



**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: June 26, 2014 Board Meeting Overview

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**At this board meeting the board will have the opportunity to:**

1. Take action on two items from the June 18 Licensing Committee Meeting (the remainder of the (Agenda Item III (a) and (b))
2. Hear a presentation on a different aspect of drug diversion, and discuss drug losses from pharmacies (Agenda Item IV)
3. Review comments and testimony to modify the patient centered labeling requirements to require 12 point font and only the patient-centered items may appear in the 50 percent dedicated space (Agenda Item V)
4. Review the proposed new draft of amendments to the board's compounding regulations. If the board believes the draft is ready for public comment, it will be given the opportunity to release it for the initial 45-day comment period (Agenda Item VI)
5. Hear an update on the status of implementation of the new sterile compounding requirements (Agenda Item VII)
6. Hear one petition for early termination of probation (Agenda Item VIII)
7. Hear one petition for reinstatement (Agenda Item IX)
8. Meet in Closed session to resolve the petitions



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GOVERNOR EDMUND G. BROWN JR.

To: Board Members

**Subject: AGENDA ITEM III -- June 18, 2014 Licensing Committee Report**

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Two Action Items from the Licensing Committee Meeting held June 18, 2014. A full report will be provided at the July 2014 Board Meeting

**a. FOR DISCUSSION AND POSSIBLE ACTION: Request for a Waiver Under California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, Sections 4128 et seq. Requests Are from Two Hospitals:**

- (a) Mercy Hospital of Folsom**
- (b) Loma Linda University Medical Center**

**Attachment 1**

Background

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are Barcoded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012).

Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read. The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals. Specifically, the board's letter to the governor included the following:

“...Bar coding is important for patient safety. Before a medication is administered to a patient, by scanning the bar code on a medication, a patient's chart and a patient's wristband the right medication, in the right dose will be ensured at the patient's bedside. This provides an important step forward to improve patient safety and decrease the rate of medication errors and potential adverse drug events...”

At the January 2014 Board Meeting, Sharp Hospital and Scripps Health San Diego appeared before the board seeking an exemption to allow them to secure a centralized packaging license, but limitations in their software that prohibit full compliance with the barcode requirements

specified in Section 4128.4. The items listed in section 4128.4 appear on the label but not in the barcode. Instead Scripps Health System and Sharp Hospital requested that the board interpret the meaning of those provisions more broadly to allow additional time following licensure for the hospitals to fully comply with the requirements in statute.

Section 4028.4 requires:

**4128.4. Barcode Required; Information Retrievable Upon Reading Barcode**

Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy.

The board approved both waivers. Excerpts of the minutes from this meeting are provided in **Attachment 1**.

Licensing Committee Discussion:

Attending the June 18, 2014 meeting were representatives from Mercy Hospital of Folsom. Loma Linda University was unable at the last minute to have a representative present; as such, Loma Linda will provide this request directly to the board at today's board meeting.

Both hospitals are requesting similar waivers from the board. **Attachment 1** also includes a copy of the waiver request from each hospital system.

The committee heard the requests and recommended for Mercy Hospital:

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**Motion: Licensing Committee:** Recommend that the board approve a five-year waiver for Mercy Hospital of Folsom that as long as the required labeling elements appear on the label and the lot number is provided on the label, and the required data elements are otherwise retrievable, waive the requirement that the data elements in section 4128.4 be retrievable at the patient's bedside by way of a barcode.

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Loma Linda University will be given time at this board meeting to make a waiver request directly to the board. The committee did request copies of the hospital's labels. These labels are provided in **Attachment 1**.

b. **FOR DISCUSSION AND POSSIBLE ACTION: Request from California Health Sciences University Possessing ACPE “Pre-Candidate” Accreditation for Recognition by the Board of Pharmacy Under Section 16 CCR § 1719 for Purposes of Issuing Intern Licenses**

**Attachment 2**

Background:

Current regulation, Title 16 CCR 1719, states that a "recognized school of pharmacy" means a school accredited, or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE). Specifically:

1719. Recognized Schools of Pharmacy.

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

There are three levels to full ACPE accreditation status for new schools of pharmacy: pre-candidate status, candidate status and full accreditation. A school may be granted candidate status once the school has produced its first class of graduates. At this point, section 1719 allows the board to issue intern licenses to current and future students. However, before possessing candidate status and while students are "moving through the program at a new school, the school may have pre-candidate status with ACPE. This means that the school is progressing to meet the ACPE accreditation standards but has not yet completed the process nor graduated its first class. In such cases, the board must recognize the school for purposes of issuing an intern license. In order to secure the training expected by ACPE, students need intern licenses.

ACPE does not award pre-candidate status to new schools that are not adequately progressing towards full accreditation.

There are at least three new schools of pharmacy seeking to establish themselves in California. Only one possesses pre-candidate status at the time of the June 18 Licensing Committee Meeting.

The California Health Sciences University School of Pharmacy, Fresno, CA, has been granted pre-candidate status by the ACPE. The first class of students will be admitted in the fall of 2014. In order for the school’s students to secure the training they need, the students need intern licenses. Lacking ACPE candidate status, the board cannot currently issue these licenses to students.

Recently, the California Health Sciences University School of Pharmacy requested board recognition of its program for purposes of issuing intern pharmacist licenses to students attending their program. A copy of the letter from the school requesting recognition by the board is provided in **Attachment 2**.

The ACPE confirms that CHSU possesses pre-candidate status and is moving through the steps required to ultimately secure ACPE full accreditation.

There was no one present from CHSU to make a presentation about the school.

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**Motion: Licensing Committee:** recommend that the board recognize California Health Sciences University School of Pharmacy for purposes of issuing intern licenses to its students. Direct Staff will maintain contact with ACPE to ensure the school continues to move towards full ACPE accreditation status in the future.

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DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

**Subject: AGENDA ITEM IV -- Presentation by Joseph F. Perz, DrPH**

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**FOR DISCUSSION:** Presentation by Joseph F. Perz, DrPH, on His Findings and Article "Outbreaks of Infections Associate with Drug Diversion by US Health Care Personnel," and Discussion by the Board on Drug Diversion Issues

**Attachment 3**

During this meeting, we will have a telephone presentation from Dr. Perz on his research involving another aspect of danger posed by drug diversion. His article is in **Attachment 3**.

The board will also have an opportunity to discuss drug diversion issues in general. At the last meeting, the board began discussions of working on a requirement that pharmacies count at periodic intervals more frequent than every two years (which is when the DEA biennial inventory is due), their top 10 controlled substances dispensed by the pharmacy. Last year, 1.5 million dosage units of controlled drugs were reported as lost/diverted/stolen to the board.



