Health Care Reform Legislation Sheds a Little Light on Drug and Device Makers’ Payments to Physicians

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On March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act (the “Act”).1 A companion bill, the Health Care Education and Afforable Care Act of 2010,2 also known as the reconciliation bill, was recently passed in the Senate, and contained amendments to the Act that reconciled certain aspects of the Senate and House versions of the legislation. Together these pieces of legislation represent the most comprehensive overhaul ever enacted of the health care system in the United States. Deep into the text of the Act is a provision that will require medical device and drug companies to disclose payments made to physician consultants. However, do not expect the sun to shine on these disclosure payments any time soon. The reporting requirements will not take effect until 2013.

Background

Originally drafted in 2007 by Senators Herb Kohl (D-Wisconsin) and Charles Grassley (R-Iowa), and re-introduced in 2009, the Physician Payment Sunshine Act (PPSA)3 was a stand-alone bill designed to bring transparency to conflicts of interest that arise when physicians receive financial benefits from drug and device makers. The impetus for the bill came, in part, as a result of Senator Grassley’s ongoing investigation of physicians, psychiatrists, and universities suspected of violating conflict-of-interest reporting rules.

In the case of three Harvard-based child psychiatrists, the reported payments were off by $3.4 million.4 In 2004, Charles Nemeroff, chair of the department of psychiatry at Emory University, reported $9,999 in income from GlaxoSmithKline as a consultant — $1 below the $10,000 National Institutes of Health threshold for disclosure. Grassley’s committee, however, found that he had actually received $171,031.5

Not only did the discoveries uncovered by Senator Grassley further public distrust, in the case of consulting work performed by psychiatrists on behalf of drug companies, a 4,000 percent increase in the use of antipsychotic drugs in children was found between 1993 and 2004.6

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3 S.B. 301, 111th Cong. (2010).
5 Id. (citing M. Angell, Drug Companies and Doctors: A Story of Corruption, N.Y. REVIEW OF BOOKS, (Jan. 15, 2009)).
6 Id. (citing G. Harris, Research Center Tied to Drug Company, N.Y. TIMES, (Nov. 25, 2008); G. Harris and B. Carey, Researchers Fail to Reveal Full Drug Pay, N.Y. TIMES, (June 8, 2008)).
Medical device manufacturers are also shelling out millions. In a 2008 whistleblower lawsuit for example, it was learned that the spine division of device-maker Medtronic paid more than $8 million to nearly 110 physician consultants. Also in 2008, it was learned that four companies that manufactured artificial hips and knees paid physicians more than $800 million in royalties and fees over a four-year period.

Under the new sunshine provisions of the Act, these drug and device manufacturers will be required to report payments to physicians and that information will be placed on the Internet for public viewing.

Sunshine Provisions

Contained in Section 6002 of the Act, the sunshine provisions clearly explain the requirements for disclosure of payments by companies to physician consultants. Beginning March 31, 2013, and each year thereafter, every manufacturer of a covered drug, device, biological, or medical supply product operating in the United States will be required to electronically report information on payments or other transfers of value made, in excess of $10, during the prior year to (1) physicians and (2) teaching hospitals. The required information to be submitted will include the following:

- the name of the recipient;
- the business address of the recipient as well as the specialty of the physician and his or her National Provider Identifier;
- the amount of the payment or other transfer of value;
- the dates on which the payment/transfer was provided;
- a description of the form of payment or transfer of value;
- a description of the nature of the payment or transfer of value;

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9 A “manufacturer” is defined as an entity engaged in the production of a product, but also includes another company under common ownership with the entity that assists it with production, promotion, sale, or distribution.


11 Descriptions of “value” in the Act include (1) cash or a cash equivalent; (2) in-kind items or services; (3) stock, stock option, or other ownership interest, dividend, profit, or other return on investment; or (4) any other form of payment or other transfer of value.

