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Client Alert

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New York and New Jersey Propose New Rules Restricting Sales and Marketing Practices of Pharmaceutical and Medical Device Companies

In the latest example of the growing trend to enact laws aimed at sales and marketing practices in the pharmaceutical and medical device industries, New York and New Jersey have proposed rules that, if enacted, would substantially limit such marketing activities. To date, states such as California, Nevada, and Massachusetts have implemented laws that require drug and device manufacturers to adopt a compliance program and/or a marketing code of conduct that affects payments made to health care professionals (HCPs). Last year, Massachusetts and Vermont were the first states to require drug and device manufactures to publicly disclose payments to HCPs licensed to practice in those states. In a new twist, if the proposed rules are enacted, New York and New Jersey would be the first states to impose restrictions and obligations directly on physicians licensed in those states.

As the number of states prohibiting gifts and entertainment and requiring financial disclosures grows, pharmaceutical and device companies will continue to face compliance challenges. Companies must review their policies and procedures and training programs to ensure that their employees understand the new restrictions imposed by the states. Further, pharmaceutical and device companies must take the necessary steps to ensure compliance with the different obligations in each state.

This Client Alert provides a brief overview of recent proposals in New York and New Jersey to limit pharmaceutical and device companies' interactions with health care professionals. The overview does not cover every aspect of the proposals in each state but provides an overview of significant points to consider.

Brief Overview of Industry codes

The Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed), two leading industry associations for drug and device companies, have each promulgated voluntary codes of ethics to guide their members' interactions with physicians. In general, the PhRMA and AdvaMed Codes 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

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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 wine, flowers, cash, or gift certificates). While New York and New Jersey's proposed rules mirror certain provisions of the PhRMA and AdvaMed Codes, in certain instances, they go beyond and would also be enforceable against physicians licensed in those states.

New York's Proposal

On January 19, 2010, New York Governor David Paterson introduced Senate Bill 6608. Senate Bill 6608, introduced as part of the 2010-11 New York State Executive Budget, includes a provision to add Section 279, "Interactions Between Pharmaceutical Companies and Health Care Professionals," to the Public Health Law (Section 279). Like other current state marketing laws and industry codes, proposed Section 279 provides a code of conduct applicable to "all companies that sell or market prescription drugs, biologics or medical devices in the state."

Significantly, Section 279 provides a code of conduct that applies directly to HCPs practicing in the state to whom such drugs, biologics or medicals devices are sold or marketed. In addition, Section 279 includes certain provisions that differ from other state marketing laws and industry codes. For instance, in many cases, provisions related to continuing medical education (CME) differ substantially from current state marketing laws and industry codes. These will be discussed shortly.

Compliance with Section 279 will be mandatory. A violation of Section 279 by a pharmaceutical or device company may result in a civil penalty of $15,000 to $250,000 per violation. Further, a violation of Section 279 by a HCP will constitute "professional misconduct." HCPs may also be subject to a civil penalty of $5,000 to $10,000 per violation and other penalties, including censure and reprimand and suspension of license.

Under Section 279, a pharmaceutical company is defined to include a medical device company. Specifically, Section 279 defines a pharmaceutical company as an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, biologics, or *medical devices*, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis. A copy of the proposal is available here.[1]

Overview of Section 279

- **Independence.** Section 279 prohibits a pharmaceutical company from offering, and HCPs from accepting:
    1. any financial support including, but not limited to, any grant, scholarship, subsidy, support, consulting contract, speaker contract or education or practice-related items to reward the

1 http://publications.budget.state.ny.us/eBudget1011/fy1011artVIIbills/HMH_ArticleVII.pdf

HCP for having prescribed particular drugs, biologics or medical devices in the past, or to induce the HCP to prescribe or continue prescribing products in the future;
2. any good or service that would interfere with the independence of the HCP's prescribing practices; or
3. any payment in cash or cash equivalents, either directly or indirectly, except as compensation for bona fide consulting services or speaker services.

- **Promotional Materials.** Section 279 prohibits a pharmaceutical company from providing any promotional materials to HCPs unless the materials:
  1. are accurate and not misleading;
  2. make claims about a product only when properly substantiated;
  3. accurately reflect the balance between risks and benefits;
  4. are consistent with all other requirements of the U.S. Food and Drug Administration; and
  5. do not violate state consumer protection law.

