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Changing landscape of physician-industry relationships: A trend toward transparency

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On his first full day in office, President Barack Obama stated in a speech welcoming senior staff and cabinet secretaries, "[t]ransparency and the rule of law will be the touchstones of this presidency."[1] Although President Obama was referring to how *government* will be more transparent and accountable to the people, this trend toward transparency transcends the corridors of the White House and is increasingly becoming part of the operating manual for many sectors of the healthcare industry. During the past year, there has been a frenzy of activity responding to the specific demand for transparency in relationships between physicians and industry groups (i.e., pharmaceutical and medical device manufacturers), which are believed to contribute to the exorbitant cost of healthcare. With a new administration committed to reigning in unnecessary costs of healthcare and several pharmaceutical companies and hospitals already pledging to publicly disclose financial arrangements between physicians and industry groups, the moment is ripe for the passage of federal legislation in 2009, namely the Physician Payments Sunshine Act, which is described in more detail below.

I. The Case for Transparency

The heightened scrutiny of physician-industry relationships is based on the concern that a physician's objectivity and independence toward patient care may be compromised by the influence of drug and device companies, resulting in costly or medically unnecessary care. Proponents of increased transparency cite a national survey recently published in *The New England Journal of Medicine* that demonstrates the pervasive ties between physicians and pharmaceutical and medical device industries.[2] According to the survey of over 3,000 physicians in six specialties (anesthesiology, cardiology, family practice, general surgery, internal medicine and pediatrics) most physicians (94 percent) reported some type of relationship with the pharmaceutical industry.[3] These relationships mainly involved receiving meals (83 percent) or drug samples (78 percent) from the pharmaceutical industry.[4] Over one-third of the physician respondents also received reimbursement for costs associated with attending professional meetings or continued medical education, and more than a quarter of the physicians reported receiving payments for consulting, giving lectures or enrolling patients in clinical trials.[5]

The money spent by pharmaceutical companies on these physician relationships has skyrocketed over the years. In 2005, it is estimated that pharmaceutical companies spent nearly $7 billion on physician detailing (physician visits by pharmaceutical sales representatives excluding money spent on gifts, meals and events), which is almost double what the industry spent in 1996.[6] Likewise, medical device companies pay physicians consulting fees and royalties to develop new products, subsidize physicians' costs of attending conferences, pay physicians to conduct postmarketing research and even give physicians equity in their companies. Both drug and device companies also sponsor significant clinical research resulting in some form of financial arrangements with physicians and/or hospitals for the enrollment and oversight of patients in clinical trials.

There are certainly benefits to close relationships between physicians and the pharmaceutical and device industries. These relationships have led to innovation, advances in medical technology, improvements in patient care and the education of physicians on the proper use of drugs and devices. Studies also have shown, however, that interactions between the pharmaceutical industry and medical professionals have impacted the prescribing practices of physicians. More specifically, physician interactions with the pharmaceutical industry were found to be associated with rapid prescribing of newer drugs and decreased prescribing of generic drugs.[7]

Furthermore, some pharmaceutical and device manufacturers may have crossed the line and have engaged in relationships with physicians that resulted in investigations and settlements by the U.S. Department of Justice (DOJ) and the Office of Inspector General (OIG). In the Fall of 2007, five major hip and knee device manufacturers agreed to be subject to federal monitoring, and four of those companies also agreed to

pay the government over $300 million in fines in order to avoid prosecution for allegedly inducing physicians to use their devices. A federal investigation found that these companies paid surgeons tens of thousands of dollars per year for consulting contracts in which surgeons were required to do little or no work but did agree to exclusively use the companies' devices.[8]

Most of the information available today regarding the impact of physician-industry relationships on the cost of healthcare is based on surveys, studies and investigation of certain company practices. The passage of a federal law requiring public disclosure of these financial relationships would provide more complete data to assist in understanding the extent of industry influence on a physicians' practice patterns and the wasteful spending to which it leads.

