

Sunshine on the Healthcare Industry

PPACA's "Physician Transparency" Provisions

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Sunshine on the Healthcare Industry

- Overview of Section 6002
- Implications
- Panel Discussion
 - Decision points
 - Practical steps to minimize compliance risk

Physician Transparency Under PPACA

- Payments
 - Section 6002 of PPACA requires drug and medical device manufacturers to publicly report gifts and payments made to physicians and teaching hospitals \geq than \$10
- Ownership/Investments
 - It also requires drug and device manufacturers and GPOs to report physician ownership and investment interests

Payments Transparency

- Who has to report payments?
 - US manufacturer of a drug, device, biological or medical supply for which payment is available under Medicare, or a state plan under Medicaid or Children's Health Insurance Program (CHIP) (or waiver of such plan)
 - Entities under "common ownership," which provide assistance or support re: the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply

Payments Transparency

- Who are covered recipients?
 - Physicians (other than an employees of the applicable manufacturer)
 - A “teaching hospital” – not presently defined
 - Any other entity or individual designated by the physician or teaching hospital

Payments Transparency

- Payment means
 - A transfer of *anything* of value
 - Consulting fees, honoraria, gifts, entertainment, food, travel, education, research, royalties/license, speakers' fees, grants, etc.
- Exception: indirect payments where the applicable manufacturer is unaware of the identity of the covered recipient

Exclusions

- Less than \$10 unless the aggregate transferred or requested exceeds \$100/year
- Product samples not intended to be sold and intended for patient use **(BUT 6004 requires manufacturers and authorized distributors of record of applicable drugs to report annually on mail order and non-mail distribution aggregated by practitioner)**
- Educational materials that directly benefit patients or are for patient use
- Loan of a covered device for evaluation (up to 90 days)
- Items or services provided under contractual warranty, where the terms of the warranty are set forth in the purchase or lease agreement
- Transfer of anything of value to a covered recipient as patient

Exclusions (cont'd)

- Discounts (including rebates)
- In-kind items used 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 (per the Stark exception)
- Payments for health care to employees under a manufacturer's self-insured plan
- Where recipient is a licensed non-medical professional, a transfer of value as payment solely for his/her non-medical professional services
- Expert witness fees and other payments solely for the services of a physician with respect to a civil or criminal action or an administrative proceeding

Payments Transparency: What Gets Reported

- Covered Recipient's name, business address, specialty and NPI (if MD), amount, dates payment made, description of form of payment as:
 - Cash or cash equivalent
 - In-kind items or services
 - Stock, stock option, other ownership interest, dividend, profit, other return on investment
 - Any other form (as defined by the Secretary)

Payments Transparency: What Gets Reported

- A description of the nature of the transfer of value, indicated as:
 - Consulting fees
 - Compensation for services other than consulting
 - Honoraria
 - Gift
 - Entertainment
 - Food
 - Travel (including the specific destinations)
 - Education
 - Research
 - Charitable contribution
 - Royalty or license
 - Current or prospective ownership or investment interest
 - Direct compensation for serving as faculty or as a speaker for a medical education program
 - Grant or
 - Any other nature of the payment or other transfer of value (as defined by the Secretary)
 - If the transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered product
 - Any other categories of information regarding the transfer of value that the Secretary deems appropriate
 - Payments to third parties at the request of or designated by the Covered Recipient, are disclosed under the name of the Covered Recipient

Ownership Transparency

- Applicable manufacturers and applicable GPOs must report ownership/investment interests held by a physician (or immediate family member)
- Excludes ownership or investment in a publicly traded security and mutual fund (per the Stark exception)

Ownership Transparency

- Applicable GPO means a US GPO (as defined by the Secretary) that purchases, arranges for or negotiates the purchase of a drug, device, biological or medical supply for which payment is available under Medicare, or a state plan under Medicaid or Children's Health Insurance Program (CHIP) (or waiver of such plan).

Ownership Transparency

- What gets reported?
 - Dollar amount invested by each physician
 - Value and terms of each such ownership/investment interest
 - Any payment or other transfer of value provided to the physician owner (or to an entity or individual designated by the physician).
 - Any other information the Secretary determines

Reporting Dates

- First reports due on March 31, 2013 (for 2012 calendar year)
- Delayed publication for payments by applicable manufacturers pursuant to product research or development agreements and clinical investigations (earlier of date of FDA approval or 4 years).

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- Information will be made public on a **searchable** internet website with information by name of Manufacturer/GPO, name of recipient, business address of recipient, specialty, value of payment/transfer or value, date made, form, nature, name of drug, device, biological or medical supply
- There will be an opportunity to submit corrections before publicized
- Annual reports to Congress
- Annual reports to States (includes summary of information with respect to covered recipients in the State)
- Secretary to consult with OIG in implementation efforts

Penalties

- \$1000 - \$10,000 per payment/interest not reported as required; \$150,000 max per submission
- For *knowing* failure to report, \$10,000 - \$100,000 per payment/interest not reported as required; \$1,000,000 max per submission

State Law

- PPACA preempts laws that require disclosure of same information, but not laws requiring disclosure of different types of information, or different payors or recipients.

Implications

- First national, public, searchable website
- New uniform reporting requirement for manufacturers/GPOs
- Transparency for patients
- Also for regulators/qui tam plaintiffs/reporters
- Curb excessive/abusive arrangements
- Public perception of arrangements with Industry will drive further restrictions (e.g., gifts)
- Part of larger trend toward greater transparency of potential conflicts of interest (e.g., AAMC recommendations, proposed rules for greater transparency/accountability re: PHS-funded research)

What the Law Does NOT Do

- Does NOT impose new legal standards or prescribe specific limitations for financial relationships
- Does NOT create a reporting obligation for physicians/teaching hospitals
- Does NOT require reporting of Industry financial relationships with anyone but teaching hospitals and physicians (e.g., CME providers, nurse practitioners, pharmacists, pharmacies, health plans, pharmacy benefit managers (See 6005 of PPACA), community hospitals, patient organizations, professional organizations).

Preparing for the Spotlight

- Manage the underlying legal risks and “optics” that will result from increased public transparency
 - Make sure you have strong vendor relations and conflict of interest policies
 - Review and update your policies NOW
 - Consider “hot button” issues—don’t become a target
 - Consider emerging standards of professional integrity
 - Are your existing COI policies broad enough?
 - A good policy will strike a balance between minimizing legal risk, safeguarding professional integrity/the best interest of patients, and not discouraging legitimate, beneficial interactions with Industry

Preparing for the Spotlight

- Train on the new disclosures and your related policies
 - Explain what will be disclosed and how that can make physicians or the organization a target of legal enforcement or public scandal
 - Train on your vendor relations/conflict policies
- Conduct random audits in high risk areas
 - Include in your policies the right to audit

Preparing for the Spotlight

- If you are a provider, consider pros/cons of voluntary transparency
 - Different types of transparency—internal and external
 - Internal disclosure and review only
 - Internal plus external disclosure
 - If external/public disclosure
 - Scope of what will be disclosed to the public?
 - How to make disclosures useful and not misleading?
 - How to frame website disclosures to give “the full picture”?
 - Consider your resources