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GOVERNOR EDMUND G. BROWN JR.

**June 20, 2014**

**To: Board Members**

**Subject: AGENDA ITEM V – Patient-Centered Prescription Container Labels**

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**DISCUSSION AND POSSIBLE ACTION:** To Make Changes in Response to Comments or to Adopt or Amend Proposed Text at 16 California Code of Regulations Section 1707.5 Relating to Patient-Centered Prescription Container Labels

At the October 2013 Board Meeting, the board voted to modify the board's patient-centered prescription label requirements at Section 1707.5 (a) (1) to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point san serif typeface.

At the January 2014 Legislation and Regulation Committee meeting, the committee motioned to make a recommendation to the board to initiate the rulemaking. At the January 2014 Board Meeting, the board approved a motion to initiate a rulemaking to amend Section 1707.5 to Title 16 of the California Code of Regulations.

The rulemaking was noticed on April 11, 2014, and the 45-day public comment period concluded on May 26, 2014. A hearing was requested and conducted on May 27, 2014. The board received four written comments and had four people provide testimony at the hearing on May 27, 2014. A copy of the proposed text, summary of comments and draft board response as well as the comments are provided in **Attachment 4**.



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DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**June 20, 2014**

**To: Board Members**

**Subject: AGENDA ITEM VI – Pharmacy Compounding**

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**DISCUSSION AND POSSIBLE ACTION: To Initiate Rulemaking to Adopt Proposed Text at 16 California Code of Regulations 1753 ET Seq. Relating to Pharmacy Compounding**

At the October 2013 Board Meeting, the board moved to notice the proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45-day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

During the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments received by section number, to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online. At the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments.

At the April 2014 Board meeting, after reviewing and considering the written and oral comments received, board staff recommended the following for the following for discussion and possible action:

1. Withdraw the current rulemaking file originally noticed November 29, 2013.
2. Provide general guidance from the sterile compounding workgroup to develop new updated language based on substantive comments received by the board and notice the revised language as a new rulemaking.

The Board voted to withdraw the current compounding rulemaking, revise the language to incorporate many comments submitted in response to the initial regulation notice and notice the new language as a new rulemaking.

Attached is a copy of tables and charts to incorporate by reference as well as the revised draft text in **Attachment 5**.

# **Attachment 1**



RECEIVED BY CAL  
BOARD OF PHARMACY  
2014 APR 30 PM 12:13

April 15<sup>th</sup>, 2014

Virginia Herold, Executive Officer  
California State Board of Pharmacy  
1625 North Market Blvd, N219  
Sacramento, CA 95834

RE: Centralized Packaging Pharmacy Request for Waiver

Dear Ms. Herold,

Mercy Hospital of Folsom has recently applied for a Centralized Packaging Pharmacy License on June 6, 2013. The state regulations request specific information to be included in the barcode for medications labeled in a Centralized Packaging Pharmacy. The specific requirements of Article 7.6 section 4128.4 of the Business and Professions Code include:

- a. The date the medication was prepared.
- b. The components used in the drug product.
- c. The lot number or control number.
- d. The expiration date.
- e. The National Drug Code (NDC) directory number.
- f. The name of the centralized hospital packaging pharmacy.

We respectfully request a waiver from the aforementioned barcode requirements of Article 7.6 Section 4128.4. Current technology utilized for bedside medication scanning by nurses to ensure that the correct medication is being administered is limited by configuration to including the NDC number. As such, if we were to add the additional required information, the barcode would not be recognized and the medication safety check would fail.

Lastly, in compliance with Article 7.6 section 4128.4 requirements, all of the information is provided in text form on the medication label.

Please contact Randy Castillo at [Randall.Castillo@DignityHealth.org](mailto:Randall.Castillo@DignityHealth.org) or (916) 983-7410 if you have any additional questions or for further discussion.

Sincerely,

A handwritten signature in black ink, appearing to read "Randy Castillo".

Randall Castillo  
Vice President  
Mercy Hospital of Folsom  
1650 Creekside Drive  
Folsom, CA 95630



LOMA LINDA UNIVERSITY

MEDICAL CENTER

RECEIVED BY CALIF  
BOARD OF PHARMACY

2014 MAY -1 AM 11:28

April 30, 2014

Virginia Herold, Executive Officer  
California State Board of Pharmacy  
1625 N. Market Street, Suite N-219  
Sacramento, CA 95834

**RE: Temporary Exemption BPC 4128.4**

Ginny,

Thank you for meeting with me last Friday, April 25<sup>th</sup>, during the CPhA Convention. It was good to see you and I appreciate the time you allowed for us to discuss the Centralized Hospital Packaging Pharmacy Licensing (CPL) for LLUMC. The application has been submitted to the Board for processing and approval.

We discussed BPC 4128.4 as it pertains to the Barcode requirements for a CPL.

**BPC 4128.4. Barcode Required; Information Retrievable Upon Reading Barcode**

Any unit dose medication produced by a centralized hospital packaging pharmacy shall be barcoded to be readable at the inpatient's bedside. Upon reading the barcode, the following information shall be retrievable:

- (a) The date the medication was prepared.
- (b) The components used in the drug product.
- (c) The lot number or control number.
- (d) The expiration date.
- (e) The National Drug Code Directory number.
- (f) The name of the centralized hospital packaging pharmacy

Currently, in the barcode, we have the National Drug Code Directory number coded in the label. We can retrieve A, B, C, D and F, however, this data is not yet inserted in the existing barcode, but we are diligently working with EPIC, our software provider, to have the required information embedded as soon as possible. Once I know the timeframe for the "fix", the information will be communicated immediately to the Board.

At this time, we are requesting a temporary exemption for BPC 4128.4

Thank you again Ginny and I appreciate your help with this licensure. We are hoping to have the license by May 30<sup>th</sup>, 2014.

Sincerely,

Paul Norris, Pharm.D.  
Executive Director of Pharmacy Services

*A Seventh-day Adventist Institution*

HOSPITAL PHARMACY | 11223 Campus Street, Loma Linda, California 92354

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**EXCERPT FROM THE CALIFORNIA STATE BOARD OF PHARMACY BOARD MEETING MINUTES  
JANUARY 30, 2014**

**7. Discussion and Possible Action on the Requests from Scripps Health San Diego and Sharp Health System for Waiver of California Business and Professions Code Section 4118 Pertaining to Licensure as a Centralized Hospital Packaging Pharmacy, California Business and Professions Code Sections 4128 et seq.**

In 2012 the California Society of Health System Pharmacists and the California Hospital Association sponsored legislation to establish a centralized hospital packaging license which would allow a hospital chain under common ownership to consolidate packaging operations into a single location in a specialized pharmacy to prepare single dose medications that are bar coded. The specific provisions were contained in AB 377 (Solorio, Chapter 687, Statutes of 2012). Included in the provisions of this measure was the requirement that the unit dose medications filled by the centralized hospital packaging license be barcoded to be readable at the inpatient's bedside and specifies the information that must be retrievable when the barcode is read.

