Arnall Golden Gregory LLP

Client Alert

Contact Attorneys Regarding This Matter:

Alan G. Minsk
404.873.8690 - direct
404.873.8691 - fax
alan.minsk@agg.com

Meredith M. Burris
404.873.8164 - direct
404.873.8165 - fax
meredith.burris@agg.com

Massachusetts State Public Health Council Passes Marketing Restrictions

The Massachusetts State Public Health Council recently unanimously passed regulations that implement a state law relating to a "Pharmaceutical and Medical Device Manufacturer Code of Conduct," which imposes marketing restrictions on pharmaceutical and device companies. The statute and implementing regulations are intended to prevent undue influence by pharmaceutical and medical device companies on healthcare professionals and to increase the transparency of interactions between the groups. The Massachusetts regulations take effect on July 1, 2009. The first public reporting by companies of payments to healthcare professionals is due by July 1, 2010.

Massachusetts is the first state to require financial disclosure of remuneration to healthcare providers by medical device manufacturers, although a number of states have passed laws requiring disclosure by pharmaceutical manufacturers. It also makes disclosure data publicly available via the internet.

General Requirements

By July 1, 2009, each pharmaceutical or medical device company must:

- adopt a marketing Code of Conduct;
- adopt and submit to the Department of Public Health a description of a training program to provide regular training to appropriate employees, including all sales and marketing staff, on the marketing Code of Conduct, which must ensure that all representatives who are employed by, or acting on behalf of, the company and who visit healthcare practitioners have sufficient knowledge of:
    1. the marketing Code of Conduct,
    2. general science, and
    3. product-specific information to provide accurate and correct information, consistent with state law and FDA requirements;
- provide for regular assessments of persons who are employed by, or acting on behalf, of the company to ensure that they comply with state requirements and other relevant company policies;
- certify to the Department, to the best of the company's belief that it is in compliance with the law;
- adopt and submit to the Department policies and procedures for investigating non-compliance, taking corrective action in response to non-compliance, and reporting instances of non-compliance to the appropriate state authorities; and

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

- submit to the Department the name, title, address, telephone number and electronic mail address of the compliance officer it has identified as responsible for certifying compliance with the law, and implementing, monitoring, and enforcing the company's marketing Code of Conduct.

Both pharmaceutical and medical device distributors are included in the definition of "pharmaceutical and medical device manufacturers" and, as such, must comply with the state requirements.

Payments to Healthcare Practitioners

Companies may engage healthcare professionals to perform bona fide services, such as conducting research, participating on advisory boards, and presenting at pharmaceutical or medical device company-sponsored medical education and training programs, so long as:

- the arrangement is formalized in writing and specifies the services to be provided, based on the fair market value of the services;
- a legitimate need for the services is clearly identified in advance;
- a connection between the competence and expertise of the healthcare practitioner and the purpose of the arrangement is made;
- the number of healthcare practitioners retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the pharmaceutical or medical device manufacturing company maintains records concerning the arrangement and makes appropriate use of the services provided by the healthcare practitioner;
- the venue and circumstances of any meeting with the healthcare practitioner is conducive to the services, and activities related to the services are the primary focus of the meeting; and
- the decision to retain a healthcare practitioner is not unduly influenced by a pharmaceutical or medical device company's sales personnel.

Pharmaceutical and medical device companies may not provide:

- entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, concerts, sporting equipment, or leisure or vacation trips, to any healthcare practitioner who is not a salaried employee of the pharmaceutical or medical device manufacturing company;
- payments of any kind, including cash or cash equivalents, equity, in kind or tangible items, including any complimentary items, such as pens, coffee mugs, and gift cards, to healthcare practitioners, either directly or indirectly, except as compensation for bona fide services;

- any grants, scholarships, subsidies, supports, consulting contracts, or educational or practice-related items in exchange for prescribing, disbursing, or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing, or using prescription drugs, biologics or medical devices;

  or

- any other payment or remuneration, in cash or in kind, directly or indirectly, including any rebate or "kickback" that is prohibited under applicable federal or state fraud and abuse laws or regulations, including the federal Anti-kickback Statute and equivalent state laws.

