Hogan Lovells

Physician Payment Transparency Provisions of the Affordable Care Act

Sunshine 101

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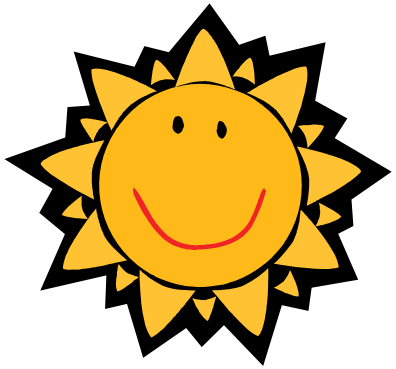
What is Sunshine?

- Deceptively simple: Applicable manufacturers of covered products must report certain payments and other transfers of value to physicians and teaching hospitals

- Goal: Shedding light on the nature and extent of relationships



Agenda- Unpacking Sunshine

- Relevant manufacturers
- Relevant products
- Relevant recipients
- Relevant payments
- Data requirements
- Special rules
- Submission and review processes
- Enforcement

Applicable Manufacturer

- Type 1: Engaged in the production, preparation, propagation, compounding or conversion of a covered product

- Type 2: Entity under common ownership with Type 1 that provides assistance or support to that entity with respect to production, preparation, propagation, compounding or conversion OR marketing, promotion, sales or distribution of a covered product

Manufacturer Clarifications

- Only if physical location in US or conducting activities in the US
- Type 1 manufacturers include:
  - Contract manufacturers
  - Distributors that take title
- Type 2 manufacturer limited to:
  - Common ownership of 5% or more in both entities
  - Assistance and support is “necessary or integral”

Covered Product

- Drug, biological, device or medical supply for which payment is available under Medicare, Medicaid or S-CHIP

- Clarifications
  - Includes any mechanism of reimbursement
  - Includes some investigational devices & monograph drugs
  - Does not include:
    - OTC drugs or biologicals
    - Devices that do not need FDA approval or notification (e.g., tongue depressors)
    - Raw materials and components that are not themselves payable
    - Food

Covered Recipient: Teaching Hospitals

- Statute did not define teaching hospital

- Clarifications
  - Defined as any institution that received a graduate medical education or indirect medical education payment in the last calendar year
  - CMS will publish a list of teaching hospitals on its website 90 days before the start of each reporting period

Covered Recipient: Physicians

- Physicians as defined by Medicare statute

  (i.e., MDs, DOs, dentists, podiatrists, optometrists and chiropractors)

- Clarifications
  - Includes licensed physicians who are not practicing
  - Does not include medical residents

Employee exception to covered physician

- Definition of physician excludes an employee of an applicable manufacturer

- Clarifications
  - Only the physician's employer has benefit of exclusion
  - Limited to individuals who meet common-law standard for employer-employee relationship under IRS rules
  - No across-the-board exclusion for board members, medical directors, retirees or prospective employees

New reporting limits for certain manufacturers

- Reporting solely on payments/transfers of value related to covered products if:
  - Less than 10% of gross revenue in prior year is from covered products
  - Type 2 manufacturer (i.e., common ownership and providing assistance or support)
  - Contract manufacturer that does not hold FDA approval/clearance and not involved in sale, marketing or distribution of covered product
- Separate operating division within a manufacturer that does not itself manufacture a covered product only needs to report payments/transfers of value related to covered products

Data to be reported

- Name and address of covered recipient
- Physician Identifiers (i.e., NPI, license, specialty)
- Amount of payment/transfer of value
  - Discretion for valuation and allocation
- Date, form and nature of payment/transfer of value
  - Flexibility to aggregate small payments
  - Flexibility to select the most appropriate nature of payment/transfer of value category
- Related product(s)
  - Up to five products, including non-covered products
  - Device manufacturers can report therapeutic area or product category

New standard for indirect payments

- Payment/transfer of value to a covered recipient through a third party is only reportable if:
  - Manufacturer requires, instructs, directs or otherwise causes the third party to pay the covered recipient
  - Manufacturer is aware or becomes aware of the identity of the covered recipient by the end of the second quarter after the reporting period ends

