

PROPOSED AND EXISTING LAWS REGARDING THE INTERACTION OF PHARMACEUTICAL AND MEDICAL DEVICE COMPANIES AND HEALTHCARE PROVIDERS

Christopher Seiber
August 17, 2009

A. BACKGROUND

1. Public Opinion. Despite the large gains in human health resulting from advances in pharmaceuticals and medical technology, the public casts an increasingly wary eye towards the manufacturers of such drugs and medical devices. While some of this view can be explained based on largely negative characterizations of these companies in the news media, entertainment industry and by politicians, one of the main reasons it persists is because of the marketing model traditionally employed by such companies. These companies have traditionally relied heavily on marketing directly to healthcare providers by advertising, providing gifts and benefits, and visits from sales representatives. This has tended to create, fairly or unfairly, a perception of conflicts of interest by physicians and a perception that high healthcare prices are significantly affected by such marketing efforts.

2. Self-Policing. A summary of research published in the Journal of the American Medical Association in 2007 indicated that early efforts at voluntary reporting, conflict avoidance and spending limits were proving ineffective and were frequently disregarded. <http://jama.ama-assn.org/cgi/content/short/297/11/1255>

3. Legislation. The perception of medical marketing as driving up costs and creating conflicts of interest, bolstered by inconsistent results from early self-policing efforts within the industry, have contributed to a legislative and regulatory trend towards “sunshine laws,” which seek to avoid conflicts of interest and facilitate disclosure and public scrutiny of medical marketing efforts and expenditures.

B. PENDING FEDERAL LEGISLATION

1. Proposed Law. In January of 2009, Senators Chuck Grassley (R-Iowa) and Herb Kohl (D-Wisconsin) introduced The Physician Payment Sunshine Act to require manufacturers and group purchasing organizations to report on a wide range of payments to physicians and physician-owned entities. The proposed law would provide that, beginning in 2010, the government will require yearly reporting of all physician payments over a cumulative value of \$100 dollars, with the first report being due by March 31, 2011 and to be made available to the public by September 30, 2011.

2. Reporting Requirement. Under the proposed law, companies would be required to report the following information:

- Name
- Business Name
- Address
- Value of the payment or transfer of value

HEALTHCARE DATASOLUTIONS

- Dates of the payments or transfers
- Description of the form of payment or transfer of value.

The reporting obligation would apply to the following expenditures:

- Consulting Fees
- Compensation for services other than consulting
- Honoraria
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable Contributions
- Royalties or licenses
- Current or prospective ownership or investment interests
- Compensation for serving as a faculty member or as a speaker for a continuing medical education program;
- Grants
- Any other nature of the payment or other transfer of value as defined by the Secretary of HSS

If the payment or other transfer of value is related to marketing, education, or research concerns, a specific covered drug, device, biological, or medical supply, companies will be required to report and include the link to the drug. Also, reporting will be required on whatever the Secretary of Health and Human Services (HHS) deems appropriate.

3. Who Must Comply. The proposed law's disclosure requirements only apply to manufacturers of a covered drug, device or biological. However, the legislation proposes a definition of "manufacturer" that explicitly includes any entity that distributes the covered drug, device or biological.

4. Research. Reporting of research payments will be required, and some reporting will be delayed by whichever date is earlier:

- Two years after the date or transfer of value was made; or
- After the date of Food and Drug Administration (FDA) Approval.

Companies will also be required to aggregate amounts of payments or transfers of value to recipients (in contrast to the current Massachusetts law, which has a per-transaction threshold for reporting).

5. Physician Ownership. The bill also requires reporting of physician ownership interests in private companies including:

- The dollar amount invested
- The current value



26741 Portola Parkway
Suite 1E #646
Foothill Ranch, CA 92610

PHONE (888) 300-4096
EFAX (949) 666-6045
WEB SITE www.HealthcareDataSolutions.com

HEALTHCARE DATASOLUTIONS

- Any payment or transfer of value to the owner, including dividends or other payments

6. Exclusions from reporting. The following do not require reporting:

- Payments in the aggregate of less than \$100
- Product samples
- Patient education materials
- The loan of a device for less than 90 days
- Warranty replacements (devices)
- Items for use as a patient
- Discounts and rebates
- In-kind items used in charity care
- Dividends or distributions from a publicly-traded company

7. Penalties. For unintentional failure to report, penalties will include fines from \$1,000 - \$10,000 for each payment not reported with a cap of \$150,000/year. For intentional failure to report, the penalties will be steeper - the fines are \$10,000 - \$100,000 for each payment not reported with a cap of \$1 million/year.

8. Implementation. The bill initially stated that the Secretary of HHS has until November of 2009 to establish procedures for implementation of the Bill. Presumably, this could be adjusted based on the time that a bill is passed. The website for which this implementation will be hosted, has a search mechanism by company or physician and is in a format that is clear, understandable, and easily downloaded. Also, the website will contain a description of any enforcement actions and penalties as a result of the legislation. The Secretary would be given tremendous leeway in adding required information to the law and can add any other information that he or his team deems helpful to “consumers.” The Secretary will be required to consult with consumers, consumer advocates, and “other interested parties” to ensure that information is made available. The federal government will also make available to each state, a report of physician payments that is specific to the respective state.

