

Physician Payments Sunshine Act Final Rule
ACA Section 6002

Program Overview

- Applicable manufacturers and applicable GPOs collect information on payments and/or ownership interests for an entire calendar year
  - For CY2013: Only collect data from August 1-December 31, 2013
- Submit data for entire year to CMS by the 90th day of the following year
  - 2013 data due March 31, 2014
- CMS aggregates all the data by individual physician or teaching hospital
- Allow manufacturers, GPOs, physicians and teaching hospitals access to their data for review/correction
  - 45-days to review and initiate disputes (if necessary)
  - 15-days to resolve disputes
- Publish data online by June 30th
  - 2013 data published on September 30, 2014

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Who is required to report?

- Applicable **manufacturers** of covered drugs, devices, biologicals and medical supplies
  - Report all payments or other transfers of value to covered recipients and physician ownership and investment interests
  - Certain entities under common ownership (defined as a 5% ownership interest) with an applicable manufacturer must also report
  - Covered products are those available for payment under Medicare, Medicaid or CHIP
  - Final rule uses statutory phrase “operating in the United States” in the definition
  - Final rule outlined some limitations on reporting by certain manufacturers (such as, manufacturers of only a few covered products)
  - Final rule allows all entities under common ownership to submit consolidated reports
- Applicable **group purchasing organizations (GPOs)**
  - Report only physician ownership and investment interests
  - Definition includes physician owned distributors (PODs) that purchase products for resale

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Who gets reported on?

- Payments or other transfers of value made to covered recipients are reportable
- Ownership or investment interests held by physicians and their immediate family members are reportable
- Covered recipient defined as physicians and teaching hospitals,
  - Physician defined using section 1861(r) of the Social Security Act
  - Excludes physicians that are employees of the applicable manufacturer
  - Teaching hospital defined as any institution that receives GME, IME or inpatient psych IME
- Final rule excludes residents from reporting requirements
- CMS will provide a list of teaching hospitals annually

What information must be reported?

- For each payment, applicable manufacturers must report:
  - Covered recipient name and address
  - Physician covered recipient specialty, NPI and state license number
  - Amount of payment
  - Date of payment
  - Form of payment
  - Nature of payment
  - Name of drug, device, biological, or medical supply associated with payment (allow up to 5 products to be reported and allows product class/therapeutic area for devices)
  - Allowed to provide short “context” for each transaction
- Payments related to research must be reported on a separate template which includes the name of institution receiving the payments the principal investigators
- For each ownership and investment interest, applicable manufacturers and GPOs must report:
  - Physician name, address, specialty, NPI and state license number
  - Value and terms of ownership or investment interest
  - Whether interest is held by an immediate family member of the physician
  - Any payments made to the physician owner or investor

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Forms & Natures of Payment

- Describes how the payment was made and the reason for making the payment
- Required to select category that best matches payment
- Changes in the final rule:
  - Provided additional explanations of the categories
  - Included multiple categories for reporting continuing education payments (both accredited and non-accredited) based on new requirements for reporting education payment
  - Clarified requirements for allocating and reporting meals and food
  - Removed the proposed “other” category
  - Added “space rentals or facility fees” for teaching hospitals

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Exclusions

- Statute lists numerous exclusions and received numerous comments recommending additional exclusions
- Final rule provided more information on statutory ones
- Final rule clarified exclusion for payments made indirectly to a covered recipient through a third party when applicable manufacturer is unaware of the identity of the covered recipient
  - Defined “indirect payments or other transfers of value” to clarify when indirect payments needed to be reported
  - Retained proposed interpretation of awareness based on the False Claims Act definition of “know, knowing or knowingly”
  - Added a time period for awareness (two quarters of the next reporting year)

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Delayed Publication

- Delayed publication allowed for certain research, development and clinical investigation payments
- Payment must be reported for the year the payment **occurred** by applicable manufacturer, but not **published publicly** until:
  - FDA approval, licensure, or clearance
  - Four years after the date of payment
- Responsibility of applicable manufacturer to notify CMS that a payment is eligible for delayed publication

45-Day Review and Correction Period

- Manufacturers, GPOs, covered recipients and physician owners and investors may review and submit corrections before CMS makes the information available to the public
- New process in final rule that allows CMS to help facilitate the review and correction process, but not get involved with arbitrating disputes
  - Physicians and teaching hospitals will be able to initiate dispute when they are reviewing their information
  - Manufacturers/GPOs and physicians/teaching hospitals resolve the dispute independently of CMS
  - Disputes that are not resolved will be published using the manufacturer's or GPO's account of the transaction, but will be marked as disputed
- Following the 45-day period, added a 15-day period to give additional time for disputes to be resolved, especially those initiated late in 45-day period
- Online review and correction system will be available beyond the 45-day period, so disputes may be initiated and resolved at any time
- CMS will update the public website at least once annually

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Penalties

- Civil monetary penalties on applicable manufacturers and GPOs for failure to submit required information
  - $1,000-$10,000 for each payment or ownership interest not reported as required
  - Annual maximum of $150,000
- Knowing failure to submit:
  - $10,000-$100,000 for each payment or ownership interest not reported as required
  - Annual maximum of $1,000,000
- Clarified that penalties based on each applicable manufacturer individually, regardless of whether they submit data as a part of a consolidated report

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Next Steps

- Program Name "National Physician Payment Transparency Program: **OPEN**PAYMENTS"
  - CMS' Center for Program Integrity will implement and administer **OPEN**PAYMENTS
  - Group led by Dr. Shantanu Agrawal, MD
- In the process of defining business requirements based on the final rule with a technical RFP release soon for system
- Data templates discussed in the final rule are available for public review and comment, as part of the PRA process
- Help desk for specific inquiries (OPENPAYMENTS@cms.hhs.gov)
- Informational website (http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program)

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