Catching Some Sun with CMS – Open Payments Reporting

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Common Industry Relationships

- Collaboration among physicians, teaching hospitals, and industry manufacturers can contribute to the design and delivery of life-saving drugs and devices.
- Manufacturers typically employ or contract with physicians to design, test and provide input into new products.
Conflict of Interest Fears

- Concerns that Physician-Industry Relationships pose conflicts of interest that could affect treatment decisions.
- Modeled largely on the recommendations of the Medicare Payment Advisory Commission (MedPAC), which voted in 2009 to recommend Congressional enactment of a new regulatory program.
- The Institute of Medicine recommended implementing a national disclosure program for payments to health care providers and prescribers in its 2009 report, “Conflict of Interest in Medical Research, Education and Practice.”

The Purpose

- To “shed light” and create greater transparency around the financial relationships of manufacturers, physicians, and teaching hospitals.
- Serve as a national resource for beneficiaries, consumers, and providers to better understand relationships between physicians, teaching hospitals, and industry.
The Law

- Patient Protection & Affordable Care Act, § 6002 (March 23, 2010), codified at 42 U.S.C. § 1128G. Nicknamed the “Sunshine Act” because designed to “shed light” on these relationships. CMS now calls it “Open Payments.”
- Final Rule implementing the “Medicare, Medicaid, Children’s Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests”, 42 C.F.R. §§ 402 and 403 (February 8, 2013)

Overview

The Open Payments program requires that the following information be reported annually to CMS:

1. Applicable manufacturers of covered products (drugs, devices, biologicals, and medical supplies) must report payments or other transfers of value they make to physicians and teaching hospitals to CMS.

2. Applicable manufacturers and applicable group purchasing organizations (GPOs) must report to CMS certain ownership or investment interests held by physicians or their immediate family members.

3. Applicable GPOs must report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.
1. Payment Information Reported to CMS by Manufacturers

- **Applicable manufacturers** of covered products (drugs, devices, biologicals, and medical supplies) must report payments or other transfers of value they make to physicians (and their family members) and teaching hospitals to CMS.

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"Applicable Manufacturer"

- Any entity engaged in the production, preparation, propagation, compounding or conversion of a covered product for sale or distribution in the U.S. (including U.S. territories)
- Any entity under common ownership" (5% ownership threshold) with such an entity and which “provides assistance or support to the entity” with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered product for sale or distribution in the U.S.
- Physical location does not determine who “operates in the U.S.” Includes a foreign-based entity if it operates in the U.S. (including by sale of a covered product) even if the product is manufactured outside the U.S.
“Applicable Manufacturer” (cont.)

- Does not include:
  - Entity that only manufactures raw materials and components if raw materials and components do not meet the definition of a covered product
  - Hospitals, hospital-based pharmacies, and laboratories that manufacture the covered product solely for use by or within the entity itself or for its patients
  - Wholesalers and distributors that do not hold title to the covered product
  - If the wholesaler or distributor does hold title at any point in the distribution chain, then it is an “applicable manufacturer.” This may come as a surprise to some wholesalers and distributors.

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“Applicable Manufacturer”

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<thead>
<tr>
<th>Characteristic</th>
<th>Applicable Type 1 Manufacturer</th>
<th>Applicable Type 2 Manufacturer</th>
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<tr>
<td><strong>Operate in the United States</strong></td>
<td>Physical location within the U.S. or conducts activities within the U.S. (includes any territory, possession or commonwealth of the U.S.)</td>
<td>Under common ownership with a Type 1 applicable manufacturer <strong>AND</strong> Provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply</td>
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<tr>
<td><strong>Activities</strong></td>
<td>Engages in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply This includes distributors or wholesalers that hold title to a covered drug, device, biological or medical supply</td>
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“Covered Products”

- “Covered products” are drugs, devices, biologicals, or medical supplies covered by Medicare, Medicaid or the Children’s Health Insurance Program (CHIP) and which
  - If a drug or biological, requires a prescription; or
  - If a device or medical supply, requires premarket approval by, or premarket notification to, the FDA
- An Applicable Manufacturer with a mix of covered and noncovered products must report all payments, even those unrelated to covered products.

Transfers of Value

- Broadly defined as direct and indirect payments and any “transfers of value” including:
  - Cash or cash equivalents
  - In-kind items or services
  - Stock, stock option or other ownership interest
  - Dividend, profit, or other return on investment
- It also includes indirect payments made to a third party on behalf of a physician
“Covered Recipients”

- Physicians, including MD, DO, dentist, podiatrist, optometrist, and licensed chiropractor
  - Does not include bona fide employees of “applicable manufacturers”
  - Does not include pharmacists, APRNs, or PAs or medical residents (but does include Fellows)
- Teaching Hospitals
  - Facilities which receive IME, GME, or psychiatric hospital IME
  - CMS will publish list of teaching hospitals annually, 90 days before reports are due

2. Ownership Information Reported to CMS by Manufacturers and GPOs

- Applicable manufacturers and applicable group purchasing organizations (GPOs) must report to CMS certain ownership or investment interests held by physicians or their immediate family members.
“Applicable GPO”

- Any entity that operates in the US and purchases, arranges for or negotiates the purchase of a covered product for a group of individuals or entities but not for use solely by itself.
- Reporting obligations of GPO apply only to ownership/investment interests.

3. Payment Information Reported to CMS by GPOs

- Applicable GPOs must report to CMS payments or other transfers of value made to physician owners or investors if they held ownership or an investment interest at any point during the reporting year.
Reporting Exceptions

- Existing personal relationships
- Payments < $10 each and collectively < $100 per year
  - increases annually, and is $10.18/$101.75 in 2014
- Small items (< $10) at events open to public
  - increases annually, and is $10.18 in 2014
- Educational materials that directly benefit patients
- Discounts and rebates
- In-kind items for charity care

Reporting Exceptions (cont.)

