

Health Devices Alerts Special Reports

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Proposition 65 Requires California Hospitals to Notify Patients of Harmful Chemicals and Materials Used in Medical Devices

Priority : Normal Priority

Summary: An ECRI member hospital in California received a letter from a medical device manufacturer informing the hospital of the use of di(2-ethylhexyl)phthalate (DEHP) and ethylene oxide (EtO) in its manufacturing processes. The manufacturer asked the hospital to provide warnings in accordance with Proposition 65, the California Safe Drinking Water and Toxic Enforcement Act of 1986, to its patients when they are treated with products that contain DEHP or are sterilized with EtO. The manufacturer stated that warnings could be given to patients either verbally or in a written statement on admission or consent forms. The member hospital has asked ECRI to clarify the warning requirements of Proposition 65 regarding potentially harmful chemicals and materials used in medical device manufacturers' products and to suggest practical ways to convey the necessary information.

Background: Proposition 65, administered by California's Office of Environmental Health Hazard Assessment (OEHHA), is intended to protect California citizens and the state's drinking water sources from chemicals that are known by the State of California to cause cancer, as well as birth defects or other reproductive harm, and to inform citizens about exposure to these chemicals. The proposition requires the governor of California to publish, at least annually, a list of chemicals known to the state to cause cancer or reproductive toxicity. The two chemicals listed above are examples of those found on the Proposition 65 list.

Current regulations require that manufacturers provide a clear and reasonable warning to their immediate customers if medical devices used in treatment would result in patient exposure to chemicals or materials on the Proposition 65 list. Manufacturers are required to specify the chemicals and courses of medical treatment associated with their devices. Many manufacturers include these warnings on device labeling, which is not specific to California. Therefore, it is possible that hospitals outside California may be familiar with these warnings even though the warnings apply only to the State of California.

ECRI Perspectives: Individual hospitals are also responsible for providing a clear and reasonable warning to patients and other individuals who may receive exposure to the chemicals or materials on the Proposition 65 list. Hospitals must inform patients which chemicals or materials on the list are involved in the procedure they are undergoing. Proposition 65 states that the warning method should be appropriate for the location in which the chemicals or materials are used (or in which exposure is most likely to occur) and conspicuous so that it is likely to be read, seen, or heard and understood by an "ordinary individual." Proposition 65 lists several methods that hospitals can use to warn patients, including posting signs.

ECRI Recommendations: Another method to fulfill the requirement to notify patients under Proposition 65 is to include disclosure language on hospital admission forms. ECRI recommends taking this approach instead of posting signs, since patients will be able to read and sign the admission form before treatment is given, and the hospital will have written verification that it has complied with Proposition 65.

The language used on admission forms should briefly describe Proposition 65 and state that some products used in the hospital contain chemicals or other materials that exceed California's OEHHA NSRL (no significant risk level) for carcinogens or MADL (maximum allowable dose level) for reproductive toxicants. These chemicals or other materials must be identified. If the products the hospital references in its disclosure

are typically used at other hospitals, it may also be appropriate to note that the referenced materials are in widespread use in hospitals throughout the United States and in other countries. For help in creating a disclosure statement, visit http://www.oehha.ca.gov/prop65/law/pdf_zip/12601Regs.pdf. The list of chemicals known to the State of California to cause cancer or reproductive toxicity is available online at http://www.oehha.ca.gov/prop65/prop65_list/files/P65single21105.pdf. ECRI recommends that hospitals periodically check the list for updates.

ECRI also encourages medical device manufacturers and hospitals to seek legal counsel from attorneys in California who are familiar with Proposition 65 before finalizing and disseminating disclosure statements.

Sources: Letter submitted by ECRI member hospital. Advamed. HIMA petitions to clarify warning requirements under California's Proposition 65 [press release online]. 2000 Feb 20 [cited 2005 Mar 1]. Available from Internet: <http://www.advamed.org/publicdocs/prop65release3800.html>. Office of Environmental Health Hazard Assessment: Chemicals known to the state to cause cancer or reproductive toxicity [online]. 2005 Feb 11 [cited 2005 Mar 1]. Available from Internet: http://www.oehha.ca.gov/prop65/prop65_list/files/P65single21105.pdf. Notice of amendments to text of regulations title 22, California code of regulations sections 12601 and 12201 [online]. [cited 2005 Mar 1]. Available from Internet: http://www.oehha.ca.gov/prop65/law/pdf_zip/12601notice9502.pdf. Proposition 65 in plain language! [online]. 2003 Feb [cited 2005 Mar 1]. Available from Internet: <http://www.oehha.ca.gov/prop65/background/p65plain.html>. Title 22, division 2, California code of regulation. Chapter 3. Safe Drinking Water and Toxic Enforcement Act of 1986. Article 6. Clear and reasonable warnings [online]. 2002 Jul [cited 2005 Mar 1]. Available from Internet: http://www.oehha.ca.gov/prop65/law/pdf_zip/12601Regs.pdf.

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