

THE SUNSHINE ACT AND YOU

building stronger
industry-provider interactions



Medical Technology Manufacturers are
committed to accurate reporting
and meaningful transparency

OPEN PAYMENTS
TRANSPARENCY REPORTING

WHAT IS THE SUNSHINE ACT?

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act ("Sunshine Act") requires manufacturers and distributors of medical devices, drugs, biologicals, and medical supplies to track and report payments and other transfers of value provided to Physicians and Teaching Hospitals. The SUPPORT Act expanded these "Covered Recipients" to include physician assistants and advance practices nurses. (See RECIPIENTS ⇨)

The Sunshine Act also requires manufacturers and Group Purchasing Organizations (GPOs) to report ownership and investment interests held by Physicians and their immediate family members.

The Centers for Medicare & Medicaid Services (CMS) receives these reports and makes the data publicly available on the Open Payments Program portal (www.cms.gov/OpenPayments)

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 (HCPs) have with life science manufacturers. It's important to note that the Sunshine Law does not restrict industry-HCP collaboration or interactions, or prohibit payments or transfers of value. ***Rather, it requires tracking & reporting of payments, transfers of value, and ownership/investment interests that result from these interactions.***

WHAT IS THE TIMING OF THE SUNSHINE LAW REQUIREMENTS?

- **March 31:** Deadline for Manufacturers to submit required data to CMS covering:
 - Payments and Transfers of Value given to Covered Recipients in previous Calendar Year (CY); and
 - Ownership / investment interests held by Physicians or their Immediate Family Members in previous CY.
- **May:** Covered Recipients may access the data via secure online portal for review and correction.
 - 45 Days to Review and Initiate Disputes
 - 15 Days to Resolve Disputes
- **June 30:** Data concerning previous CY Payments, Transfers of Value, and Ownership / Investment Interests will be published on a CMS public website by this date.

WHO IS REQUIRED TO REPORT?

- **Manufacturers** of PMA or 510(k) 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 Covered Recipients, if at least one product produced by the Manufacturer is reimbursed by Medicare, Medicaid, or CHIP.
- **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?

Manufacturers must report Payments and Transfers of Value to any of the following COVERED RECIPIENTS:

- **PHYSICIANS:** defined to include the following types of providers:
 - **Doctors of Medicine (MD)**
 - **Doctors Osteopathy (DO)**
 - **Dentists (DMD/DDS)**
 - **Podiatrists (DPM)**
 - **Optometrists (OD)**
 - **Chiropractors (DC/DCM)**

Residents are *excluded* from the requirement

As long as they hold a current U.S. license to practice, Providers are subject to the law regardless of whether or not they are enrolled in Medicare, Medicaid, or CHIP.
 - **Physician Assistants (PA)**★
 - **Nurse Practitioners (NP)**★
 - **Clinical Nurse Specialists (CNS)**★
 - **Certified Registered Nurse Anesthetists (CRNA)**★
 - **Anesthesiologist Assistants (AA/CAA)**⌘
 - **Certified Nurse Midwives (CNM)**★
 - **Teaching Hospitals** - CMS publishes a Teaching Hospital List on its Open Payments website, identifying all teaching hospitals subject to Manufacturer & GPO reporting. The List is accessible on the following webpage: <https://go.cms.gov/3zDMvgW>
- Payments made to a Covered Recipient above through a third party or those made to a third party **at the request of** or **on behalf of** a or **in the name of** a Covered Recipient are reported and include the name of the third party.

★=added in 2021 by the SUPPORT Act

⌘=CMS clarified Anesthesiologist Assistants are included in the expanded list of Covered Recipients

WHAT MUST BE REPORTED?

Payments, Transfers of Value and Ownership / Investment Interests must be reported.

Payments and Transfers of Value: must be reported when (a) an item is worth \$10* or more and (b) if items are worth less than \$10, when the sum of all items given to a particular Covered Recipient over the calendar 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 Covered Recipient.

***Thresholds:** Payment and Transfer of Value reporting thresholds are adjusted based on the consumer price index. For the current thresholds visit: <https://go.cms.gov/3NwJUuY>

Ownership & Investment Interests held by **Physicians (MD, DO, DMD/DDS, DPM, OD, DC/DCM)** 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 OR TRANSFER OF VALUE?

