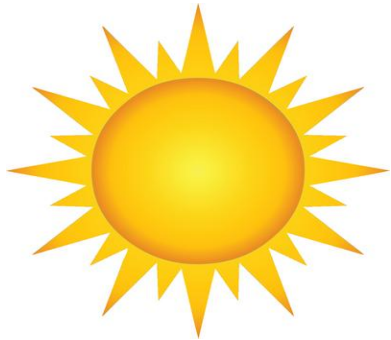


MININGS

MEETINGS | *defined*

defined



Let the Sunshine In

Presentation for MPINCC

Dana Marshall, CMP, CMM

Principal, Meetings Defined

defined

- Agenda
 - Interactions with Physicians
 - Sunshine Act Overview
 - What is Reportable?
 - Data Requirements/Accuracy
 - Penalties & Disputes
 - Key Dates
 - Intent of the Law
 - Resources / Articles
 - Q & A



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Manufacturers interactions with Physicians

- Speaker Programs
- Advisory Board Meetings/Scientific, Marketing
- 1:1 or Small Group Consulting
- Investigator Meetings
- KOL Speaker to Employees
- Office visits by Sales Representatives
- Congress & Conventions/Events, Symposia

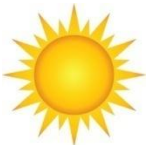
PhRMA and AdvaMED Codes of Ethics were updated in 2009 to include 7 elements of an effective compliance program: includes written policies, procedures & guidelines, conducting effective training and enforcing standards through disciplinary action.



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Physician Payments Sunshine Act Overview

- Commonly referred to as the “Sunshine Act”.
- Passed by Congress in March 2010 as part of the Affordable Care Act; final rule published February 1, 2013.
- Applies to all pharmaceutical and medical device manufacturers who operate in the U.S.
- The law is intended to provide more transparency in the relationships between the healthcare industry and healthcare providers to ensure no “conflict of interest” occurs.



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The Sunshine Act requires that.

Applicable manufacturers of drugs, devices, biologicals or medical supplies covered by Medicare and Medicaid or the Children's Health Insurance Program (CHIP)

*track certain payments or “**transfers of value**” provided to physicians or teaching hospitals.*

***and** report those payments – **in detail** – to the department of Health and Human Services (HHS) annually.*

This data will be posted on a publicly available website annually with a 45 day period for physician review prior to publication.



Let the Sunshine In

Who is a “Physician” per the law?

Applies to
U.S.
licensed
physicians

- Medical Doctor (M.D.)
- Doctor of Osteopathy (D.O.)
- Doctor of Dental Surgery (D.D.S.)
- Doctor of Dental Medicine (D.M.D.)
- Doctor of Optometry (O.D.)
- Doctor of Podiatry (D.P.M.)
- Doctor of Chiropractic Medicine (D.C.)

-- Payments to Teaching Hospitals also have to be reported. The CMS published a list of applicable organizations and maintains it on their website.

-- There are broader definitions of HCP's and HCO's for some State Reporting and/or other Internal Compliance Policies.



Let the Sunshine In

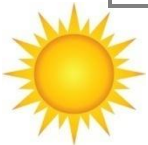
What is Reportable?

- Any transfers of value over \$10
- Transfers of value under \$10 when combined exceed \$100 in a calendar year

Conclusion by *most* pharmaceutical and medical device companies:

Every payment must be tracked

Sunshine Act leaves many details up to interpretation by the manufacturers. Adherence to and implementation of the law is not standard across industry.



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What is a Reportable Transfer of Value?

Nature of Payment

- Consulting fees
- Compensation for services
- Honoraria
- Gift
- Entertainment
- Food and beverage
- Travel and lodging
- Education
- Research
- Charitable contributions
- Royalty or license
- Ownership or investment interest
- Compensation for serving as faculty or as a speaker for accredited or continuing education programs
- Grant
- Space rental or facility fees (Teaching Hospitals only)



Let the Sunshine In

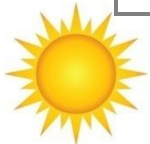
What is a Reportable Transfer of Value?

Nature of Payment

Food and beverage

- Report cost per covered recipient receiving the meal
 - Ability of physician to “opt out” & communicate to manufacturer
- Buffets, meals, snacks at conferences or large-scale events – Trade Shows / Conventions or Congresses
 - If difficult to establish identities of physicians who partook, then do not need to be reported

Most manufacturers have set specific meal guidelines by meal period. Some may include tax & gratuity and others may be ++. Need to ask. Room rental does not need to be allocated. Service fees for small groups may or may not be allocated.