II. Industry Group Developments

Beginning in 2007, industry groups were faced with the fact that the federal government was seeking to regulate relationships between physicians and the drug and device industries. A new bill, the Physician Payments Sunshine Act of 2007, was introduced requiring public disclosure of certain payments from drug and device companies to physicians and the basis for such payments.[9] By 2008, associations representing pharmaceutical and device companies released revised ethics codes, demonstrating their ability to self-regulate physician-industry relationships.

A. PhRMA

In July of 2008, the Pharmaceutical Research and Manufacturers of America (PhRMA) reinforced its commitment to transparency and responsible marketing of drugs by publishing a revised Code on Interactions with Healthcare Professionals. Effective as of January 1, 2009, the revised Code establishes a number of new guidelines, including those that (1) prohibit distribution of gifts that are not designed primarily for patient education (e.g., pens, notepads and mugs with the company's logo) to healthcare professionals; (2) prohibit sales representatives from providing restaurant meals to healthcare professionals and their staff and, instead, permit sales representatives to provide occasional meals at the health care practitioners' offices in conjunction with informational presentations; and (3) require any healthcare professional who is a member of a formulary or clinical guidelines committee of a hospital and also serves as a speaker or consultant for the drug company to disclose to the hospital committee the existence and nature of the relationship with the drug company.[10]

The revised Code also adds an element of accountability by requiring all companies that publicly announce adherence to the Code to complete an annual certification (signed by the CEO or Chief Compliance Officer) stating that the company has policies and procedures in place to comply with the Code. PhRMA's public Web site will disclose such certifying companies and include contact information for the companies' Chief Compliance Officers. Furthermore, the Code strongly encourages those companies that annually certify to seek external verification—at least every three years—that the company has policies and procedures in compliance with the Code. Although adoption of the Code is voluntary, as of February 4, 2009, forty-two pharmaceutical companies (including many multi-national research-based companies such as, Pfizer, Eli Lilly, Merck, Johnson & Johnson, Abbott, Bayer, GlaxoSmithKline and Bristol-Myers Squibb) became signatories and publicly announced their intentions to abide by the revised Code.[11]

B. AdvaMed

In December of 2008, the Advanced Medical Technology Association (AdvaMed), which includes in its membership medical device companies, also published a revised Code of Ethics on Interactions with Health Care Professionals. The revised AdvaMed Code becomes effective July 1, 2009 and makes several significant changes that mirror many of the guidelines in the revised PhRMA Code, including a ban on non-educational promotional items (e.g., pens and mugs) and an annual certification requirement (signed by the CEO of Chief Compliance Officer) by companies that publicly announce adherence to the revised AdvaMed Code.

The AdvaMed Code, however, is not as strict as the PhRMA Code regarding the provision of restaurant meals to healthcare professionals. Unlike the PhRMA Code, which permits the provision of occasional meals only within the physician's office or hospital setting, the AdvaMed Code permits the provision of meals off-site if the onsite setting is not conducive to the presentation of information or if it is impracticable or inappropriate to provide meals in an onsite setting. These exceptions to the onsite rule may be interpreted so broadly that virtually all meals may fit within the exceptions.

The AdvaMed Code also addresses an important area of potential inducement activity - the payment of royalties to healthcare professionals. The Code permits companies to enter into royalty arrangements only when a healthcare professional is expected to make or has made a novel, significant or innovative contribution to the development of a product or method.

AdvaMed has developed a special logo, much like the "Good Housekeeping" logo, to provide a visible symbol of a company's commitment to the ethical standards embodied by the AdvaMed Code. It will be interesting to see if this AdvaMed logo will help device companies gain credibility in the marketplace, as there is no external verification of compliance with the AdvaMed Code.

