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 Law”) 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.

Teaching Hospitals are defined as hospitals that received payment for Medicare direct graduate medical education (GME), inpatient prospective payment system (IPPS) indirect medical education (IME), or psychiatric hospital IME programs during the last calendar year for which such information is available. CMS will publish a list on annual basis of hospitals which it considers to be teaching hospitals.

The Sunshine Law 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.

WHERE CAN I FIND MORE INFORMATION?
The Official CMS Website for the Sunshine Law, also referred to as the National Physician Payment Transparency Program:

- OPEN PAYMENTS: https://go.cms.gov/2FYSAuV
- CMS FAQs: https://go.cms.gov/2FYS4aV
- Information from the AMA: www.ama-assn.org/go/sunshine
- Information from AdvaMed: www.adavemed.org/sunshine

WHAT IS THE COMPLIANCE TIMELINE ON THE SUNSHINE LAW REQUIREMENTS?
- March 31: Deadline for Manufacturers to submit required data to CMS covering:
  - Payments and Transfers of Value given to Physicians and 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 Out
- 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 wholesale distributors and entities under common ownership (3% 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.

WHICH 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.

Teaching Hospital List - published by CMS on its Open Payments website, identifies all teaching hospitals subject to Manufacturer & GPO reporting. The List is accessible on the following webpage: https://www.cms.gov/OpenPayments/About/Resources.html

The Sunshine Law applies to all of the following types of doctors, as long as they hold a current license to practice in the United States: Doctors of Medicine; Doctors Osteopathy; Dentists; Podiatrists; Optometrists; and Chiropractors.

Residents are excluded from the requirement (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.

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://www.cms.gov/OpenPayments/Program-Participants/Applicable-Manufacturers-and-GPOs/Data-Submission.html

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 (including 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 Physician
- Specialty, NPI, and State Professional License Number
- Dollar Value and Date of the payment/transfer of value;
- Form of Payment / Transfer of Value (i.e., 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 predefined Categorizes (see next column)
- Therapeutic Area or Product Category related to the payment/transfer of value and Marketed Name (if the covered product has one);
- 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 ARE THE NATURE OF PAYMENT CATEGORIES THAT MUST BE DESCRIBED IN PAYMENTS AND TRANSFERS OF VALUE?
The Payment/Transfer of Value must be categorized as one of the following:
- Consulting fee;
- Compensation for serving as faculty or as a speaker for an accredited or certified CE program;
- Compensation for serving as 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 educational CE program; and
- Honoraria; Gift;
- Entertainment;
- Food and beverage;
- Travel & lodging (including specifying the destination);
- Education;
- Research;
- Charitable Contribution;
- Royalty or License;
- Ownership or Investment Interest (Current /Prospective);
- Grant; and
- Space rental or facility fees (Teaching Hospital only).

CAN TEACHING HOSPITALS REVIEW THE DATA AND MAKE CORRECTIONS, IF NECESSARY?
Before information is publicly posted, a Teaching Hospital will have 45 days to Review submitted data and Initiate Disputes once access to its 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.

Teaching Hospitals are able to see correction or contest reports for two years after access has been provided to a report with disputed information.

THE PHYSICIAN PAYMENTS SUNSHINE ACT: A teaching hospital guide to industry transparency reporting requirements
IF A NON-MEDICAL PHARMACEUTICAL MANUFACTURER OR GPO MAKES A PAYMENT TO A TEACHING HOSPITAL, DOES THIS PAYMENT NEED TO BE REPORTED?

Yes. There is no reporting exclusion for payments made to covered recipients for the purpose of purchasing products or materials.

WHAT WILL BE DONE WITH THE REPORTED INFORMATION?

Most of what is provided in the Transparency Reports is published annually on a searchable public website (www.cms.gov/openpayments). By June 30, (a) data regarding previous Calendar Year (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 published by CMS to the states. By April 1, CMS submits an annual report to Congress that will include aggregated information submitted during the previous CY, 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:

- Not made to a Covered Recipient Physician or Teaching Hospital
- Not made under a research agreement for which the research is intended to benefit the teaching hospital
- Made to a non-physician employee of a teaching hospital
- Made to a non-physician employee of a teaching hospital that is intended to benefit the teaching hospital
- Indirect payments, as defined in the Sunshine Act regulations.

ARE PAYMENTS FROM A MANUFACTURER TO A TEACHING HOSPITAL IN ORDER TO PURCHASE PRODUCTS OR MATERIALS CONSIDERED REPORTABLE UNDER OPEN PAYMENTS?

Yes. There is no reporting exclusion for payments made to covered recipients for the purpose of purchasing products or materials.

WHAT PAYMENTS/TRANSFERS OF VALUE ARE INCLUDED IN THE REPORTS?

Payments related to research must be reported separately and sub- mitted 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 if the following conditions are met:

1. The payment or transfer of value was made under a research agreement for which the research is intended to benefit the teaching hospital.
2. The research or development of a new drug, device, biological, or medical supply is a new application of an existing drug, device, biological, or medical supply.
3. Clinical investigations (Phases I - IV clinical research for drugs & biologics, and approval trials for devices) related to new applications of existing products do not qualify for delayed publication.
4. Payments related to research on new applications of existing products will be granted a delay only if the research does not meet the definition of "clinical investigation."
5. Information about payments and other transfers of value that are delayed from publication must be publicly available on the CMS website if the following conditions are met:
   a. the approval, licensure or clearance of the FDA of the covered drug, device, biological or medical supply.
   b. 4 calendar years after the date of payment or other transfer of value.

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 if the following conditions are met:

1. The payment or transfer of value was made under a product research or development agreement, which must include either a written agreement or a research protocol.
2. The payment or transfer of value was made in connection with:
   a. Research or development of a new drug, device, biological, or medical supply or a new application of an existing drug, device, biological, or medical supply.
   b. Clinical investigations regarding a new drug, device, biological, or medical supply.
   c. Clinical investigations (Phases I - IV clinical research for drugs & biologics, and approval trials for devices) related to new applications of existing products.
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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 Act’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 be imposed against a Manufacturer or GPO is $1,150,000 per year.

WHAT PAYMENTS/TRANSFERS OF VALUE WOULD THE TRANSFER OF VALUE NEED TO BE REPORTED AS A TRANSFER OF VALUE TO THE TEACHING HOSPITAL?

- Generally, No, these would not need to be reported (e.g., a meal).
- Non-physician employees of a Teaching Hospital are not considered recipients for the purposes of Open Payments. Accordingly, payments or other transfers of value made to these non-physician employees generally do not need to be reported.
- Transfers of Value to Non-Physician Employees would need to be reported if:

  a. the payments were made to the non-physician employees at the request of or designated by the Manufacturer on behalf of a covered recipient Physician or Teaching Hospital (pursuant to 42 C.F.R. §403.904(a) and (c)(10))
  b. they were in fact Indirect Payments to a covered recipient Physician or Teaching Hospital being made through the non-physician employee (as defined at §403.902):
     - Indirect payments or other transfers of value occur when an applicable manufacturer or GPO requires, instructs, directs or otherwise causes a third party to provide the payment or other transfer of value, in whole or in part, to a covered recipient.
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- Payments made to the non-physician employees of a Teaching Hospital are not considered transfers of value.

ASSUMPTIONS AND LIMITATIONS

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Ways to report:

- Direct: $$; ID: institution
- Indirect: $$; ID: institution

A manufacturer or GPO may only submit a single report for a single reportable transaction, irrespective of the number of recipients.

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