ReedSmith
UNIVERSITY

Physician Sunshine Rules Update: Final Rule

Katie C. Pawlitz

Nancy E. Bonifant

March 26, 2013

Agenda

I. Overview of Sunshine Law
II. Who must report?
III. What must be reported?
IV. Special rules for research-related payments
V. How is disputed information handled?
VI. Penalties
VII. Open questions, challenges, and preparation
VIII. Questions

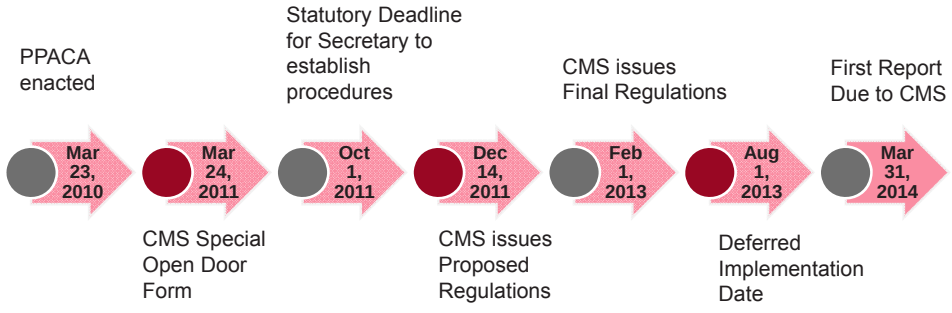
I. Overview of Sunshine Law

- Requires "applicable manufacturers" to report "payments or other transfers of value" to "covered recipients"
  - *Payments or other transfers of value* means a transfer of anything of value. Certain identified payments/transfers are excluded
  - *Covered Recipients* are limited to physicians and teaching hospitals
  - Reportable information includes name and address of covered recipient, amount + date of payment, form of payment (*e.g.*, cash, stock), nature of payment (*e.g.*, consulting fees, gift, entertainment)
- Requires "any applicable manufacturer or applicable group purchasing organization" to report information regarding any physician ownership or investment interests

3

I. Overview of Sunshine Law

Sunshine Law Final Implementation Timeline



4

I. Overview of Sunshine Law

- Section 6002 of the Affordable Care Act added section 1128G to the Social Security Act. Pub. L. No. 111-148 ("Transparency Reports and Reporting of Physician Ownership or Investment Interests") (codified at 42 U.S.C. § 1320a-7h)
- The proposed rule was published in the Federal Register on December 19, 2011 at 76 Fed. Reg. 78,742
- The final rule was published in the Federal Register on February 8, 2013 at 78 Fed. Reg. 9,458
- Regulations are at 42 C.F.R. §§ 403.900 – 403.914

5

II. Who must report?

- Payments and Transfers of Value to Covered Recipients:

Applicable Manufacturers

- Physician (or Immediate Family Member) Ownership or Investment Interests:

Applicable Manufacturers

Applicable Group Purchasing Organizations

6

II. Who must report?

Definition of Applicable Manufacturer

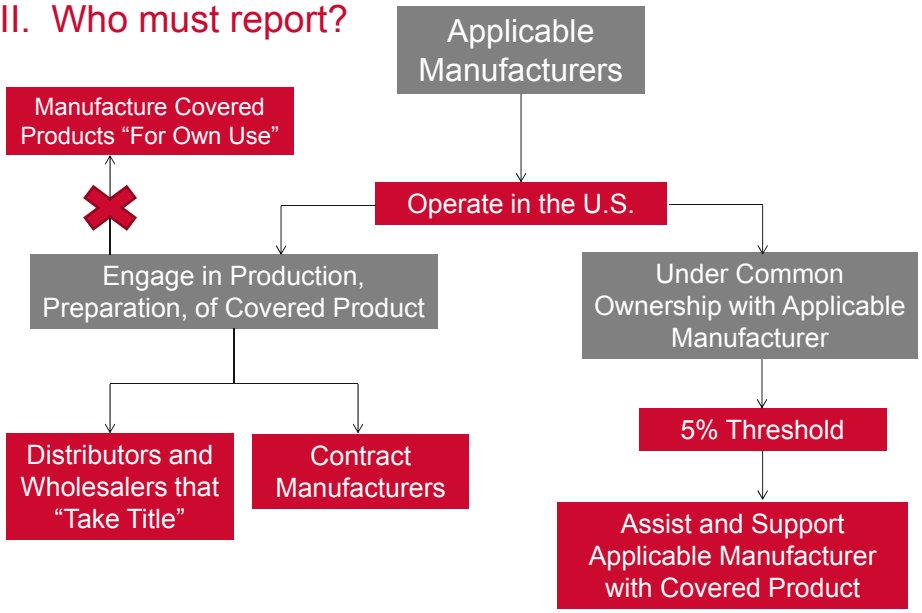
- "Applicable manufacturer" means an entity that is "operating in the United States" and is either:

  (1) engaged in the production, preparation, propagation, compounding or conversion of a covered product; or

  (2) under common ownership (5%) with an entity described in (1) and provides "assistance or support" to such entity with respect to the production, marketing, sale, or distribution of a covered product.

7

II. Who must report?



8

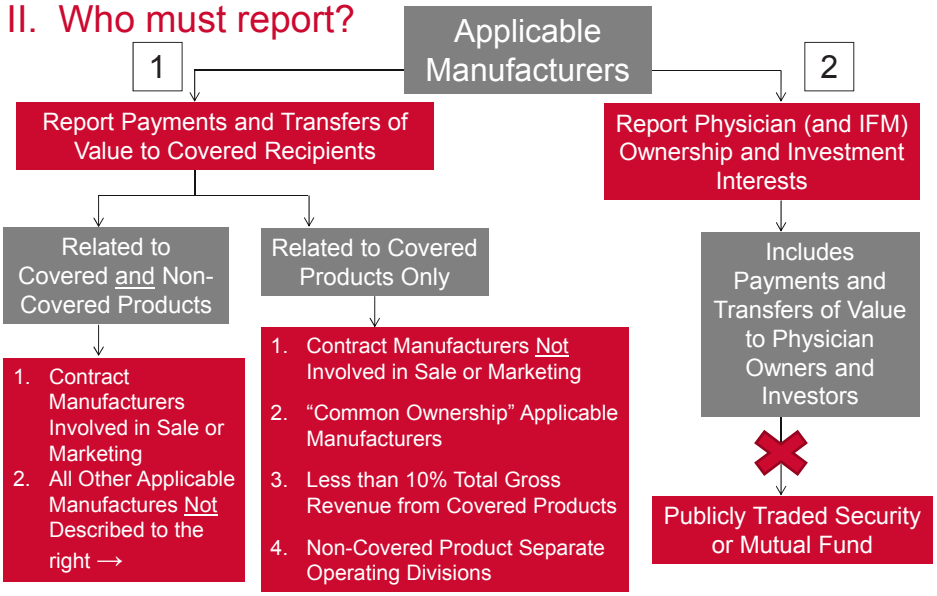
II. Who must report?

Diversified Applicable Manufacturers

- If a manufacturer meets the definition by selling or distributing at least one covered product in the U.S., then the manufacturer must report payments and other transfers of value made to covered recipients for both covered and non-covered products.
- **Notable Exceptions for Diversified Applicable Manufacturers**. The following narrow grouping of applicable manufacturers are required to report only payments and other transfers of value that relate to covered products:
  - Applicable manufacturers with <10 percent of total (gross) revenue from covered products during the previous fiscal year;
  - "Common ownership" (5%) applicable manufacturers;
  - Applicable manufacturers that have separate operating divisions that only produce non-covered products and do not meet the definition of providing "assistance and support" to other divisions that produce covered products; and
  - Contract manufacturers that do not hold FDA approval, licensure, or clearance for the covered product, and are not involved in the sale, marketing or distribution of the product.

9

II. Who must report?



10

II. Who must report?

Applicable Manufacturers and Consolidated Reports

- **Flexibility to Submit Consolidated Reports.** Applicable manufacturers under common ownership with separate entities that are themselves applicable manufacturers may, but are not required to, file a consolidated report for all of the entities.
- **Content of Consolidated Reports.** Manufacturers filing consolidated reports must provide information specified by CMS to identify each applicable manufacturer and entity (or entities) under common ownership that the report covers. They must also specify on each payment line which entity made which discrete payment or other transfer of value.

