Bringing Transparency to Physician-Industry Relationships: What the Physician Payment Sunshine Act Will Mean for Interventional Radiologists

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ABBREVIATIONS

CME = continuing medical education, CMS = Centers for Medicare and Medicaid Services, GPO = group purchasing organization

The Physician Patient Sunshine Act of 2010 mandates new disclosure and publication requirements for certain financial relationships between physicians and industry. Sponsored by Senators Charles Grassley (Republican, Iowa) and Herb Kohl (Democrat, Wisconsin), the Physician Patient Sunshine Act is premised on the belief that providing transparency to these relationships will deter quid pro quo dealings between physicians and industry that may contribute to inappropriate use of health care resources and increasing health care costs (1). The tracking and reporting requirements under the law are expected to take effect August 1, 2013, and all physicians, including interventional radiologists, are likely to be affected to some extent. The purpose of this commentary is to provide historical context to this issue, clarify the reporting requirements of the Physician Payment Sunshine Act, and discuss its potential impact on the interventional radiology community and steps that interventional radiologists can take to manage their own public profile vis-à-vis physician-industry relationships and this new law.

HISTORICAL CONTEXT

The past decade has seen increasing attention directed to relationships between physicians and pharmaceutical, medical device, and other medically related companies (2). A 2003–2004 national survey of physicians across six specialties demonstrated that physician-industry relationships had become commonplace, with 94% of responding physicians reporting some type of relationship (3). These relationships had various forms, with more than half of respondents benefiting from gifts, industry-provided food in the workplace, or drug samples; one third receiving reimbursement for costs associated with professional meetings or continuing medical education (CME); and one quarter collecting payments for consulting, lecturing, or enrolling patients in clinical trials. Although some of these relationships are ostensibly constructive—adding value and potentially improving patient care—they also create conflicts of interests that are difficult to eliminate and can negatively influence clinical decision making (2). Evidence suggests that industry-sponsored drug samples and CME events are associated with nonrational physician prescribing behaviors, including increased use of the sponsoring company's product in ways that are inconsistent with evidence-based recommendations (4).

Recognizing the mounting public distaste for physician-industry relationships, the Institute of Medicine issued a proactive report in 2009 entitled *Conflict of Interest in Medical Research, Education, and Practice* (5). The take-home message of the report was a uniform call for full disclosure of physician-industry relationships. Bernard Lo, chair of the Institute of Medicine commission, minced no words when discussing the findings of the report: "It's time to end a number of long-accepted practices that create unacceptable conflicts of interest, threaten the integrity of the medical profession, and erode public trust while providing no meaningful benefits to patients or society" (6). Included among the report's recommendations was an appeal for Congress to implement a national reporting program that would require pharmaceutical, medical device, and biotechnology companies to disclose all payments to physicians and health care

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institutions. Multiple states, including California, Maine, Minnesota, Vermont, and West Virginia, had already passed varying forms of legislation relating to the disclosure of physicians and industry relationships.

Although Congress did not immediately act on the report, the report sparked a wave of self-regulation in the medical community, manifested by new and strengthened conflict of interest policies in health systems across the United States (7). Partners HealthCare in Massachusetts prohibited physicians from accepting any gifts from drug or device manufacturers (including meals and entertainment), regardless of value (8). In 2002, industry also recognized the importance of this issue when Pharmaceutical Research and Manufacturers of America, the largest trade group of research-based pharmaceutical and biotechnology companies in the United States, established a code of ethics to guide industry interactions with health care professionals. This code was strengthened further in 2009 to discourage member organizations from providing physicians with any items that do not advance the treatment of disease, such as pens or note pads, even if accompanied by patient or physician educational materials (9). However, such self-regulatory efforts remained largely voluntary and lacked uniform participation at the individual level. Congress finally seized the opportunity to make its own mark on physician-industry conflicts of interest in the massive Patient Protection and Affordable Care Act, signed into law in March 2010 (10). Section 6002 of the Patient Protection and Affordable Care Act sets forth the Physician Payment Sunshine Act.

PHYSICIAN PAYMENT SUNSHINE ACT

On February 1, 2013, the Centers for Medicare and Medicaid Services (CMS) released its final rule interpreting the Congressional mandate for the Physician Payment Sunshine Act (1). The final rule came after a year of wait time during which the CMS wrestled with the extensive stakeholder feedback received during the public comment period. The final rule contains two primary requirements: (*i*) Applicable manufacturers of covered drug, device, biologic, or medical supplies must track and report to the CMS certain payments or other transfers of value provided to physicians and teaching hospitals, and (ii) applicable manufacturers and group purchasing organizations (GPOs) must track and report to the CMS certain ownership or investment interests held by physicians and their immediate family members.

The final rule pertains to all physicians and clinical fellows but excludes medical residents. Examples of reportable payments and transfers of value include consulting fees, honoraria or speaking fees, gifts, entertainment, certain food and beverages, research grants, and certain subsidies for educational activities. Only payments or transfers of value of $10 or less must be reported, unless transfers of less than $10 add up to or exceed $100 in a calendar year. Among the limited exemptions to the reporting requirements, there are two that are likely to arise often for interventional radiologists: (*i*) industry-sponsored educational events that comply with certified or accredited CME standards are exempt from reporting, and (*ii*) certain complementary food and beverages that are offered in a buffet style to all participants of a conference or similar large-scale event are exempt from reporting.

Under the Act, physicians have no duty to self-report. Instead, all responsibility for collecting and reporting the required information falls on the shoulders of manufacturers and GPOs. For a qualifying payment or transfer of value to a physician, the CMS requires a manufacturer to report the name, business address, specialty, and National Provider Identifier number of the covered recipient; the amount and date of the payment or transfer of value; the form (eg, cash, in-kind item, or service) and nature (eg, consulting fee, gift, honoraria, food and beverage, education) of the transfer; and the drug, device, biologic, or medical supply associated with the transfer, if applicable. Similar information is required for physician ownership or investment interests in an applicable manufacturer or GPO. The National Plan and Provider Enumeration System, a public database of physician information maintained by the CMS, will be available to facilitate manufacturers in gathering this information (1). The cost of industry compliance with the requirements of the Physician Payment Sunshine Act is estimated at $269 million in the first year and $180 million annually thereafter (1).

Applicable manufacturers and GPOs are expected to begin collecting these data on August 1, 2013, and must file the first reports with the CMS by March 31, 2014. After receiving these reports, the CMS will organize the data and prepare it for display on a publicly available website by September 30, 2014. Before making the information available to the public, the CMS first will make it available to physicians, who will have 45 days to review and dispute any purported inaccuracies with the manufacturer or GPO. When the 45-day window is complete, the CMS will give manufacturers and GPOs an additional 15 days to submit any necessary corrections. At the end of this combined 60-day period, the CMS will publish the data on the public website in its current form. If a dispute has not yet been resolved, the disputed data nonetheless will be presented on the website, but the data will be accompanied by an annotation to note that it remains under dispute. The CMS will make subsequent corrections to the data at least on an annual basis.

TAKING CONTROL OF YOUR PUBLIC PROFILE

Even though interventional radiologists have no affirmative reporting duties under the Physician Payment