



California Medical Association
Physicians dedicated to the health of Californians

March 24, 2015

Monet Vela
Office of Environmental Health Hazard Assessment
P. O. Box 4010
1001 I Street
Sacramento, California 95812-4010

RE: Clear and Reasonable Warning Regulations

Ms. Vela:

The California Medical Association (CMA) appreciates the opportunity to comment on the Office of Environmental Health Hazard Assessment (OEHHA) proposed regulations regarding Title 27, California Code of Regulations, Article 6: Clear and Reasonable Warnings. CMA is a professional organization that represents more than 40,000 California physicians dedicated to the health of all Californians, and as such takes great interest in how Proposition 65 relates to prescription drugs.

§ 25608.7 Prescription Drug Exposure Warnings, Subsection (a)

As described in the Initial Statement of Reasons (ISOR), CMA and other healthcare stakeholders met with OEHHA staff during the pre-regulatory period and all parties agreed that it made sense to retain the existing prescription drug exposure provisions. Prescription drugs are very closely regulated by the federal Food and Drug Administration, and federal law prohibits businesses from deviating from an approved label or related materials. As also noted, a prescriber's accepted practice of obtaining informed consent meets the Article's requirements and is consistent with existing duties of health care providers under state and federal law.

CMA strongly supports the proposed language for § 25608.7, Subsection (a).

§ 25608.7 Prescription Drug Exposure Warnings, Subsection (b)

According to the ISOR, subsection (b) of the proposed regulation maintains the existing regulatory language concerning emergency medical care. However, this is not the case and the language in the proposed regulation has changed in ways that would create new problems for emergency medical care. In communication with OEHHA staff, we were told that the revised language for subsection (b) was included erroneously in the proposed regulation and will be reverted to existing language.

There is one change to existing language that would address a long-standing issue with this section. The current language mistakenly implies that it is possible to obtain informed consent from an unconscious patient and in other emergency situations, rather than make clear that the warning requirement is waived because it is impossible for a patient to provide in such situations. Rephrasing would resolve the issue:

“(b) For exposures resulting from emergency or urgent medical or dental care as defined in Section 25102(g), ~~the accepted practice of obtaining the patient's informed consent shall be deemed to be a clear and reasonable~~ no warning is required when any of the following circumstances exists:”

Therefore, *CMA advocates for replacing OEHHA’s proposed language for § 25608.7, Subsection (b) with the following:*

(b) For exposures resulting from emergency or urgent medical or dental care as defined in Section 25102(g), no warning is required when any of the following circumstances exists:

- (1) the patient is unconscious; or**
- (2) the procedure must be undertaken because the licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering the care, as these terms are defined in Sections 25102(q), 25102(d), and 25102(b), respectively, reasonably believes that the procedure should be undertaken immediately; and therefore, there is insufficient time to fully inform the patient; or**
- (3) the procedure must be performed on a person legally incapable of giving consent, and the licensed medical personnel, licensed dental personnel, or certified emergency medical personnel responsible for administering the care reasonably believes the procedure should be undertaken immediately; and therefore, there is insufficient time to obtain the informed consent of a person authorized to give such consent for the patient.**

CMA welcomes the opportunity to continue work with OEHHA on language related to medical practice and patient consent. If you have any questions, feel free to contact me at sclark@cmanet.org or 916-551-2887. Thank you for your consideration.

Sincerely,



Scott Clark
Associate Director, Center for Medical & Regulatory Policy