

INITIAL STATEMENT OF REASONS
22 CALIFORNIA CODE OF REGULATIONS

SECTION 12601. CLEAR AND REASONABLE WARNINGS

SECTIONS 12201. DEFINITIONS

The Safe Drinking Water and Toxic Enforcement Act of 1986, commonly known as Proposition 65 (hereinafter referred to as “Proposition 65” or “the Act”), prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual (Health and Safety Code Section 25249.6.) Implementing regulations were adopted in Title 22, California Code of Regulations, Section 12601 (unless otherwise specified, all section references are to Title 22, California Code of Regulations) to interpret and make specific the “clear and reasonable” warning requirement.

The existing regulation establishes the language and methods of transmitting a warning which are deemed to be in compliance with the clear and reasonable warning requirement specified in the Act. Currently, the regulations establish “safe harbor” language for consumer product exposures, occupational exposures, and environmental exposures. A warning is considered “clear” if it clearly communicates that the chemical in question is known to the State to cause cancer, or birth defects or other reproductive harm and is “reasonable” if the method employed to transmit the message is reasonably calculated, considering the alternative methods available under the circumstances, to make the warning message available to the individual prior to exposure. Warnings of exposures to chemicals listed under the Act are required to be given without qualification before an exposure above specified risk levels occurs.

In February 2000, the Office of Environmental Health Hazard Assessment (OEHHA) received a petition from the Advanced Medical Technology Association filed pursuant to Government Code Section 11340.6 proposing specific amendments concerning medical devices to the warning regulation under Proposition 65 (Section 12601). The petition sought to have OEHHA adopt a regulation requiring passage of the warning from the manufacturer through the distribution chain to the health care provider to the patient; amendments that differentiate between the categories of medical devices (prescription, non-prescription, and in vitro diagnostic); and specific warning language applicable to all medical devices. OEHHA convened a public workshop on September 21, 2000 to solicit input on the need for the proposed amendments. After closely reviewing the petition and the oral and written comments received on the subject, OEHHA denied the requests for generalized warning regulations pertaining to all medical devices. OEHHA determined that the petition was overly broad and did not provide an adequate basis for creating unique warning rules for virtually all medical device products. OEHHA, however, did believe there was merit to the development of a regulation that addressed the administering of Proposition 65 warnings to an unconscious patient, a patient undergoing an urgent medical procedure, and a person who is legally incapable of giving consent. OEHHA recognizes that there are some emergency situations in which prior notification by the person responsible for an exposure to a listed chemical is not possible. Accordingly, OEHHA proposes to amend Section 12601 to create an exemption from the warning requirement in such situations.

In determining the limitations upon which emergency situations should be included in such an exemption, OEHHA referred to the practice of obtaining “informed consent,” which is an established doctrine within the medical and dental professions. Informed consent is a person’s agreement to allow something to happen to him or her that is based on a full disclosure of facts needed to make the decision intelligently. The items which a physician or dentist must disclose in order to obtain informed consent are the nature of the procedure to be performed; the risks, complications, and expected benefits or effects of the procedure; and any alternatives to the treatment and their risks and benefits. Under certain limited emergency circumstances, obtaining informed consent prior to performing a procedure is not required. These circumstances are: 1) the patient is unconscious; or 2) the medical or dental procedure is undertaken because the physician or dentist reasonably believes that a medical or dental procedure should be undertaken immediately and that there is insufficient time to fully inform the patient; or 3) the patient is legally incapable of giving consent and the physician or dentist reasonably believes that a medical or dental procedure should be undertaken immediately and that there is insufficient time to obtain the informed consent of a person authorized to give such consent for the patient (Business and Professions Code Sections 1627.7(a) and 2397(a).)

The proposed amendment to Section 12601(b)(6) identifies similar limited medical and dental circumstances under which a warning pursuant to Health and Safety Code Section 25249.6 would not be required. In addition, definitions for new terms proposed in this amendment are adopted in Section 12201.

Section 12601

The proposed amendment to Section 12601(b)(6) parallels the circumstances under which obtaining informed consent for medical or dental procedures is not required. OEHHA recognizes that there are emergency situations that require immediate medical or dental services to alleviate severe pain, or to preserve life and limb. A delay in administering services may be detrimental to the well being of the patient. It is for these types of situations that OEHHA proposes to adopt an exemption from the Proposition 65 warning requirement. While the existing obligation of obtaining informed consent prior to performing medical or dental procedures rests with the physician or dentist, OEHHA believes that there are certain other professionals within the medical and dental fields that encounter these similar emergency situations on a routine basis. The other professionals include medical personnel, emergency medical personnel, and to a lesser extent, dental personnel. Accordingly, the proposed amendment is intended to include these other medical and dental professionals among those who are exempted from the Proposition 65 warning requirement for the circumstances specified.