The board supported this measure and actively advocated for its passage because of the significant positive impact the use of barcoding would have on the reduction of medication errors that occur in hospitals.

Recently board staff was advised that Scripps Health San Diego had limitations in its software that prohibit full compliance with the barcode requirements specified in section 4128.4. Scripps Health System is requesting that the board interpret the meaning of the provisions more broadly to allow additional time following licensure to fully comply with the requirements. Scripps indicated that it does have a bar code that is readable at the bedside that identifies the drug, dosage and strength.

Sharp Health Care also notified the board that it was unable to affix a barcode to each container to read the specific information identified in section 4128.4.

In preparing for this meeting, board staff conferred with counsel on the applicability of such a waiver given the specificity of the language in Business and Professions Code section 4118. This request is being brought to the board for consideration and to provide direction to staff on the waiver request as well as interpretation and application of section 4118.

Bob Miller stated that Scripps became aware that the provision in section 4128.4 that speaks to the retrieval of patient information at the patient's bedside was being interpreted by the board differently than what they had expected. Their expectation was that if they put a barcode on all their doses which included the lot number, then based on the lot number, they would be able to retrieve the patient information at the bedside. Their barcoding system, however, doesn't actually pull up that information and show it to the nurse. The purpose of the appearance before the board is to ask the board to adopt a broader interpretation of the provisions of the new law and make the case as to why their system is in compliance, or alternatively, to ask the board for a waiver until the technology becomes available to permit the reading of the additional bar code information.

Ken Scott explained that all the required patient information is actually retrievable from the label of each unit dose medication container, it is not encoded into the barcode.

Mr. Room provided information regarding Business and Professions Code section 4128.4 which states that upon reading the barcode, the six data elements shall be immediately retrievable. In his opinion, one of the conditions of licensure is that the licensee has the ability to perform that technological service.

Mr. Room presented three different options with which the board could deal with this situation.

1. Pursuant to Business and Professions Code section 4118, the board has the ability to waive a requirement for licensure.
2. The board could exercise enforcement discretion and allow a specified time period to come into compliance. This option would have to be applied to all licensees.
3. The board could return to the legislature and to clarify which data elements, if any, have to be retrievable at the bedside.

Dr. Gutierrez stated the data elements need to be retrievable in case of a recall. She asked for an explanation of Scripps' process if a medication is recalled. Ms. Benner stated that the batch record is an electronic record and they capture all data elements including the lot number, expiration date, and all components of the compound. The recalled medication could be traced back to a patient by conducting a search. Mr. Room stated that although the data elements are readable (on the label), he thinks the intent of the law was to link the data elements on the barcode to a database where the elements would be present and retrievable.

Mr. Santiago stated that it was arguable whether the board could grant a waiver pursuant to Business and Professions Code section 4118 because the language is a waiver for a requirement of licensure. Ms. Herold clarified that Scripps had not been issued a license based on their inability to meet the law's requirements.

Mr. Santiago also stated that the board could not use its enforcement discretion across the board because that would constitute an underground regulation. Mr. Room agreed. Steve Gray, representing the California Society of Health-System Pharmacists (CSHP), stated that CSHP was the sponsor of the bill and he was personally involved in developing the language. He stated that the board's interpretation of the law is incorrect and that the intent was not to have the data readable at the bedside. He didn't believe that a waiver was necessary, but he offered to work with the CHA to create some clarifying language.

Perry Flowers, representing Kaiser Permanente, spoke in support of Scripps and Sharp.

Board Discussion Ms. Veale asked if the board waives this requirement for Scripps and Sharp they would open it up for anyone to seek waiver. Mr. Room confirmed that the board would have to review and approve each request for waiver and added that CSHP has already created some language and is searching for an author.

Jonathan Nelson, CSHP, commented that currently they are working with the legislature to get this issue resolved.

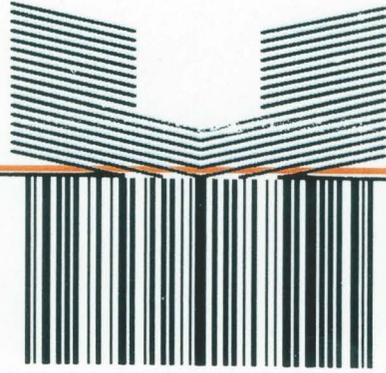
**Committee Recommendation (Motion):**

Support: 10 Oppose: 0 Abstain: 0

Jonathan Nelson, CSHP, commented that they will be including the lot number requirement in their proposed legislation language.

This Bag Made With EarthAware™  
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LOT: 31185/061814



NDC 0075-8018-10  
EXP: 07/16

ENOXAPARIN  
80MG INJ  
LOVENOX

Loma Linda Medical Center  
11223 Campus Street  
Loma Linda, CA 92354

Virginia

THE LAST SIX DIGITS ARE THE PREPARATION DATE.  
THE ACTUAL LOT NUMBER IS KEPT IN OUR PRODUCTION  
LOG.

M

ROBOT READY PACKAGE  
METHOCARBAMOL  
500 MG TAB  
METHOCARBAMOL

Rx Only

BULK1 EXP 05/15  
LOMA LINDA MEDICAL CENTER  
LOT E140122/061814  
31722-533-01



# **Attachment 2**

May 19, 2014

Virginia Herold, Executive Director  
California State Board of Pharmacy  
1625 North Market Blvd, Suite N219  
Sacramento, CA 95834

**Re: California Code of Regulation Section 1719 Requesting Approval**

Dear Executive Director,

California Health Sciences University College of Pharmacy (CHSUCOP) Doctor of Pharmacy program has applied for accreditation status by the Accreditation Council of Pharmacy Education (ACPE) and has been granted precandidate status in January of 2014.

Pursuant to California Code of Regulation section 1719, I am requesting board approval of the California Health Sciences University College of Pharmacy (CHSUCOP) for purposes of issuing intern licenses for schools who possess Accreditation Council of Pharmacy Education (ACPE) precandidate status. The board's recognition of CHSUCOP for purposes of issuing intern licenses will ensure that our students are able to pursue intern requirements while they earn their education as CHSUCOP is moving towards full candidate status with ACPE.

I will provide updates to the board on the status of our ACPE accreditation and when we secure candidate status.

Please feel free to contact me at any time.