11

II. Who must report?

Applicable Group Purchasing Organizations

- "Applicable GPO" is an entity that:

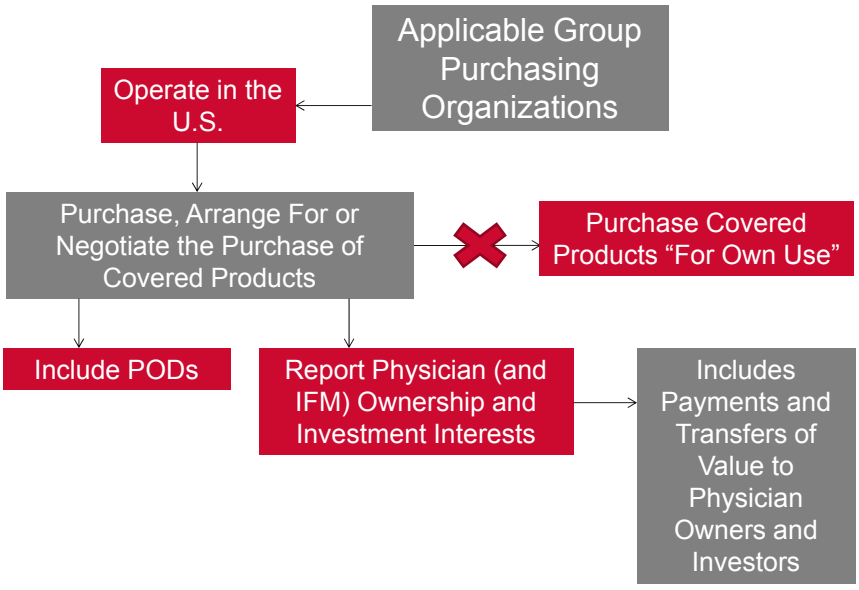
  (1) Operates in the U.S., or in a territory, possession or commonwealth of the U.S., and

  (2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, and not solely for use by the entity itself.

- Inclusion of Physician Owned Distributors (or PODs)

12

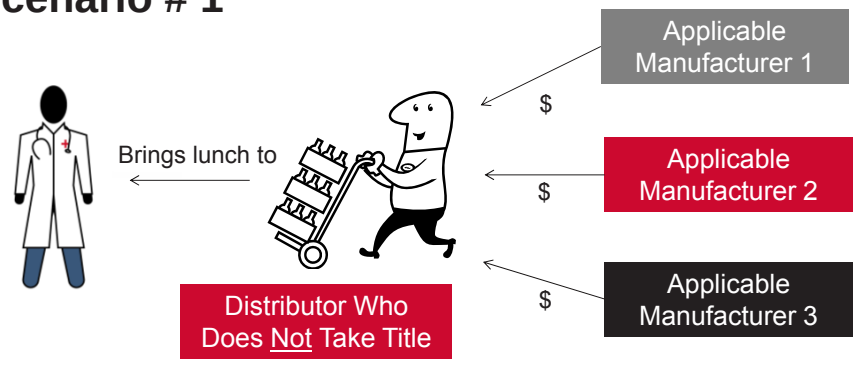
II. Who must report?



13

II. Who must report?

Scenario # 1

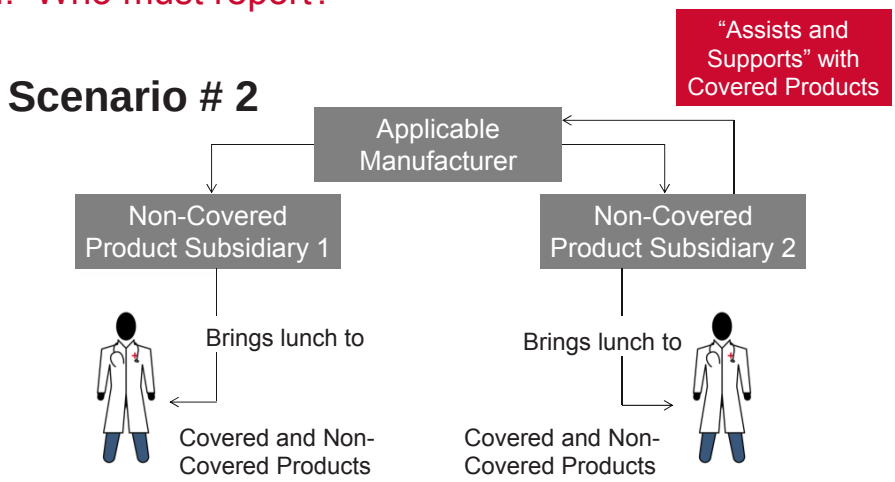


And how is that accomplished?

