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Health Care Newsletter

Environmental Health News: New Proposition 65 Rules Are Now In Effect

By [Anne Marie Ellis](#)

What Is Proposition 65?

Proposition 65 (often referred to as “Prop 65”) is an environmental health law enacted in California as the “Safe Drinking Water and Toxic Enforcement Act” in 1986. Despite this official title, the scope of Prop 65 regulates far more than just water pollution. The purported goal of Prop 65 is to protect Californians from exposure to substances known to the State of California to cause cancer, birth defects or reproductive harm. California’s Office of Environmental Health Hazard Assessment (“OEHHA”) is tasked with publishing a list of chemicals and updating the list at least annually to include any chemicals known to cause cancer or reproductive toxicity. To date, there are over 900 chemicals listed by OEHHA, which can be found at <https://www.p65warnings.ca.gov/chemicals>. Prop 65 not only prohibits the introduction of such chemicals into the water, but also requires businesses to provide warnings to Californians about significant exposures to listed chemicals in products, homes, workplaces, or in the environment.

In addition to consumer products generally, Prop 65 warnings are required on the following products: alcoholic beverages, diesel engine exhaust, food, furniture products, passenger and off-highway vehicles, petroleum products, recreational vessels and wood dust. Prop 65 warnings are also required at the following places: amusement parks, dental offices, designated smoking areas, enclosed parking facilities, hotels, restaurants, service stations, and vehicle repair facilities. Given the confined scope of this newsletter, I will address just a few of the most relevant places where you must display a warning sign, and how to address product labeling issues if you distribute products carrying Prop 65 warnings.

Since Prop 65 took effect in 1986, warnings were simply required to state that a chemical may be present that could cause cancer or reproductive harm. In 2016, OEHHA adopted new regulations that took full effect on August 30, 2018. The new regulations do not substantively change the purpose of Prop 65, but instead change the suggested language and form of warnings, and shift the responsibility to warn to higher up through the supply chain. These new requirements are described in detail below.

When Prop 65 Warnings Are Required

Prop 65 requires businesses with 10 or more employees (businesses with less than 10 employees are exempt) to provide “clear and reasonable warnings” for “exposure” to chemicals that are known to cause cancer and reproductive harm at locations within California and for goods sold in California. The warning requirement applies to all companies in the chain of distribution—manufacturers, distributors, and retailers, including online retailers such as Amazon.com.

It is important to note, particularly for healthcare providers, that Prop 65 warning requirements do not apply to prescription drugs in compliance with FDA regulation. For example, an acute care hospital administering a prescription drug that contains a chemical on the Prop 65 list would not have to provide separate or additional warnings in order to comply with California law. However, the same acute care hospital may be responsible to make sure patients have clear and reasonable warnings regarding the vinyl medical identification wristbands they wear if the bracelet contains a listed chemical, such as phthalates.

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While there are over 900 chemicals listed by the state of California, there are about 12-15 extremely common chemicals including lead, mercury, acrylamide and phthalates that are frequently found in the warnings. The mere existence of an enumerated chemical does not automatically mean a warning is required. The regulations provide safe harbor levels for many chemicals, meaning that there is an allowable amount of exposure before a company is required to provide Prop 65 warnings.

New Safe Harbor Warning Label Requirements for Consumer Products

In the event a product contains a chemical that exceeds the limits prescribed by the regulations, the clear and reasonable warnings must be provided. OEHHA created “safe harbor warnings” or warnings for consumer product, environmental, and occupational exposures that are guaranteed to be deemed in compliance with Prop 65 regulations. While a business is not required to use the safe harbor warnings, it is highly recommended to avoid possible litigation challenging any unique warning methods. The new regulations include but are not limited to a yellow triangle with an exclamation point, new requirements for catalogs and internet sales, reference to p65warnings.ca.gov, and specific font sizes.

Prop 65 and the Distribution Chain

The new warning requirements will mean downstream healthcare personnel, such as medical supply buyers for inpatient settings will shoulder less of the burden in determining which supplies are Prop 65 compliant. The new regulations clarify that manufacturers have the primary responsibility for providing Prop 65 warnings. Manufacturers can choose whether to (a) affix warning labels on their products prior to shipping, or (b) to provide written notice to their distributors, importers or retailers that a product requires a warning, provide the warning signs or other warning materials, and get confirmation that retailers received the notice. Manufacturers can also enter written agreements with retailers to modify their responsibility so long as the consumer receives a clear and reasonable warning prior to exposure to a Prop 65 chemical. Even if manufacturers do not sell to any entity in California, if the product is sold by any distributor, importer, or reseller into the state, that manufacturer can still be held liable. If for example, you sell products that require a Prop 65 warning, you should confirm through a contractual arrangement which entity is required to do the warning. If you have received products with Prop 65 warnings or received a Prop 65 notice, it is imperative that you maintain Prop 65 compliance to avoid being held liable.

New Safe Harbor Warning Requirements for Specific Places

In addition to specific products, Prop 65 warnings are required in specific locations, and the “safe harbor” language for each of these locations is found at p65warnings.ca.gov. A few of the most common locations are:

1. *Dental Offices*: signage requires warnings about sedation with nitrous oxide, root canals, placement or removal of crowns, bridges, and restorations such as mercury-containing fillings and use of dental appliances causing cancer and reproductive harm.
2. *Smoking areas*: signage requires reference to tobacco smoke and nicotine causing cancer and reproductive harm.
3. *Enclosed parking facilities*: signage requires reference to carbon monoxide and gasoline or diesel engine exhaust causing cancer and reproductive harm.

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Enforcement and Liability for Non-Compliance

While the California Attorney General's Office is tasked with the official enforcement of Prop 65, any district attorney, city attorney (for cities whose population exceeds 750,000), consumer advocacy group, private citizen, or law firm may also enforce Proposition 65. Penalties for violating Proposition 65 by failing to provide warnings can be as high as \$2,500 per violation per day, meaning private groups and attorneys are highly motivated to seek out Prop 65 violators.

Healthcare businesses may face unique risks with respect to enforcement because they are exposed to potential litigation brought via Prop 65's individual enforcement mechanism. Where businesses engage in activities related to health and wellness, there are demonstrable risks associated with retaliatory or litigation borne out of adverse medical outcomes. Since individuals are able to file actions for Prop 65 violations without the backing of government agencies, proper compliance is essential.

These new requirements went into full effect on August 30, 2018—make sure your business is prepared. Please do not hesitate to contact us, as we can help with your compliance efforts and help defend your business if you are served with a Notice of Violation or lawsuit involving Prop 65 violations.



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