

CDA Regulatory Compliance

Proposition 65 -Frequently Asked Questions

This FAQ is part of the CDA Regulatory Compliance Manual. It was updated February 2017.

What is Proposition 65?

Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, prohibits businesses with 10 or more employees from knowingly discharging any chemical listed as “known to the state of California to cause cancer or reproductive toxicity” to a source of drinking water and requires that such businesses provide a “clear and reasonable warning” prior to exposing any person to a listed chemical.

Under Proposition 65, the governor is required to publish a list of chemicals known to be carcinogens and/or reproductive toxicants, as determined by the state of California. This list must be updated annually. More than 900 chemicals have been listed as of May 2016. The State Office of Environmental Health Hazard Assessment (OEHHA) administers the listing process. The list and additional information are available at oehha.ca.gov.

Does the law apply to all dentists?

The law applies to dental businesses, including dental offices in California, that cause exposure to listed chemicals in the scope of dentistry and employ 10 or more employees. These dental businesses must provide a warning notice to any individual who may be exposed to Proposition 65 chemicals at the respective place of business.

How is the law enforced?

The attorney general, any district attorney or any city attorney of a city with a population in excess of 750,000 may enforce Proposition 65. In addition, Proposition 65 has a private enforcement provision that allows individuals and organizations acting in the public’s interest to initiate cases. Private enforcers, however, must first provide a 60-day notice to targeted businesses, the attorney general, district attorneys and city attorneys that set forth the alleged violations before any lawsuit is formally initiated. The law specifies that any business found in violation is liable for a civil penalty not to exceed \$2,500 per day for each violation.

How is employee defined?

All full-time and part-time staff members are counted as employees. The definition of employee is broad, and encompasses part-time employees who provide only limited services in the office, including janitors, gardeners, delivery staff and bookkeepers. When in doubt, an office should err on the side of inclusion to be certain.

If a dentist has two offices or businesses, by statutory definition, signage could be required for each location even if one location has fewer than 10 employees. If each location is a different business, in a legal context, and the number of employees does not exceed nine in either one, then no signage would be required under the law.

What do I tell patients who ask about the notices?

You may provide a copy of Dental Patients’ Frequently Asked Questions About Proposition 65, a resource included in the same zip file as this document. With regard to nitrous oxide, CDA has prepared a fact sheet for patients. Dentists or the patient can download the fact sheet at cda.org/member-resources/patient-education-tools.

Also, you will notice that the notice directs individuals to a website, P65Warnings.ca.gov/dental, that is managed by OEHHA. When discussing the materials and procedures listed in the warning notice for dental offices, note that all restorative materials used in dentistry have been cleared by the U.S. Food and Drug Administration. The Food and Drug Administration, the National Institutes of Health, the U.S. Public Health Service, the Centers for Disease Control and Prevention, the World Health Organization, the Agency for Toxic Substances and Disease Registry and other respected U.S. and international health agencies continue to review and monitor scientific evidence with regard to the use of restorative (filling) materials and, to date, have determined that they are safe and effective to use in treating dental patients. With regard to dental amalgam, the Food and Drug Administration has concluded “there is overwhelming agreement among major health authorities that have assessed these risks that there is no evidence of a serious threat to the general population whose dental caries are treated with amalgam.” The California Dental Association always encourages dentists to discuss patient options before beginning dental treatment.

Are dentists required to post a notice sign in their offices?

Proposition 65 regulations were amended September 2016 with the result being the replacement of multiple warning notices with one notice for dental offices to post or provide. A dentist employing 10 or more employees must do one or both of the following: (1) post at the public entry of the office a sign with the required language and (2) include a warning notice with the informed consent form a patient must sign. CDA strongly encourages dental offices with fewer than 10 employees to post the sign or use the warning notice, because, as mentioned above, the definition of employee is broad and dentists should err on the safe side.

The sign and notice must have the word “WARNING” in all capital letters and bold print and use all these words: “Certain dental procedures performed in this office can expose you to chemicals known to the State of California to cause cancer or birth defects or other reproductive harm or both. Those procedures can include sedation with nitrous oxide, root canals, placement or removal of crowns, bridges and restorations such as mercury-containing fillings and use of dental appliances. Consult your dental care provider about these exposures and which materials are appropriate for your treatment. Additional information is also available at P65Warnings.ca.gov/dental.” The sign and notice may not be smaller than 5 by 5 inches and printed in no smaller than 20-point type. See the last page for an example. The new regulation is effective Aug. 30, 2018. However, dental practices may choose to comply with the new regulations now and will be considered in compliance. The posting of the old Proposition 65 warning notices for restorative materials, nitrous oxide and bisphenol A is deemed compliant until the effective date of the new regulation.

What chemicals used in dentistry require Proposition 65 warnings?

Out of the approximately 900 chemicals currently listed as known to the state to cause cancer or reproductive harm, several dozen are used in dental materials and treatments. Proposition 65 states that warnings are required prior to any detectable exposure, unless it can be shown that the exposure poses no significant risk. However, as conservatively defined in the law, “no significant risk” is an exposure usually about a thousand times less than is generally regarded as a safe exposure. A 2003 legal settlement between CDA and the environmental group As You Sow, and arbitrated by the Attorney General’s Office, focused the warning on those chemicals that could not be shown to present no significant risk. The list of dental materials and chemicals considered to be included in the settlement agreement is at the end of this document.