- **Manufacturer** or **GPO** Name;
- **Name** and **Business Address** of the Covered Recipient;
- **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 18 pre-defined Nature of Payment Categories (see next column)
- **Therapeutic Area** or **Product Category** related to the payment/transfer of value, **Marketed Name** (if the covered product has a marketed name), and **Device Identifier**;
- **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 Covered Recipient 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**.

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.

WHAT IS THE LEGAL STANDARD REQUIRED FOR THE VALUATION OF TRANSFERS?

- The Sunshine Law requires Manufacturers to report **Timely**, **Accurately**, and **Completely**.
- Manufacturers are subject to monetary penalties for each failure to report timely, accurately, or completely a payment or other transfer of value or ownership / investment interest. Other disincentives include:
 - negative media attention when the data is publicly posted; and
 - potential harm to the manufacturer's relationship with the medical community on whom they rely to help innovate and train on the safe and effective use of medical devices.
- MedTech Manufacturers are committed to ensuring accurate reporting, through mechanisms such as: the utilization of financial controls; data review & validation; monitoring & auditing data quality; employee attestations; and extensive training, among others.

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 services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program;
- Honoraria;
- Gift;
- Entertainment;
- Food and beverage;
- Travel & lodging (including specifying the destination);
- Education;
- Research;
- Debt Forgiveness;
- Royalty or License;
- Charitable Contribution (only available if provided to a tax exempt organization under the Internal Revenue Code)
- Ownership or Investment Interest (Current /Prospective);
- Compensation for serving as faculty or as a speaker for a medical education program;
- Long term medical supply or device loan (>90 days)
- Grant;
- Space rental or facility fees (Teaching Hospital only); and
- Acquisitions.

CAN PROVIDERS REVIEW THE DATA AND MAKE CORRECTIONS, IF NECESSARY?

Before information is publicly posted, Covered Recipients will have 45 days to review submitted data and initiate disputes once access to data is made available by CMS on the Open Payments web 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.

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

WHAT WILL BE DONE WITH THE REPORTED INFORMATION?

Most of what is provided in the Transparency Reports is published annually on a searchable CMS public website (www.cms.gov/openpayments)

By **June 30**, (a) data regarding previous CY payments, transfers of value and ownership interests will be **published** on the CMS public website and (b) **reports** summarizing payments made to covered recipients in each state will be submitted by CMS **to the states**.

By **April 1**, CMS submits an annual report to Congress that will include aggregated information submitted during the previous calendar year (ex: report issued April 2017 covers data collected in CY 2015 and submitted March 2016), as well as any enforcement actions taken and any penalties paid.

WHAT PAYMENTS/TRANSFERS OF VALUE ARE EXCLUDED FROM REPORTING?

Payments Or Transfers Of Value (POTOV) that are:

- 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 aggregate POTOV to a Covered Recipient for the year is less than or equal to \$100** (adjusted annually with consumer price index; see <https://go.cms.gov/3NwJUuY> for the current thresholds)
- **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 **Covered Recipient as a Patient** (e.g., Product Samples, Coupons, or Vouchers or as a subject in a research study)
- for the **Provision of Health-care 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)
- For payments made in connection with continuing education programs, Companies should determine whether these payments are considered to be “indirect payments,” as that term is defined in the Sunshine Act regulations (see FAQ 8165 at <https://go.cms.gov/2FYSAuV>)

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, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse midwives, certified registered nurse anesthetists, and anesthesiologist assistants, 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 imposed against a Manufacturer or GPO is \$1,150,000 per year.

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. For this reason, AdvaMed supports the Physician Payments Sunshine Act.

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



WHERE CAN I FIND MORE INFORMATION?

The Official CMS Website for the Sunshine Act, also referred to as the National Physician Payment Transparency Program - OPEN PAYMENTS: www.cms.gov/openpayments

CMS FAQs: <https://go.cms.gov/3T0Q2gf>

Information from the AMA: www.ama-assn.org/go/sunshine

Information from AdvaMed: www.advamed.org/sunshine



HOW CAN I WORK TOGETHER WITH MEDICAL TECHNOLOGY COMPANIES TO PROMOTE ETHICAL COLLABORATION?

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

- Industry collaboration with 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 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.

For more information about the value of interacting with a company that has certified to the AdvaMed Code of Ethics

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