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HEALTH AND SAFETY CODE - HSC

DIVISION 104. ENVIRONMENTAL HEALTH [106500 - 119406] (*Division 104 added by Stats. 1995, Ch. 415, Sec. 6.*)

PART 15. MISCELLANEOUS REQUIREMENTS [118375 - 119406] (*Part 15 added by Stats. 1995, Ch. 415, Sec. 6.*)

CHAPTER 8. Drug Marketing Practices [119400 - 119402] (*Chapter 8 added by Stats. 2004, Ch. 927, Sec. 2.*)

119400. The following definitions shall apply for purposes of this chapter:

(a) "Dangerous drug" means any drug that is unsafe for self-use and includes either of the following:

(1) Any drug that bears the legend "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(2) Any drug or device that, pursuant to federal or state law, may be dispensed only by prescription, or that is furnished pursuant to Section 4006 of the Business and Professions Code. "Dangerous drug" does not include labeled veterinary drugs.

(b) "Medical or health professional" means any of the following:

(1) A person licensed by state law to prescribe drugs for human patients.

(2) A medical student.

(3) A member of a drug formulary committee.

(c) "Pharmaceutical company" means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, 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. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in this state on behalf of a pharmaceutical company. "Pharmaceutical company" does not include a licensed pharmacist.

(*Added by Stats. 2004, Ch. 927, Sec. 2. Effective January 1, 2005.*)

119402. (a) Every pharmaceutical company shall adopt a Comprehensive Compliance Program that is in accordance with the April 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers," which was developed by the United States Department of Health and Human Services Office of Inspector General (OIG). A pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revision to the "Compliance Program Guidance for Pharmaceutical Manufacturers."

(b) Every pharmaceutical company shall include in its Comprehensive Compliance Program policies for compliance with the Pharmaceutical Research and Manufacturers of America (PhRMA) "Code on Interactions with Health Care Professionals," dated July 1, 2002. The pharmaceutical company shall make conforming changes to its Comprehensive Compliance Program within six months of any update or revision of the "Code on Interactions with Health Care Professionals."

(c) Each pharmaceutical company shall include in its Comprehensive Compliance Program limits on gifts or incentives provided to medical or health professionals, in accordance with this chapter.

(d) (1) Each pharmaceutical company shall establish explicitly in its Comprehensive Compliance Program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers" and with the "Code on Interactions with Health Care Professionals."

(2) Notwithstanding paragraph (1), drug samples given to physicians and healthcare professionals intended for free distribution to patients, financial support for continuing medical education forums, and financial support for health educational scholarships are exempt from any limits if that support is provided in a manner that conforms to the "Compliance Program Guidance for Pharmaceutical Manufacturers" and the "Code on Interactions with Health Care Professionals."

(3) Payments made for legitimate professional services provided by a health care or medical professional, including, but not limited to, consulting, are exempt from any limits, provided that the payment does not exceed the fair market value of the services rendered, and those payments are provided in a manner that conforms to the "Compliance Program Guidance for Pharmaceutical Manufacturers" and with the "Code on Interactions with Health Care Professionals."

(e) The pharmaceutical company shall annually declare, in writing, that it is in compliance with both its Comprehensive Compliance Program and this chapter. The pharmaceutical company shall make its Comprehensive Compliance Program and its annual written declaration of compliance with the program available to the public on the pharmaceutical company's Web site and shall also provide a toll-free telephone number where a copy or copies of the Comprehensive Compliance Program and written declaration of compliance may be obtained.

(f) This section shall become operative on July 1, 2005.

(Added by Stats. 2004, Ch. 927, Sec. 2. Effective January 1, 2005. Section operative July 1, 2005, by its own provisions.)