New standard for “special rule”

- Payment/transfer of value to a third party at the request of or designated on behalf of a covered recipient is reportable as a payment/transfer of value to the covered recipient
- Clarifications
  - “At the request of” means covered recipient directs the applicable manufacturer to provide the payment/transfer of value to a specific 3d party rather than receiving it personally (e.g., consultant asks that payment be donated to a particular charity)
  - “Designated on behalf of” means covered recipient does not receive payment/transfer of value but applicable manufacturer provides payment/transfer of value to a 3d party in the name of the covered recipient (e.g., payment to a charity in the name of a covered recipient who waived payment)

New research reporting rule

- Replaces complex framework in proposed rule
- If a payment/transfer of value meets definition of "research" AND is subject to a written agreement or protocol, then report separately from other payments
  - Applies to preclinical research, Phase I-IV and investigator-initiated trials
  - Report all payments/transfers of value for the research as one transaction
  - Required data are: payment recipient, PI & total payment as well as study name & associated products, if applicable
  - Research on new product is eligible for publication delay of up to 4 years

New rules for continuing education

- New separate “nature of payment” categories for
  - Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program AND
  - Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program
- Payment/transfer of value for speaking at an accredited or certified continuing education program is not reportable if the applicable manufacturer:
  - Does not pay the speaker directly AND
  - Does not select the speaker or provide a distinct and identifiable list of individuals as potential speakers

New rules for meals

- Cost of meals to groups allocated based on the number that partook in the meal (including covered and non-covered recipients) and reported only to those physicians who ate
- No tracking or reporting for buffet meals, snacks and refreshments provided to all attendees at large-scale conferences

New rules for gifts

- Items for the education of physicians (e.g., textbooks, journal articles) are subject to reporting
  - Items and services to educate patients are exempt from reporting
- Payments/transfers of value to a group of physicians should be allocated in the manner that most fairly represents the situation
- No tracking or reporting of items under $10 provided at large-scale conferences and events open to the public

Broad interpretations of certain exclusions

- Product samples
  - Includes demonstration and evaluation units intended for patient use
  - Includes coupons and vouchers
- Loan of covered device for evaluation
  - 90-day trial period need not be consecutive days
  - Applies to disposable and single use devices
- Items or services under contractual warranty
  - Applies to maintenance and service contracts

Reporting Procedures

- Registration within 90 days of end of each year
  - No registration (or reporting) if no reportable payments/transfers
- First report due March 31, 2014 with data from August 1-December 31, 2013
- Attestation by a corporate officer that information is timely, accurate and complete must be included with each report and any update
- Assumptions document explaining methodologies and assumptions may be included with report
- Corrections of confirmed errors and omissions must be submitted immediately

Review Period

- CMS notifies covered recipients of process to review manufacturers' submissions
- Covered recipients have 45-days to review and dispute data about them for the previous calendar year
- If a covered recipient initiates a dispute, it is referred to the manufacturer for resolution
  - If resolved within 15 days of end of review period, then confirmed/corrected data is posted
  - Otherwise, the manufacturer's data is posted but marked as disputed

Enforcement

- HHS, CMS, and OIG may audit records that pertain to compliance with requirement for timely, accurate and complete submissions
- Civil monetary penalties for each failure to report timely, accurate, complete information
  - $1K- $10K per each failure to report with a cap of $150K in CMPs for failures per annual submission
  - $10K-$100K per each knowing failure to report with a separate cap of $1M in CMPs for knowing failures per annual submission

Assessing the Final Rule

- Problematic provisions in proposed rule replaced with more logical approaches (e.g., OUS entities, research, meals allocation)
- New limits on reporting obligations for certain manufacturers
- Theme of flexibility to adopt reasonable assumptions (e.g., payment date, allocation among groups)
- Manufacturers have until August to implement
- Some state preemption for 2012 filings, more to come?

Enjoy the Sunshine!

Questions?

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