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California Health Care Providers May Be Required to Provide Proposition 65 Warnings to Patients, Employees, and Visitors

Recently, California health care providers have received California Proposition 65 Warning Letters from manufacturers and suppliers of medical devices and over-the-counter drugs containing Di (2-ethylhexyl) phthalate (DEHP), Ethylene Oxide (EO), and Vitamin A. Health care providers using these products are required to provide “clear and reasonable” warnings to patients, employees, and visitors.

Proposition 65 is a California state law that regulates chemical carcinogens and reproductive toxins in order to protect public and environmental health. The statute requires that manufacturers, distributors, and health care providers who administer or provide medical devices and over-the-counter drugs containing chemicals known to the state of California to cause cancer or reproductive harm, provide a “clear and reasonable” warning when the concentration of those chemicals exceeds the safe harbor levels established by the California Office of Environmental Health Hazard Assessment (OEHHA). OEHHA has established the following carcinogenic “No Significant Risk Level” (NSRL) and reproductive toxicity “Maximum Allowable Dose Level” (MADL) for DEHP, EO, and Vitamin A:

Compound	NSRL	MADL
DEHP	310	micrograms per day
EO	2 micrograms per day	20 micrograms per day
Vitamin A	10,000 international units per day	

Under Proposition 65, once a chemical has been found in a product, the burden shifts to the defendant to show that the daily exposures are below the NSRL and MADL set by OEHHA, or that a “clear and reasonable” warning has been provided. Establishing that the compound concentrations

are below the safe harbor level may involve additional testing as well as an evaluation of such issues as the amount of the compound to which an individual is exposed and the frequency of that exposure.

Products containing these compounds include, but are not limited to:

- Catheters
- Trays
- Irrigation Sets
- Syringes
- Specimen Containers
- Midstream Collection Sets
- Penrose Drains
- Mucous Traps
- Airways
- Enema Kits
- Blood Draw Kits
- Wound Care Kits
- Vitamin A

Proposition 65 is enforceable by the State Attorney General, County District Attorneys, and City Attorneys in cities with populations in excess of 100,000. In addition, Proposition 65 is enforceable by citizen suits. In 2005, over 500 citizen suits were brought under Proposition 65.

The penalties for violating the warning provisions of Proposition 65 include injunctive relief, civil fines of up to \$2,500 per violation, and

the payment of the prevailing plaintiffs' legal fees. Each exposure is considered a separate violation with a statute of limitations running back one year from the date of the complaint. Prevailing citizen plaintiffs also are entitled to 25 percent of the penalties recovered.

What to Do

Generally, health care providers operating in California with more than 10 employees have a duty to provide clear and reasonable warnings when the exposure thresholds described above are met. As described below, this can be done through the admissions process for patients, notice boards for employees, and signage for guests.

Patient Warnings

Prescription Drugs

Regulations promulgated by OEHHA pursuant to Proposition 65 state that "[for] prescription drugs, the labeling approved or otherwise provided under federal law and the prescriber's accepted practice of obtaining a patient's informed consent shall be deemed to be a clear and reasonable warning" [Title 22, California Code of Regulations, Section 12601 (b)(2)(A)]. The reference to labeling pursuant to federal law means labeling required or approved by the federal U.S. Food and Drug Administration (FDA). Hospitals and hospital pharmacies are in compliance with Proposition 65 with regard to prescription drugs if the drugs comply with all FDA labeling requirements and the prescriber obtains the patient's informed consent.

Over the Counter Drugs, Medical Devices, or Supplies

A Proposition 65 warning is required if patients are exposed to a listed chemical in excess of specified levels from an over-the-counter drug or a medical device or supply (or any other source). OEHHA regulations identify emergency circumstances under which the accepted practice of obtaining informed consent from patients would

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satisfy the Proposition 65 warning requirement for exposures related to over-the-counter drugs and medical devices or supplies resulting from emergency or urgent medical or dental care. These regulations can be found in the California Code of Regulations Title 22, Section 12102(g).

Employee Warnings

Employees also must be warned of potential exposures to Proposition 65 compounds in excess of the specified thresholds. A clear and reasonable warning may be provided by postings on employee wage and hour boards, or through notices accompanying pay checks.

Visitor Warnings

Health care facilities also are required to provide clear and reasonable warnings to visitors. These warnings generally are provided by posting signs at the entrances to the facility.

Conclusion

Health care providers that use and expose their patients, employees, and visitors to the medical devices and over-the-counter drugs described above can avoid potential liability under Proposition 65 by complying with the foregoing relatively simple steps. Providers should address this issue as part of their regulatory compliance efforts.