14

II. Who must report?

Scenario # 2



And regarding what products?

15

III. What must be reported?

What types/categories of payments must be reported by manufacturers?

- Charitable contributions
- Food and beverage
- Faculty/speaker payments
- Consulting fees
- Honoraria
- Gifts/entertainment
- Travel + lodging
- Education
- Royalty or license
- Current or prospective ownership interests
- Grants
- Research
- Space rental or facility fee

16

III. What must be reported?

What types/categories of payments are excluded from reporting?

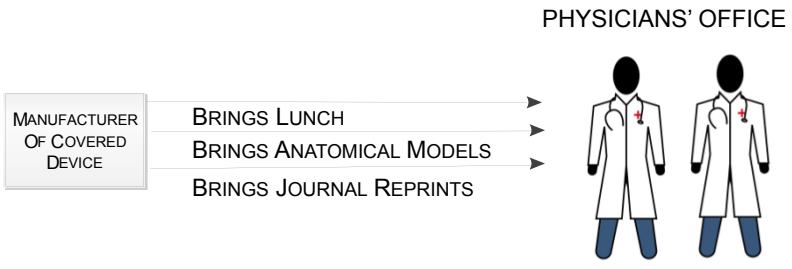
- Existing personal relationships
- Payments/transfers < $10 (up to $100)
- Patient educational materials
- Discounts/rebates
- In-kind charity care items
- Publicly traded fund payments
- Product samples
- Short term loans
- Contractual warranty
- Physicians as patients
- Provision of health care
- Nonmedical professional
- Payments as part of civil/criminal action or administrative proceeding

Other exclusions

17

III. What must be reported?

Scenario # 3



18

III. What must be reported?

What ownership/investment interests must be reported?

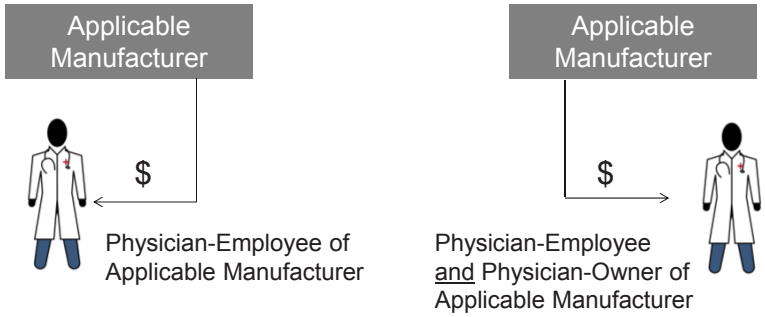
Reported	Not Reported
• Stocks and stock options (other than those received as compensation, until exercised) • Partnership shares • Limited liability company memberships • Loans, bonds, or other financial instruments that are secured with an entity's property or revenue (or a portion of that property or revenue)	• An ownership or investment interest in a publicly traded security or mutual fund • An interest that arises from a retirement plan offered by the applicable manufacturer or GPO to the physician (or IFM) through the physician's (or IFM's) employment with that applicable manufacturer or GPO • Stock options and convertible securities received as compensation, until exercised • Unsecured loan subordinated to a credit facility • An ownership or investment interest that the applicable manufacturer or GPO does not know about

19

III. What must be reported?

Scenario # 4

Payments to a physician owner who is an employee



20

III. What must be reported?

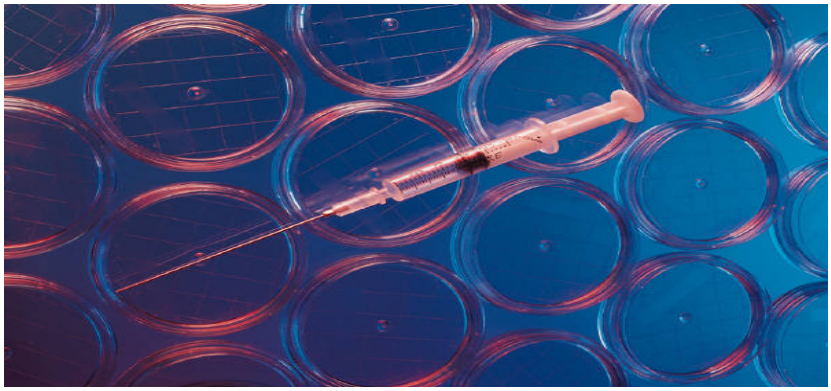
A note on indirect payments and ownership interests…