Warmest Regards,



Grant D. Lackey, PharmD, CSPI, FASCP, FCSHP  
Cell: 916-204-0192

[glackey@chsu.org](mailto:glackey@chsu.org)

cc: David Hawkins, PharmD; Provost and Dean  
Florance Dunn, President

# **Attachment 3**

# Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel

Melissa K. Schaefer, MD, and Joseph F. Perz, DrPH

## Abstract

**Objective:** To summarize available information about outbreaks of infections stemming from drug diversion in US health care settings and describe recommended protocols and public health actions.

**Patients and Methods:** We reviewed records at the Centers for Disease Control and Prevention related to outbreaks of infections from drug diversion by health care personnel in US health care settings from January 1, 2000, through December 31, 2013. Searches of the medical literature published during the same period were also conducted using PubMed. Information compiled included health care setting(s), infection type(s), specialty of the implicated health care professional, implicated medication(s), mechanism(s) of diversion, number of infected patients, number of patients with potential exposure to blood-borne pathogens, and resolution of the investigation.

**Results:** We identified 6 outbreaks over a 10-year period beginning in 2004; all occurred in hospital settings. Implicated health care professionals included 3 technicians and 3 nurses, one of whom was a nurse anesthetist. The mechanism by which infections were spread was tampering with injectable controlled substances. Two outbreaks involved tampering with opioids administered via patient-controlled analgesia pumps and resulted in gram-negative bacteremia in 34 patients. The remaining 4 outbreaks involved tampering with syringes or vials containing fentanyl; hepatitis C virus infection was transmitted to 84 patients. In each of these outbreaks, the implicated health care professional was infected with hepatitis C virus and served as the source; nearly 30,000 patients were potentially exposed to blood-borne pathogens and targeted for notification advising testing.

**Conclusion:** These outbreaks revealed gaps in prevention, detection, and response to drug diversion in US health care facilities. Drug diversion is best prevented by health care facilities having strong narcotics security measures and active monitoring systems. Appropriate response includes assessment of harm to patients, consultation with public health officials when tampering with injectable medication is suspected, and prompt reporting to enforcement agencies.

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In May 2012, the New Hampshire Department of Health and Human Services began investigating a cluster of hepatitis C virus (HCV) infections at a single hospital.<sup>1</sup> This investigation uncovered a large HCV outbreak spanning several years, involving more than a dozen hospitals, and impacting thousands of patients in 8 states. This outbreak was caused by an HCV-infected traveling radiology technician who, in August 2013, admitted to having been addicted to narcotics and diverting medications such as fentanyl from patients.<sup>2</sup> The mechanism of diversion used by the technician involved a form of tampering that exposed patients to his blood. This outbreak has resulted in multiple lawsuits involving the staffing agencies and institutions that employed the technician.<sup>3</sup> This multistate outbreak and others

like it have revealed multiple gaps in prevention, detection, and response to drug diversion in US health care facilities.<sup>4-6</sup>

The National Association of Drug Diversion Investigators defines drug diversion as

any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient. This can include the outright theft of the drugs, or it can take the form of a variety of deceptions such as doctor shopping, forged prescriptions, counterfeit drugs and international smuggling.<sup>7</sup>

Diversion by health care personnel represents one facet of drug diversion that is gaining recognition as a ubiquitous and poorly controlled patient safety risk.<sup>8</sup> Mechanisms



**For editorial comment, see page XX**

From the Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, GA.

of diversion by health care personnel can include documentation of a medication dose not actually administered to the patient but saved for use by the health care professional, theft by scavenging of wasted medication (eg, removal of residual medication from used syringes), and theft by tampering (eg, removal of medication from a medication container or syringe and replacement with saline or other similar-appearing solution that may be administered to patients). Patient safety is compromised whenever diversion by health care personnel occurs. Harms can include patients not obtaining adequate pain management, exposure to substandard care from an impaired health care professional, and exposure to life-threatening infections.<sup>8</sup> However, when diversion is suspected or identified, the potential for patient harm may be overlooked.

In light of the multistate outbreak of HCV infections identified in New Hampshire and the gaps it highlighted, we reviewed reported outbreaks of infections resulting from drug diversion by health care personnel in US health care settings. In this article, we offer a summary of available information about the types of infections, drugs, mechanisms of diversion, and health care personnel that have been associated with outbreaks stemming from this activity. We conclude with a summary of recommended standard protocols and public health actions that should be considered when diversion by health care personnel is suspected or identified.

## PATIENTS AND METHODS

The Division of Healthcare Quality Promotion at the Centers for Disease Control and Prevention (CDC) frequently assists health departments and institutions with investigations of outbreaks involving health care exposures, including drug diversion. We reviewed our internal records and CDC-authored reports related to US outbreaks from drug diversion by health care personnel for the 14-year period extending from January 1, 2000, through December 31, 2013. A PubMed search was conducted for outbreak investigations occurring during the same time period using combinations of key words including *outbreak*, *diversion*, and *narcotics*. We also examined reference lists from selected publications seeking to identify additional outbreaks meeting our inclusion criteria.

For the purposes of this review, an *outbreak* was defined as a health care–associated infection occurring in 2 or more patients in whom disease transmission likely resulted from drug diversion by health care personnel in a US health care facility. We excluded outbreaks occurring prior to January 1, 2000, outbreaks occurring in health care settings outside the United States, as well as reports of drug diversion in which no resulting patients infections were documented.

We compiled the following information for each outbreak identified: year investigated, state(s), health care setting(s), specialty of the implicated health care professional, implicated medication(s), infection type(s), number of patients with documented or suspected infection, mechanism(s) of diversion, and resolution of the investigation. We relied on case definitions developed by investigators for each specific outbreak when enumerating the number of infected patients. Typically, case definitions were based on results of laboratory testing and temporal associations between health care exposures and symptom or infection onset among affected patients.

Patient notification, with recommendations for blood-borne pathogen testing, is often performed when health care–associated viral hepatitis transmission risks are identified.<sup>9</sup> For outbreaks of HCV infection, we compiled information about the number of facilities performing notification and the number of potentially exposed patients, using information from media reports and other sources that were available online or in our files.

## RESULTS

We identified 6 outbreaks of infections that resulted from drug diversion by health care personnel in US health care settings in the past 10 years. Two outbreaks resulted in gram-negative bacteremia in 34 patients; the remaining 4 outbreaks resulted in HCV infection in 84 patients. All of the outbreaks occurred in one or more hospitals; these facilities were located in 8 states. Tampering with injectable controlled substances was documented or suspected in all of the outbreaks; fentanyl was diverted in at least 4 of these events.

