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Physician-Industry Transparency: The U.S. Physician Payment Sunshine Act

### The Sunshine Act





The Sunshine Act will make interactions between U.S. physicians and pharmaceutical, biologics and medical device manufacturers significantly more visible to the public.



Boston Scientific has developed systems to enable accurate tracking and reporting of payments and items of value provided to U.S. physicians and teaching hospitals in compliance with the Sunshine Act.

### PRESENTATION INCLUDES:

- Overview of Sunshine Act
- Rollout Dates
- Requirements
- How Physicians Can Prepare

### Rollout Dates & Requirements





Pharmaceutical, biologic and medical device companies are required to:

- Track payments and items of value provided to U.S. physicians and teaching hospitals.
- Be prepared to publically disclose any meal, educational item, consulting payment or other financial interaction between the industry and a physician or teaching hospital.

Pharmaceutical, biologic and medical device companies are required to provide the U.S. government with data regarding their interactions with U.S. physicians and teaching hospitals between August 1 and December 31, 2013.

#### \*\*ANNUAL EVENT\*\*

**Each March 31:** Pharmaceutical, biologic and medical device companies are required to submit a report as to interactions in the prior calendar year.

The U.S. government will post data on a public, searchable government-maintained website and continue to post the data annually.

 U.S. physicians will have an opportunity to review and submit corrections to the data within 45 days of the data being made available to the public.

#### \*\*ANNUAL EVENT\*\*

Each September 30: The U.S. government will post data on a public, searchable government-maintained website and continue to post the data annually.

## What Information are Pharmaceutical, Biologics and Medical Device Companies Required to Report?



- All payments or transfers of value to a U.S. physician or teaching hospital over \$10.
- Any payments made to another entity "at the request of" or "on behalf of" a physician or teaching hospital.
  - Example: If a physician requests the consulting payment be made to an entity (such as his/her LLC), the regulations require companies to disclose this as a payment to the physician and also report the name of the entity receiving the payment.
- If within a calendar year, a manufacturer makes payments to or provides a physician or teaching hospital in excess of \$100 in total, then all payments and items of value provided during that calendar year must be reported (even if they are individually less than \$10).
- A manufacturer is required to report research payments made to institutions conducting clinical research on the manufacturer's behalf, including the name(s) of the Principal Investigator(s), even if the manufacturer does not direct funds to those specific physicians.

## Types of payments or items of value that must be reported include:

- Consulting Payments and Honoraria
- Research & Clinical-Trial Related Expenditures
- Educational Items (e.g., textbooks, journal reprints)
- Educational and Research Grants
- Royalty Payments and Licensing Fees
- Expenses such as Travel, Lodging and Meals
- ► Training & Education Expenses
- Charitable Donations

## What Information are Pharmaceutical, Biologics and Medical Device Companies Required to Report?



### **Sunshine Act Reporting Requirements:**

### **INCLUDED**

- Name of recipient HCP, contact information, specialty
- HCP's National Provider Identifier
- State License Number of HCP
- Date of the payment or transfer of the item of value
- Dollar value
- Product associated with the interaction
- Description of the type and nature of the payment or item of value
- Destination (for travel expenses)

### **EXCLUDED**

- Payments made or transfers of value provided to physician assistants, nurses, lab technicians or hospital administrative staff.
- Anatomical models or wall models used to educate patients on a particular procedure or product.
- Coffee, snacks or other refreshments provided at booths or during large events at third-party conferences.
- Short-term loan of devices/capital equipment.

Important Note: Even if the Sunshine Act excludes these types of payments from its reporting requirements, manufacturers may still be required to disclose this information for other purposes.

## How Can Physicians Prepare?



### Physicians can prepare by:

- Reviewing their hospital/medical facility policies that limit interaction with industry and avoiding interactions that are not consistent with those policies.
- Understanding and being comfortable with the reason for any payments or transfers of value they receive from pharmaceutical, biologics and medical device companies.
- ► Proactively reviewing the data disclosed under their names during the annual open window provided by the government.
- Being mindful of responding to media requests and understanding any data posted under their names before they choose to talk with the media.



### In Closing



We value and look forward to continuing our essential collaboration with physicians, hospitals and other health care providers, which allows us to deliver innovative, less-invasive medical devices and procedures for the benefit of patients.

We are committed to acting with integrity in all of our interactions with physicians.

### Thank you!

Note: The contents of this presentation are not intended to be legal advice. For information about how the Sunshine Act impacts you specifically, please contact your attorney or your institution's Legal Department.