

Video Webcast:

Transparency Reporting: Meeting the Challenge of PPACA and Beyond

July 21, 2010



Daniel A. Kracov, Chair, FDA and Healthcare Practice, 202.942.5999

Keith M. Korenchuk, Partner, FDA and Healthcare Practice, 202.942.5817

Comprehensive Health Reform

- The Patient Protection and Affordable Care Act (PPACA) passed March 23, 2010
- PPACA Section 6002
 - Requires reporting of payments to physicians and teaching hospitals, and ownership interests
 - Version of the Physician Payments Sunshine Act provisions that had been pending in Congress for several years
- PPACA Section 6004
 - Requires reporting of drug sample information

Transparency Reporting -- Timeline

- Timing of Implementation:
 - Not later than *October 1, 2011*, the Secretary of HHS must provide guidance on the definitions of terms and “establish procedures” for the submission and posting to the internet of physician payment information.
 - First report on payments and ownership interests due *March 31, 2013*, based on transactions that occurred in 2012, and then annually
 - Section 6004 - - first report on drug sample information is due in 2012 (not later than *April 1, 2012*).

Transparency Reporting Requirements

- PPACA requires an “**applicable manufacturer**” of a “**covered drug, device, biological, or medical supply**” that provides “**payments or other transfers of value**” to a “**covered recipient**” (or to an entity or individual at the request of or designated on behalf of a covered recipient) to submit “Transparency Reports” about those payments to HHS
- Reports will be submitted to HHS electronically

Key Definitions

- **Applicable Manufacturer**
 - “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.”
- **Covered Drug, Device, or Medical Supply**
 - “Any drug, biological product, device, or medical supply for which payment is available under title XVIII [Medicare] or a State plan under title XIX [Medicaid] or XXI [the Children’s Health Insurance Program] (or a waiver of such a plan).”
- **Covered Recipient**
 - “Physicians” and teaching hospitals
 - Does not include employees of an applicable manufacturer
- **Payment or Other Transfer of Value**
 - A transfer of anything of value, unless excluded
 - Transfers of value do not include a transfer that is made indirectly to a covered recipient through a third party where the manufacturer is unaware of the identity of the covered recipient

Transparency Reports Must Include:

- Name of covered recipient
- Business address of covered recipient and, if a physician, the specialty and NPI number
- The amount of the payment or other transfer of value
- The dates of the payment or other transfer of value
- A description of the form of the payment or transfer, indicated as: (a) cash or cash equivalent; (b) in-kind items or services; (c) stock, stock option, or ownership interest, dividend, profit, or other return on investment; or (d) other (as defined by HHS)
- If payment is related to a particular drug, device or medical supply, report must identify the drug, device, or supply
- A description of the payment or transfer
- Any other categories of information regarding the payment or other transfer of value HHS determines appropriate

Transparency Reports - - Description of the Payment or Transfer

- Providing a description of the payment or transfer of value will require indicating whether the payment relates to:
 - Consulting fees
 - Compensation for services other than consulting
 - Honoraria
 - Gifts
 - Entertainment
 - Food
 - Travel (including the destination)
 - Education
 - Research
 - Charitable Contribution
 - Royalty or License
 - Current or Prospective Ownership Interest
 - Direct compensation for service as speaker
 - Grant
 - Other (as defined by HHS)

Exclusions From Reporting

- Any transfers of value less than \$10, unless the aggregate transfer of value to the covered recipient exceeds \$100 during the calendar year (not taking into account items below)
- Product samples not intended to be sold and intended for patient use
- Educational materials that directly benefit patients or are intended for patient use
- Trial loan (not more than 90 days) of a covered device to permit evaluation by the covered recipient
- Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device
- Transfer to a physician where physician is a patient and not acting in the professional capacity of a covered recipient

Exclusions From Reporting (cont'd.)

- Discounts (including rebates)
- In-kind items for the provision of charity care
- A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund
- For covered recipients who are licensed non-medical professionals, transfers solely for non-medical professional services
- Payments solely for the services of the covered recipient with respect to expert or other services in connection with litigation matters
- If the applicable manufacturer self-insures for healthcare, payments for the provision of healthcare to employees under the plan

Physician Ownership Reporting

- Any applicable manufacturer or GPO must report the following information regarding any ownership or investment interest held by a physician (or an immediate family member) in the applicable manufacturer or GPO during the preceding year
 - The dollar amount invested by any physician
 - The “value and terms” of each such investment
 - For any payment or other transfer of value provided to a physician holding such an investment interest, all the information listed in the prior slides
 - Any other information the Secretary determines appropriate
- Exception: No reporting obligations for ownership or investment interest in a "publicly traded security" or mutual fund

Government Disclosure of Reports

- Reporting of transfers under an R&D agreement or clinical investigation regarding a new product is delayed until after the earlier of
 - FDA approval / clearance or
 - Four calendar years after the date of payment
- Information available on a public website by 2013
- Website will
 - Identify manufacturers and recipients
 - List values of transfers, nature of transfers, and any other information the Secretary determines would be helpful to the average consumer
- Manufacturers and recipients can review and submit corrections for at least 45 days prior to information being made public

Drug Sample Reporting

- Each manufacturer and authorized distributor of record must report
 - The identity and quantity of drug samples requested and distributed in a year, aggregated by name, address, professional designation and signature of practitioner and **any other category of information determined appropriate by the Secretary**
 - Reporting will be required for samples distributed by mail or common carrier, or otherwise
- Drug = prescription drug for which payment is made under Medicare, Medicaid, or CHIP
- Manufacturers should already have access to this information by virtue of PDMA compliance (if HHS does not add non-PDMA required information to the Section 6004 reports)

Transparency Reporting -- Limited Preemption

- States can require disclosures of information if the information is:
 - Not “of the type” required to be disclosed under PPACA,
 - Excluded from PPACA’s reporting requirements (with an exception noted below), or
 - Regarding a payment by someone other than an applicable manufacturer and/or to someone other than a covered recipient
- Exception: 6002 "shall not preempt any [State law] . . . that requires the disclosure or reporting of information" excluded from Transparency Reports, "except in the case of information described in" the *de minimis* reporting exclusion
- State gift bans would not be preempted

Beyond the PPACA: Transparency Themes

- Pressure on industry to report payments to physician-consultants and expose potential conflicts of interest
- A worldwide trend:
 - WHO Good Governance for Medicines (GGM) Program
 - World Bank—Overview of Anti-corruption
 - UN Global Compact-Principle 10
 - WTO Working Group on Transparency in Government Procurement
 - Transparency International-Business Principles for Countering Bribery
 - The Medicines Transparency Alliance (MeTA) UK
 - US CIAs require multi-phase posting of payments to HCPs
 - Massachusetts and Vermont legislation

The Forces Driving Transparency: The Future

- Transparency trends converge with off-label and bribery issues
- Governance and senior management accountability drives/is driven by transparency

Key Questions to Consider in the Transparency Debate

- What impact will transparency developments have on your own efforts?
- What will be done with transparency data?
- What impact will these efforts have on customer relationships?
- What new compliance challenges are likely to occur in this new environment?
- How do you prepare your organization for these new challenges?

Contact

- Daniel A. Kracov, Chair, FDA and Healthcare Practice, 202.942.5999, Daniel.Kracov@aporter.com
- Keith M. Korenchuk, Partner, FDA and Healthcare Practice, 202.942.5817, Keith.Korenchuk@aporter.com