

California Declaration of Compliance Guidance

Scope:

- The law applies to all pharma & medical device companies who pursue or have existing contacts with medical or health professionals in California (e.g., companies with sales representatives who market to doctors in California).
- “[A]n entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of **dangerous drugs defined as** “[A]ny 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., 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.”

Compliance Program Requirements:

- Manufacturers must establish a Comprehensive Compliance Program (“CCP”) in accordance with the HHS OIG Guidelines and the PhRMA Code) The guide sets forth internal policies governing company interactions with healthcare providers;
- Manufacturers must establish a specific annual aggregate dollar limit on gifts, promotional materials, and items and activities provided to California medical or health professionals. (see Cal. Health & Safety Code § 119402(d)(1))

Additional Compliance Obligations and Action Items:

1. Conduct an assessment of transfers of value that fall within the scope of being a covered activity and assure that the value of the aggregate transfers of value to do not exceed the limit set forth by the companies’ threshold.
2. Provide an annual written declaration confirming compliance with their respective compliance programs and state law;

3. Provide public access to their compliance programs by posting both the compliance program and the written declaration on the company website; and
4. Provide a toll-free number where copies of the compliance program and the written declaration of compliance may be obtained. See Cal. Safety & Health Code § 119402(e)

Exemptions from annual aggregate dollar limit assessment

- Drug samples given to medical or health professionals that are intended for free distribution to patients
- Financial support for continuing medical education forums;
- Funding provided for health educational scholarships; and
- Payments for legitimate professional services provided by a medical or health professional including, but not limited to, consulting services, provided that such service does not exceed the fair market value of the services rendered.

Please follow up with us if you have any questions.

DEADLINE FOR COMPLETION IS JUNE 30th

Resources:

[K&S Client Alert - New California Law Requires Pharmaceutical Companies to Adopt Corporate Compliance Programs \(October 2004\)](#)

[California Comprehensive Compliance Program Law for Pharmaceutical Companies](#)