Implicated health care professionals included 3 technicians and 3 nurses (including 1 certified registered nurse anesthetist [CRNA]); 2 of the health care professionals were

women.<sup>10,11</sup> Four of the health care professionals were documented to be infected with HCV. Of the remaining 2 health care professionals, 1 was tested in the midst of the outbreak and did not have hepatitis B virus, HCV, or human immunodeficiency virus<sup>12</sup>; blood-borne pathogen testing was either not performed or not reported for the other health care professional.<sup>10</sup>

### Summary of Bacterial Outbreaks

**Illinois Hospital, 2006.** From January 1 through July 15, 2006, 9 medical-surgical patients at an Illinois hospital had development of *Achromobacter xylosoxidans* bacteremia.<sup>10</sup> All of the infected patients received morphine via a patient-controlled analgesia pump (PCA) before bacteremia developed. Having a PCA pump cartridge started by one nurse was statistically significantly associated with becoming a case-patient. This nurse was the only nurse on the unit who worked during the period from hospital admission to before fever onset for all 9 cases. Investigators hypothesized that the nurse may have substituted contaminated water for the morphine or used contaminated needles or syringes to extract the morphine from cartridges. The nurse resigned from the hospital upon being informed of the association with *A. xylosoxidans* bacteremia. The state licensing board was informed, but no disciplinary action was taken.

**Minnesota Hospital, 2011.** Gram-negative bacteremia developed in 25 surgical patients at a Minnesota hospital between October 2010 and March 2011.<sup>12,13</sup> The predominant pathogens identified in blood cultures from infected patients were *Klebsiella oxytoca* and *Ochrobactrum anthropi*. The 6 infected patients initially identified all received hydromorphone via a PCA. The identification of the same bacteria in 2 patients' blood and 2 hydromorphone bags in use by these patients led to concerns about possible drug diversion as the source of the outbreak. A review of automated dispensing logs identified a nurse who had an access rate several times greater than that of any other staff during the outbreak period. This nurse admitted to tampering with narcotic bags from locked narcotic boxes. The nurse reported peeling back the foil covering on the ports of bags containing drugs such as hydromorphone, withdrawing narcotic with a syringe, replacing displaced

liquid with saline solution, and returning the bags to the lock box. *O. anthropi* was found in a saline bottle collected from the nurse's desk. The nurse was removed from practice and, in 2012, pled guilty to obtaining a controlled substance by fraud and was sentenced to 2 years in prison.

### Summary of HCV Outbreaks

**Texas Hospital, 2004.** Between July and October 2004, 16 surgical patients at a Texas hospital had development of HCV infection (CDC, unpublished data, 2004).<sup>14-16</sup> All 16 patients had received care from an HCV-infected CRNA. The 2 index patients were detected in September 2004 when acute HCV infection was diagnosed following surgical procedures on consecutive days in August 2004. The infected CRNA was identified early in the investigation as a result of health care personnel testing that targeted surgical staff who had cared for the first 5 infected patients identified. The CRNA denied having engaged in diversion activities but was suspended from clinical care duties and was offered treatment for HCV infection. The CRNA left Texas and went on to practice in other states. In 2009, the CRNA admitted to diverting fentanyl by a variety of methods. One of those methods involved removing portions of fentanyl from vials that were designated for an impending patient procedure; a syringe was used to transfer this fentanyl to a vial kept for personal use, which was likely contaminated with the CRNA's blood. Reportedly, the remainder of the fentanyl in the patient vials was then administered to patients using the same syringe that was used to make the transfer. This mechanism of transmission by indirect syringe reuse, involving accessing contaminated vials or containers, has been well documented in other viral hepatitis outbreaks associated with health care and injection drug use.<sup>17,18</sup> Epidemiological and laboratory evidence indicated that the CRNA became infected, sequentially, with 2 different strains of HCV from chronically infected patients and subsequently transmitted them to susceptible patients. The CRNA pled guilty to aggravated assault and possession of a controlled substance by fraud and, in 2009, was sentenced to 41 months in prison.

**Florida Hospital, 2008.** Five interventional radiology patients at a Florida hospital had

development of HCV infection.<sup>19,20</sup> The 3 initially detected patients were identified between January 2007 and December 2008; none were identified because of symptomatic infection. Rather, 2 were organ transplant patients identified through routine screening conducted as part of facility protocols, and 1 was identified through evaluation of an unexplained increase in liver enzymes. All had previously negative HCV RNA test results. Through molecular analysis, the HCV isolates from the patients were found to be genetically related, further supporting the likelihood of health care–associated transmission. Record review of these 3 patients revealed that all had received fentanyl in the interventional radiology unit of the hospital. Twenty-one employees assigned to the interventional radiology area were recorded as being at work when these patients received fentanyl and submitted blood specimens for testing. A radiology technician was found to be infected with an HCV strain that was genetically related to the patient isolates. The technician reported the following methods of diversion: (1) removing syringes containing residual fentanyl from used sharps containers and (2) self-administering fentanyl from a syringe that had been filled in anticipation of patient care, refilling the syringe with saline, and returning the syringe to the patient care area. The technician pled guilty to tampering with a consumer product resulting in death, tampering with a consumer product resulting in serious bodily injury, and stealing fentanyl by deception and, in 2012, was sentenced to 30 years in prison.

**Colorado Hospital, 2009.** Hepatitis C virus infection developed in 18 surgical patients at a Colorado hospital (Colorado Department of Public Health and Environment [CDPHE], unpublished data, 2010).<sup>11</sup> Two cases of acute HCV infection were initially reported to the health department in April 2009. Both patients denied traditional risk factors for HCV infection but had undergone surgical procedures at the same hospital during their exposure period and shared a common HCV genotype. An HCV-infected surgical technician, who had recently been terminated for suspicion of narcotics diversion, was identified early in the investigation as a possible source of the infections. Following termination from the hospital, the technician had gained

employment at an ambulatory surgical center. The technician reported removing predrawn syringes of fentanyl from unattended anesthesia carts, self-injecting the fentanyl, refilling the syringes with saline, and returning the syringes to the cart. The technician pled guilty to tampering with a consumer product and obtaining a controlled substance by deception and, in 2010, was sentenced to 30 years in prison.

**New Hampshire, Kansas, and Maryland Hospitals, 2012.** Forty-five cardiac catheterization/interventional radiology patients from 4 hospitals in 3 states had development of HCV infection.<sup>1,2,21</sup> An HCV-infected traveling radiology technician was part of a cluster of HCV-infected patients reported to the health department by a single New Hampshire hospital in May 2012. The technician was suspected as the source of the outbreak on the basis of factors including review of work schedule and key card access, reports of behavior concerning for drug abuse, suspected duration of the outbreak, and results of molecular testing. The technician eventually admitted to stealing syringes filled with narcotics, self-injecting, refilling them with saline, and placing them back into the procedure area. This act had been repeated at multiple hospitals over several years. The technician pled guilty to tampering with a consumer product and obtaining controlled substances by fraud and, in 2013, was sentenced to 39 years in prison.

