



INDUSTRY UPDATE: LESSONS LEARNED FROM FIRST OPEN PAYMENT REPORTING PERIOD



Understanding Public Perception and How It May
Drive Decisions on Future Spending

4th ANNUAL PROGRAM ON
MEDICAL COMMUNICATIONS AND DISSEMINATION
OF HEALTHCARE INFORMATION

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- The first round of reporting regarding the Sunshine Act's open payments was publicly released on September 30, 2014
- What are the lessons learned following the first reporting period?
- What questions are still being debated regarding compliance provisions of open payment reporting?

Reporting: payments or other transfers of value to covered recipients

For each reportable payment or transfer to a covered recipient, the applicable manufacturer must disclose the following information:

- The **name** of the physician.
- The physician's primary **business address** of the physician.
- The physician's **specialty**.
- The physician's **National Provider Identifier**.
- The physician's state professional **license number(s)**.
- The **amount** of the payment or transfer.
- The **date** of the payment or transfer.
- A description of the **form** of the payment/transfer (e.g., cash, in-kind, etc.)
- A description of **nature** of the payment or transfer (e.g., consulting fees, gift, education, travel, royalty, etc.)
- The **covered drugs, devices, biologicals, or medical supplies**.
- **Categorization** of whether the payment or transfer is related to marketing, education, or research specific to a product.

Reporting: ownership/investment interests and payments/transfers of value to physician owners or investors.

- The **name** of the physician.
- An indication of whether the ownership or investment interest was **held by the physician or an immediate family member** of the physician.
- The physician's primary **business address** of the physician.
- The physician's **specialty**.
- The physician's **National Provider Identifier**.
- The physician's state professional **license number(s)**.
- The **dollar amount invested** by each physician or immediate family member of the physician.
- The **value and terms** of each ownership or investment interest.

Big Picture Concerns Regarding Valuation

- Valuation of marketed products impacts:
 - Reimbursement levels
 - Potential False Claims Act exposure
 - Kickback issues
- Valuing items of de minimis value impacts:
 - Public reporting (must you report, and what is the value of what is reported)
 - Physician sensibilities regarding how they are perceived by the public
 - Access to information (reporting will discourage HCPs from accessing reprints)

Open Payment Data Published on 9/30/2014

Categories

- Total Value
- Total Number of Records
- Total Number of Physicians
- Total Number of Teaching Hospitals
- Total Number of Reporting Applicable Manufacturers and Group Purchasing Organizations

Total

\$3.5 billion in payments

4.4 million records

546,000 physicians

1,360 hospitals

1,419 organizations

The State of Industry Spending

- Royalties and licensing are not going away, even if speakers bureaus and dinners do.