In addition, the settlement agreement includes a provision, which provides that if initially within 180 days of the consent judgment and thereafter if new scientific information becomes available, any dental material or chemical, except for amalgam or mercury, which may be reviewed under other circumstances may be eliminated if scientific data warrants an exemption. Nickel and chromium in orthodontic treatment devices were originally included in the consent judgment with As You Sow. However, after reviewing a scientific analysis, the Attorney General’s Office in 2004 agreed that they do not create an exposure that requires a Proposition 65 warning.

OEHHA continues to review chemicals for possible Proposition 65 listing. Nitrous oxide was added on Aug. 1, 2008, to the list of chemicals “known to the state to cause developmental toxicity” and, therefore, triggered the “clear and reasonable warning” requirement effective Aug. 1, 2009. Chloral hydrate was added to the Proposition 65 list in 2013, but dental practices using this drug are not required to have a notice sign. The courts have determined that informed consent used with pharmaceutical drugs that are on the Proposition 65 list is adequate notice. Bisphenol A was listed in May 2015. Additional chemicals used in dentistry may be added to a Proposition 65 list in the future. CDA monitors and participates in the OEHHA review process and will communicate with members when chemicals present in dental offices are added to the list.

Are specialty clinics that do not utilize any chemicals on the list, such as oral surgery clinics and orthodontic offices, required to post a notice sign?

Dental businesses that do not utilize any chemicals on the Proposition 65 list are not subject to the requirements of Proposition 65 and are not required to post the notice sign.

What if I have over nine employees and decide not to post the restorative material notice sign?

Offices with 10 or more employees who decide not to follow CDA’s guidelines will be subject to Proposition 65 violation enforcement. Refer to the earlier question on how the law is enforced.

If I post the Proposition 65 warning notice, does this mean I must continue distributing the Dental Materials Fact Sheet to each patient undergoing restorative treatment?

Yes. The two documents are separate but equal entities — it is necessary for dental offices to comply with two separate laws. The Dental Board of California is responsible for developing and distributing the Dental Materials Fact Sheet, which describes and compares the risks and efficacy of the various types of dental restorative materials that may be used to repair a dental patient’s oral condition or defect. The Dental Board is required to develop, distribute and administer the Fact Sheet to licensed dentists in California. In turn, each licensed dentist must provide a copy of the Fact Sheet at least once to patients of record and to new patients prior to commencing any dental restorative work. The current Fact Sheet is dated May 2004. A dentist may not revise the Fact Sheet but may provide supplemental educational material.

What has CDA done to help mitigate the impact of the law on dental practices?

Although the law became effective in 1986, uncertainty about the law’s applicability to medical devices was the subject of legal proceedings for many years. Dentistry was not affected by Proposition 65 until 1993 when a consumer group,

the Environmental Law Foundation, served violation notices on several dental amalgam manufacturers for not providing proper notices to customers and the public. Most manufacturers banded together and began legal challenges. On behalf of all members, CDA participated in settlement discussions between the Environmental Law Foundation (ELF) and amalgam manufacturers. On two separate occasions during negotiations, in an effort to extend legal protection for dentists with regard to other chemicals not part of ELF's action, CDA submitted proposed warnings to the Attorney General's Office requesting approval. The Attorney General's Office declined, stating that the warnings did not meet the Proposition 65 requirements.

The ELF and another organization called Consumer Cause served additional notices of violation to other dental supply manufacturers for failing to post warnings of mercury, nickel and hexavalent chromium exposure. In late 2000, the amalgam suppliers and manufacturers, collectively known as the Committee of Dental Amalgam Manufacturers and Distributors, settled with the private enforcers, which resulted in the dissemination of warning signs and educational mailings to their customers.

In 2001, individual dental offices became directly involved when another environmental group, As You Sow, served 80 offices in Southern California with violation notices. Through meetings and other communications between As You Sow, CDA and the attorney general, a settlement was negotiated to devise an appropriate Proposition 65 notice for distribution to dentists for posting. As You Sow agreed to amend its action to include other dental chemicals on the Proposition 65 list. After more than a year of negotiations, in January 2003, CDA entered into a formal Consent Judgment with As You Sow and the Attorney General's Office on acceptable language to be incorporated into the notice signs. The Consent Judgment is not an admission of any violation and no civil penalties were assessed. This settlement was intended to eliminate further piecemeal litigation brought by private enforcers against dental offices.

More recently, CDA worked with the governor's administration, OEHAA and other stakeholders to craft regulations that provide consumers with easier access to information about chemicals on the Proposition 65 list. The new warning regulations were approved August 2016 and take effect in Aug. 30, 2018. Dental practices now have just one Proposition 65 notice to post and have the option to include a warning with a written informed consent form that the patient must sign.

Proposition 65 Chemicals In Dental Offices-Listed in the 2003 Settlement Agreement

Amalgam fillings

Mercury

Mercury compounds

Materials associated with non-amalgam restorations, including but not limited to crowns, bridges and composite fillings

Beryllium

Ceramic Fibers

Chloroform

Chromium (Hexavalent)

Crystalline Silica

Formaldehyde

Methylene chloride

Nickel

Materials used in other dental treatments, including but not limited to root canal treatments, dental impressioning and dental sealant applications

Chloroform

Methylene chloride

Toluene