#### **Patient Notification and Blood-borne Pathogen Testing**

Patient notification and blood-borne pathogen testing was described for the 4 HCV outbreaks<sup>1,19,22-25</sup> (CDC, unpublished data, 2004, 2013; CDPHE, unpublished data, 2010) (Table 1). These activities supported case-finding efforts as part of the public health investigations. In each of these instances, additional cases of documented HCV transmission, reflected in the total case counts described previously, were identified. In total, nearly 30,000 patients were determined to have been potentially exposed and were targeted for notifications advising blood-borne pathogen testing. Of note, the number notified may have been less than the number potentially exposed; for example, patients who had died in the interval

**TABLE 1. Summary of Patient Notification Efforts for Outbreaks of HCV Infection Associated With Diversion of Narcotics by HCV-Infected Health Care Personnel<sup>a</sup>**

Year investigated	State(s) that notified patients	Time period for potential exposure	No. of health care facilities that notified patients	No. of potentially exposed patients	Reference
2004	Texas, District of Columbia	2004-2006	3: Hospital where the outbreak was initially identified, hospital where the CRNA worked at the same time as the outbreak hospital, and hospital where the CRNA worked after the outbreak hospital	1497: 1135 patients at the outbreak hospital and 362 patients at the 2 additional hospitals	CDC, unpublished data, 2004
2008	Florida	2004-2010	1: Hospital where the outbreak was initially identified	6132	19
2009	Colorado, New York	2007-2009	3: Hospital where the outbreak was initially identified, ASC where the surgical technician worked after the outbreak hospital, and hospital where the technician worked before the outbreak hospital	8770: 4748 patients at the outbreak hospital, 1222 patients at the ASC, and approximately 2800 patients at the additional hospital	22, Colorado Department of Public Health and Environment, unpublished data, 2010
2012	Arizona, Georgia, Kansas, Maryland, Michigan, New Hampshire, New York, Pennsylvania	2005-2012	16: Hospital where the outbreak was initially identified and 15 hospitals where the radiology technician worked before the outbreak hospital	>12,000 patients: 4719 patients at the outbreak hospital and more than 7500 <sup>b</sup> patients from the 15 additional hospitals	1,23-25, CDC unpublished data, 2013

<sup>a</sup>ASC = ambulatory surgical center; CRNA = certified registered nurse anesthetist; HCV = hepatitis C virus.  
<sup>b</sup>Exact number of patients notified at all 15 hospitals not available.

between the potential exposure and patient notification were not always included in the actual notifications. In 3 of the outbreaks, because of concerns about previous or ongoing diversion activities, patient notification expanded beyond the facility where the outbreak was detected to include other facilities where the implicated health care professional had worked or was working (CDC, unpublished data, 2004, 2013; CDPHE, unpublished data, 2010).<sup>1,22-25</sup>

## DISCUSSION

Over the past 10 years, outbreak investigations have documented more than 100 infections and nearly 30,000 potentially exposed patients stemming from drug diversion in US health care facilities. The frequency with which these events have been detected appears to have increased; using similar methods, we identified 3 additional US outbreaks of this type in the previous 20 years.<sup>26-28</sup> For HCV, drug diversion has emerged as the leading cause of health care transmission between infected health care professionals and patients.<sup>29</sup> All of the

outbreaks described herein involved diversion of injectable controlled substances, with contamination and infections resulting from some form of tampering by the implicated health care professional. A variety of health care professionals were implicated in these outbreaks; 3 of the 6 were employed as technicians who lacked authorized primary access to the diverted medication. In most of these events, diversion was not suspected or identified by the affected facilities until many patients had become infected. In several cases, implicated health care professionals were able to gain subsequent employment at other health care facilities, despite evidence or concerns about diversion. As a result, thousands of additional patients were placed at risk.

These outbreaks highlight gaps in the prevention, detection, and response to drug diversion in US health care facilities. Under Title 21, CFR Section 1301.71(a), the Drug Enforcement Administration (DEA) "requires that all registrants provide effective controls and procedures to guard against theft and diversion of controlled substances."<sup>30</sup> In their Conditions

**TABLE 2. Steps for Health Care Facilities to Address Patient Safety When Drug Diversion Is Identified**

1. Prevent further risk to patients at the facility
  - a. Remove the implicated health care professional from the clinical environment and revoke any previously authorized access to controlled substances (eg, suspend computerized access to automated medication dispensing machines) pending further investigation
  - b. Evaluate security of controlled substances to address gaps in adherence to recommended and required practices
2. Prevent risk to patients at other health care facilities
  - a. Engage law enforcement
    - i. Local law enforcement
    - ii. Drug Enforcement Administration (DEA)
      - a. DEA registrants are required to notify the DEA of the theft or significant loss of any controlled substance within 1 business day of discovery of such loss or theft
    - iii. Food and Drug Administration Office of Criminal Investigation, particularly if product tampering, including substitution, is suspected
  - b. File report with applicable licensure agencies (eg, physician or nursing board, state board of pharmacy)
3. Assess retrospective risk to patients
  - a. Attempt to ascertain the mechanism(s) of diversion used by the implicated health care professional
    - i. Were injectable medications diverted?
    - ii. Was any type of tampering with injectable medication performed? If yes, assess potential for patients to be exposed to the health care professional's blood (eg, through swapping with syringes previously used by the health care professional)
  - b. If tampering with injectable medication is suspected, pursue blood-borne pathogen testing of the implicated health care professional
  - c. Use information from steps 3 a-b to determine need for patient notification and testing. This should be performed in consultation with the local or state health department

of Participation for hospitals, the Centers for Medicare and Medicaid Services requires that “drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.”<sup>31</sup> Injectable schedule II drugs, primarily fentanyl, were implicated in all of the outbreaks included in this review. In 3 of the outbreaks, technicians were able to access syringes of fentanyl that had been prepared and left unlocked in an operating room or procedure area in anticipation of a patient's procedure. In these instances, health care personnel may have believed these fentanyl syringes did not need to be kept in a locked container while they were outside their immediate possession, perhaps because they considered the area itself to be secure (ie, access restricted to health care personnel). However, in this period of time, the addicted technicians were able to remove the syringes and replace them with decoy syringes (eg, syringes they had previously used and filled with another clear solution such as saline or water). Of note, unsafe injection practices involving various forms of syringe reuse represent a well-documented mechanism of blood-borne pathogen transmission in US health care settings.<sup>17</sup>