Overall, even though the guidelines established by industry associations such as PhRMA and AdvaMed have become more stringent to reduce the influence of drug and devices companies on the practice of physicians, the guidelines still do not require the public disclosure of specific physician-industry relationships. Drug and device companies that choose to adhere to these codes are required only to create internal policies and procedures. Furthermore, because these codes are voluntary and there is no mandatory requirement for external oversight, non-compliance with these guidelines will persist.

III. State Developments

A. Early Adoption of State Laws

Currently, only a handful of states (Minnesota, Vermont, Maine, West Virginia and Massachusetts) and the District of Columbia have laws mandating the disclosure of physician-industry compensation relationships. Each of these state laws vary in the payment thresholds that trigger disclosure, the types of payments that need to be disclosed, and the scope of healthcare providers to whom the payments are made. Although these state laws require disclosure of payments to physicians, often times the complete payment data disclosed is not made available to the public.

Minnesota was the first state to pass such legislation, in 1993. It requires the

reporting of payments over $100 by pharmaceutical manufacturers to physicians.[12] The physician-specific data reported to the state is made part of the public record; however, the state is under no obligation to analyze the data it collects. Vermont has a lower threshold and requires the reporting of economic benefit over $25 in value from pharmaceutical companies.[13] Because of a trade secret exemption, however, much of the data disclosed is not made available to the public.

Similar to the Vermont law, Maine requires the disclosure of payments over $25.[14] Even though physician-specific payment data is collected, only aggregate data is available to the public. The District of Columbia requires the disclosure of payments over $25 in addition to the disclosure of anything provided to a health care professional at less than market value. Like the Maine law, the District of Columbia makes only aggregate data available in the public record.

West Virginia has the weakest of these state laws, which requires only that pharmaceutical companies disclose the total number of prescribers who have received payments above $100.[15] Thus, no individual physicians are identified in the reported information.

California and Nevada have enacted laws requiring pharmaceutical and device companies to adopt compliance programs and codes of conduct that are no less restrictive than the most recent version of the PhRMA and AdvaMed codes. Because these codes do not have public disclosure requirements, companies operating in California and Nevada are not required to disclose physician-industry ties.

B. Stringent Massachusetts Law

As of January 1, 2009, a new law enacted in Massachusetts took effect and is considered the most stringent of the current state laws.[16] The Massachusetts law requires both drug and device companies to adopt a state-authored marketing code of conduct (the "Marketing Code"). The law also requires drug and device companies to publicly disclose any economic benefit provided to physicians and other healthcare providers of $50 or more in value. All publicly disclosed information will be available on a searchable Web site.

The Massachusetts Department of Public Health has proposed regulations, which contain the Marketing Code; however, these regulations are still in the comment period.[17] The proposed Marketing Code is much more restrictive than the PhRMA and AdvaMed codes. Under this new Massachusetts law, drug and device companies operating in Massachusetts face a number of new compliance requirements, including (1) adopting the Marketing Code published by the Department of Public Health; (2) adopting and submitting to the Department the description of a training program to provide regular training to appropriate employees, including all sales and marketing staff, on the Marketing Code; (3) certifying to the Department that the company is in compliance with the Marketing Code; (4) adopting and submitting to the Department policies and procedures for investigating instances of non-compliance with the Marketing Code, taking corrective action in response to such noncompliance and reporting of instances of noncompliance to state authorities; and (5) submitting to the Department information regarding the compliance officer responsible for operating, monitoring and enforcing the Marketing Code.

C. Illinois House Bill

At least ten states had bills pending during the 2008 legislative session aimed at regulating the marketing activities of pharmaceutical companies.[18] One of those states was Illinois. On January 23, 2009, Representative Jack Franks reintroduced a House Bill creating the Prescription Drug Ethical Marketing Act.[19] The purpose of the Act is to lower prescription costs and to protect the health of residents by deterring the practice of unethical gift giving.

