Act in 2013.

Question: (FAQ #8364)

To determine if an applicable manufacturer or applicable group purchasing organization (GPO) has met the aggregate threshold for reporting small payments to a covered recipient or physician owner/investor (see CMS website for current key reporting thresholds), is it required to aggregate small payments or other transfers of value that are made across different nature of payment categories?

Answer:

Yes. To determine if small payments or other transfers of value made to a physician or teaching hospital exceed the aggregate threshold and must be reported, applicable manufacturers and applicable GPOs must combine all payments made across the multiple nature of payment categories. For example, if an applicable manufacturer or applicable GPO made payments to a physician for: (1) six hot dog lunches for \$9 each, (2) three cab fares for \$9 each, and (3) three sporting event tickets for \$9 each, the total payment amount would be calculated to be \$108 and all of these payments must be reported.

Question: (FAQ #12376)

Do physicians and teaching hospitals have a chance to review the financial data reported about them prior to its publication?

Answer:

Yes. During the 45-day physician and teaching hospital review and dispute period, the dollar values and information about each transaction listed are available for review by doctors and teaching hospitals registered in the Open Payments system. They can confirm the information as correct or pursue corrections, via the dispute option, to remove, clarify, or adjust the information that had been attributed to them. This required 45-day review and dispute process affords the opportunity for physicians and teaching hospitals to review and dispute any data they feel is inaccurate or incomplete.

Question: (FAQ #8155)

Are payments provided to a consulting firm or third-party, whom in turn provide the payment (in whole or in part), to a physician reportable under Open Payments?

Answer:

Yes. Open Payments requires reporting of both direct and indirect payments and other transfers of value provided by an applicable manufacturer or applicable GPO to a covered recipient. An indirect payment is a payment or transfer of value made by an applicable manufacturer, or applicable GPO, to a covered recipient, or a physician owner or investor, through a third-party, where the applicable manufacturer, or applicable GPO, requires, instructs, directs, or otherwise causes the third-party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s), or a physician owner or investor.

Question: (FAQ #8163)

Applicable manufacturers with less than 10% total (gross) revenue from covered drugs, devices, biologicals, or medical supplies have limited reporting requirements regarding payments or other transfers of value provided to covered recipients. Does total (gross) revenue include both domestic sales and global sales, or only domestic sales?

Answer:

Both domestic and global sales are included in the company's total (gross) revenue. Applicable manufacturers with less than 10 percent of total (gross) revenue from covered drugs, devices, biologicals, or medical supplies during the previous fiscal year are required to report only payments or other transfers of value specifically related to covered drugs, devices, biologicals, or medical supplies. Applicable manufacturers with less than 10 percent of total gross revenue from covered products during the previous year must register with CMS and attest that less than 10 percent of total (gross) revenues are from covered products, along with their attestation of the submitted data. **Note: Mission cannot attest to this. Therefore, transfers of value for both covered and non-covered products must be reported to CMS.**

Question: (FAQ #8992)

Is a payment or other transfer of value considered indirect if an applicable manufacturer utilizes a market research company's services to conduct double-blind market research with primary care physicians, which includes paying physicians for participating?

Answer:

No, a payment or other transfer of value provided to a market research company to conduct doubleblinded market research with physicians is not considered an indirect payment. The applicable manufacturer clearly intends a portion of the payment to be provided to physicians, but given that the reason for the third-party's involvement is specifically to maintain the anonymity of the respondents and sponsor, we do not intend this to be considered a reportable indirect payment or other transfer of value. Additionally, Open Payments excludes reporting of payments when an applicable manufacturer is unaware of the covered recipient, and the payment to the covered recipient is made indirectly through a third-party, such as the market research company, in the above facts. **Note: It is Mission's position for an indirect payment to be considered exempt from reporting, neither the sponsor nor the covered recipient(s) is aware of the identity of the other.**

U.S. STATE REPORTING

In addition to federal Open Payments requirements, California, Massachusetts, Minnesota, Connecticut, Nevada, Vermont, and the District of Columbia have established broader definitions and policies for monitoring and reporting industry interactions with HCPs and HCOs. Each state has a unique set of requirements.

If you have any questions, you may contact Anita J. Scott at anita.scott@missionpharmcal.com.