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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item IX - Pending Compounding Regulations, Title 16 California Code of Regulations, 1735 et seq., and 1751 et seq.; Status Update and Discussion and Consideration of Next Steps, if Necessary

Attachment 1

Background:

On September 14, the Office of Administrative Law approved the board's compounding regulations. These regulations commanded considerable board effort over the last few years, and are scheduled to take effect January 1, 2017.

A subscriber alert was released on September 15 to alert licensees about the completed adoption of the regulation. This alert is provided as an attachment to this memorandum.

The compounding regulations contain provisions that will require construction be undertaken in some pharmacies. Such construction may require a temporary time waiver to permit a pharmacy to do the structural modifications required. A process has been developed to do this which will be completed shortly.

This section contains a PowerPoint presentation made at the Enforcement and Compounding Committee Meeting providing the general process for submitting waivers in **Attachment 1**.

Attachment 1

Damoth, Debbie@DCA

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> on behalf of Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Thursday, September 15, 2016 1:49 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: COMPREHENSIVE CHANGES TO DRUG COMPOUNDING REGULATIONS APPROVED

CALIFORNIA STATE BOARD OF PHARMACY ANNOUNCES COMPREHENSIVE CHANGES TO DRUG COMPOUNDING REGULATIONS

The California State Board of Pharmacy today 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: http://www.pharmacy.ca.gov/laws_regs/1735_ooa_aprvd.pdf

"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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Making a Request for a Construction Waiver to Comply with CA's Compounding Regs

Draft Procedures

16 CA Code of Regulations

As proposed in the regulation (as subdivision 1735.6(f) and in 1751.4(l)), the waiver request shall:

1. be made in writing;

2. identify the provision(s) requiring physical construction, alteration, or improvement; *and*

3. contain a timeline for any such change.

Additional Requirements

- The board or its designee may grant the waiver for construction when, in its discretion, good cause is demonstrated for the waiver.

- The waiver provision is not an exemption from compliance with the compounding structural requirements, but a delay in required compliance.

Status of the Compounding Regulation Provisions

Once the compounding regulations have been approved (the expected decision date is about September 13), the board will begin accepting waiver requests. Information will be added to the website announcing the option and how to submit a waiver request.

However, if the regulation is not approved by the Office of Administrative Law and returned to the board for correction and future resubmittal, waiver requests will not be accepted until the regulation is approved.

Regulation Status

However, if the regulation is not approved by the Office of Administrative Law and returned to the board for correction and future resubmittal, waiver requests will not be accepted until the regulation is approved.

Process

The board expects to see in the pharmacy's or facility's written request for a waiver to permit construction the following items:

1. The name of the pharmacy, name of the individual submitting the request, title and contact information (address, email and phone number),
2. The reason for submitting the request, including the specific sections of California's compounding requirements requiring physical construction, alteration or improvement that are the reason for the waiver request,

Process

3. A description of the status of the construction process in the pharmacy:
   - Is there an architect, if so who?
   - Is this a structural modification, describe
   - Have building plans been developed?
   - Has a building permit been secured?
   - Time frame for completion of construction.

Remaining Components

4. If review by OSHPD is required, provide a copy of “Project Completion Timeline” and the “General OSHPD Project Number.”

5. A written description of how the pharmacy will perform compounding while the construction waiver is in effect.