Prescriber Data

Each pharmaceutical manufacturing company that uses non-patient identified prescriber data to facilitate communications with healthcare practitioners must: (1) maintain the confidential nature of prescriber data; (2) develop policies regarding the use of the data; (3) educate employees and agents about these policies; (4) designate an internal contact person to handle inquiries regarding the use of the data; (5) identify appropriate disciplinary actions for misuse of the data; and (6) comply with the request of any healthcare practitioner not to make the prescriber data available to company sales representatives.

Disclosure of Consultant Relationship

In all speaker and commercial consultant contracts, pharmaceutical companies must require any healthcare practitioner who (1) is a member of a committee that sets formularies or develops clinical guidelines and also (2) serves as a speaker or commercial consultant for the company to disclose to the committee the nature and existence of the relationship with the company. This disclosure requirement must extend for at least two years beyond the termination of any speaker or consultant arrangement.

Meals

With limited exception described in the next section, pharmaceutical and medical device companies may not provide or pay for meals for healthcare practitioners that:

- are part of an entertainment or recreational event;

- are offered without an informational presentation made by a company representative or agent or without such a representative being present;
- are offered, consumed, or provided outside of the healthcare practitioner's office or a hospital setting; and/or

- are provided to a healthcare practitioner's spouse or other guest.

Continuing Medical Education, Third-Party Scientific or Educational Conferences, or Professional Meetings

Pharmaceutical and medical device companies may not provide:

- financial support for the costs of travel, lodging, or other personal expenses of non-faculty healthcare practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, either directly to the individuals participating in the event or indirectly to the event's sponsor;

- funding to compensate for the time spent by healthcare practitioners participating in any CME event, third-party scientific or educational conferences, or professional meetings;

- payment for meals directly to a healthcare practitioner at any CME event, third-party scientific or educational conferences, or professional meeting; however, a CME provider or conference or meeting organizer may, at its own discretion, apply any financial support provided by a pharmaceutical or medical device company for the event to provide meals for all participants; or

- sponsorship or payment for CME, also known as independent medical education, that (1) does not meet the Standards for Commercial Support, as established by the Accreditation Council for Continuing Medical Education, or (2) does not meet equivalent commercial support standards of a relevant continuing education accrediting body, or (3) that provides payment directly to a healthcare practitioner.

In addition, a pharmaceutical or device manufacturing company must separate its CME grant-making functions from its sales and marketing departments. The company must not provide any advice or guidance to a CME provider regarding the content or faculty for a particular CME program funded by the company.

The regulations do not prohibit the following:

- compensation or reimbursement made to a healthcare practitioner serving as a speaker or providing actual and substantive services as a faculty organizer or academic program consultant for a CME event, third-party scientific or educational conference, or professional meeting, provided that the payment:

    1. is reasonable,
    2. is based on fair market value, and
    3. complies with the standards for commercial support as established by the relevant ac creditation entity;

- sponsorship or payment for any portion of a third-party scientific or educational conference, charitable conference or meeting, or professional meeting, where the payment is made directly to the conference or meeting organizers; or

- the use of hotel facilities, convention center facilities or other special event venues for CME or other third-party scientific, educational or professional meetings or conferences (i.e., not limited to hospital settings).

The regulations further allow scientists employed by drug and medical device companies to participate in CME and third-party meetings and to "present on specific products or treatment methodologies, as long as it is in the context of providing attendees a balanced and objective presentation of all alternative treatments and therapies."

Training on Device Usage

The state law does not limit where training on medical devices may occur. However, the regulations provide:

> Meals may only be provided in a "hospital setting," which is defined, for the purposes of training, not in terms of venue, but in terms of the activity which is taking place. As long as a facility is specially designed to approximate the conditions of a surgical suite, or the conditions of a working clinical laboratory or to provide medical training on large and/or technical medical devices, the facility meets the conditions of a "hospital setting" where medical training and meals in conjunction with such training may occur.

It is important to note, however, that, according to the Massachusetts regulations, a sales contract must be in place before a company can pay for a healthcare professional's travel and lodging expenses to attend a training on device usage. A company no longer can cover costs for a healthcare professional who wants evaluate a device before deciding whether or not to purchase it.

Disclosure of Payments

Beginning July 1, 2010, and annually on or before July 1 of each year thereafter, every pharmaceutical or medical device company must disclose to the Department of Public Health the value, nature, purpose and particular recipient of any fee, payment, subsidy or other economic benefit with a value of at least $50, which the company provides, directly or through its agents, to any covered recipient in connection with the company's sales and marketing activities. For the purposes of computing the $50 threshold, fees, payments, subsidies and other economic benefits relating to separate events or transactions must be calculated on an individual transactional basis and must not be aggregated.

