The Sunshine Law and You:

Overview

BIOMET 3i™

PROVIDING SOLUTIONS – ONE PATIENT AT A TIME™

What is the 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 clinicians and teaching hospitals.

The Sunshine Law also requires manufacturers and group purchasing organizations (GPOs) to report certain ownership and investment interests held by clinicians 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-clinician 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 on the Sunshine Law Requirements?

- **August 1, 2013:** Manufacturers and GPOs are required to begin collecting information about payments, transfers of value, and ownership interests.
- **March 31, 2014:** First manufacturer/GPO report is due. This report must cover August - December 2013 payments/transfers of value and ownership interests. Subsequent reports will cover an entire calendar year and be due the 90th day of the following year.
- **August 2014** (in subsequent years, during the month of May): clinicians and teaching hospitals may access their own data via a secure online portal for review and correction.
  - 45 Days to Review and Initiate Disputes
  - 15 Days to Resolve Disputes
- **September 30, 2014:** 2013 data published on a public website by CMS. In subsequent years, information will be published on June 30.

Who is Required to Report?

Manufacturers of medical devices, drugs, biological, 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 clinicians and teaching hospitals.

Which Recipients of Payments or Transfers of Value Must Be Reported?

Payments and transfers of value made by manufacturers to clinicians and teaching hospitals must be reported.

Payments made to clinicians and teaching hospitals through a third party or those made to a third party at the request of or on behalf of a clinician or teaching hospital must be reported and include the name of the third party.

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

These doctors are subject to the law regardless of whether or not they are enrolled to review payments from Medicare, Medicaid or CHIP.

- Medical residents are excluded from the requirement (including residents in medicine, osteopathy, dentistry, podiatry, optometry and chiropractic).
- The Third Party Entity of a payment/transfer of value made at the request of or in the name of a clinician or teaching hospital, must be reported in the name of the clinician and the recipient.

What Must Be Reported?

Payments, transfers of value and ownership/investment interests.

Payments and transfers of value must be reported when an item is worth $10 or more, and if items are worth less than $10, when the sum of all items given to a particular recipient over a year exceeds $100.

Manufacturers are required to report:
(a) Direct payments and transfers of value
(b) Indirect payments and transfers of value
(c) Payments and transfers of value that are made to a third party at the request of or on behalf of a clinician
(d) Ownership and investment interests held by clinicians 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 clinician owner or investor.

What Details Must Be Included in the Report About the Payment/Transfer of Value?

- *Manufacturer* or *GPO* name
- *Name* and *Business Address* of the clinician
- *Specialty, NPI* and *State Professional License Number*
- *Dollar Value* and *Date* of the payment/transfer or value
- Form of payment / transfer of value (e.g., cash or 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 categories (see next column)
- *Device Product Name*,*Therapeutic Area* or *Product Category* related to the payment/transfer of value
- *Context* - (options) 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 clinician directly
- Whether the payment/transfer of value was provided to a clinician holding ownership/investment interests in the manufacturer
- Whether the clinician or an immediate family member holds the ownership/investment interest

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 and principal investigators. Some of these details may qualify for delayed publication to the public CMS website.

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 faculty or as a speaker for an accredited or certified Continuing Medical Education (CME) program
- Compensation for serving as faculty or as a speaker for an unaccredited and non-certified CME program
- Compensation for services other than consulting, including serving as faculty at an event other than a CME program
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging (including specifying the destination)
- Education
- Research
- Charitable contribution
- Royalty or license
- Ownership or investment interest (current/prospective)
- Grant
- Space rental or facility fees (teaching hospital only)

Can Clinicians Review the Data and Make Corrections, if Necessary?

Before information is publicly posted, a clinician 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 reach a resolution.

If the dispute continues, the data will still be posted on the public web page but will be flagged as disputed.

Clinicians are also able to seek correction or contest reports for two years after access has been provided to a report with disputed information.

What Payments/Transfers of Value are Excluded from Reporting?

Payments/Transfers of Value that are:

- For speaking at a Continuing Medical Education Program if three conditions are met:
  1) Program meets accreditation/certification requirements and standards of ACCME, AOA, AMA, AAFP or ADA CERP
  2) The manufacturer does not select the speaker and does not provide a distinct, identifiable set of individuals to be considered as speakers
  3) The manufacturer does not directly pay the clinician speaker
- From existing personal relationships (e.g., one spouse who works for a manufacturer giving a gift to their spouse who is a clinician)
- Less than $10 when the total value for the year is less than or equal to $100 (This amount to be adjusted beginning of 2014 with the consumer price index)
- Education materials that directly benefit patients or are intended for patient use
- 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 - of 90 days or less average daily use
- Items and services provided under a contractual warranty, service or maintenance agreement
- Received by the clinician for 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 non-medical professional services (e.g., a clinician-attorney paid only for legal services)
- For services with respect to a civil or criminal action or administrative proceeding (e.g., as an expert witness)

What Will be Done with the Reported Information?

Most of what is provided in the Transparency Reports will be published annually on a public website that is searchable. 2013 data will be published on September 30, 2014.

In subsequent years, information made public on June 30.

The Secretary of HHS will also be required to submit a report to Congress on an annual basis.

How are Manufacturers Preparing for Compliance with the Sunshine Law?

BIOMET ***3i*** is enhancing our existing tracking systems to capture the required payment data beginning on August 1, 2013.

How Can I Work Together with BIOMET ***3i*** to Promote Ethical Collaboration?

BIOMET ***3i*** supports the transparency goal of the Sunshine Law to ensure that health care professionals, like you, continue to make independent decisions regarding the healthcare and treatment of patients and the development and improvement of medical technology.

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 to design innovative and advanced technologies
- Your patients and other stakeholders may not understand the benefits of industry collaborations with healthcare 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 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.

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:

go.cms.gov/openpayments

Information from the AMA:
ama-assn.org/go/sunshine

Information from AdvaMed:
advamed.org/sunshine

This brochure is intended to provide a brief educational summary of Sunshine Law's key transparency provisions.
BIOMET ***3i*** does not provide legal or accounting services. Consult your representative advisor for more details about the Sunshine Law.

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For more information about the value of interacting with a company that has certified to the AdvaMed Code of Ethics.

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