Are You Ready for Sunshine?
Navigate the Physician Payments Sunshine Act

Hosted by the American College of Cardiology’s Council on Clinical Practice

JUNE 27, 2013
2-3 PM ET

Thank you for joining us this afternoon!

Learning Objectives:

• The participant will learn what the Physician Payments Sunshine Act is.
• The participant will learn how the Sunshine Act will affect interactions between physicians and industry.
• The participant will learn what you and your practice need to do to prepare for Aug. 1.
Speakers:

- **Dipti Itchhaporia, MD, FACC**, Cardiologist, Newport Coast Cardiology; Robert and Georgia Roth Chair of Cardiac Excellence & Director of Disease Management, Hoag Heart and Vascular Institute

- **Lisa Goldstein, JD**, Associate Director, Regulatory Affairs, American College of Cardiology

Dipti Itchhaporia, MD, FACC, Disclosures:

- Nothing to Disclose
Lisa Goldstein, JD, Disclosures:

• Nothing to Disclose

National Physician Payments Transparency Program

Dipti Itchhaporia, MD, FACC
Immediate Past Chair
ACC Board of Governors

Lisa P. Goldstein, JD
Associate Director
ACC Regulatory Affairs
Disclaimers

Information provided in this presentation is for educational purposes only and should not be construed as legal advice.

The scenarios posed are hypothetical. Any individuals and/or companies mentioned in examples are used purely to help illustrate and reinforce key principles.

Agenda

- Overview of regulation
- ACC advocacy efforts
- Scenarios
- Questions
Background

- Included as part of ACA
- Requires manufacturers to report direct and indirect payments or transfers of value to physicians and teaching hospitals
- Does not apply to clinical personnel other than physicians
- Purpose is to promote transparency in relationships between industry and physicians/teaching hospitals
- Final rule released on Feb. 1 and published on Feb. 8
Why now?

- General trend in transparency
- Studies showing effects of relationships with industry on physician prescribing patterns
- Media attention and messaging on physician relationships with industry
- Concerns from patient/consumer/good government groups
- Changes to government COI policies within the last few years – FDA Advisory Committees, NIH grants, etc

Important dates

- Data collection by industry begins on August 1, 2013
- Industry reports information to CMS by March 31 of each year
- First reports made public on September 30, 2014
- After 2014, reports available annually on June 30
Limitations

- Trigger for reporting: $100 in aggregate
- Does not apply to payments or transfers of value of less than $10
  - BUT still must track to determine $100 aggregate trigger
- EXCEPT items/payments provided in large scale conference or similar event open to the public

Who does the law apply to?

- Applies to all physicians except employees of applicable manufacturers
  - No exclusion for physicians who do not treat patients
  - Ownership interests of employees of manufacturers and immediate family members must be reported
- Does not apply to residents
- Does not apply to physicians in their capacity as patients
What interactions are affected?
- Relevant industry includes those who manufacture drugs, devices, biologicals or medical supplies that:
  - Are paid for under Medicare, Medicaid or CHIP
  - Require a prescription to be dispensed or premarket approval by or notification to the FDA
- Applies to manufacturers with operations in the US, whether or not based in the US
- Cannot circumvent by providing payments through foreign entity – indirect payment
- Also group purchasing organizations (GPOs)

Direct payment vs. Indirect payment
- Direct and indirect payments to be reported
- Direct is made to a covered physician or teaching hospital or to a third party on behalf of or at the request of the covered physician or teaching hospital
- Indirect is made to a covered physician or teaching hospital through a third party at the direction, instruction or requirement of an applicable manufacturer or GPO.
What constitutes awareness?

- Applicable manufacturers need not report information on indirect payments where they are unaware of the identities of covered recipients
- Unaware = no knowledge
  - Actual knowledge
  - Acts in deliberate ignorance of truth or falsity of information
  - Acts in reckless disregard of the truth or falsity of the information

What categories of activities are affected?

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Direct compensation for serving as faculty or as a speaker for a medical education program
- Grant
Education

- Compensation for faculty at certified CME need not be reported for faculty where:
  - Certified and/or accredited by the Accreditation Council for Continuing Medical Education (ACCME), the AMA or three other professional society accreditation and certification entities
  - Applicable manufacturer does not pay the covered recipient directly
  - Applicable manufacturer does not select the covered recipient speaker or provide the third party, such as ACC, with a distinct, identifiable set of individuals to be considered as speakers for the CME
- No exception for compensation for faculty for non-certified CME events
- No exceptions for attendees UNLESS awareness standard applies

Food and beverages

- Industry funds spent on food and beverages must be reported unless:
  - Served at a large-scale event or conference buffet style
  - Made available to all conference attendees
  - Difficult to establish identities of physicians who partook
- Specific information on per person calculation provided in the rule
Travel

- Industry funds used to pay for physician travel must be reported
- No exceptions, unlike food and CME