Let the Sunshine In

What is a Reportable Transfer of Value?

Nature of Payment

Travel & lodging

- Travel includes any means of transportation
 - Cost of airline or train ticket
 - Cost of airport transfers
 - Group transportation?

Entertainment

- Cost to include attendance at recreational, cultural, sporting or other events that would generally have a cost

Airfare costs may be perceived as high by a physician, especially if travel was booked very short term and may become a dispute



Let the Sunshine In

Data Requirements and Accuracy

Report Content

- Report Content is specified for 3 specific transfers of value
 - For each payment and other transfer of value
 - 15 data elements
 - For each *research-related payment* or other transfer of value
 - 12 data elements
 - For each physician *ownership or investment interest*
 - 18 data elements
- Some ***data element overlap*** between the 3 reports

Bottom line: Manufacturers have spent ***billions*** to add technology, create or adjust processes and establish accountability/experts for data capture & reporting.



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Data Requirements and Accuracy

Sample Report Snapshot

	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB
	HCP_COMPLIANCE ID	HCP_FIRST_NAME	HCP_MIDDLE_NAME	HCP_LAST_NAME	HCP_SUFFIX	CREDENTIAL S	ADDR1	ADDR2	CITY	STATE	ZIP	PHONE	SPECIALTY	LOCATION	LADDRESS1	LCITY	LSTATE
39																	
40																	
41																	
42																	
43																	
44																	
45																	

Data and Report Format:

Will vary by company

Most will contain 35 to 45 data fields

Automated reporting preferred to manual

Data is captured from multiple sources



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Penalties and Disputes

Penalties

- Failure to report timely, accurately or completely a payment or transfer of value can result in a penalty of not more than \$10,000 per transaction

Maximum of \$150,000 annually.

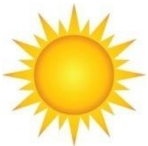
- For each knowing failure to report timely, accurately or completely can result in a penalty of not more than \$100,000 per transaction .

Maximum of \$1,000,000 annually

Disputes

- CMS intends to provide healthcare providers with access to a secure website so they can review the payments and transfers attributed to them and dispute them if necessary.

- The responsibility will be on each manufacturer to resolve any disputes with healthcare providers and provide CMS with a revised submission as appropriate.

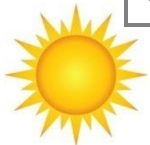


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Key Dates

- Data collection officially began August 1, 2013
- Data for YE 2013 – Report submitted to CMS by March 31st, 2014 with final detailed report due May 31st, 2014
 - Requires signed attestation by CEO, CFO or CCO
- 2013 Data will be Published on Website by September 30th, 2014
- Data for 2014 & subsequent years
Reports submitted by March 31st
- Published on website by June 30th

Delay in Publication – some payments may be granted delayed publication (up to 4 years) if they were made in the context of a relationship for **bona fide research** or **clinical investigation activities** for **new** drugs, not new applications of existing drugs.



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What is the Intent of the Law?

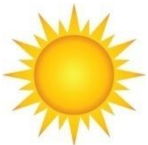
The law is intended to provide more transparency in the relationships between the healthcare industry and healthcare providers to ensure no “conflict of interest” occurs.

Industry concerns

Press & Headlines will distort the intent of the law

Public information about payment amounts may cause doctors to be less collaborative

This could slow drug development process even further



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Sample Headlines from 2013 & 2014

Merck pays 2,000-plus docs
\$20.4M for speaking

Drugmakers paid millions to
Massachusetts health providers

As full disclosure nears,
doctors pay for drug talks
plummets

Study: Pharma
payments do sway
doctors' prescribing
habits

Merck, Lilly, Pfizer top \$1B
doc-payments list

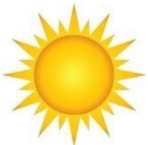
Docs brace for sunshine as industry
gifts go public



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Resources

- CMS is the Center for Medicare & Medicaid Services and hosts the official website for Open Payments. CMS is part of the Department of Health & Human Services.
 - Website: www.CMS.gov includes links to
 - The Final Rule – 70+ pages of detail
 - The list of Teaching Hospitals
 - Will host Public Website with collected report data
- PhRMA is the Pharmaceutical Research & Manufacturers of America.
 - Website: www.phrma.org
 - Search “Sunshine” for a list of articles & press releases
- AdvaMed is the Advanced Medical Technology Association. It represents 80% of medical technology firms in the U.S.
 - Website: www.advamed.org
 - Search “Sunshine”
- American Medical Association for the doctors perspective
 - Website: www.ama-assn.org



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