The law defines "sales and marketing activities" as:

> advertising, promotion, or other activity that is intended to be used or is used to influence sales or the market share of a prescription drug, biologic or medical device; to influence or evaluate the prescribing behavior of a covered recipient to promote a prescription drug, biologic, or medical device; to market a prescription drug, biologic, or medical device; or to evaluate the effectiveness of a professional pharmaceutical or medical device detailing sales force. Sales and marketing activities also include any product education, training, or research project that is designed or

sponsored by the marketing division of a pharmaceutical or medical device manufacturing company or has marketing, product promotion, or advertising as its purpose.

While companies may conduct certain sales and marketing activities to benefit healthcare professionals, these must be transparent. Sales and marketing activities do not include clinical trials and genuine research, particularly where the primary purpose is to generate data in support of an application filed with FDA seeking approval for a new drug, biologic or medical device or "new use" or similar marketing or labeling claim requiring FDA approval.

The Department regulations require disclosure of industry payments to such physicians if they are made:

- indirectly through charitable donations to universities or hospitals where a healthcare practitioner is employed or affiliated;
- pursuant to a bona fide services agreement (except for genuine research or clinical trials), as compensation for serving as a faculty at a conference;
- to sponsor a CME, third-party professional, or scientific meeting or conference; or
- for meals or for any other permissible activity under the regulations.

The Department expressly exempted from disclosure the provision of price concessions, such as rebates and discounts, prescription drugs provided to a covered recipient solely and exclusively for use by patients (e.g., samples), and demonstration and evaluation units. The Department determined that requiring disclosure of price concessions, such as rebates and discounts, may lead to a restraint of trade in violation of Federal Trade Commission requirements and lead to increases in the costs of products.

Charitable donations by drug and medical device companies are permitted, but should "not [be] provided in exchange for prescribing, disbursing or using prescription drugs, biologics or medical devices or for a commitment to continue prescribing, disbursing or using prescription drugs, biologics or medical devices."

Clinical trials that are posted on clinicaltrials.gov are exempt from disclosure.

Each annual disclosure report must be accompanied by a fee of $2,000. The first annual payment of $2,000 is due on July 1, 2009. There will be no sliding scale for the imposition of the $2,000 disclosure fee on smaller medical companies and start-ups.

Disclosures must be made for the previous calendar year using a standardized reporting format developed by the Department. The first required disclosure report must cover the period from July 1, 2009 through December 31, 2009. Each annual disclosure report may be submitted to the Department electronically.

These regulations caution that pharmaceutical or medical device companies must not structure fees, payments, subsidies or other economic benefits to healthcare practitioners to circumvent the reporting requirements. Pharmaceutical or medical device companies must also certify that, to the best of the company's knowledge, their reports are true and accurate.

Audits

Beginning on July 1, 2010, and annually on or before July 1 of each year thereafter, each pharmaceutical and medical device company must certify to the Department that it has conducted annual audits to monitor compliance with the state regulations.

Penalties

- Entities authorized to enforce these regulations include the Attorney General of Massachusetts, the District Attorney "with jurisdiction over a violation," or the Department of Public Health.
- A person who knowingly and willfully violates the regulations faces a fine of not more than $5,000 for each transaction, occurrence or event.
- No pharmaceutical or medical device company may retaliate or take any adverse action against anyone who seeks to ensure compliance.
- Ten days prior to the issuance of any fine, the government must provide notice and an informal opportunity to dispute the issuance of the fine.
- Anyone issued a fine may seek judicial review in the Superior Court.

Observations

More states are expected to issue laws to restrict companies' marketing activities and make more transparent interactions with healthcare professionals. In addition, in light of current state budgetary shortfalls, state enforcement in this area may increase, including the imposition of fines for non-compliance in those states that have passed laws.

It is too early to predict whether federal legislation addressing these issues will be enacted, and, if so, what impact such legislation would have on state initiatives. In the interim, companies must continue to ensure corporate policies comply with applicable state laws and trade association codes of conduct to minimize risk. Furthermore, auditing and monitoring is necessary to track such compliance and, if needed, to take corrective action.