In addition to adhering to the basic Centers for Medicare and Medicaid Services and DEA controlled substance security requirements,

strategies founded on technological advances hold promise in prevention and early detection of diversion. These include tamper-resistant and tamper-evident syringes, automated dispensing cabinets with security features that allow for control and tracking of drug distribution, algorithmic auditing of pharmacy and other dispensing records, and testing to verify the identity or concentration of wasted drugs (ie, unused drugs that are returned to pharmacy or discarded by health care personnel). Several of the outbreaks involved syringe substitutions; tamper-resistant or tamper-evident syringes may have prevented this type of deception (ie, passing off syringes that had been used for self-injection as unused fentanyl syringes). Of course, simple actions like preparing medications as close as possible to the time of administration and properly labeling pre-drawn syringes to include patient name can also make it more challenging for health care personnel to tamper with or swap pre-drawn syringes. During investigation of the Minnesota outbreak, review of access records from an automated medication dispensing system identified a nurse who had an access rate several times greater than that of other staff.<sup>12</sup> Routine review of access records as a component of diversion prevention programs, absent an identified outbreak, may help detect diversion and prevent further harm.

Health care facilities need sound policies and systems to address suspected or confirmed diversion activity, in addition to systems addressing primary prevention (Table 2). Although appropriate personnel actions and treatment referrals are important considerations when responding to diversion events, patient harm and risk mitigation should also be prioritized.<sup>8</sup> To prevent further risk to patients at the facility, initial steps include removing the implicated health care professional from the clinical environment and revoking any previously authorized access to controlled substances pending further investigation. In addition, the facility should ascertain the specific types of medications diverted and the mechanisms of diversion used by the health care professional. If injectable medications were diverted and tampering is suspected, it is highly recommended that the health care facility pursue blood-borne pathogen testing of the implicated health care professional. The need for patient notification is best assessed in consultation with the local or state health department and guided by information gathered about mechanisms of diversion (eg, was tampering involved?) and results of the implicated health care professional's blood-borne pathogen testing.<sup>9,32,33</sup> In addition, other forms of disclosure or reparations may be warranted (eg, to ensure that patients and their insurance companies were not improperly billed for medications that were never administered).<sup>34,35</sup>

Early engagement of state and federal regulatory bodies (eg, DEA, Federal Bureau of Narcotics, Food and Drug Administration Office of Criminal Investigations, pharmacy and licensing boards), as well as local law enforcement, is also critical. Such reporting may facilitate better tracking and identification (eg, via preemployment background checks) of health care personnel who have diverted, with protection of "downstream" facilities. Current systems such as the National Practitioner Data Bank may require enhancements to better address oversight of all health care personnel (including technicians or other categories not holding controlled substances registrations) and the timeliness of action taken to investigate or manage reported concerns.<sup>4,36</sup> The multi-state outbreak of HCV infections identified in New Hampshire is the most recent example of a health care professional being able to repeatedly gain employment, even after diversion

had been strongly suspected or documented by previous employers.<sup>4</sup> The New Hampshire hospital has filed suit against the staffing agencies that employed the implicated technician, alleging that their "actions, including failing to report [the technician] for improper conduct, enabled him to secure employment in [New Hampshire]."<sup>37</sup> Facilities will benefit from ensuring that they are aware of state and federal reporting requirements when diversion is identified (eg, requirement to notify the DEA Field Division Office in their area, in writing, of the "theft or significant loss of any controlled substance" within 1 business day of the discovery of such loss or theft<sup>38</sup>) and protections offered (immunity statutes) regarding disclosure of adverse information to prospective employers,<sup>4</sup>

The outbreaks summarized in this article are likely an underestimate of the burden of infections resulting from diversion in health care settings. We did not include outbreaks occurring outside the United States that may have been associated with diversion.<sup>39-41</sup> Further, linking health care-associated infections to drug diversion, which itself may be difficult to detect, can be incredibly challenging.<sup>19,42</sup> For example, most patients with HCV infection do not experience symptoms of acute disease, and infections may go undetected for years, making it difficult to identify an exposure window or likely source of their infection.<sup>19,43</sup> For most of the HCV outbreaks reported herein, confirmed case definitions relied on advanced molecular testing demonstrating genetic relatedness between the virus of the implicated health care professional and infected patients. However, many patients had died or had evidence of resolved infection at the time the outbreak was detected and patient notification was performed. Thus, additional patients may have been part of the outbreak but were not included as confirmed cases.

In addition to underestimating the burden of infections resulting from diversion, this summary also does not adequately reflect the frequency of diversion by health care personnel or other harms resulting from this act.<sup>8,36,44</sup> There are no reliable national estimates of the prevalence of drug diversion activities by health care personnel in the United States. However, one useful data point comes from a recent study that examined substance abuse disorders among anesthesiology residents; the prevalence

was nearly 1%, with fentanyl and other intravenous opioids accounting for 57% of reports.<sup>45</sup> From a state perspective, a task force in Minnesota identified 345 events of theft or loss of controlled substances reported to the DEA during 2005-2011.<sup>46</sup> These numbers only reflected the events that were actually identified and reported, thus representing a lower bound estimate. Nonetheless, 39% of the Minnesota events involved intravenous or intramuscular medications; depending on the methods used to divert, some may have posed risks similar to those in the reported outbreaks.

The outbreaks summarized herein illustrate some of the devastating and wide-reaching impacts of drug diversion in US health care settings. Health care facilities should ensure that patients safely receive medications as prescribed. This effort includes having systems in place to prevent drug diversion as well as developing protocols for early detection and appropriate response if, despite safeguards, diversion does occur. Appropriate response includes assessment of potential for patient harm, including consultation with public health officials when diversion involving tampering with injectable controlled substances is suspected. Prompt reporting to enforcement agencies and applicable licensure/credentialing bodies should be pursued when any form of diversion is identified to help mitigate risks including exposure to potential liability for subsequent actions by the implicated health care professional. Actions by state licensing boards and other legal mechanisms may be required to prevent health care professionals with a history of drug diversion from perpetrating similar acts elsewhere.

## CONCLUSION

Outbreaks of HCV and other infections have highlighted the need for system-wide improvements to address the problem of drug diversion in the health care community. Basic patient safety depends on effective, reliable safeguards to maintain the security of injectable medication in any health care setting.

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**Abbreviations and Acronyms:** CDC = Centers for Disease Control and Prevention; CDPHE = Colorado Department of Public Health and Environment; CRNA = certified registered nurse anesthetist; DEA = Drug Enforcement Administration; HCV = hepatitis C virus; PCA = patient-controlled analgesia pump

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# **Attachment 4**

## **Title 16. Board of Pharmacy Proposed Language**

**Proposal to Amend Section 1707.5 of Title 16 of the California Code of Regulations to read:**

### **§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.**

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans serif typeface or, if requested by the consumer, at least a 12-point~~ sans serif typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

(2) For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).

