

# The Impact of the Physician Payments Sunshine Act on Clinical Research

Who is required to report?  
What information must be reported?  
When should the reports be filed?

# Welcome


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# Objectives

- ▶ Identify payments or transfers of value that must be reported.
  - ▶ Identify ways the Act applies to your institution.
  - ▶ Discuss the specific research requirements.
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# Overview of Section 6002 of the ACA

- ▶ The Physician Payments Sunshine Act (“Act”) is established by Section 6002 of the Affordable Care Act.
- ▶ Act requires pharmaceutical & medical device manufacturers to report annually to the DHHS payments and other transfers of value furnished to physicians and teaching hospitals.
- ▶ Designed to encourage greater transparency in the relationships between manufacturers and physicians.
  - Allows consumers to identify potential sources of bias
  - Provides the federal government with a means of identifying potential kickbacks & other improper relationships.
  - Deters conflicts of interest in research and education.
  - Deters manufacturers from paying remuneration in excess of fair market value to a referral source.


# Effective Dates

- ▶ Start Date for Collecting/Tracking: **August 1, 2013.**
  - ▶ Must Report to CMS by **March 31, 2014.**
  - ▶ Reporting will be on a quarterly basis.
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# Who Must Report What?

- ▶ **Applicable Manufacturers**
  - A manufacturer of a covered drug, device, biological or medical supply which is operating in the United States (or a US territory, possession, or commonwealth).
- ▶ **Covered Product**
  - A covered drug, device, biological, or medical supply (“Covered Product”) is a drug, device, biological, or medical supply covered under Medicare, Medicaid, or CHIP and by law requires premarket approval by or premarket notification to the FDA.
- ▶ **Covered Recipients**
  - Physicians and teaching hospitals.
  - Does not include nurse practitioners, physician assistants, other allied health professionals, or Ph.Ds.
  - Does not include physicians who are employees of an applicable manufacturer that is required to submit a report.

# Pharmaceuticals and Medical Devices

- ▶ Drugs and biologicals that are reimbursable under Medicare, Medicaid, or CHIP and that are not over-the-counter products are considered covered drugs or biologicals.
  - ▶ If a medical device is used to perform a service that is reimbursable under Medicare, Medicaid, or CHIP, the device is considered a covered device so long as it is the type of device that by law requires premarket approval by or premarket notification to the FDA.
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# Preemption of State Law

- ▶ Sunshine Act preempts state law that requires a manufacturer to disclose the information covered by the Sunshine Act.
  - ▶ Sunshine Act does NOT preempt state law:
    - Requiring the disclosure of information not covered by the Act.
    - Requiring the disclosure of information expressly excluded by the Act.
    - Requiring the disclosure of information by any person or entity other than an applicable manufacturer or covered recipient.
    - Concerning the reporting of information for public health surveillance, investigation, or other public health purposes.
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# Reportable Payments and Transfers of Value




# Reportable Payments

- ▶ Direct monetary payments plus “transfers of value”.
- ▶ Transfers of value include:
  - Consulting fees
  - Compensation for services other than consulting
  - Honoraria
  - Gifts
  - Entertainment
  - Food
  - Travel
  - Education
  - Research
  - Charitable contribution
  - Royalty or license
  - Current or prospective ownership or investment interest
  - Compensation for serving as faculty/speaker at a medical education program
  - Grants

# Educational Materials

- ▶ What is not reportable:
    - Educational materials and items that directly benefit patients or are intended to be used by or with patients.
    - Reporting exclusion is limited to materials and items directly benefiting patients or intended for patient use.
  
  - ▶ What is reportable:
    - Educational materials (e.g. medical textbooks or journal reprints) that are educational to covered recipients but aren't intended for patient use or directly beneficial to patients.
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# Miscellaneous Reportable Payments

- ▶ Journal reprints provided by an applicable manufacturer to a covered recipient, as they are educational to the covered recipient and not intended for patient use, nor directly beneficial to patients.
  - ▶ Newsletters created by an ad agency for an applicable manufacturer and sent to covered recipients that include journal abstracts if the newsletter's value is \$10 or more or if the aggregate value amount provided to a covered recipient exceeds \$100 in a calendar year.
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# Textbooks

- ▶ A textbook donation to a medical center library for the general use of all employees is reportable if:
  - The medical center library is part of a teaching hospital, or
  - The donation was an indirect payment or transfer of value to a designated physician or group of physicians.
- ▶ Payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient must be reported in the name of the covered recipient, as well as the name of the entity that received the payment at the covered recipient's request.


# Third Parties and Indirect Payments

- ▶ Both direct and indirect payments or transfers of value to covered recipients must be reported by applicable manufacturers under the Act.
  - ▶ A payment is considered indirect if an applicable manufacturer requires, instructs, directs, or otherwise causes a third party to provide the payment in whole or in part to the covered recipient.
    - Example: payments made by a CRO on the manufacturer's behalf.
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# Research Payments


- ▶ CMS definition of “Research”: “....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.”