Manufacturer General Payments Breakdown

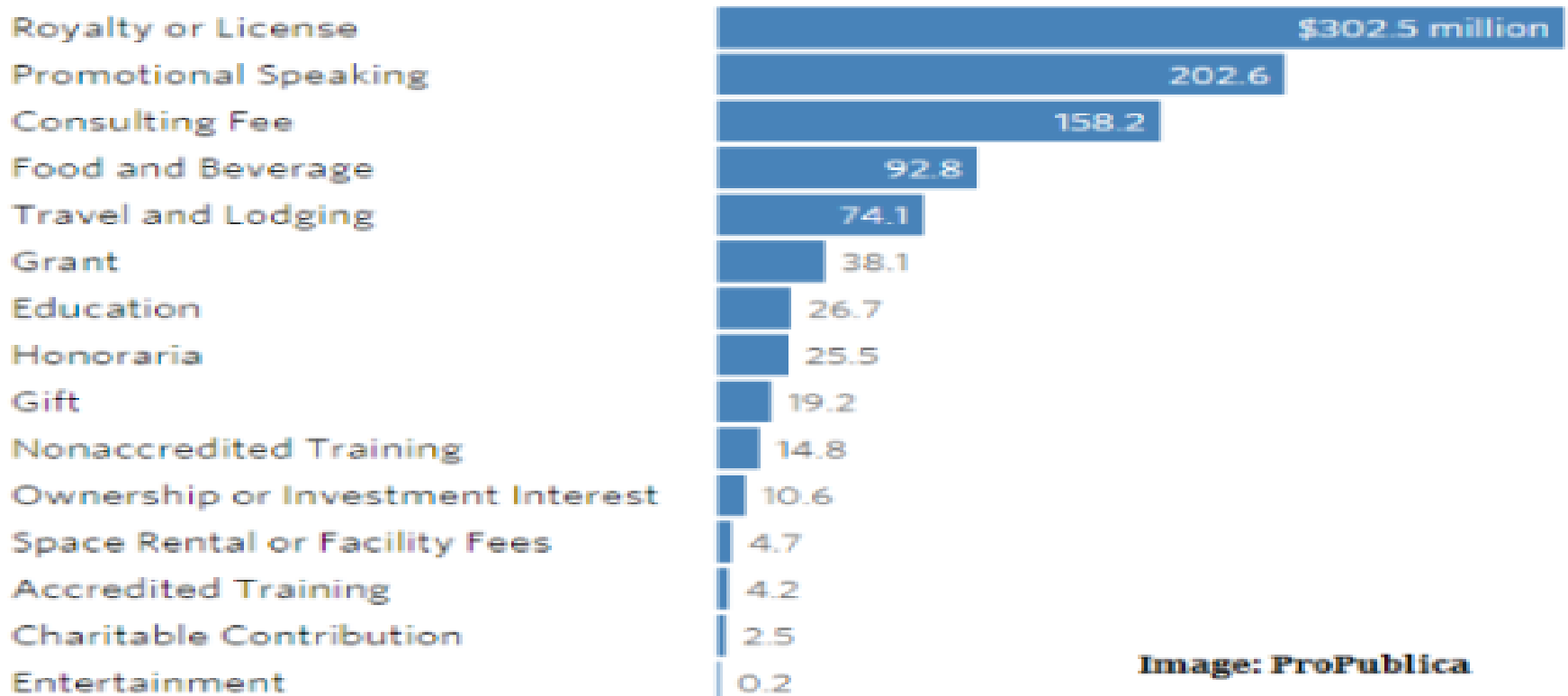


Image: ProPublica

Media Coverage of the Release of Public Reports

- “So Much For Transparency, Open Payments Database Toggles the Mind,” Wall Street Journal
- “Another Government Website Rollout That Is Found Wanting,” New York Times
- “Doctor Payments Show Little Value at Launch Time,” USNews

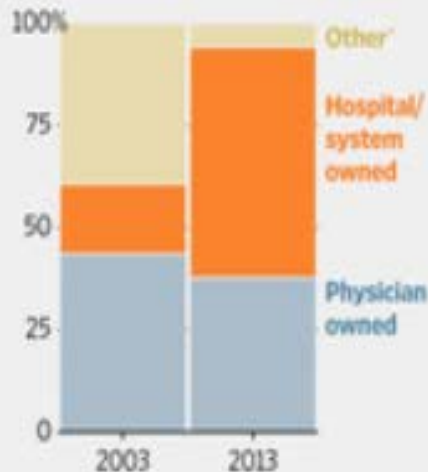
Is the Debate About Dealing with HCPs Already Over? Pharma Reacts....

- “As Doctors Lose Clout, Drug Firms Redirect the Sales Call: At Big Hospital Systems, Salespeople Woo Administrators to Get on 'Formulary,” Wall Street Journal, September 24, 2014

Moving Target for Drug Sales

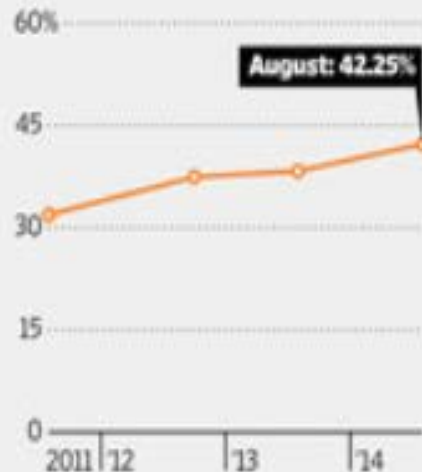
As U.S. hospital systems expand by absorbing doctors' practices...

Ownership of doctors' practices



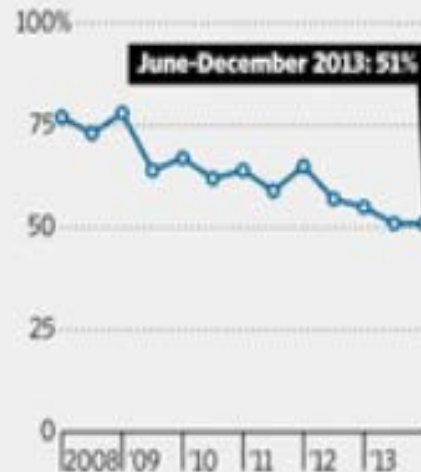
...doctors are increasingly employed by those health systems...

Percentage of physicians employed by health systems



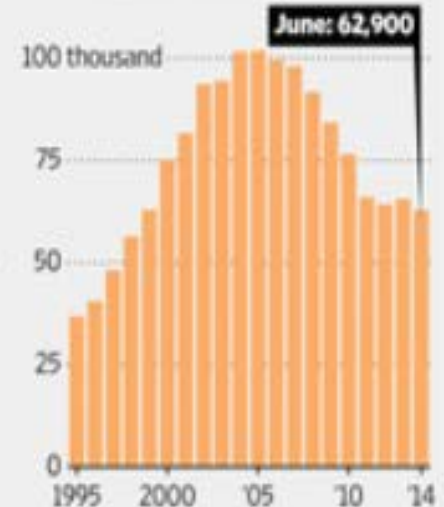
...and salespeople are finding doctors less accessible...

