

April 7, 2015

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

SUBJECT: PROPOSITION 65 WARNING REGULATION

Dear Ms. Vela:

The California Hospital Association (CHA), which represents approximately 400 hospitals and health systems, thanks the Office of Environmental Health Hazard Assessment (OEHHA) for the opportunity to comment on the proposed regulations in Title 27, Article 6 relating to Clear and Reasonable Warnings.

As we have discussed in previous meetings, prescription drugs are regulated by the Food and Drug Administration (FDA) and federal law prohibits businesses from deviating from an approved label and related materials. Also, 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.

CHA recommends that for Section 25608.7(b) related to prescription drug exposure warnings, language we developed in conjunction with the California Medical Association, be substituted for OEHHA's proposed Section 25608.7, subsection (b) language as follows:

(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.**

Hospitals are complex organizations and are very vulnerable to frivolous Prop 65 lawsuits. Hospitals provide food services, operate fleets of motor vehicles, operate garages and store oil, fuel and cleaning chemicals. Therefore, we have joined other members of the California Chamber of Commerce in expressing concern, as delineated in the Chamber's coalition letter, submitted to you under separate cover, that the proposed Clear and Reasonable Warning Regulations, as drafted, will actually lead to more frivolous Prop 65 lawsuits.

OEHHA's proposed additional specificity in warning signs and the further product testing requirements which will result, will add a significant amount of costs to businesses. In the case of hospitals this will also lead to higher health care costs. The difference between OEHHA's "no significant economic impact" and the Andrew Chang and Company economic impact assessment projecting twelve year additional costs from \$410 million to \$818 million indicates the effect of the economic impact needs to be further studied prior to adopting the proposed changes to Article 6.

Again, CHA thanks you for making the pre-regulatory and regulatory process very open and your consideration of CHA's comments.

If you have any questions, please contact me at (916) 552-7681 or chummel@calhospital.org

Sincerely,

A handwritten signature in black ink that reads "Cheri Hummel". The signature is written in a cursive, flowing style.

Cheri Hummel
Vice President Emergency Management and Facilities