# Reportable Research-Related Payments


- ▶ Any payments or transfers of value made in connection with research have to be reported.
  - ▶ To be reportable, the payment must have:
    - Been made pursuant to an activity that meets the definition of research, and
    - Been made pursuant to a written agreement, contract, or protocol between the manufacturer and the entity conducting the research (including an unbroken chain of agreements between the manufacturer, CRO/SMO, and the covered recipient).
  - ▶ Research related payments are reportable even if the PI receiving payment isn't a physician who regularly treats patients.
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# Reportable Research-Related Payments

- ▶ The value of study equipment, implantable devices, instrumentation, and other supplies provided to a covered recipient by an applicable manufacturer in connection with a FDA approved clinical trial should be included in the total amount of the research payment.
  - ▶ Payments for medical research writing and/or publication is included in the research payment if the activity was included in the written agreement and paid as part of the research payment.
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# How Research Payments Are Reported

- Who: the applicable manufacturer must identify the entity of individual who received the payment.
  - What: a description of the item transferred, including the value of the transfer.
  - When: the date of the transfer.
  - Where: the address of the recipient.
  - Why: why the item was transferred.
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# Fair Market Value – Key to Transparency

- ▶ Sunshine Act covers transfers of value, requiring FMV analysis of items such as food, education, travel, honoraria, etc.
  - ▶ Must have a consistent process in place and apply to every transaction.
  - ▶ Risk Management:
    - Add FMV review to your organization's contractual analysis process.
    - Develop and implement SOPs regarding FMV procedures – use to train employees and audit transactions.
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# Excluded Payments and Transfers of Value



# Excluded Payments & Transfers of Value

- ▶ Transfer of anything valued less than \$10, unless the aggregate annual amount per covered recipient exceeds \$100.
    - Dollar amount will be increased annually by the same percentage as the percentage increase in the CPI for all urban consumers for the 12 month period.
  - ▶ Product samples.
  - ▶ Educational materials solely intended for patients' use and benefit.
  - ▶ Loan of a covered device for a trial period (not to exceed 90 days).
  - ▶ Items or services provided under a contractual warranty, including the replacement of a covered device.
  - ▶ Discounts.
  - ▶ In kind items used for the provision of charity care.
  - ▶ Dividends or other profit distribution forms.
  - ▶ Several others related to covered recipients when not in the context of their professional capacity.
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# CME Programs

- ▶ Speaker compensation for Continuing Medical Education (“CME”) events is not required to be reported if the following criteria are met:
    - The CME program meets the accreditation or certification requirements and standards of the Accreditation Council for Continuing Medical Education, the American Academy of Family Physicians, the American Dental Association’s Continuing Education Recognition Program, the American Medical Association, or the American Osteopathic Association;
    - The applicable manufacturer doesn’t select or suggest the covered recipient speaker, nor does it provide the third party vendor with distinct, identifiable individuals to be considered as speakers for the CME programs; AND
    - The applicable manufacturer doesn’t directly pay the covered recipient speaker.
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# CME Programs

- ▶ Travel, lodging, meals, & all other payments provided by an applicable manufacturer in conjunction with CME events will need to be reported for physician attendees who are not speakers.
- ▶ Educational materials that are included in the tuition fees for an accredited or certified CME program that meets all three exemption conditions are excluded from reporting provided that:
  - the content doesn't contain any CME sponsor information,
  - The content is related to the CME program,
  - The value is de minimus, and
  - The funds used for the materials came from the same CME program grant.

# Reporting and Beyond







# Information Required in Reports

- ▶ For each covered recipient, an applicable manufacturer must annually report:
  - Name.
  - Business address.
  - If the covered recipient is a physician, the physician's NPI and specialty.
  - Amount of each payment or transfer of value.
  - Date of each payment.
  - Description of the type of payment.
  - Nature of the payment or other transfer of value.
  - If the payment or transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of such item.
  - Any other information that the Secretary of DHHS may require.
- ▶ Information from the reports will be available to the public on a searchable database.


# Corrections and Disputes

- ▶ All applicable manufacturers who have information to report must register annually with CMS prior to submitting data.
  - ▶ Covered recipients are encouraged to register with CMS so that they can review submitted data for completeness & accuracy, dispute the information, & make any necessary corrections before the information is made public.
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# Corrections and Disputes

- ▶ Important for physicians to register so that they can take an active role in preserving their reputations.
  - ▶ Information is public – incorrect reports could easily be detrimental to a physician's reputation in the medical community and with patients.
  - ▶ Important to take advantage of the dispute period to prevent:
    - Perception of bias.
    - Perception of impropriety.
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# Corrections and Disputes