- Any payment or transfer value provided to a covered recipient through a third party must be reported if the applicable manufacturer is aware of the covered recipient's identity
  - Indirect payment or other transfer of value = one that a manufacturer requires, instructs, or directs to be provided to a covered recipient, regardless of whether the applicable manufacturer specifies the specific covered recipient.
  - A manufacturer is "unaware" if it does not know the identity of a covered recipient; "know" means that the manufacturer has actual knowledge of the identity or acts in deliberate ignorance or reckless disregard of the identity.
- Direct and indirect ownership and investment interests are reportable.

21

IV. Research-related payments

- What is "research"?
- What needs to be reported?
- When can reporting of confidential/proprietary research/development be delayed?



22

IV. Research-related payments

- "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.
  - Includes pre-clinical research and FDA Phases I-IV research, as well as investigator-initiated investigations
  - Requires a written agreement or contract or a research protocol
- "Clinical Investigation" means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed, or used.
  - Includes include Phases I through IV clinical research for drugs and biologicals, and approval trials for devices (including medical supplies).

23

IV. Research-related payments

- For each research-related payment or other transfer of value, the following information is required:
  - Applicable manufacturer's name;
  - Name of research institution/entity receiving payment;
  - Total amount of research payment;
  - Name of study;
  - Name(s) of related covered product(s) (if any);
  - NDCs of related covered drugs and biologicals, if any;
  - Principal investigator(s) (including name, NPI, State licensure information, specialty and primary business address);
  - Context of research (optional);
  - ClinicalTrials.gov identifier (optional); and
  - Whether the payment or other transfer of value should be granted a delay in publication because it was made pursuant to a product research agreement, development agreement, or clinical investigation (Yes or No response).

24

IV. Research-related payments

- Delayed publication available for payments or transfers of value related to:
  - Research on or development of a new product
  - Research on or development of a new application of an existing product
  - Clinical investigations regarding a new product
- Examples of "new products" include new generic products, including drugs receiving approval under an Abbreviated New Drug Application, and devices under the 501(k) process.
- Publication delayed until the earlier of:
  - the date of FDA approval, licensure or clearance, or
  - 4 calendar years after the data of payment or transfer of value

25

V. How is disputed information handled?

- 45-day review period
  - o Applicable manufacturers, applicable GPOs, covered recipients, and physician owners or investors have 45 days to review the data reported to CMS
  - o CMS will be responsible for notifying covered recipients and physician owners or investors of the review period
- 15-day correction period
  - Additional 15-day correction period to allow applicable manufacturers and GPOs time to correct data for purposes of resolving disputes (such corrections may also occur during the 45-day review period)
- "Disputed" transactions published

26

VI. What are the penalties for non-reporting and inaccurate reporting?

- Civil monetary penalties (CMPs) of at least $1000 but no more than $10,000 for each payment that is not reported
- Maximum = $150,000
- Knowing failure = CMPs of at least $10,000 up to $100,000 (annual maximum = $1 million - but these could be aggregated)
- Other considerations

27

VII. Open questions, challenges, and preparation

Open Questions

- How to determine value
- New products vs. new applications
- What does it mean for a manufacturer to use a covered product "solely for use by or within the entity itself or by the entity's own patients"?

28

VII. Open questions, challenges, and preparation

Challenges / Preparation

- Determining which entities within your organization will be reporting and what
- Communications with covered recipients
- Arrangements with vendors
- Policy/procedure updates and training
- Systems development/updates
- Assumptions document
- Consolidated reporting

29

Questions?

- Katie C. Pawlitz
- kpawlitz@reedsmith.com
- 202-414-9233

- Nancy E. Bonifant
- nbonifant@reedsmith.com
- 202-414-9353

30