

## Let the Sun Shine in...



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### **ACA Physician Payments Sunshine Act**

- This portion of the ACA requires pharmaceutical and medical device manufacturers (“applicable manufacturers”) to report to the Secretary of the Department of Health and Human Services, on an annual basis, payments and other transfers of value (“economic benefit” of \$10 and greater”) furnished to physicians and teaching hospitals (“covered recipients”).

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**Dollars for Docs**  
How Industry Dollars Reach Your Doctors

By *Jeremy B. Merrill, Charles Ornstein, Tracy Weber, Siel Wei and Dan Nguyen, ProPublica*, Updated June 24, 2013

Drug companies have long kept secret details of the payments they make to doctors and other health professionals for promoting their drugs. But 15 companies have begun publishing the information, some because of legal settlements. Use this tool to search for payments. [Read more about the data.](#)

**Has Your Health Professional Received Drug Company Money?**

Name  State  **SEARCH**

Example searches: Klein, Duke University, Miami [More options.](#)

With 2 million records, this database represents:

- \$2.1 billion** in disclosed payments
- 15** companies
- ~47%** of total market share

**Payments in Your State**

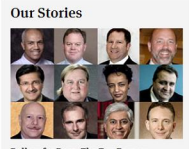
Click on a state to see payments made to practitioners and institutions there. See notes below.

State	Total
Alabama	\$26,650,785
Alaska	\$497,619
Arizona	\$31,322,594
Arkansas	\$13,093,875
California	\$245,426,008
Colorado	\$31,726,642
Connecticut	\$28,789,982
Delaware	\$3,806,129
District of Columbia	\$8,182,279
Florida	\$172,940,919

**Company Disclosures**

The totals listed here cover different time periods and spending categories, and aren't directly comparable. See notes below. See what each company discloses.

Company	Total Disclosed
<b>AbbVie</b>	<b>\$6.9M</b>
<i>Disclosed: July to Sept. 2012</i>	
<b>Allergan</b>	<b>Ranges*</b>
<i>Disclosed: July 2011 to Sept. 2012</i>	
<b>AstraZeneca</b>	<b>\$236.1M</b>
<i>Disclosed: Jan. 2010 to Sept. 2012</i>	
<b>Cephalon</b>	<b>\$89.7M</b>
<i>Disclosed: Jan. 2009 to Dec. 2012</i>	



**Dollars for Docs: The Top Earners**  
We've identified 22 doctors who've earned at least \$500,000 since 2009.

**Dollars for Docs Mints a Millionaire**  
New data show drugmakers' payments to hundreds of thousands of doctors, and some have made well over \$500,000.

**Background Stories**

- Docs on Pharma Payroll Have Blemished Records, Limited Credentials
- Med Schools Flunk at Keeping Faculty Off Pharma Speaking Circuit
- Big Pharma's Big Fines
- What Companies Disclose

[Read the entire series.](#)

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Collaboration is critical to improving patient care.

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Biopharmaceutical companies account for approximately 70% of all U.S. trial research.

The new Physician Payments Sunshine Act requires public reporting of interactions between physicians and biopharmaceutical professionals through a new public database.

6:48 AM 7/24/2013

## Maine's Former Sunshine Law

On July 8, 2011, the state of Maine officially repealed its pharmaceutical transparency and reporting requirements. Me. Rev. Stat. Ann. tit. 22, § 2698-A, required manufacturers and labelers that employed or used marketing representatives in Maine to submit an annual report of certain marketing costs to Maine's Department of Health and Human Services. The Maine law would have largely been preempted by the federal disclosure law.

## Physician Payment Provision Facts

- Section 6002 of ACA
- Data collection starts August 2013
- Information posted on web site September 30 2014 and each year thereafter
- Name, specialty and ID# of physician listed
- Includes payment of any kind and any device or drug provided
- In kind payments are included in disclosure requirement

## Section 6002 Reporting Requirements

- By March 31, 2014, each “applicable manufacturer” that provided a payment or other “transfer of value” to a “covered recipient” for the period beginning August 1, 2013 and ending December 31, 2013 must report such payment or other transfer of value to the U.S. Department of Health and Human Services.
- Subsequent reports due on the 90<sup>th</sup> day of each calendar year thereafter, for transfers of value during the previous calendar year.