- ▶ Applicable manufacturers and covered recipients must have an opportunity to review and submit corrections to the information submitted to the Secretary of DHHS for 45 days before the information is made available to the public.
  - ▶ Covered recipients may initiate disputes at any time after the 45 day period begins, but before the end of the calendar year.
  - ▶ If a dispute is not resolved by 15 days after the end of the 45 day period, the applicable manufacturer's version of the payment will be reported, but will be marked as disputed.
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# Corrections and Disputes

- ▶ Steps covered recipients can take to minimize the impact of inaccurate reporting:
    - Establish a payment tracking system.
    - Maintain accurate and complete documentation of all transactions.
    - Communicate with sales representatives.
    - Register with the open payments system to ensure timely notification of reports.
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# Practical Considerations



# Operational Issues


- ▶ Biggest Issue: Everyone will know!
  - Patients
  - Other physicians
- ▶ Penalties in do not apply to physicians or teaching hospitals; however, pay attention to the certification wording.
  - False attestations are likely to result in criminal prosecution for perjury.
  - Do not knowingly make a false statement to the government.
  - Even if no criminal prosecution, face reputation damage.

# Effects on Research


- ▶ Research funding and projects will be public.
- ▶ Study specific?
- ▶ Open up budgets to scrutiny?




# Interaction with Conflicts of Interest

- ▶ What is the physician required to report at your organization?
  - ▶ Does it match the Act's reports?
  - ▶ Payments exempt from reporting under the Act may still be required by your COI policy.
  - ▶ Are you a State entity and the physician's COI disclosure is public?
  - ▶ Who will be watching this?
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# Questions for Sites

- ▶ Will physicians have responsibility for reviewing “response time” reports?
  - ▶ Will physicians review the reports correctly and in a timely fashion?
  - ▶ Will someone have to coordinate with the physician?
  - ▶ Will you check reports against COI disclosures to verify?
  - ▶ If your organization has multiple sites and there is no common contracting process, how will you handle reports of research funds for the same study which may be different for different PIs/sites?
  - ▶ Who will handle PR?
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# Provider Responsibilities

- ▶ To understand that payments made to them will be disclosed on public websites and whether they want to continue to accept payments from sponsors in the future.
  - ▶ To ensure that they have appropriate mechanisms in place to report and monitor payments and gratuities made to them by sponsors.
  - ▶ To determine if they want to continue to accept educational grants and other gratuities from sponsors.
  - ▶ To develop monitoring mechanisms to ensure ongoing accuracy of reportable information.
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# Implications for Sites

- ▶ Research sites need to review and/or edit their conflict of interest policies and procedures in order to determine if they are consistent with the Act and their states' reporting rules.
  - ▶ Research sites need to educate health care providers to ensure that they report payments made to them by sponsors.
  - ▶ Research sites need to develop monitoring mechanisms to ensure appropriate monitoring of payment accuracy.
  - ▶ Research sites may want to implement mechanisms to reconcile sponsors' disclosures with disclosures made to physicians.
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# Implications for Sponsors

- ▶ Sponsors need to develop and implement policies, procedures, and training for marketing and members of Medical Affairs to ensure understanding.
  - ▶ Sponsors need to develop and implement mechanisms for individual reporting and tracking of payments made to covered recipients.
  - ▶ Sponsors need to develop and implement monitoring mechanisms to ensure reporting accuracy.
  - ▶ Sponsors may need to develop an interface function for the sponsor to reconcile this information with covered recipients.
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# Risk Management: Steps You Should Be Taking Now

- ▶ Develop and implement policies and procedures for the collection of reportable information.
  - ▶ Identify common interactions your organization has with covered recipients and whether those interactions involve transfers of value.
  - ▶ Hire a compliance officer.
  - ▶ Identify which people or which department within your organization will be responsible for filing reports and reviewing the reported data for potential errors.
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# Risk Management: Steps You Should Be Taking Now

- ▶ Develop written standards for determining FMO and COI.
  - ▶ Independent audits of current practices.
  - ▶ Establish contract management process to fully understand the relationship between a physician and a particular manufacturer.
  - ▶ Identify communication gaps within your organization.
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# Hypotheticals





# Hypo 1

- ▶ **Question:** Should an applicable manufacturer report a payment to a physician or to a clinic if the applicable manufacturer contracts with a clinic for consulting services, and the applicable manufacturer requests that a specific physician practicing at the clinic perform the services?

# Hypo 1

- ▶ **Answer:** Yes, an indirect payment was made to the physician since the applicable manufacturer requested that a certain physician at the clinic perform the services. This payment must, therefore, be reported by the applicable manufacturer.

# Hypo 2

- ▶ **Question:** An applicable manufacturer is considering hiring a physician. The applicable manufacturer pays for the physician to fly into the applicable manufacturer's city and pays for the physician's hotel as well as his food while he is in town. Is the applicable manufacturer required to report these payments under the Act?

# Hypo 2

- ▶ **Answer:** Yes, compensation paid by an applicable manufacturer to a physician for expenses made in connection with the hiring process.

# For Questions, Please Contact:

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