The Physician Payments Sunshine Act (the “Sunshine Act”) was signed into law in 2010 as part of the Affordable Care Act. The Sunshine Law is designed to provide patients with enhanced transparency into the relationships their healthcare providers have with life science manufacturers, including medical technology companies. It's important to note that the Sunshine Law does not restrict industry-physician collaborations 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.

### Why Was the Sunshine Law Enacted? 

The main purpose of the Sunshine Law is to provide patients with enhanced transparency into the relationships their healthcare providers have with life science manufacturers, including medical technology companies. It’s important to note that the Sunshine Law does not restrict industry-physician collaborations 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 Must Be Reported? 

Payments, Transfers of Value and Ownership / Investment Interests must be reported. For the 2015 calendar year, manufacturers must report ownership and investment interests held by physicians and their immediate family members and payments to physicians and teaching hospitals through May 2016. Payments made to physicians and teaching hospitals through June 30, 2016 must be reported by March 31, 2017. Payments made to physicians and teaching hospitals through March 31, 2016 must be reported by June 30, 2016.

### 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 IS THE TIMING OF THE SUNSHINE LAW REQUIREMENTS? 

- March 31, 2016: Deadline for Manufacturers to submit required data to CMS covering:
  - Payments and Transfers of Value given to Physicians and Teaching Hospitals in 2015; and
  - Ownership / Investment interests held by Physicians or their Immediate Family Members in 2015.
- May 2016: 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, 2016: Data concerning 2015 Payments, Transfers of Value, and Ownership / Investment Interests will be published on a CMS public website by this date.

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

- The Sunshine Law requires Manufacturers to report timely, accurately, and completely all payments and transfers of value. 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.

### WHICH RECIPIENTS 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 reporting (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic). 
- Third Party Entity recipients of a Payment / Transfer of Value made “at the request of or in the name of a Physician or Teaching Hospital, must be reported in the name of the physician and the recipient.

- These doctors are subject to the law regardless of whether or not they are enrolled in Medicare, Medicaid or CHIP.

### WHO IS REQUIRED TO REPORT? 

- 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 next page);
- 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 PHYSICIAN PAYMENTS SUNSHINE ACT? 

The Physician Payments Sunshine ACT is designed to ensure 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.

### WHY WAS THE SUNSHINE LAW ENACTED? 

The main purpose of the Sunshine Law is to provide patients with enhanced transparency into the relationships their healthcare providers have with life science manufacturers, including medical technology companies. It’s important to note that the Sunshine Law does not restrict industry-physician collaborations 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 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 a faculty or as a speaker for 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:
- Made in 2015 for Speaking at a Continuing Education Program if the conditions are met:
  1) Program meets accreditation or certification requirements and standards of ACMEC, AOA, AMA, AAPF or ADA CERP
  2) the manufacturer does not select the speaker and does not provide a direct, identifiable set of individuals to be considered as speakers; and
  3) the manufacturer does not directly pay the Physician Speaker
- The above exclusion was eliminated for 2016 POTOV 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 physician for the year is less than or equal to $100 (adjusted with consumer price index)
- POTOV Thresholds (Indiv. / Agg):
  - 2015: $10.21 / $102.07
  - 2016: $10.22 / $102.19
- Educational Materials That Directly Benefit Patients or are Intended For Patient Use
- Discounts and Rebates
- In Kind Items for the Provi
- Product Samples (including coupons and vouchers) where there is an agreement in writing that the products will be provided to patients
- Education; Research; Charitable Contribution; Royalty or License; Ownership or Investment Interest (Current/Prospective); Grant; and
- Space rental or facility fees (Teaching Hospital only).

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 their 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, 2016, (a) data regarding 2015 payments, transfers of value and ownership interests will be published on the CMS public website and (b) reports summarizing payments made to physicians and other covered recipients in each state will be submitted by CMS to the states.

By April 1, 2016, CMS submits an annual report to Congress that will include aggregated information submitted during the previous calendar year (data collected in CY 2014 and submitted March 2015), as well as any enforcement actions taken and any penalties paid.

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 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.

WHERE CAN I FIND MORE INFORMATION?


Value of Industry-Provider Collaborations

Collaboration and interactions between medical technology companies and health care providers is 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 collaboration. It is by driving ethical collaborations that we help protect patients.

To see the companies that have certified to the Code, visit: www.adamed.org/CodeCertification

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 in
- 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 on a public website.