



Dentists’ Frequently Asked Questions About Proposition 65

What is Proposition 65?

Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986, prohibits businesses with ten 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. Over 800 chemicals have been listed as of June 2009. 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 which utilize listed chemicals in the scope of dentistry and employ ten 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. 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 even 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 ten 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?

With regard to nitrous oxide, CDA has prepared a fact sheet for patients. You can download the fact sheet at http://www.cda.org/page/patient_education_tools. An FAQ written for dental patients also is available at http://www.cda.org/page/Environment_&_Waste_Management.

When discussing the materials and procedures listed in the original notice for dental offices, you can note that the notice does not state that the dental products or procedures cause cancer or reproductive harm. It states only that the products or procedures may expose the patient to “chemicals known to the state” to cause cancer or reproductive harm. The notice makes it clear that all restorative materials have been approved by the U.S. Food and Drug Administration. That agency 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.” In addition, the U.S. 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 dental patients. 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?

All dentists employing 10 or more employees must post the required notice sign or signs. There is a restorative materials notice and a separate nitrous oxide notice. CDA strongly encourages offices with less than ten employees to post the restorative materials notice sign, because, as mentioned above, the definition of employee is broad, and dentists should err on the safe side by posting the sign.

Currently, the Dental Materials Fact Sheet published by the Dental Board of California describes the contents of the various restorative (filling) materials used today, and must be provided to patients the first time they seek restorative treatment. CDA encourages dentists to communicate with patients on all aspects of dental treatment, including options for selecting dental materials best suited for the patients’ dental needs.

What chemicals used in dentistry require Proposition 65 warnings?

Out of the approximately 800 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. Therefore, the settlement arbitrated by the Attorney General’s Office focused the warning on those chemicals which could not be shown to present no significant risk, and eliminated warnings about chemicals used in dentistry which clearly are not significant. This approach avoided what could have been expensive and counterproductive litigation given Proposition 65’s conservative definition of significant risk. The list of dental materials considered to be included in the warning 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 August 1, 2008 to the list of chemicals “known to the state to cause developmental toxicity” and therefore triggering the “clear and reasonable warning” requirement effective August 1, 2009. 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 if additional warning notices are required.

I don’t use some of the chemicals included in the restorative materials notice sign – do I have to include them in my Proposition 65 notice?

Yes, the Consent Judgment with As You Sow requires that the notice given below be posted in dental facilities employing more than nine employees. Some of the chemicals on the list commonly used in dentistry include mercury, nickel compounds, hexavalent chromium, and formaldehyde; refer to the table provided on the next page. However, while there are other chemicals on the list that are used in dentistry, most, if not all, are perceived to provide “no significant risk” to the public, as that term is defined in the statute. Until scientific data is introduced which warrants a qualification for exemption, the warning requirements for those chemicals other than amalgam must remain.

I don’t use nitrous oxide in my practice. Am I still required to post the nitrous oxide notice sign?

No, only those providers who use nitrous oxide in their practice need to post the warning.

Can I combine the notice for nitrous oxide with the notice for amalgam and other dental materials?

CDA recommends that you post two separate signs. The posting for amalgam and other dental materials was specifically created as part of a settlement in an earlier lawsuit and was approved by the court. CDA does not recommend changing that language. Providers who utilize nitrous oxide should post a sign specific to nitrous oxide.

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 restorative material notice sign, 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, necessary for dental offices to comply with two separate laws. The governing agency responsible for administering Proposition 65 is OEHHA, the Office of Environmental Health Hazard Assessment, which is a division of the California Environmental Protection Agency.

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.

Must I adhere to the restorative material notice language distributed by CDA?

Yes. In order to be protected by the Consent Judgment, dental offices with ten or more employees must post the original notice language given below.

The notice sign must be prominently placed in a location which will afford the patient a reasonable opportunity to receive notice of the exposure and which provides a “clear and reasonable warning” to all patients and visitors prior to exposure. There is sufficient leeway in the Consent Judgment to allow dental offices to determine whether the signs should be posted at the entrance, in the waiting room, in the operatory, or in more than one of these locations. However, a sign prominently displayed in the waiting room is deemed to be in compliance.

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 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 Environmental Law Foundation 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 lists. 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.



RESTORATIVE MATERIAL WARNING

NOTICE TO PATIENTS

PROPOSITION 65 WARNING: Dental Amalgam , used in many dental fillings, causes exposure to mercury, a chemical known to the State of California to cause birth defects or other reproductive harm.

Root canal treatment and restorations, including fillings, crowns, and bridges, use chemicals known to the State of California to cause cancer.

The US Food and Drug Administration has studied the situation and approved all dental restorative materials for use.

Consult your dentist to determine which materials are appropriate for your treatment.

NITROUS OXIDE WARNING

NOTICE TO PATIENTS

PROPOSITION 65 WARNING: Nitrous oxide anesthetic gas is a chemical known to the state of California to cause birth defects or other reproductive harm.

Consult your dentist to determine which materials are appropriate for your treatment.

Full-size copies of the notices are available for downloading on cda.org. If you have additional questions or concerns about the Proposition 65 notice requirements, please call the CDA Contact Center, 800.232.7645, or visit cda.org.

PROPOSITION 65 CHEMICALS IN DENTAL OFFICES LISTED IN THE 2003 SETTLEMENT AGREEMENT	
MATERIAL/USE	PROPOSITION 65 CHEMICALS
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

Updated July 2009