## 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 in a territory, possession or commonwealth of the United States
  - A covered drug, device, biological, or medical supply is a drug, device, biological, or medical supply covered under Medicare, Medicaid, or SCHIP
- **Covered Recipient**
  - Physicians and teaching hospitals
  - Does not include nurse practitioners, physician assistants, other allied health professionals, or PhDs
  - Does not include “a physician is an employee of the applicable manufacturer that is required to submit a report”

## Nature of Reportable Payments

- A transfer of value includes:
- 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
- Direct compensation as faculty/speaker for medical educ. program
- Grant
- Any other transfer of value

## Excluded Payments and “Transfers of Value”

- Transfer of anything of value less than \$10, unless aggregate annual amount per covered recipient exceeding \$100 in a calendar year; the dollar amounts shall be increased by the same percentage as the percentage increase in the CPI for all urban consumers for the 12-month period ending with June of the previous year
- Product samples
- Educational materials for patients’ use/benefit
- Loan of a covered device for a short-term trial period, not exceed 90 days
- Items or services provided under a contractual warranty, included 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 (e.g., as patient, legal proceeding)

## Information Required in Reports

- The following information is required in the annual report, per each covered recipient:
  - Name
  - Business address
  - If the covered recipient is a physician, the NPI and specialty of the physician
  - Amount of EACH payment or transfer of value
  - Date of EACH payment provided
  - Description of form of payment (e.g., cash, in-kind items or services, stock)
  - 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

## Other tidbits...

- Vendors, providers, and other covered entities will have 45 days to review or dispute data to be published
- The final ruling exempts manufacturer sponsorship of speakers at a Continuing Medical Education (CME) event from the Sunshine Act
- Food purchases by manufacturer reps will be divided by the total number of employees, not just the number of physicians, but only the physicians' portions will be reported.

## Civil Penalties for Noncompliance

Covered entities are subject to penalties for failure to comply with the federal reporting requirements.

	Minimum	Maximum	Total Annual Limitation
Failure to Report	\$1,000	\$10,000	\$150,000
Failure to Report, <i>Knowingly</i>	\$10,000	\$100,000	\$1,000,000

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## Excerpts from section 8.061 of the Code of Medical Ethics of the AMA

- (1) Any *gifts* accepted by physicians individually should primarily entail a benefit to patients and should not be of substantial value. (emphasis added)

...

- (5) It is also appropriate for consultants who provide genuine services to received reasonable compensation and to accept reimbursement for reasonable [travel].

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## **Excerpt from PhRMA Code on Interactions with Healthcare Professionals**

- **Interactions with healthcare professionals are professional exchanges designed to benefit patients and to enhance the practice of medicine**
- **Healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and expertise.**
- **Promotional materials provided to healthcare professionals by or on behalf of a company should:**
  - **be accurate and not misleading;**
  - **make claims about a product only when properly substantiated;**
  - **reflect the balance between risks and benefits; and**
  - **be consistent with all other FDA requirements governing such communications.**

## **So, what should I do when I get back?**

1. CMS suggests that physicians and other care providers would do well to keep their own records of any value exchanges
2. they should monitor it for accuracy and completeness
3. Physicians should review any and all manufacturer relationships to get an overview of what the reporting will look like
4. regularly review the information that is publicly available in September of 2014, even after checking with the manufacturers before they report, and reconciling this information with your own records



### **Questions providers may be asked by patients:**

1. What are the specific circumstances of this payment?
2. What is your current relationship with this drug company?
3. What drugs have you prescribed me that are manufactured by companies you've taken payments from?
4. Are there non-drug alternatives that I may want to consider first?
5. Are there less expensive generic alternatives to the drugs you have prescribed?

## **Q & A**

## Who's who and what's what?

“covered recipients”

“economic benefit” (\$10 or greater)

“applicable manufacturers”

## Or else what?

- A civil money penalty of not less than \$1,000, but not more than \$10,000, for each payment or other transfer of value or ownership or investment interest not reported. The total amount of civil money penalties will not exceed \$150,000.
- Knowingly failing to submit payment information will result in a civil money penalty of not less than \$10,000, but not more than \$100,000, for each payment. The penalty will not exceed \$1,000,000.
- Combined, penalties may not exceed \$1,150,000.