Research

- PIs will be listed together under the total amount associated with a particular study, rather than separately
- Up to five will be reported
- Institution receiving research funding will be listed
- Food and travel expenses are not included in research funding; they will be listed separately
Reporting

- Burden on industry, not physicians, to report
- 45-day review period followed by 15-day dispute resolution period
- No requirement that industry or CMS provide actual notice to physicians
- CMS will promote through listservs, etc.
- Physicians will also have opportunity to register to receive notice
Advocacy efforts

- Ongoing dialogue with other physician organizations
- Ongoing dialogue with CMS
- Future outreach to industry
  - Provide actual notice to physicians
  - Provide multiple opportunities to review information before reported to CMS

Problem 1

The Coca-Cola Company is a sponsor of the Olympics, and as such, asks the ACC if one of its members would run a leg of the Olympic torch relay for the upcoming Olympics in Sochi, Russia. The Coca-Cola Company will reimburse the ACC for the expenses of that member. The ACC selects Dr. Smith and publicly announces it to the media, staff and members.

- Are the expenses reportable?
- Does this change if we substitute Bristol Myers Squibb for The Coca-Cola Company?
Question 1.1

- Are the expenses reportable?
  - Yes
  - No

Question 1.2

- What if, instead of Coca Cola Company, Bristol Myers Squibb is the sponsor and pays for Dr. Smith’s travel and expenses? Are the expenses reportable?
  - Yes
  - No
Problem 2

Dr. Jones enters into an agreement with Eli Lilly to provide consulting services. Dr. Jones requests that, rather than paying him directly for his services, Eli Lilly donate that amount to the ACC.

- Is this a reportable arrangement?

Question 2

- Is this a reportable arrangement?
  - Yes
  - No
Problem 3

Edwards enters into an agreement with ACC to fund educational programming on TAVR. ACC prepares material and selects speakers for ACCME accredited CME program and invites Dr. Clark to speak. Dr. Clark is paid an honorarium. Additionally, he is reimbursed for meals and travel expenses.

- Is the honorarium reportable?
- What about the meals and travel expenses?

Question 3.1

○ Is the honorarium reportable?
  ○ Yes
  ○ No
Question 3.2

- Are the meals and travel expenses reportable?
  - Yes
  - No

Problem 4

AstraZeneca sponsors an educational program, including dinner. Faculty have their travel and meal expenses paid for. Attendees, including physicians and nonphysicians, pay their own travel. A plated dinner is included as part of the program. There is no cost to attend.

- Are speakers’ travel expenses reportable?
- Are speakers’ meal expenses reportable
- Is the value of attendance reportable?
- Is the value of attendees’ food reportable?
Question 4.1

- Which of the payments or transfers of value are reportable for speakers?
  - Honoraria
  - Travel expenses
  - Meals
  - All of the above
  - None of the above

Question 4.2

- Which of the payments or transfers of value are reportable for attendees?
  - Cost of program attendance
  - Travel expenses
  - Meal expenses
  - All of the above
  - None of the above
Problem 5

Staff at Cardiovascular Associates of the Lower Hudson Valley schedules a briefing on a new heart failure drug manufactured by Novartis for physicians and other clinicians. The representative from Novartis brings bagels, cream cheese, coffee and juice for the office. Drs. Hu, Washington and Chopra partake, as do three of the nurse practitioners and all of the billing staff. Drs. Garcia, Hernandez and Anderson do not, nor do their nurse practitioners.

• Are the food and beverages reportable for everyone?

Question 5.1

○ Are the food and beverages reportable for everyone?
  ○ Yes
  ○ No
Question 5.2

- For whom will the food and beverages be reported?
  - All of the physicians
  - All of the clinical staff
  - Just the nurse practitioners who partook
  - Just the physicians who partook
  - Just the NPs and physicians who partook
  - The billing staff

Problem 6

Abbott Vascular decides to sponsor a study of the next version of its transcatheter mitral valve. The principal investigators will be Dr. Chen at Cleveland Clinic and Dr. Johnson of Geisinger Health System. The study will also involve investigators at hospitals around the country. These investigators will also be compensated, including reimbursement for travel and meals to meetings related to the study.

- What will be reported and for whom?
Question 6.1

- For whom will payments or transfers of value be reported?
  - Dr. Chen
  - Dr. Johnson
  - Local investigators
  - All of the above
  - None of the above

Question 6.2

- Which expenses will be reported?
  - Investigators’ compensation
  - Meal expenses
  - Travel expenses
  - All of the above
  - None of the above
Resources


Sunshine or colonoscopy?
Questions??

- Contact ACC’s Advocacy Division
  - E-mail: advodiv@acc.org
  - Telephone: (800) 253-4636, ext. 5603

**Improve Your Practice from the Inside Out**
**Series Calendar**

**OCTOBER 22, 2013, 2 – 3 PM ET:** Promoting Patient Outcomes Through Physician/Hospital Alignment
QUESTION & ANSWER SESSION