

KING & SPALDING LLP

California's New Compliance Law

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Overview

- Background and History
- Definitions, Scope and Coverage
- Compliance Program Requirements
- Per-Physician Spending Limit
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- Enforcement

Background and History

- SB1765: Signed into law on September 30, 2004 by Gov. Schwarzenegger
- Becomes “operative” on July 1, 2005
- CALPIRG report on pharmaceutical marketing activities played critical role in enactment – and CALPIRG is closely monitoring implementation
- Legislative staff advised law is “self-executing” – the law does not assign a state agency for responsibility to implement and/or enforce the new law, and no implementing regulations (or guidance) is anticipated

Definitions, Scope and Coverage

- Pharmaceutical company: an entity engaged in “production, preparation, propagation, compounding, conversion, or processing of dangerous drugs”
- Dangerous drug: “any drug that is unsafe for self-use and includes either . . . the legend ‘Caution: federal law prohibits dispensing without a prescription’, ‘Rx only’, [or] . . . any drug or device that... may be dispensed only by prescription.”
(emphasis added)
- While there are strong arguments why it does not make sense to include device manufacturers within the scope of the law (e.g., it requires compliance with the PhRMA Code), no CA official with jurisdiction has said that device manufacturers are exempt.
- Until then, Rx device manufacturers should carefully consider

Compliance Program Requirements

- Requires covered companies to:
 - Adopt a Comprehensive Compliance Program “in accordance with” the HHS OIG Compliance Program Guidance for Pharmaceutical Manufacturers (April 2003);
 - Implement policies “in compliance with” the PhRMA Code on Interactions with Health Care Professionals (July 2002); and
 - Adopt limits “on gifts and incentives provided to

Per-Physician Spending Limit

- Requires every covered company to “establish explicitly in its Comprehensive Compliance Program a specific annual dollar limit” for certain spending on medical or health care professionals.
- Categories of spending: “gifts, promotional materials or items or activities” provided to medical or health care professionals in accordance with HHS OIG Guidance and PhRMA Code.
- Excluded from spending limit: Drug samples, financial support CME, certain educational scholarships, and payments for bona fide professional services.
- “Medical or health professional”: “(1) A person licensed by state law to prescribe drugs for human patients. (2)

Disclosure Requirements

- Requires covered companies to:
 - Make an annual public declaration of compliance with the company's compliance program and the statute;
 - Post the company's compliance program and the written declaration of compliance on the company website; and
 - Provide a toll-free telephone number where the public can call to obtain hard copies of the

Enforcement

- While the compliance law does not include separate enforcement provisions, legislative history states that suits may be brought under CA's "Unfair Competition Law" (UCL) (Cal Bus. & Prof. Code § 17200) for failure to comply with the law.
- The UCL permits both government and private citizens to bring a suit against a company for "any unlawful, unfair or fraudulent business act or practice," and successful plaintiffs can recover civil penalties and attorney's fees.
- November 2004 ballot initiative imposed important new standing requirement (now requires showing of actual

Fine Print

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