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CALIFORNIA STATE BOARD OF PHARMACY ANNOUNCES

COMPREHENSIVE CHANGES TO DRUG COMPOUNDING REGULATIONS

The California State Board of Pharmacy announces the completion of a significant overhaul of regulations governing the preparation of compounded drugs by pharmacies, culminating a major effort to strengthen the oversight and enforcement of pharmacies that produce or ship compounded drug products for use by consumers in California.

The comprehensive changes includes amendments to multiple sections of Article 4.5. and Article 7 of Division 17 of Title 16 of the California Code of Regulations. The new regulations have been approved by the Office of Administrative Law (a required step in establishing regulations) and will take effect on Jan. 1, 2017.

The full text of the final requirements is available from the Board of Pharmacy website [here](#).

"These new regulations will enhance public safety and protect the health and well-being of California consumers who receive compounded medications," said Dr. Amy Gutierrez, president of the Board of Pharmacy. "The board has worked very closely with stakeholders to maximize the patient safety impact of these regulations within all licensed pharmacies."

The board launched its effort to strengthen California regulations governing drug compounding in the wake of national news reports of deaths and illnesses resulting from contaminated compounded products shipped to patients throughout the country. One of the worst cases occurred in 2012, when the New England Compounding Center in Massachusetts shipped tainted products to patients nationwide that resulted in more than 60 deaths and left hundreds of other patients injured from tainted injections.

Amendments to regulations in Article 4.5 cover a broad range of topics related to general drug compounding, including requirements for recordkeeping, labeling, policies and procedures, maintaining facilities and equipment, staff training and quality assurance.

Article 7 has been amended to expand sterile compounding requirements to drug products that are produced for administration by inhalation or into the eye as well as by injection. Specific sections in Article 7 set requirements for a wide range of topics, including recordkeeping; labeling; attire; training of staff, patients and caregivers; beyond use dating; and single-dose and multi-dose containers.

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