



Health Law Alert

Legal and political developments affecting the health care industry

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New Jersey Attorney General recommends new regulations to curtail potential conflicts of interest between physicians and industry

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On December 3, 2009, New Jersey Attorney General Anne Milgram released a “Report on Physician Compensation” authored by the Division of Consumer Affairs and endorsed its recommendations for a reform initiative aimed at regulating the financial relationships between physicians and industry. The report recommends a series of regulations that would ban doctors from accepting free meals, gifts, fees, or travel-expense reimbursement from pharmaceutical or medical-device companies. Under the proposed rules, doctors could still serve as consultants to drug and device companies, but would have to publicly disclose any consulting fees, honoraria or funding for research or education in amounts of \$200 or more. Although several states have imposed similar gift bans and disclosure requirements on pharmaceutical and medical device manufacturers, New Jersey would become the first state to impose such restrictions and obligations directly on physicians if it adopts the Report’s recommendations.

Prohibitions on gifts, meals, and reimbursements

The Pharmaceutical Research and Manufacturers of America (PhRMA) and Advanced Medical Technology Association (AdvaMed), the two leading industry associations for drug and device companies, have each promulgated voluntary codes of ethics to guide their members’ interactions with physicians. The PhRMA and AdvaMed codes generally prohibit companies from providing physicians with entertainment or recreational items (such as tickets to theater or sporting events, sporting equipment, or vacations), non-educational items (such as pens, note pads, mugs, and similar “reminder” items with company or product logos), items that can be used by doctors or their families for non-educational or non-patient-related purposes (such as DVD players or i-Pods), and other types of gifts (such as cookies, wine, flowers, cash, or gift certificates). Although many drug and device companies voluntarily adhere to these industry standards, the report endorsed by the New Jersey Attorney General recommends regulations that would not only mirror and—in certain instances—go beyond, the PhRMA and AdvaMed codes, but would also be enforceable against physicians licensed by the state.

The report recommends amendments to the New Jersey Board of Medical Examiners (BME) regulations that would forbid physicians from accepting any of the following from a drug or device company:

- Any payment or other subsidy (including tuition, fees, travel, lodging, or other incidental expenses) to support attendance as a participant at an accredited continuing medical education (CME) program.
- Any fees or travel or lodging reimbursement for non-faculty or non-consultant attendees at company-sponsored meetings.
- Items intended for a physician's personal benefit (such as tickets to sporting events, flowers, CDs, or DVDs) or items that may be used in both a professional and non-professional setting (such as DVD or CD players).
- Any payment in cash or a cash equivalent (such as a gift certificate) unless it is compensation for bona-fide services.
- Any company-funded entertainment or recreational item.

The suggested regulations would allow doctors to accept items that could directly benefit patients, such as drug samples or anatomical models for use in examination rooms. In addition, physicians would be permitted to accept things of value, such as remuneration for serving as a speaker or faculty organizer for CME events, which directly benefit patients by advancing physician learning or legitimate research goals.

The PhRMA and AdvaMed codes generally permit drug and device companies to provide physicians with modest meals in clinical settings if these are accompanied by an informational presentation. The report, however, recommends that doctors be prohibited from accepting any free food or meals from manufacturers, whether in-office, at health-care facilities, or in commercial settings such as restaurants. The report notes that doctors interested in learning about new products can accept literature about new treatments and therapies and listen to informational company presentations in a clinical setting, but should be required to pay the fair-market value for any food provided in connection with such events.

Disclosure obligations

The report recognizes that physicians should be allowed to serve as consultants to manufacturers, provide training on behalf of companies, and participate in the research and development of new treatments and therapies. Under the suggested regulations, however, a physician would have to disclose these financial relationships every two years when renewing his or her license. If adopted, the new rules would obligate doctors to disclose, in a publicly available, searchable database, the receipt of more than \$200 during the preceding two years from manufacturers in the form of compensation, food, travel, consulting fees, or honoraria; funding for research; funding for education; stock or stock options; ownership or investment interests; or any other economic benefit. Physicians also would be required to post notices in their offices advising their patients about the database.

Requiring physicians to disclose research funding may prove to be especially controversial, as public disclosure of a company's arrangements with the investigators of its clinical trials could reveal sensitive and proprietary business information to its competitors.

Continuing Medical Education

The report notes that, while CME providers maintain control of program planning, many observers believe that industry-funded courses are nonetheless promotional in nature. The report therefore recommends new regulations to provide credit only for those CME courses that meet standards issued by the Accreditation Council for Continuing Medical Education (ACCME) that bar CME providers from obtaining advice from a subsidizing company as to faculty or content. Under the proposed regulations, physicians engaged to serve as CME speakers would be required to disclose to attendees, at the beginning of their presentations, the receipt of any reportable compensation from manufacturers.

Prescription data

The report recommends strict controls on the use of physician prescription information. Under the suggested rules, all doctors would be notified when renewing their licenses of their right to opt out of having information about their prescribing sold by pharmacies to health-care information organizations. The report suggests that the state Board of Pharmacy amend its regulations to require pharmacies to maintain documentation confirming that prescribers have consented to the sale of their prescribing information. In addition, the report recommends legislation to restrict the use and sale of prescriber information for commercial purposes (the constitutionality of which may be subject to challenge on free-speech grounds).

Health-care facilities

The suggested regulations also concern the potential conflicts of interest that may arise in academic medical centers, hospitals, and other health-care institutions licensed by the New Jersey Department of Health and Senior Services (DHSS). The report encourages DHSS to promulgate policies and procedures that address the following:

- Creating a standardized conflict of interest form for use by all licensed New Jersey health-care facilities.
- Whether physicians with financial interests should serve on advisory bodies, such as formulary committees, purchasing committees, or groups established to develop practice guidelines, or should conduct clinical trials or participate in institutional review boards.
- Whether disclosures of interests should be mandated in in-hospital educational venues before presentations begin (such as grand rounds, patient rounds, and classroom sessions).
- Creating programs that allow community hospitals to ensure that the acceptance of industry funding for CME does not skew the message of educational sessions.
- Creating a system to manage conflicts, to avoid potential detriment to the safety of clinical trial participants or to the integrity of the research.

The rule-making process

Attorney General Milgram has asked the New Jersey Board of Medicine and Board of Pharmacy to review the report and initiate a rule-making process to adopt its recommendations. Any regulations the boards propose will be published in the *New Jersey Register* and will be subject to public comment. Nixon Peabody will continue to monitor this process and will issue additional alerts regarding any future developments.

A copy of the “Report on Physician Compensation Arrangements” can be found at the website of the New Jersey Attorney General: <http://www.nj.gov/oag/newsreleases09/pr20091203b-ReportOnPhysicianCompensationArrangements.pdf>

Contact us

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