



PHYSICIAN PAYMENTS - SUNSHINE ACT

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

As of January 2021, 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 & Anesthesiologist assistants
- 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, 2022, CMS published the Open Payments data for the period between January 1, 2021 – December 31, 2021. This data can be found and searched on the Open Payments website (<http://go.cms.gov/openpayments>).

For the 2021 federal reporting completed by Mission, the following chart provides the areas for which payments were made to covered recipients:

2021 Natures of Payment



NATURES OF PAYMENT

When reporting and reviewing Open Payments data, it helps to understand the different types of payments that must be reported. The examples below describe various types of financial transactions between reporting entities and covered recipients.

These definitions and examples were chosen based on input from Open Payments stakeholders. **They are for illustrative and educational purposes only and are not all-inclusive.**

Acquisitions*

Definition: Buyout payments made to covered recipients who have ownership interest in a company that has been acquired.

Example: A drug manufacturer buys a share of ownership in a company that is at least partially owned by a physician or a physician's immediate family member.

Compensation for non-consulting services (e.g., faculty/speaker at an event other than a continuing education program)

Definition: Includes payments that a company makes to physicians for speaking, training, and education engagements that are not for continuing education.

Charitable contribution

Definition: A payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986. *Charitable contributions do **not** include payments or transfers of value that would be more specifically described by one of the other payment categories.*

Example: A medical device manufacturer donates funds to a teaching hospital to help pay for a health education program.

Consulting fee

Definition: A payment that a company makes to a physician for advice and expertise about a medical product or treatment. Consulting fees are typically arranged with a written agreement between a company and physician based on the company's particular business needs. These payments often vary depending on the consulting physician's expertise.

Example 1: Company A has developed a drug to treat patients with a particular disease and wants advice from physicians on how to design a large study to test the drug on patients. Dr. J has many patients with this disease and has experience researching medicines that could treat this condition. Company A asks Dr. J if she would spend about 10 hours per month to work with other physicians to create a new research study. Dr. J agrees and is paid for her time.

Example 2: Company B has designed a new tool for surgeons to use when they perform heart surgery. Company B pays some physicians to give the new tool a “test drive” on a computer-simulated patient at the company headquarters. The physicians are paid an hourly fee to test the tool and provide feedback on how to make it work better. They are also paid for flights, hotel rooms, and meals.

Example 3: Company C makes a drug and invites a physician who frequently prescribes the drug to talk about the medicine to other physicians at a local restaurant. The physician is paid for preparation time as well as the time spent giving the talk.

Current or prospective ownership or investment interest

Definition: Ownership or investment interest currently held by physicians and teaching hospitals, as well as ownership or investment interest that could potentially be held by physicians and teaching hospitals.

Example: Dr. M hears about a new antibiotic that Pharmaceutical Company F is developing. Dr. M thinks the drug might become successful and asks if he can invest in Company F. Company F agrees, and Dr. M ends up owning a percentage of Company F.

Debt forgiveness*

Definition: Forgiving the debt of a covered recipient, a physician owner, or the immediate family of the physician.

Example: A physician owes Company A an amount of money for medical supplies. Company A forgives the debt so that the physician can keep the supplies without providing payment.

Education

Definition: Payments or transfers of value for classes, activities, programs, or events that involve learning or teaching a profession skill. This payment can include things like textbooks and medical journal articles.

Example: Companies that produce or sell drugs or devices for a particular medical condition may offer textbooks to physicians, free of charge, related to the latest treatments for that condition.

Entertainment

Definition: Attendance at recreational, cultural, sporting, or other events that would generally have a cost.

Example: A physician receives tickets to a local football game from a device manufacturer that owns season tickets.

Food and beverage

Definition: Food and beverage.

Example: A drug manufacturer salesperson asks to speak with a physician about a new drug. The salesperson and physician meet for lunch, and the salesperson pays for the meal.

Gift

Definition: A general category which includes anything a company provides to a physician or teaching hospital that does not fit into another category.

Example: Promotional items such as clocks or flash drives that have the company's name printed on them.

Grant

Definition: A payment to a physician or teaching hospital to support a specific cause or activity.

Example: Company G is a medical device manufacturer. Company G gives a grant to a teaching hospital to pay for special training for physicians who want to learn more about how to perform surgeries to give patients Company G's device.

Honoraria

Definition: Similar to consulting fees, but generally reserved for a brief, one-time activity. Another distinction is that honoraria are generally provided for services without a set price.

Example: A medical device manufacturer representative goes to a medical meeting. At the meeting, the representative asks physicians for an hour of their time to talk about features they would like to see on a particular medical device. The representative pays each physician a one-time honorarium.

Long-term medical supply or device loan*

Definition: The loan of supplies or a device for 91 days or longer.

Example: A device manufacturer lends one of its devices to a teaching hospital for 120 days.

Medical education faculty/speaker compensation*

Definition: Compensation for serving as faculty or as a speaker for medical education program.

Example: Drug company Y gives money to a teaching hospital to help pay for the hospital's annual course for its physicians. The course is an update on the latest treatments for diseases.

Research

Definition: Payments for different types of research activities, including the time a physician spends enrolling patients in studies for new drugs or devices. Research payments can include direct compensation to physicians, funding for research study coordination and implementation, or payments to study participants to cover expenses associated with the study.

Example: A physician wants to study treatments for a specific ailment. Pharmaceutical Company H is interested in the results and offers to provide funds for the incentives the physician uses to recruit participants.

Royalty or license

Definition: Payments based on sales of products that use a physician's intellectual property.

Example: A device manufacturer may promise a certain amount of payment in royalties – 1% of all device sales, for example – to a physician who worked with the device manufacturer to invent a new product.

Space rental or facility fees

Definition: Payments for fees associated with renting a space or facility (such as a teaching hospital).

Example: A drug manufacturer wants to offer training to physicians on how to administer a drug. The drug manufacturer pays a teaching hospital to reserve space within the hospital to conduct the training.

Travel and lodging

Definition: Any compensation for costs associated with travel, such as hotel fees, airfare, mileage, and cab fare.

Example: A medical device company offers yearly training events for physicians on how to use their device on patients. The medical device company pays for the physicians' airfare and hotel rooms when the physicians travel to the medical device company's headquarters for the training.

*These natures of payment categories are added or updated as of January 1, 2021.

U.S. STATE REPORTING

In addition to federal Open Payments requirements, some states have established broader definitions and policies for monitoring and reporting industry interactions with HCPs and HCOs. Each state has a unique set of requirements.

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