9. Preemption.

a. The bill will preempt state laws for disclosure of payments or transfers of value for items described. It would not preempt state laws that have additional reporting requirements on information not required in the bill. Further, if a state wanted to require disclosure for samples or rebates, this proposed law would not limit that activity. This presents a potential problem for companies, in that states can add anything they want to the reporting requirements, and the companies will still be in the same position (reporting to multiple states) as they were before the federal legislation passed.

b. Several states, including Minnesota, Massachusetts, Vermont, Maine, West Virginia and the District of Columbia have existing gift disclosure laws. Moreover, Oregon, Mississippi, Illinois, Connecticut, and Texas have already introduced such legislation in 2009. Colorado has a draft bill that would require distributors to report gifts, but it has not yet been introduced. However, the federal law would preempt state laws requiring disclosure of any payments or transfers of value that must be reported under it. Thus, states would not be able to collect the same information that the federal government is collecting.



26741 Portola Parkway
Suite 1E #646
Foothill Ranch, CA 92610

PHONE (888) 300-4096
EFAX (949) 666-6045
WEB SITE www.HealthcareDataSolutions.com

c. Nevertheless, the bill would not preempt state laws that contain reporting requirements seeking information outside the scope of the federal law. As a result of this narrow preemption, a patchwork of state law requirements more far-reaching than the requirements of the proposed legislation may emerge despite the attempt to establish a uniform national standard. Moreover, states still would be able to prohibit certain marketing practices, such as the ban on gifts over a certain amount in Minnesota and Massachusetts.

10. For Continuing Medical Education (CME). The language is for direct payments or transfers of value, at the request of, on behalf of, or designated on behalf of, a covered recipient (a physician, physician medical practice or physician group practice). For direct payments to those entities, reporting will be required for education, compensation for serving as faculty, or as a speaker for a CME program, and grants.

11. Links.

Text of the bill:

<http://policymed.typepad.com/files/physician-payment-sunshine-act-2009-1-22-09.pdf>

Press release by Sens. Grassley and Kohl: <http://aging.senate.gov/record.cfm?id=307097>

C. MASSACHUSETTS LAW.

1. Overview. In August 2008, Massachusetts enacted “An Act to Promote Cost Containment, Transparency, and Efficiency in the Delivery of Quality Healthcare.” The purpose was to address potential undue influence in interactions between pharmaceutical or medical device manufacturing companies and healthcare practitioners. The law is considered to be the most stringent state regulations on the subject to date. The law has the following general components:

- a. Basic rules on permissible and prohibited conduct for drug and medical device companies related to the sales and marketing of drugs and devices.
- b. A requirement that the Massachusetts Department of Public Health promulgate and update a code of conduct for drug and medical device companies every two years.
- c. A requirement that companies which employ persons in the sales or marketing of a drug or device in Massachusetts to adopt the code of conduct and to create a training program about it for those employees. Said companies must also conduct annual compliance audits and investigate and report any breaches, then certify that to the DPH.
- d. A requirement that companies submit an annual report to the DPH of the purpose, nature, value and recipient of any payment or economic benefit with a value of \$50 or more which was provided to a covered healthcare provider by agents of a drug or device company.
- e. A requirement that the DPH establish a public database listing payments to healthcare practitioners.



26741 Portola Parkway
Suite 1E #646
Foothill Ranch, CA 92610

PHONE (888) 300-4096
EFAX (949) 666-6045
WEB SITE www.HealthcareDataSolutions.com

HEALTHCARE DATASOLUTIONS

2. **Regulations.** On March 11, 2009, the DPH issued its initial regulations. They include the following requirements:

- a. By July 1, 2009, companies must have adopted a code of conduct specified in the regulations, certify compliance with regulations, and create policies and procedures for investigations and corrective action.
- b. Starting July 1, 2010, companies must make annual disclosures of payments to healthcare providers in connection with marketing and sales activities.
- c. Payment of a \$2,000 annual fee to the DPH, due on each July 1 starting in 2009.

3. **Prohibited Marketing Practices.** The regulations set forth various prohibitions on marketing activities by pharmaceutical and medical device companies. Prohibited conduct includes:

- a. Providing recreation or entertainment of any value to anyone other than salaried employees of the company.
- b. Paying for or providing meals which (i) are related to recreation or entertainment, (ii) take place outside of the medical practitioner's office or hospital setting, or (iii) take place without being accompanied by the sales or marketing agent and a presentation. The same prohibition applies to the spouse, family or guest of a healthcare provider.
- c. Sponsorship of continuing medical education (CME) that does not meet ACCME Standards for Commercial Support or that offers direct payment to a medical practitioner.
- d. Direct payment to a medical practitioner unless it is for a bona fide service agreement.
- f. Direct or indirect payment for lodging, travel or personal expenses of CME attendees, other than CME faculty.
- g. Grants, subsidies, scholarships, consulting contracts, support or educational or practice items to any medical practitioner in exchange for the practitioner's use of a drug or medical device.
- h. Provision of complimentary items such as pens, coffee mugs, gift cards, flowers, etc.