Often times during the course of their jobs, individuals in the medical, emergency medical care and, again to a lesser extent, dental professions are confronted with an emergency situation in which they must administer immediate care and treatment to avert a serious adverse health outcome. In the course of treatment, an exposure to a listed chemical that would ordinarily require a Proposition 65 warning may occur. The proposed amendment would exempt specified personnel from the warning requirement in specified circumstances. Among the rights declared by the people in the preamble to the Act was the right to be informed about exposures to chemicals that cause cancer, birth defects or other reproductive harm and to make their own choices about being exposed to these chemicals. In emergency situations, medical, dental and emergency personnel may make life-altering decisions

affecting a patient's health based upon the patient's best interest. In keeping with the patient's best interest in mind, OEHHA believes that in situations such as these, the ability to make an informed choice concerning a chemical exposure is superseded by the professional judgment of the attending medical, dental or emergency personnel as to the need for immediate care and treatment. Thus, it is appropriate to not require a Proposition 65 warning in an emergency or urgent medical or dental situation provided the circumstances as proposed in Section 12601(b)(6) exist. The adoption of this amendment does not preempt or in any way limit any other exemptions from the warning requirement that would otherwise be applicable, such as that which is specified in Health and Safety Code Section 25249.11(b) for businesses that employ fewer than ten people, or for any city, county, district, state, or federal governmental department or agency.

Section 12201

In conjunction with the proposed amendment to Section 12601(b)(6), several new definitions are proposed as additions to Section 12201. While there may be a general understanding of what is considered emergency medical or dental care and which professions are recognized as attendants who provide emergency medical or dental care, OEHHA proposes to adopt definitions for "emergency or urgent medical or dental care," "medical personnel," "dental personnel," and "emergency medical personnel" to clarify under what circumstances and to whom the exemption applies. Definitions for "emergency situations occurring in a hospital or physician's or dentist's office" are set out in Business and Professions Code Sections 1627.7(c)(2) and 2397(c)(2). The definition of the term "emergency or urgent medical or dental care" proposed here is parallel to that used for "emergency situations occurring in a hospital or physician's or dentist's office." The definition of "medical personnel" as specified in Penal Code Section 3823.93 includes physicians, nurse practitioners, physician assistants, and nurses and is proposed here for adoption with the same meaning. "Dental personnel" includes licensed dentists and dental auxiliary staff as that term is defined in Business and Professions Code Section 1741(e). In particular, "dental auxiliary" staff is defined as "... includ[ing] all of the following: (1) a dental assistant pursuant to [Business and Professions Code] Section 1750. (2) a registered dental assistant pursuant to [Business and Professions Code] Section 1753. (3) a registered dental assistant in extended functions pursuant to [Business and Professions Code] Section 1756. (4) a registered dental hygienist pursuant to [Business and Professions Code] Section 1758. (5) a registered dental hygienist in extended functions pursuant to [Business and Professions Code] Section 1761. (6) a registered dental hygienist in alternative practice pursuant to [Business and Professions Code] Section 1768." "Emergency medical personnel" includes emergency medical technicians I and II and emergency medical technician-paramedics as those terms are defined in Health and Safety Code Sections 1797.80, 1797.82 and 1797.84, respectively. As set out in the respective sections of the Health and Safety Code, emergency medical technician I or EMT-I means "... an individual trained in all facets of basic life support according to standards prescribed by this part [Part 1 which has since been repealed, but the section is still within Division 2.5] and who has a valid certificate issued pursuant to this part [Part 1 which has since been repealed, but the section is still within Division 2.5]. This definition shall include, but not be limited to EMT-I (FS) and EMT-I-A;" Emergency medical technician II or EMT-II means "... an EMT-I with additional training in limited advanced life support according to standards prescribed by this part [Part 1 which has since been repealed, but the section is still within Division 2.5] and who has a valid certificate issued pursuant to this part [Part 1 which has since been repealed, but the section is still within Division 2.5];" and Emergency medical technician paramedic, EMT-P, paramedic, or mobile intensive care paramedic means "...

an individual whose scope of practice to provide advanced life support is according to standards prescribed by this division [Division 2.5] and who has a valid certificate issued pursuant to this division [Division 2.5].” Utilizing definitions already referenced in other areas of law will minimize confusion regarding what is included within the various professions. Also, the terminology should be familiar to those individuals working in the relevant fields.