

CHAPTER 111N

PHARMACEUTICAL AND MEDICAL DEVICE MANUFACTURER CONDUCT

Section 1. As used in this chapter, the following words shall have the following meanings:

"Department", the department of public health.

"Health care practitioner", a person who prescribes prescription drugs for any person and is licensed to provide health care, or a partnership or corporation comprised of such persons, or an officer, employee, agent or contractor of such person acting in the course and scope of his employment, agency or contract related to or in support of the provision of health care to individuals.

"Marketing code of conduct" practices and standards that govern the marketing and sale of prescription drugs or medical devices by a pharmaceutical or medical device manufacturing company to health care practitioners.

"Medical device", an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory, which is: (1) recognized in the official National Formulary or the United States Pharmacopeia or any supplement thereto; (2) intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment or prevention of disease, in persons or animals; or (3) intended to affect the structure or function of the body of a person or animal, and which does not achieve its primary intended purposes through chemical action within or on such body and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

"Person", a business, individual, corporation, union, association, firm, partnership, committee or other organization.

"Pharmaceutical or medical device manufacturer agent", a pharmaceutical or medical device marketer or any other person who for compensation or reward does any act to promote, oppose or influence the prescribing of a particular prescription drug, medical device, or category of prescription drugs or medical devices; provided, however, that "pharmaceutical or medical device manufacturer agent" shall not include a licensed pharmacist, licensed physician or any other licensed health care practitioner with authority to prescribe prescription drugs who is acting within the ordinary scope of the practice for which he is licensed.

"Pharmaceutical or medical device manufacturing company", any entity that participates in a commonwealth health care program and which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs 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, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs; provided, however, that "pharmaceutical or medical device manufacturing company" shall not include a wholesale drug distributor licensed under section 36A of chapter 112 or a retail pharmacist registered under section 37 of said chapter 112.

"Pharmaceutical or medical device marketer", a person who, while employed by or under contract with a pharmaceutical or medical device manufacturing company that participates in a commonwealth health care program, engages in detailing, promotional activities or other marketing of prescription drugs or medical devices in the

commonwealth to any physician, hospital, nursing home, pharmacist, health benefits plan administrator, other health care practitioner or person authorized to prescribe, dispense or purchase prescription drugs; provided, however, that the "pharmaceutical or medical device marketer" shall not include a wholesale drug distributor licensed under section 36A of chapter 112, a representative of such a distributor who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug or a retail pharmacist registered under section 37 of said chapter 112 if such person is not engaging in such practices under contract with a manufacturing company.

"Physician", a person licensed to practice medicine by the board of registration in medicine under section 2 of chapter 112 who prescribes prescription drugs, or the physician's employees or agents.

"Prescription drugs", drugs upon which the manufacturer or distributor has placed or is required by federal law and regulations to place the following or a comparable warning: "Caution federal law prohibits dispensing without prescription".

Section 2. Notwithstanding any general or special law to the contrary, the department shall adopt a standard marketing code of conduct for all pharmaceutical or medical device manufacturing companies that employ a person to sell or market prescription drugs or medical devices in the commonwealth. The marketing code of conduct shall be based on applicable legal standards and incorporate principles of health care including, without limitation, requirements that the activities of the pharmaceutical or medical device manufacturer agents be intended to benefit patients, enhance the practice of medicine and not interfere with the independent judgment of health care practitioners. In promulgating regulations for a marketing code of conduct, the department adopt regulations that shall be no less restrictive than the most recent version of the Code on Interactions with Healthcare Professionals developed by the Pharmaceutical Research and Manufacturers of America and the Code on Interactions with Healthcare Professionals developed by the Advanced Medical Technology Association.