4. **Permitted Marketing Practices.** Pursuant to the regulations, the following remain permitted:

- a. Providing drug samples solely for use by patients.
- b. Paying for reasonable expenses of technical training on the use of a medical device, provided the expense is part of the purchase contract for the device.
- c. Purchasing advertisements in peer-reviewed scientific, academic or clinical journals.



26741 Portola Parkway
Suite 1E #646
Foothill Ranch, CA 92610

PHONE (888) 300-4096
EFAX (949) 666-6045
WEB SITE www.HealthcareDataSolutions.com

HEALTHCARE DATASOLUTIONS

- d. Paying for professional or consulting services by a medical practitioner in connection with a bona fide research project or clinical trial.
- e. Providing peer-reviewed scientific, academic or clinical information.
- f. Modest and occasional meals in connection with informational sessions in specified clinical training sessions.
- g. Sponsorship of meals at third-party scientific, educational or charitable conferences or professional meetings.
- h. Charitable donations.
- i. Payments for bona fide participation in company-sponsored training and education

5. Disclosure Requirements. Companies must make their first annual reporting on July 1, 2010.

a. Healthcare Practitioner. This is defined as “a person who prescribes prescription drugs for any person and is licensed to provide healthcare in the commonwealth or a partnership or corporation comprised of such persons, or an office, employee, agent or contractor of such persons, or an officer, employee, agent, or contractor of such person acting the course and scope of his employment, agency or contract related to or in support of the provision of healthcare to individuals.” In essence, this includes any doctor, hospital, pharmacist, nursing home, health plan benefit administrator or other healthcare practitioner. But it excludes bona fide employees of the company, health insurers, distributors, drugstores, and consumers.

b. Reporting Threshold. Companies must disclose all individual payments, fees, subsidies and other economic benefits which are \$50 or greater. This is on a per-transaction basis, not an aggregate basis. For example, if a company were to provide two different benefits of \$40 each to a recipient, neither would need to be reported. Companies must also disclose payments to healthcare practitioners for advertising, promotion, product education and training, sponsorship of CME, and marketing based research.

c. Reporting Exclusions. The items listed in Section C.4 above do not need to be disclosed. Additionally, companies do not need to disclose the following: charitable donations, rebates and discounts, reimbursement information, and patient assistant program support.

d. Form over Substance. The Act prohibits pharmaceutical and medical device manufacturers from intentionally structuring payments in order to avoid the substance of the Act’s disclosure requirements (for example, planning out a sequence of \$49 payments to avoid having to disclose what is, in substance, a significantly larger payment).

6. Enforcement.

a. Fines. Knowing and willful violations of the regulations are subject to a penalty of \$5,000 per violation.



26741 Portola Parkway
Suite 1E #646
Foothill Ranch, CA 92610

PHONE (888) 300-4096
EFAX (949) 666-6045
WEB SITE www.HealthcareDataSolutions.com

b. Enforcing Agencies. The DPH, attorney general and district attorneys have the authority to enforce the law and regulations and to issue notices and fines. They may pursue civil actions in court to obtain payment of fines.

c. Appeal. Companies may dispute a fine, including obtaining judicial review.

D. OTHER STATE LAWS.

1. The proposed Federal law would preempt state laws for disclosure of payments or transfers of value for items described. It would not preempt state laws that have additional reporting requirements on information not required in the bill. Further, if a state wanted to require disclosure for samples or rebates, this proposed law would not limit that activity. This presents a potential problem for companies, in that states can add anything they want to the reporting requirements, and the companies will still be in the same position (reporting to multiple states) as they were before the federal legislation passed.

2. Several states, including Minnesota, Massachusetts, Vermont, Maine, West Virginia and the District of Columbia have existing gift disclosure laws. Moreover, Oregon, Mississippi, Illinois, Connecticut, and Texas have already introduced such legislation in 2009. Colorado has a draft bill that would require distributors to report gifts, but it has not yet been introduced. However, the federal law would preempt state laws requiring disclosure of any payments or transfers of value that must be reported under it. Thus, states would not be able to collect the same information that the federal government is collecting.

3. Nevertheless, the proposed Federal law would not preempt state laws that contain reporting requirements seeking information outside the scope of the federal law. As a result of this narrow preemption, a patchwork of state law requirements more far-reaching than the requirements of the proposed legislation may emerge despite the attempt to establish a uniform national standard. Moreover, states still would still be able to prohibit certain marketing practices, such as the ban on gifts over a certain amount in Minnesota and Massachusetts.

This is a summary of the laws described above which is set forth in general terms. It is not legal advice and does not create any attorney-client relationship or privilege. If you have a specific fact situation related to the subject matter above, you should seek legal representation and should not rely on statements and opinions set forth in this article.

Law Office of Christopher Seiber



26741 Portola Parkway
Suite 1E #646
Foothill Ranch, CA 92610

PHONE (888) 300-4096
EFAX (949) 666-6045
WEB SITE www.HealthcareDataSolutions.com