

West's Annotated California Codes Currentness
Health and Safety Code (Refs & Annos)
Division 104. Environmental Health (Refs & Annos)
Part 15. Miscellaneous Requirements (Refs & Annos)
Chapter 8. Drug Marketing Practices (Refs & Annos)

§ 119402. Adoption of Comprehensive Compliance Program by pharmaceutical companies; contents of policy; annual dollar limits on certain items; drug samples; annual declaration of compliance

(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.

CREDIT(S)

(Added by Stats.2004, c. 927 (S.B.1765), § 2, operative July 1, 2005.)

Current with all 2009 Reg.Sess. laws; all 2009-2010 1st through 5th and 7th Ex.Sess. laws; urgency legislation through Ch. 5 of the 2010 Reg.Sess.; and propositions on the 6/8/2010 ballot received as of 1/1/2010.