- **Meals.** Section 279 permits occasional, modest meals by a pharmaceutical company to HCPs and staff if certain conditions are met. Specifically, meals must be provided in connection with a structured, oral informational presentation that provides scientific and educational value and may only be provided to the HCP and members of their staff attending the presentation. Meals may not be offered or provided to spouses or other guests of the HCP. If the meal is provided by a pharmaceutical company's field representative or manager, the meal must be provided in the HCP's office or hospital setting, except meals provided in connection with a bona fide consulting or speaking agreement. A pharmaceutical company may not provide meals as part of any entertainment or recreational event.[2]

- **Entertainment.** A pharmaceutical company may not offer or provide, and HCPs may not accept, entertainment or recreational items, including sporting event tickets and leisure trips.

- **CME.** Pharmaceutical companies are prohibited from being a CME provider in the State of New York. A pharmaceutical company cannot sponsor a CME program unless the company has adopted a specific policy and is in compliance with such policy. The policies must include the following provisions:
  1. the company's CME grant-making functions are separate from sales and marketing;
  2. the company has developed and utilizes objective criteria for making CME grant decisions;
  3. the company agrees to respect the independent judgment of the CME provider and to follow standards for commercial support established by the Accreditation Council for CME or an equivalent national accreditation body. Further, pharmaceutical companies are prohibited from providing a CME provider any advice or guidance related to program faculty or content, even if requested by the CME provider. Pharmaceutical companies may provide certain information to a HCP presenter at a CME program if the criteria for promotional materials, discussed

2 Section 279 permits a pharmaceutical company to provide modest meals or receptions during company-sponsored meetings to HCPs with whom they have bona fide consulting or speaker arrangements, but may not provide recreational or entertainment events in conjunction with such meetings.

above, is met. Pharmaceutical companies are also prohibited from offering or providing an HCP any financial support in connection with the HCP's attendance or presentation at a CME program including, but not limited to, financial support to compensate the HCP for time spent attending or presenting the CME or reimbursement for costs of travel, lodging, or other personal expenses incurred from attendance or presentation at the CME.[3]

Section 279 also imposes several requirements on HCPs related to CME. For instance, a HCP may not attend or present at a CME event in New York that is sponsored by a pharmaceutical company, unless the CME provider advises the HCP that the pharmaceutical company sponsor has provided assurances that it has the required policies in place and is in compliance with such policies. A HCP may not present or make available any materials provided by a pharmaceutical company at a CME unless such materials are, to the best of the HCP's knowledge, based on a reasonable inquiry, consistent with the requirements for promotional materials discussed above.[4] Furthermore, a HCP presenter may not represent that the HCP authored any materials discussed, distributed or presented by the HCP unless the HCP made "substantial contributions to the intellectual content" of the materials. Additionally, an HCP is obligated to disclose the existence and nature of any financial support that the HCP received or expects to receive from a pharmaceutical company that sponsors the CME event or a pharmaceutical company that manufactures, distributes or markets any drug, biologic or medical device discussed in the presentation or commonly prescribed for a disease, injury or condition discussed in the presentation.

- **Professional Conferences and Meetings.** Section 279 prohibits a pharmaceutical company from offering or providing support to compensate an HCP's attendance or participation in a professional conference or meeting or as reimbursement for travel, lodging and other personal expenses. However, a conference or meeting planner may, at its own discretion, use support from a pharmaceutical company to reduce the overall registration fee for all attendees. With the exception of company-sponsored meetings, a pharmaceutical company may not provide support for a professional conference or meeting in which it has responsibility for or control over the selection of content, faculty, educational methods, materials or venue.

- **Consulting and Speaking Agreements.** A pharmaceutical company may not provide financial support to a HCP and a HCP may not accept financial support pursuant to a consulting or speaker agreement unless:

3 Section 279 permits a pharmaceutical company to provide financial support for the costs of travel, lodging, or other personal expenses to a HCP attending or presenting at a CME program who is a full-time salaried employee of the pharmaceutical company, or who is engaged by the company as a speaker or consultant pursuant to a bona fide agreement and such financial support is provided pursuant to such agreement. Further, a pharmaceutical company may provide financial support to the sponsor of a conference or meeting, which may be used by the sponsor to reduce the overall conference registration fee for all attendees.

