THE PHYSICIAN PAYMENTS SUNSHINE ACT AND YOU

building stronger industry-physician interactions

Medical Technology Manufacturers are committed to accurate reporting and meaningful transparency.

WHAT IS THE PHYSICIAN PAYMENTS SUNSHINE ACT?

Signed into law in 2010 as part of the Affordable Care Act, the Physician Payments Sunshine Act (the "Sunshine Act") requires manufacturers, including certain distributors, of medical devices, drugs, biologicals, and medical supplies to track and report certain payments made to and transfers of value provided to physicians and teaching hospitals. The Sunshine Act also requires manufacturers and Group Purchasing Organizations (GPOs) to report certain ownership and investment interests held by physicians and their immediate family members.

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 have with life science manufacturers, including medical technology companies. It’s important to note that the Sunshine Law does not restrict industry-physician collaboration or interactions, or prohibit payments or transfers of value. Rather, it requires tracking and reporting of payments and transfers of value 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 Physicians & Teaching Hospitals in previous Calendar Year (CY); and
  - Ownership / investment interests held by Physicians or their Immediate Family Members in previous CY.
- **May**: Physicians and Teaching Hospitals may access their own 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.

WHO IS REQUIRED TO REPORT?

- **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% or more) with a Manufacturer (collectively, "Manufacturers") must submit Transparency Reports annually to CMS on Payments / Transfers of Value given to Physicians and Teaching Hospitals.
- **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.

WHAT RECIPENTS OF PAYMENTS OR TRANSFERS OF VALUE MUST BE REPORTED?

Payments and Transfers of Value made by Manufacturers to "Physicians" and "Teaching Hospitals" must be reported. Payments made to physicians and teaching hospitals through a third party or those made to a third party at the request of or on behalf of a physician or teaching hospital are reported and include the name of the third party.

- **The Sunshine Law** applies to all of the following types of doctors, as long as they hold a current U.S. license to practice:
  - Doctors of Medicine;
  - Doctors Osteopathy;
  - Dentists;
  - Podiatrists;
  - Optometrists; and
  - Chiropractors.
- Residents are excluded from the requirement (including resi dents in medicine, osteopathy, dentistry, podiatry, optometry, and veterinary medicine who are not partners in the practice of medicine).

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 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 physician.

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/2ybd8G4

Ownership & Investment Interests held by Physicians 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.

HOW WILL RESEARCH PAYMENTS BE HANDLED?

Payments related to research must be reported separately and submitted by 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 DETAILS MUST BE INCLUDED IN THE REPORT ABOUT THE PAYMENT OR TRANSFER OF VALUE?

- Manufacturer or GPO Name;
- Name and Business Address of the Physician;
- 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 16 pre-defined Nature of Payment Categories (see right column)
- Therapeutic Area or Product Category related to the payment/transfer of value and Marketed Name (if the covered product has a marketed name);
- 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 Physician 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.

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 IS THE LEGAL STANDARD REQUIRED FOR THE VALUATION OF TRANSFERS?

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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 for serving as a faculty or as a speaker for an accredited or certified CE program;
- Compensation for serving as an unaccredited and non-certified CE program;
- Compensation for services other than consulting, including serving as faculty at an event other than a Continuing Education (CE) program;
- Honoraria;
- Gift.

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 $50 when the aggregate POTOV to a physician for the year is less than or equal to $100 (adjusted annually with consumer price index);
- Educational Materials That Directly Benefit Patients or Are Intended For Patient Use such as patient education textbooks and anatomical models, but excluding journal articles and textbooks;
- Travel & lodging (including entertainment) for two years after access has been provided to a report with disputed information;
- Educational Materials That Directly Benefit Patients or Are Intended For Patient Use such as patient education textbooks 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 – 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, 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 Proceedings (e.g., as an expert witness);
- For payments made in connection with incoming education programs, Companies should determine whether these payments are considered to be “indirect payments,” as that term is defined in the Employee Retirement Income Security Act regulations (see FAQ 1865 at https://go.cms.gov/2FYSAuV);
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CAN PHYSICIANS REVIEW THE DATA AND MAKE CORRECTIONS, IF NECESSARY?

Before information is publicly posted, a Physician will have 45 days to Review submitted data and Initiate Disputes once access to his/her 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 will still be posted to the public webpage but will be flagged as Disputed.

Physicians 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.

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 Code of Ethics on Interactions with Health Care Professionals which also supports ethical collaborations 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/2FYSAuV

Information from the AMA:

www.ama-assn.org/go/sunshine

Information from AdvaMed:

www.advamed.org/sunshine