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, biologics, 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 practice nurses. See recipients 14.

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 the 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 by this date.

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, “Manufac 
- 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 Owners/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
- Doctors Osteopathy (DO)
- Dentists (DMD/DDS)
- Podiatrists (DPM)
- Optometrists (OD)
- Chiropractors (DC/DCM)
- Physician Assistants (PA)
- Nurse Practitioners (NP)
- Certified Registered Nurse Anesthetists (CRNA)
- Anesthesiologists Assistants (AA/CAA)
- Certified Nurse Midwives (CNM)
- Nurse Anesthetists (CRNA)
- Physicians (MD, DO, DPM, OD, DC/DCM) or their Immediate Family Members, in GPOs and Manufacturers-
- the Dollar Amount and the Value and Terms of the ownership / 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 – a 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 Interest in the Manufacturer, and
- Whether the Physician or an Immediate Family Member holds the Ownership / Investment Interest.

HOW WILL PAYMENTS BE HANDLED?
Payments related to research must be reported separately and submitted by the end of the calendar year following the year the payment occurs stating the institution name & principal investigator. 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.

- 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, transparent, and meaningful transparency 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 SUNSHINE ACT AND YOU?
building stronger industry-provider interactions.

OPEN PAYMENTS TRANSPARENCY REPORTING
Medical Technology Manufacturers are committed to accurately reporting and meaningfully transparent.
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);
- Educational Materials;
- Research;
- Debt Forgiveness;
- Royalty or License.

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 works for a manufacturer);
- 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/2ybZ84G 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 - 90 days or less average daily use.

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 obligations 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 with providers and industry. 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

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 care and treatment of patients and the development and improvement of medical technology. You can work with us to promote strong standards and 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 collaboration 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.