4 Any materials presented or made available by the HCP must be consistent with the following requirements: (1) materials are accurate and not misleading; (2) claims are properly substantiated; (3) materials accurately reflect the balance between risks and benefits; (4) materials are consistent with all other FDA requirements; and (5) materials do not violate state consumer protection law.

1. the agreement is a bona fide consulting or speaker agreement; and
2. the financial support constitutes reasonable compensation for the professional's consulting or speaker services and reasonable reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing such services, and is based on fair market value. With respect to speaking agreements, the HCP must possess general medical expertise, reputation, knowledge and experience regarding a particular therapeutic area and communication skills reasonably expected from a speaker in the relevant field. Moreover, Section 279 requires each pharmaceutical company to set a cap for the total amount of annual compensation that it will pay to a HCP in connection with all speaking agreements. Each company must periodically monitor speaker programs for compliance with FDA requirements and provide to HCPs "extensive training on the company's drug products or other specific topic to be presented and on compliance with [FDA] regulatory requirements for communications." Speaker training must be held in a venue conducive to the training and a pharmaceutical company must reasonably believe that the training will result in the HCP providing a valuable service to the company.

- **Promotional Speaker Programs.** A pharmaceutical company may provide modest meals at a speaker program if the meal is offered to all attendees and the venue is conducive to an information presentation. In addition, the pharmaceutical company is responsible for ensuring that each speaker and his or her materials clearly identify:
  1. that the company is sponsoring the event;
  2. the speaker is presenting on behalf of the company; and
  3. the speaker is presenting information consistent with FDA guidelines.

- **Scholarships and Other Financial Support.** A pharmaceutical company may provide scholarships or other financial support for medical students, residents, fellows and other HCPs in training to attend major educational, scientific or policy-making meetings or conferences held by national, regional or specialty medical associations if the recipient is chosen by the academic or training institution.

- **Prescriber Data.** Section 279 describes specific requirements on pharmaceutical companies that obtain prescriber data. For instance, pharmaceutical companies that obtain prescriber data from HCPs are required to:
  1. comply with all applicable laws and regulations to maintain the confidential nature of the data;
  2. develop written policies regarding the use of the prescriber data;
  3. educate its employees on such policies;
  4. designate an internal person to handle inquiries regarding the data; and
  5. identify appropriate disciplinary action for misuse of the data. Further, if a HCP requests that his/her prescriber data not be available for sales and marketing purposes, the pharmaceutical company must abide by the request.

- **Gifts and Educational Items.** A pharmaceutical company is prohibited from offering or providing to a HCP and/or the HCP's staff any item or service intended for personal benefit, cash or cash equivalents (except as compensation for bona fide services), and any other tangible item except certain permissible educational items. This prohibition includes items, such as floral arrangements, artwork, compact discs or tickets to a sporting event, and items with minimal value, such as pens, note pads, or mugs. Educational items are permitted under Section 279 so long as the items are provided on an occasional basis, are of limited value, and do not have value to the HCP outside of his or her professional responsibilities, such as an anatomical model for use in an examination room.

- **Representative Training.** Pharmaceutical company representatives that visit HCPs must be trained on applicable laws and regulations, general science, and product-specific information "sufficient to allow the representatives to provide accurate, up-to-date information, consistent with" FDA requirements. Further, companies must periodically monitor their representatives to ensure compliance with applicable laws, regulations and company policies and to take appropriate action if a representative is not compliant in those areas.

New Jersey's Proposal

On December 3, 2009, the New Jersey Attorney General released a report entitled, "Report on Physician Compensation" (the Report), authored by the Division of Consumer Affairs. A copy of the Report is available here.[5] The Report recommends the drafting of regulations governing the financial relationships between physicians and pharmaceutical and device manufacturers. The Report recommends banning physicians from accepting certain gifts, meals, fees, or travel expenses from any pharmaceutical or medical device manufacturer. In addition, the Report would require physicians to publicly disclose any consulting fees, honoraria or funding for research or education in amounts of $200 or more.[6]

The Report recommends certain amendments to the New Jersey Board of Medical Examiners (BME) regulations including, but not limited to, the following.