If passed as currently drafted, the Act would require every pharmaceutical manufacturer and labeler licensed in Illinois to annually disclose the value, nature, and purpose of any payment or other economic benefit of $25 in value or more provided in connection with marketing activities to any physician, hospital, nursing home, health benefit plan administrator or any other person in Illinois authorized to prescribe prescription drugs. Like other current state laws, this disclosure requirement would exempt (1) free samples for patients; (2) compensation associated with clinical trials; and (3) scholarships for medical students, residents or fellows to attend certain types of conferences.

State legislatures, including the Illinois legislature, may be reticent to pass legislation as they wait for the status of the proposed federal law, which, as currently drafted, would preempt certain provisions of state legislation.

IV. Federal Developments

A. MedPAC Report and Recommendations

In June of 2008, the Medicare Payment Advisory Commission (MedPAC), an independent Congressional agency established to advise Congress on issues affecting the Medicare program, published its semi-annual report.[20] In this report, MedPAC evaluated the need for federal legislation mandating disclosure of physician-industry relationships. MedPAC concluded that a public reporting system would be effective because it would (1) encourage physicians to reflect on the propriety of their relationships with drug and device companies; (2) deter inappropriate arrangements; (3) assist in understanding the role of drug and device companies in the practice patterns of physicians; (4) allow the media to explore potential conflicts of interest; and (5) highlight those physicians who have chosen not to engage in inappropriate relationships.

MedPAC recommended that Congress enact legislation that requires all manufacturers and distributors of drugs, biologicals, medical devices and medical supplies to report the Secretary of the U.S Department of Health and Human Services (HHS) their financial relationships with physicians and other prescribers, pharmacies and pharmacists, health plans, pharmacy benefit managers, hospital and medical schools, organizations sponsoring continuing medical education, patient organizations and professional organizations. MedPAC further recommended that such information be available via a public Web site. Lastly, MedPAC recommended that Congress require manufacturers and distributors of drugs to report to the Secretary certain information about the distribution of drug samples.

B. Baucus Plan

In November of 2008, Senator Max Baucus, Chairman of the Senate Finance Committee, authored a report entitled "Reforming America's Health Care System: A Call To Action" in which he devoted a section to three areas that would benefit from increased transparency, one of which is physician-industry relationships.[21] Citing the MedPAC report, the Baucus plan echoed the need

for a federal disclosure requirement. He reasoned that disclosure is the only way to determine if there are inappropriate influences on the delivery of care and use of taxpayer dollars.

C. Physician Payments Sunshine Act of 2009

On January 22, 2009, Senators Grassley and Kohl reintroduced the Physician Payments Sunshine Act of 2009 (the "Act"), a bill similar to the 2007 and 2008 versions.[22] If enacted, the Act would require all manufacturers and distributors of drugs and devices covered under Medicare, Medicaid and SCHIP to disclose financial relationships with physicians and physician groups. The Act would exempt from disclosure educational material provided by the drug or device company for the benefit of patients, rebates and discounts, and prescription drug and device samples. The Act would also exempt all payments under the aggregate annual total per physician of $100.

The Secretary of HHS would be required to disclose this information to the public on a searchable Web site that is available no later than September of 2011. Furthermore, the Act would preempt state law, creating a disincentive for states to pass their own laws. States, however, would still be permitted to collect other types of information and to take steps to limit marketing.

The Act has received a groundswell of support from industry, physician and consumer groups alike. Senator Grassley, in his press release regarding the introduction of this bill, was confident that this legislation would pass during this year.

V. Voluntary Public Disclosure of Relationships

In an effort to get ahead of the anticipated enactment of the Physician Payments Sunshine Act, several large pharmaceutical companies, including Eli Lilly, Merck, GlaxoSmithKline, and Pfizer, and some healthcare providers have pledged to voluntarily disclose certain financial relationships between physicians and industry.