Doctors surveyed who say they are 'accessible' to pharmaceutical reps



...leading drug companies to shift marketing toward administrators and to rely less on reps.

Pharmaceutical sales reps



*Includes universities, medical schools, HMOs, government entities

Sources: Health Strategies Group (hospital systems); Cepedim Relationship Management (doctors employed); ZS Associates

The Wall Street Journal

Consumer Groups and Doctors React

- ProPublica: “As Full Disclosure Nears, Doctors’ Pay for Drug Talks Plummet: As transparency increases and blockbuster drugs lose patent protection, drug companies have dramatically scaled back payments to doctors for promotional talks.”
- Who’s My Doctor?” project
 - is a new campaign where doctors produce a voluntary, public disclosure statement, *The Total Transparency Manifesto*, <http://www.whosmydoctor.com/>
 - “Studies show that patients are more likely to follow recommendations and to have better outcomes when the advice comes from a doctor they trust. Experience with other transparency pilots such as Open Notes shows that openness leads to better communication, more trust, and better care, and we predict that Who’s My Doctor will have similar outcomes.”

Qui Tam, Status Quo?

- If the data is not accurate, it does not help anyone.
- Disclosures could help *qui tam* plaintiffs:
 - Publicly available data such could provide missing pieces of information sufficient to build a viable *qui tam* case; or
 - Allows relators to support allegations of wrongdoing where those allegations might otherwise fail for lack of specificity.
- Disclosures could hurt *qui tam* plaintiffs:
 - Public disclosure might bar some *qui tam* filings;
 - The False Claims Act's public disclosure bar mandates the dismissal of any *qui tam* action, unless dismissal is opposed by the Government, if substantially the same allegations or transactions alleged in the action were publicly disclosed in a federal criminal, civil, or administrative hearing in which the government is a party, a congressional or other federal report, hearing, audit, or investigation, or by the news media.
- No clear data yet on whether disclosure helps or hurts the *qui tam* business.

On to the Second Reporting Period

- Beginning February 3, 2015 applicable manufacturers and applicable Group Purchasing Organizations (GPOs) could register or recertify their registration in the Open Payments system and begin data submission for any payments or transfers of value that occurred in the 2014 CY.
- Applicable manufacturers and GPOs can now submit corrected 2013 data (if needed) and submit their 2014 data to the Open Payments system.
- March 31, 2015, is the deadline for all submissions.
- The review and dispute period for physicians and teaching hospitals is anticipated to start in April.
- CMS plans to publish the 2014 payment data and make any applicable updates to the 2013 data in June 2015.

And Still More Changes for Future Reporting Periods

- Four revisions took place effective October 31, 2014, and will be implemented for the 2016 program year, with reporting to CMS in 2017:
 - Deletion of the definition of “covered device.”
 - Deletion of the Continuing Education Exclusion in its entirety.
 - Required reporting of the marketed name and therapeutic area or product category of the related covered drugs, devices, biologicals, or medical supplies, unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological or medical supply.
 - Required reporting by applicable manufacturers of stocks, stock options, or any other ownership interest as distinct categories.

Guidelines regarding valuation of authorship resources and reprints

- The ACA outlined specific exclusions from Sunshine Act reporting, including “[e]ducational materials that directly benefit patients or are intended for patient use.”
- CMS took the view that medical textbooks and reprints of peer-reviewed scientific clinical journal articles were not "directly beneficial to patients," nor are they "intended for patient use“ and that these education materials have to be reported under the Sunshine Act.

Pushback on CMS regarding valuation of authorship resources and reprints

- The AMA has noted that CMS's conclusion is "inconsistent with the statutory language on its face, congressional intent, and the reality of clinical practice where patients benefit directly from improved physician medical knowledge."
- April 26, 2013, AMA letter to CMS, available at <http://www.ama-assn.org/resources/doc/washington/sunshine-act-comment-letter-26april2013.pdf>:

“The AMA recommends that the Centers for Medicare & Medicaid Services (CMS) clarify that the Sunshine Act final regulations do not apply to reprints where large numbers of physicians: (1) have a subscription to the journal in which the article is published; (2) are able to obtain the reprint for free through an institutional, organizational, or employment affiliation; or (3) have free access to the article along with the public. In brief, in the foregoing circumstances, physicians are not receiving a payment or transfer of value; therefore, such reprints are not subject to reporting under the Sunshine Act

- CMS has waived on whether to exempt accredited or certified continuing medical education.
- “21st Century Cures Act” would remove reprints from reporting.

Appendix A

- The Official Website for OPEN PAYMENTS (Physician Payments Sunshine Act): <http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html>
- User Guide: [http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/OPEN-PAYMENTS-User-Guide-\[August-2013\].pdf](http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/OPEN-PAYMENTS-User-Guide-[August-2013].pdf)
- 21st Century Cures Act: <http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Analysis/Cures/20150127-Cures-Discussion-Document.pdf>



QUESTIONS/COMMENTS?



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