- **Gifts.** The Report recommends that BME regulations be amended to prohibit a physician from accepting from any pharmaceutical or medical device manufacturer any of the following:
  1. payments, including tuition, fees, travel, lodging or other incidental expenses, to support attendance as a participant at an accredited CME program;
  2. fees, travel, or lodging reimbursement for non-faculty or non-consultant attendees at company-sponsored meetings;
  3. items intended for the personal benefit of a physician (such as floral arrangements, artwork, CDs, DVDs or tickets to a sporting event), or items that may have utility in both the professional and non-professional setting (such as a DVD or a CD player);

5 http://www.nj.gov/oag/newsreleases09/pr20091203b-ReportOnPhysicianCompensationArrangements.pdf
6 The Report does not include any recommendations relating to penalties for non-compliance.

4. payments in cash or a cash equivalent (such as a gift certificate) unless it is compensation for bona fide services such as serving as a consultant or participating in research or publication activities; and
5. company-funded entertainment or recreational items, unless the physician is a salaried employee of the company.

- **Meals.** The Report recommends that BME regulations be amended to:
  1. prohibit physicians and office staff from accepting any food from manufacturers, regardless of the setting;
  2. require physicians attending unaccredited educational or promotional sessions organized by manufacturers at which meals are served to pay the fair market value for the meals; and
  3. allow the receipt of modest meals at continuing medical education seminars, third-party conferences and professional meetings accredited by the Accreditation Council for Continuing Medical Education, where the provision of meals facilitates the scheduling of the educational program to maximize physician learning, and where such meals are provided at the discretion of the CME provider, and are not paid for directly by manufacturers.

- **Free Samples.** The Report recommends that BME regulations permit continued receipt of sample medications by physicians for the exclusive benefit of patients.

- **Disclosure Obligations.** The Report recognizes that physicians should be allowed to serve as consultants to manufacturers, participate in the development of new treatments and therapies, and provide training on behalf of the companies. However, the Report recommends that BME regulations mandate that physicians disclose whether they accepted more than $200 from manufacturers, whether in cash, food, travel, consulting fees, research funding, or any other economic benefit, every two years as part of the license renewal process. The required disclosure would include the name of the company, the value, date and nature of the payment, and if applicable, the name of the product, and whether the payment is related to marketing, education or research pertaining to a specific drug, device, biological or medical supply. The Report also recommends legislation requiring manufacturers to disclose payments and other things of value made to physicians, physician practices and physician groups.

- **CME.** The Report recommends that CME regulations be amended to:
  1. provide credit only for those CME courses that meet the Accreditation Council for Continuing Medical Education or American Osteopathic Association standards that specifically bar the CME provider from obtaining advice from a subsidizing company as to faculty or content;
  2. impose an obligation on physicians who are engaged as CME speakers to directly disclose to attendees, at the beginning of the presentation, the receipt of reportable compensation from manufacturers; and
  3. initiate a requirement that 25 percent of CME be obtained in evidence-based educational programs

(i.e., educational programs that are not funded by industry or promotional in nature) or through academic detailing.

- **Data Mining.** The Report recommends strict controls on the use of physician prescription information. The Report recommends that BME regulations be amended to provide that all doctors be notified when renewing their licenses of their right to opt out of having information about their prescribing sold by pharmacies to healthcare information organizations. In addition, the Report recommends that the New Jersey Board of Pharmacy regulations be amended to require pharmacies to maintain documentation confirming that prescribers have consented to the sale of their prescribing information. The Report also recommends the enactment of legislation to restrict the transfer, use or sale of prescriber-identifiable prescription information for commercial purposes.

- **Physicians-in-training.** The Report recommends amending BME regulations to hold physicians, who are serving as faculty and preceptors, accountable to adhere to the Association of American Medical Colleges (AAMC) guidelines, both on and off campus.

- **Physician Accountability.** The Report recommends that BME regulations be amended to prohibit physicians from:
  1. recklessly providing inaccurate and misleading information in educational or promotional venues;
  2. claiming authorship of any article or study unless they, in fact, authored the work in question; and
  3. misrepresenting financial interests in any required disclosure form, including through the omission of required information.

The Report also addresses concerns regarding academic detailing and the potential conflict of interest that may arise in academic medical centers, hospitals, and other healthcare institutions licensed by the New Jersey Department of Health and Senior Services (DHHS).