PPACA: Illuminating The Dark Side Of Health Care

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“Sunlight is the best disinfectant,” wrote Supreme Court Justice Louis Brandeis in 1913, addressing corruption and the banking industry. President Obama is particularly fond of citing this adage, and his administration is putting it into practice in a proposed regulation implementing the transparency provisions of the Affordable Care Act (ACA). This legislation seeks to shine the light of day on financial relationships among providers and manufacturers that may indicate potential conflicts of interest. Both legitimate and questionable arrangements will be exposed to greater scrutiny under these rules, so physicians should be prepared for potentially unwelcome publicity.

Unlike many of the more technical elements of the ACA, the transparency rules are grabbing mainstream media attention, both locally and nationally. A January 20, 2012, *Post-Gazette* editorial titled “Hidden Charge: Lobbying Has No Place in the Doctor's Office” commended the rules. The *New York Times* cited its own research in a January 16, 2012, piece titled “U.S. to Force Drug Firms to Report Money Paid to Doctors,” claiming “The Times has found that doctors who take money from drug makers often practice medicine differently from those who do not and that they are more willing to prescribe drugs in risky and unapproved ways, such as prescribing powerful antipsychotic medicines for children.”

The ACA requires applicable manufacturers of drugs, devices, biological or medical supplies covered by Medicare and other government programs to report annually to the Secretary of Health and Human Services certain payments or transfers of value provided to physicians or teaching hospitals. In addition, applicable manufacturers and applicable group purchasing organizations (GPOs) are required to report annually certain physician ownership or investment interests. Electronic reporting to CMS must begin by March 31, 2013, and continue on the 90th day of each calendar year thereafter.

On December 19, 2011, the Centers for Medicare and Medicaid Services (CMS) released proposed regulations implementing the ACA’s transparency requirements. The proposed regulation was developed after an extensive open-door forum with industry representatives was held on March 24, 2011. Although CMS has been responsible for the interpretation of the Stark physician self-referral law since its inception, the agency felt a need to better understand the relationships between drug and device manufacturers and prescribing physicians before crafting the regulatory framework governing these relationships.

Many of you may recall reading front-page articles detailing orthopedic device company payments to physicians. Disclosure of such payments was required by agreements between the Department of Justice and five manufacturers: Biomet, Inc., DePuy Orthopaedics, Inc., Smith & Nephew, Inc., Zimmer, Inc. and Howmedica Osteonics Corp./Stryker Orthopedics. These companies, who represented nearly 95 percent of the market in knee and hip implants, had been accused of overpaying orthopedic surgeons for consulting services and providing travel and other inducements in exchange for the surgeons recommending the use of their products. Four of the five companies agreed to engage independent monitors and paid significant financial penalties. All five companies agreed to disclose the name of each consultant and what they have been paid on their company web sites. Many media outlets mined the data looking for physicians in their area and published lists of recipients and dollar amounts, sometimes not distinguishing between consulting fees and sizeable royalties paid to physician patent holders. Expect more of the same when the ACA rules take effect.

The proposed rules require that “applicable manufacturers” report payments or “transfers of value” in excess of $10 each or $100 per year in the aggregate. Transfer of value includes all payments or other transfers of value given to a covered recipient, regardless of whether the recipient specifically requested the payment or other transfer of value. The term does not include a transfer made indirectly to a covered recipient through a third party if the manufacturer is unaware of the identity of the covered recipient. The report must describe the form of each payment or transfer as either cash or cash equivalent; in-kind items or services; or stock, stock option or other ownership interest, dividend, profit or other return on investment. The payment or transfer must be classified as one of the following:

- Consulting fees
- Compensation for services other than consulting
- Honoraria
- Gift
- Entertainment
- Food and beverage (Query: will this bring an end to pizza for the office staff and other drug company freebies?)
- Travel and lodging
- Education
- Research (direct or indirect)
- Charitable contribution
- Royalty or license
- Current or prospective ownership or investment interest
- Compensation for serving as a faculty or as a speaker for a medical education program
- Grant
- Other

In addition, payments or transfers of value made to an individual or entity (such as the physician’s professional corporation or employer) at the request of or designated on behalf of a covered recipient must be reported under the name of the covered recipient.

An “applicable manufacturer” is a manufacturer of at least one prescription drug, device, biological or medical supply that is covered by Medicare, Medicaid, state Children’s Health Insurance Plan (SCHIP) or other state program that is operating in the United States. The term also includes entities that outsource the physical manufacturing process but hold the applicable FDA approval, licensure or clearance.
The rule also requires GPOs to report payments and transfers. GPOs are defined as entities that purchase, arrange for or negotiate the purchase of a covered drug, device, biological or medical supply for a group of individuals or entities, and not solely for use by the entity itself, and would include physician-owned distributors (PODs).

Payments made to teaching hospitals must be reported under the name of the physician designated as the principal investigator. If this rule does not change in the final version, physicians acting in this capacity can anticipate inquiries about the substantial amounts that will be reported as if they received them personally. I predict this will be one area of the proposed rule that will draw significant criticism during the comment period.

Some payments or transfers are exempt from reporting, including product samples and other in-kind items intended for patient use, educational materials that directly benefit patients or are intended for patient use, loans of devices for up to 90 days for evaluation, discounts, warranties, items provided to a physician as a patient and expert witness fees in litigation.

The rules also require manufacturers and GPOs to report physician ownership or investment interests, including the amount invested. Publicly traded securities and stock benefits in retirement plans covering employees are exempt, and stock options must only be reported when they are exercised. CMS is looking into whether to require reporting of ownership interests held by physicians’ immediate family members as well.

The final component of transparency is public access to the information gathered under the CMS rule. CMS proposes to post all data online in a searchable and downloadable format.

Now may be a timely opportunity for physicians to review their relationships with drug and device companies and evaluate them for compliance with health care counsel before the regulations are finalized and reporting begins on March 31, 2013. Newspapers, broadcast media, web sites and other watchdogs will be combing the data for suggestions of impropriety. Make sure you have nothing to fear from a little sunlight.

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