- Product samples
- Loans of covered devices for short term trial (<90 days)
- Covered recipient is acting as a patient
What Information is Reported to CMS

- Name of the physician
- Indication of whether interest is held in name of physician or immediate family member
- Address of the physician
- NPI, specialty and state professional license number
- Dollar amount of investment
- Value and terms of each ownership or investment interest
- Direct and indirect payments or other “transfers of value” provided to physician with ownership/investment interest or to third party at request of physician

What Information is Reported to CMS: Non-Research Payment Categories

- Consulting Fee
- Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program
- Honoraria
- Gift
- Entertainment
- Food and Beverage
- Travel and Lodging
- Education
- Charitable Contribution
- Royalty or License
- Current or prospective ownership or investment interest
- Compensation for serving as faculty or as a speaker for a non-accredited and non-certified continuing education program
- Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Grant
- Space rental or facility fees (teaching hospital only)
What Information is Reported to CMS: Research Payment Categories

- Professional Salary Support
- Medical Research Writing or Publication
- Patient Care
- Non-patient Care
- Overhead
- Other

How Is Information Reported?

- CMS has three templates for data submission:
  - General Payments (Non-Research)
  - Research
  - Ownership/Investment
- We recommend reviewing these templates to make sure all of the necessary data is being collected.
Data Collection Periods

- Initial, short year, starting August 1, 2013-December 2013
- Thereafter, data is collected for calendar years

Tracking Data - “There’s an app for that”

- CMS has created free Android and Apple applications, for physicians and industry, to help track financial data to be reported. Search for “Open Payments” in the App Store. Here are examples of how these apps might be used:
  - A physician receives a consulting fee from a drug manufacturer. The physician doesn’t have a reporting requirement, since reporting is done by manufacturers and other companies, but she wants to be sure that the drug manufacturer accurately reports the consulting fee to CMS. Using the physician app, she can record a detailed summary of the transaction for her own records—by manually entering the data.
  - A physician collaborates with the health care industry using the app. The physician can use the “Read Quick Response (QR) Code” functionality that allows the manufacturer to create a record of the interaction and transfer it to the physician for her review. Additionally, to help ensure the drug manufacturer correctly attributes the consulting fee to her, she can share her profile information with the drug company using the “Create QR Code” function. Months later, when she is reviewing the data the drug manufacturer reported to CMS, and before the data is made public, she can retrieve her original record from her mobile device and do a comparison to confirm that the information is correct.
Reviewing/Disputing Reports

“Covered recipients” and physician owners/investors will have 45 days to review the report prior to CMS making the report public

- CMS will notify the “applicable manufacturer,” “applicable GPO,” “covered recipients” and physician owners/investors when the report is ready for review
- If the respective entity agrees with the report, then it certifies the report is accurate
- If the “covered recipient” or physician owner/investor does not agree with the report, then it can initiate a dispute which is sent to the “applicable manufacturer” or “GPO”

Reviewing/Disputing Reports (cont.)

- If the “covered recipient” or physician owner/investor does not agree with the report, it can initiate a dispute which is sent to the “applicable manufacturer” or “GPO”
- Parties have 15 days after the 45 day review period ends to resolve the dispute
- If the dispute is not resolved within the 15 day period, CMS will post the original report but will note that the information is disputed
- Disputes not resolved within the 15 day period may still be resolved but any resulting revisions to the data will not be reflected on the CMS website until the next time the data is updated
Data Publication

- CMS will collect this data, aggregate it, and publish it on a public website

Delay in Publication to Protect Research

- Applicable Manufacturer/GPO may requesting a delay in publication of a payment or other transfer of value when the payment or transfer of value is made in connection with: (1) research on or development of a new product (drug, device, biological, or medical supply) or (2) clinical investigation regarding a new product (drug, device, biological, or medical supply).
- Applicable Manufacturer/GPO must still report
Important Dates

- Applicable manufacturers and GPOs must:
  - August 1, 2013: begin collection of required data
- Physician, teaching hospitals and applicable manufacturers may:
  - August 2014: access and review reports and begin to dispute any errors
  - September 30, 2014: CMS will post reports on public website
  - April 1, 2015: CMS will make first report to Congress

Non-Teaching Hospital Issues

- Manufacturers may report payments made to non-teaching hospitals.
- Because non-teaching hospitals will not have access to reports, they should:
  - require all hospital-employed physicians to log-in to the database and print out a copy of the reports
  - review these reports to determine what reports are being made that could trigger government investigations into their compensation arrangements with the hospital.
Penalties

- Failure to submit a timely, accurate and complete report
  - Subject to civil monetary penalty of not less than $1000, but not more than $10,000 for each payment or other “transfer of value,” or ownership or investment interest not reported timely, accurately or completely up to a maximum penalty of $150,000

- Knowing failure to report
  - Subject to civil monetary penalty of not less than $10,000, but not more than $100,000 for each payment or other “transfer of value” or ownership or investment interest not reported timely, accurately or completely
  - up to a maximum penalty of $1,000,000

Don’t Forget State Sunshine Laws

- States with Sunshine Laws: California, DC, Maine, Massachusetts, Minnesota, Nevada, Vermont, West Virginia, Illinois, and New York
- Generally, the Sunshine Act preempts State laws
- No preemption for:
  - “Gift bans”
    - i.e., Vermont
  - Disclosures relating to payments to health care providers other than physicians or teaching hospitals
  - Massachusetts indicated that it will continue to require annual reporting of payments and transfers to, for example, nurse practitioners and physician assistants
  - Public health
Resources

- CMS’s Open Payments Website:
- CMS Frequently Asked Questions:

Questions

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