Eli Lilly was the first pharmaceutical company to commit to creating a publicly-accessible and searchable internet database listing 2009 payments to physicians who serve as speakers and advisors to the company.[23] Likewise, Merck declared that it would disclose all 2009 payments to physicians who speak on behalf of Merck.[24] In addition to publicly disclosing compensation made to physician speakers, Pfizer committed to disclosing all compensation that it pays to U.S. healthcare professionals and providers (including principal investigators, academic institutions, and clinical research sites) for consulting and clinical trials.[25] Pfizer plans to publish its first annual report on its Web site in early 2010, which will include compensation made from July 1, 2009 onward. The annual report will include the healthcare professional's name or institution receiving compensation, the payment made and the services provided in exchange for the compensation. Pfizer has not set a dollar threshold but is considering reporting payments whose aggregate amount exceeds $500 in a calendar year, including the value of non-monetary items, such as meals, that exceed $25 in value.

A few healthcare institutions, including Cleveland Clinic, University of Pennsylvania School of Medicine and its health system (Penn Medicine) and Park Nicollet Health Services in Minnesota have also committed to publicly disclosing ties that its medical staff members have with drug and device companies. Currently, every scientist and physician employed by Cleveland Clinic (about 1,800) must report any drug and device industry relationship to the Clinic at least once a year. The Clinic has been working, for more than a year, on setting up a Web site that lists all consulting payments of more than $5,000 per year and all royalty payments from and equity interests in drug and device companies.[26]

Similarly, in spring of 2009, Penn Medicine plans to launch a Web site that contains searchable information on all the outside activities of its physicians and scientists.[27] Penn Medicine's proposed Web site would expand on its current internal policies aimed at reducing the influence of drug and device companies that ban staff from accepting gifts, meals and free drug samples.

Park Nicollet Health Services requires all credentialed health care professionals, including doctors, physician assistants, nurse midwives and physical therapists, to disclose industry ties.[28] The compensation relationships are currently listed in $5,000 increments on the hospital's Web site, which is updated quarterly.

Over the past six months, there has been at least a monthly announcement of an entity that has decided to voluntarily disclose ties between physicians and industry to the public. This trend will most likely continue until the federal law is passed mandating public disclosure.

VI. Conclusion

There is no doubt that transparency and accountability are the trend in many sectors of the healthcare industry. As with the new transparency requirements from the Internal Revenue Service on nonprofit hospitals, the federal government is now seeking transparency from the drug and device companies on their relationships with physicians. The revised PhRMA and AdvaMed codes are steps in the right direction, but in light of the momentum behind federal legislation, such self-regulation may be a little too late to avoid government oversight. Industry and provider groups are beginning to embrace this impending federal legislation and some have decided to voluntarily disclose these ties to the public with new Web sites.

There are several questions that still remain. What will be the effect of publicly disclosing physician-industry ties? How will patients view the disclosure of this information? There may be a "chilling effect" on research and development in the United States. Multi-national drug and device manufacturers may begin to shift their research and development overseas.

Although there is a wave of public pressure and economic necessity driving us toward this new age of transparency and accountability, there is also a tremendous potential through these measures to achieve the goals of lowering costs, alerting patients to their providers' conflicts, gaining patient trust and ultimately enhancing the quality and efficacy of drugs and devices on the market.

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13. Vt. Stat. Ann. tit. 33, § 2005.

14. Me. Rev. Stat. Ann. tit. 22, § 2698-A.

15. W. Va. Code Ann. § 5A-3C-13.

16. Ma. Gen. Laws ch. 111N.

17. Mass. Regs. Code tit. 105, § 970.000.

18. Arizona (S.B. 1250), Hawaii (S.B. 2534), Illinois (H.B. 872 and H.B. 4486), New Hampshire (H.B. 1518), New Jersey (A. 754), New York (A. 1550 and A. 7468a/S. 2971), Rhode Island (S. 653), Washington (S.B. 5917 and S.B. 6307) and Wisconsin (A.B. 12).

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