12 A “description” as stated in the Act include (1) consulting fees; (2) compensation for services other than consulting; (3) honoraria; (4) gift; (5) entertainment; (6) food; (7) travel – including destinations; (8) education; (9) research; (10) charitable contribution; (11) royalty or license; (12) current or prospective ownership or investment interest; (13) direct compensation for serving as faculty or as a speaker for a medical education program; (14) grant; or (15) any other nature of the payment or other transfer of value.
if the payment/transfer is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of the covered drug, device, biological, or medical supply; and

any other categories of information regarding the payment or transfer of value.\textsuperscript{13}

Additional reporting requirements are included for any ownership or investment interest, other than stock or mutual fund, held by a physician or an immediate family member, in the manufacturer or associated entity.\textsuperscript{14} The information reported must include the amount invested by each physician, the value and terms of the ownership or investment interest, and any payments from the manufacturer to such physician.\textsuperscript{15}

Some payments are exempt from reporting, including transfers of $10 or less,\textsuperscript{16} samples provided to patients, patient educational materials, and a 90-day loan of a device for evaluation.\textsuperscript{17}

By October 1, 2011, the Secretary of the Department of Health and Human Services (HHS), must establish procedures and guidelines for manufacturers to submit the required information and also procedures to make the information public. And by September 30, 2013, the HHS Secretary must have the reported information in place on the Internet in a searchable format. However, those payments made under an ongoing product development agreement or clinical trial will be delayed until product approval or four years after the payment is made, whichever comes first.\textsuperscript{18}

Penalties

The monetary fines imposed on a manufacturer for not reporting payment information to a physician or teaching hospital can get fairly steep. Any manufacturer that simply fails to timely submit payment information as required may be subject to a civil penalty of up to $10,000 for each payment or other transfer of value not reported – with an aggregate of $150,000 annually for each manufacturer.\textsuperscript{19} However, if a company knowingly refuses or fails to report the required information, the fines increase substantially – between $10,000 and $100,000 per payment not reported with an aggregate of $1 million annually for each manufacturer.

A Word About Preemption

Some states such as Vermont, Minnesota, California, Maine, West Virginia, Massachusetts, and the District of Columbia, beat the federal government to the punch and currently have legislation in place requiring drug companies to disclose the payments they make to physicians. The disclosure provisions of the Act preempt state laws that

\textsuperscript{13} \textit{Pub. L. No. 111-148, § 6002(a) (2010).}
\textsuperscript{14} \textit{Id. at § 6002(a)(2) (2010).}
\textsuperscript{15} \textit{Id.; see also Memorandum, \textit{supra} note 10.}
\textsuperscript{16} Unless the aggregate annual total is $100 or more.
\textsuperscript{17} \textit{Pub. L. No. 111-148, § 6002(e)(10) (2010); see also Memorandum, \textit{supra} note 10.}
\textsuperscript{18} \textit{Pub. L. No. 111-148, § 6002(c) (2010); see also Memorandum, \textit{supra} note 10.}
\textsuperscript{19} \textit{Pub. L. No. 111-148, § 6002(b) (2010).}
require the same type of information to be reported. However, the Act does not preempt more stringent or different information reporting requirements at the state level.

Other Transparency Provisions

Section 6004 of the Act dictates that by April 1, 2012, and every year thereafter, manufacturers and distributors will be required to report to HHS the identity and quantity of samples requested by and distributed to each physician, for drugs covered under Medicare and Medicaid.20

Finally, section 6005 of the Act requires pharmacy benefit managers (PBMs) that manage the drug benefit for a Medicare Part D plan or any plan offered through a health insurance exchange to disclose to HHS, as well as the plan the PBM contracts with, the aggregate amount and types of rebates, discounts, and other price concessions negotiated on behalf of the plan, the amount passed through to the plan, and the aggregate difference between the amount the plan pays the PBM and the amount the PBM pays retail and mail order pharmacies.21

Conclusion

Whistleblowers have alleged that drug and device makers use the financial relationships with physicians to influence their decisions about which products to use. Medical companies say the payments are legitimate expenses paid to further technological advancement of drugs and devices. Regardless, patients should be assured that physicians are prescribing drugs and recommending medical devices for sound medical purposes – not because they are a de facto sales arm of the company.

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20 See Memorandum, supra note 10.
21 Id.