The marketing code of conduct adopted by the department shall not allow:

- (1) the provision of or payment for meals for health care practitioners that:
 - (a) are part of an entertainment or recreational event;
 - (b) are offered without an informational presentation made by pharmaceutical marketing agent or without the pharmaceutical marketing agent being present;
 - (c) are offered, consumed, or provided outside of the health care practitioner's office or hospital setting; or
 - (d) are provided to a healthcare practitioner's spouse or other guest;
- (2) the provision or payment of entertainment or recreational items of any value, including, but not limited to, tickets to the theater or sporting events, sporting equipment, or leisure or vacation trips, to any health care practitioner who is not a salaried employee of the company;
- (3) sponsorship or payment for continuing medical education, in this section referred to as CME, also known as independent medical education, that does not meet the Accreditation Council for Continuing Medical Education Standards For Commercial Support, or that provides payment directly to a health care practitioner;

(4) 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, except in cases as determined by the department.

(5) funding to compensate for the time spent by health care practitioners participating in any CME

event, third-party scientific or educational conferences, or professional meetings;

(6) the provision of or payment for meals directly at any CME event, third-party scientific or educational conferences, or professional meetings;

(7) payments in cash or cash equivalents to healthcare practitioners either directly or indirectly, except as compensation for bona fide services;

(8) any grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items to a healthcare practitioner in exchange for prescribing prescription drugs or using medical devices or for a commitment to continue prescribing prescription drugs or using medical devices.

The marketing code of conduct adopted by the department shall allow:

(1) the provision, distribution, dissemination or receipt of peer reviewed academic, scientific or clinical information;

(2) the purchase of advertising in peer reviewed academic, scientific or clinical journals;

(3) prescription drugs provided to a health care practitioner solely and exclusively for use by the health care practitioner's patients;

(4) compensation for the substantial professional or consulting services of a health care practitioner in connection with a genuine research project or a clinical trial;

(5) payment for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

The department shall update the marketing code of conduct no less than every two years. The department may promulgate regulations or other guidelines as necessary to implement this section.

Section 3. No pharmaceutical or medical device manufacturer company or pharmaceutical or medical device manufacturer agent shall knowingly and willfully violate the marketing code of conduct as adopted by the department.

Section 4. (a) A pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, or medical device in the commonwealth shall adopt and comply with the most recent marketing code of conduct as adopted by the department.

(b) A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall adopt a training program to provide regular training to appropriate employees including, without limitation, all sales and marketing staff, on the marketing code of conduct.

(c) A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall conduct annual audits to monitor compliance with the marketing code of conduct.

(d) A pharmaceutical or medical device manufacturing company that employs a person to sell or market a prescription drugs or medical devices in the commonwealth shall adopt policies and procedures for investigating instances of noncompliance with the marketing code of conduct and take corrective action in response to noncompliance and the reporting of instances of noncompliance to the appropriate state authorities.

(e) A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall identify a compliance officer responsible for operating and monitoring the marketing code of conduct.

Section 5. A pharmaceutical or medical device manufacturing company that employs a person to sell or market prescription drugs or medical devices in the commonwealth shall annually submit to the department: (i) a description of its training program; (ii) a description of its investigation policies; (iii) the name, title, address, telephone number and electronic mail address of its compliance officer; and (iv) certification that it has conducted its annual audit and is in compliance with the marketing code of conduct.

Section 6. (1) By July 1 of each year, every pharmaceutical or medical device manufacturing company that employs a person to sell or market a drug, medicine, chemical, device or appliance in the commonwealth shall 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 physician, hospital, nursing home, pharmacist, health benefit plan administrator, health care practitioner or other person in the commonwealth authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the commonwealth. The disclosure shall be accompanied by the payment of a fee, to be determined by the department, to pay the costs of administering this section.

(2) The department of public health shall make all disclosed data publicly available and easily searchable on its website.

(3) The department of public health shall report to the attorney general any payment, entertainment, meals, travel, honorarium, subscription, advance, services or anything of value provided in violation of the market code of conduct as adopted by the department of public health.

Section 7. This chapter shall be enforced by the attorney general, the district attorney with jurisdiction over a violation or the department of public health.

A person that violates this chapter shall be punished by a fine of not more than \$5,000 for each transaction, occurrence or event that violates this chapter.