(3) The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.

(4) When applicable, directions for use shall use one of the following phrases:

(A) Take 1 [insert appropriate dosage form] at bedtime

(B) Take 2 [insert appropriate dosage form] at bedtime

(C) Take 3 [insert appropriate dosage form] at bedtime

(D) Take 1 [insert appropriate dosage form] in the morning

(E) Take 2 [insert appropriate dosage form] in the morning

(F) Take 3 [insert appropriate dosage form] in the morning

(G) Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime

(H) Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime

(I) Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime

(J) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and 1 [insert appropriate dosage form] in the evening

(K) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening

(M) Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime

(N) Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime

(O) Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime

(P) If you have pain, take \_\_ [insert appropriate dosage form] at a time. Wait at least \_\_ hours before taking again. Do not take more than \_\_ [appropriate dosage form] in one day

(b) By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.

(c) The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.

(d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

(e) The board shall re-evaluate the requirements of this section by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

(f) As used in this section, "appropriate dosage form" includes pill, caplet, capsule or tablet.

Note: Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076 and 4076.5, Business and Professions Code.

**Summary of Written Comments and Testimony  
Provided at the Regulation Hearing on May 27, 2014**

Comment Number	Name	Summary of Comments/Testimony and Draft Board Responses
Written Comment 1a and 1b	Corey Whitney, Vice President Pacific West Pharmacy (PWP)	<p>The proposed change will have no benefit in our practice setting of long term care patients.</p> <p>Board response: Current pharmacy law requires pharmacies to be able to provide consumers 12-point font upon request by the consumer. If the pharmacy is unable to provide this to consumers currently, they are in violation of current pharmacy law. Exemptions are based in Business and Professions Code section 4076.5.</p> <p>The proposed change will negatively impact our current and future business.</p> <p>Board response: Pursuant to Business and Professions Code section 4001.1. Protection of the Public is Board’s Highest Priority. “Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.”</p>
Written Comment 2	Barry Solomon, R.Ph., M.Ed	<p>Pharmacist Solomon suggested certain instructions to be added to the regulation.</p> <p>Board Response: Outside of the scope of the regulation as the regulation does not address the text of the directions on the labels.</p>
Written Comment 3	Anandi V. Law B.Pharm., MS, PhD, FAACP, FAPhA	<p>Pharmacist Law suggested a table of administration times be added to the regulation.</p> <p>Board Response: Outside of the scope of the regulation as the regulation does not address the text of the directions on the labels.</p>

Comment Number	Name	Summary of Comments/Testimony and Draft Board Responses
Written Comment 4	Fred S. Mayer, RPH, MPH	<p>Pharmacist Mayer requested information about the regulation, information about publishing an article, and clarification on current law.</p> <p>Board response: Outside the scope of the regulation; comment consists of general questions about the content of the regulations, interest in publishing an article, current law clarification.</p>
Regulation Hearing Testimony #1	Corey Whitney, Vice President of Pacific West Pharmacy (PWP)	<p>Comment #A - Mr. Corey Whitney explained the language states the board may exempt the requirements if a licensed health care professional was the person administering the medication. Mr. Whitney requested clarification if the board has exempted that.</p> <p>Board response: Outside of the scope of the regulation as the regulation does not address exemptions. Exemptions are based in Business and Professions Code section 4076.5.</p> <p>Comment #B - Mr. Whitney stated in essence by increasing the font size, PWP would not be able to put 2-3 prescriptions in a packet which would limit the use of this technology in a care facility.</p> <p>Board response: Current pharmacy law requires pharmacies to be able to provide consumers 12-point font upon request by the consumer. If the pharmacy is unable to provide this to consumers currently, they are in violation of current pharmacy law. Exemptions are based in Business and Professions Code section 4076.5.</p>

Comment Number	Name	Summary of Comments/Testimony and Draft Board Responses
Regulation Hearing Testimony #2	Art Whitney, Pacific West Pharmacy (PWP) and California Council for the Advancement of Pharmacy (CCAP)	<p>Comment A - Pharmacist Whitney stated for the packets they were looking for an exemption to ensure they are exempt as they do not go home with the patient.</p> <p>Board response: Outside of the scope of the regulation as the regulation does not address exemptions. Exemptions are based in Business and Professions Code section 4076.5.</p> <p>Comment B - Pharmacist clarified his other comment was for those patients in home settings and that would eliminate the use of this type of packaging for those patients.</p> <p>Board response: Current pharmacy law requires pharmacies to be able to provide consumers 12-point font upon request by the consumer. If the pharmacy is unable to provide this to consumers currently, they are in violation of current pharmacy law. Exemptions are based in Business and Professions Code section 4076.5.</p>
Regulation Hearing Testimony #3	Paige Talley, California Council for the Advancement of Pharmacy (CCAP)	<p>Ms. Talley wanted to clarify regarding the institutional meds with packets, the multi-unit dose packages they would not get into the patients hands because they are labeled at the time of dispensing through a specific machine. As technology advances, there will be lots of changes and might be challenging to always come back to the table to exempt those.</p> <p>Board response: Outside of the scope of the regulation as the regulation does not address exemptions. Exemptions are based in Business and Professions Code section 4076.5.</p>

Comment Number	Name	Summary of Comments/Testimony and Draft Board Responses
Regulation Hearing Testimony #4	Valerie Wiebe, University of California, Davis – Veterinary Medical Teaching Hospital	<p data-bbox="618 275 1390 506">Comment A - Ms. Wiebe stated she has a lot of issues with labeling prescriptions for animals and now that regular pharmacies on the outside are also capable of selling veterinary labeled prescriptions for animals out of Costco, Walmart, etc. Ms. Wiebe stated she has concerns with labeling of all those products.</p> <p data-bbox="618 548 1414 737">Board Response: Current pharmacy law requires pharmacies to be able to provide consumers 12-point font upon violations. If the pharmacy is unable to provide this to the consumers currently, they are in violation of current pharmacy law.</p> <p data-bbox="618 779 1398 968">Comment B - Ms. Wiebe stated there a lot of veterinarians and as far as being able to label things according to big industry requirements, its be cost ineffective for them and they are not going to be able to comply. Ms. Wiebe wanted to confirm that is being kept in mind.</p> <p data-bbox="618 1010 1414 1199">Board Response: Current pharmacy law requires pharmacies to be able to provide consumers 12-point font upon violations. If the pharmacy is unable to provide this to the consumers currently, they are in violation of current pharmacy law.</p>

Comment #1a

**Damoth, Debbie@DCA**

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**From:** Corey Whitney <CoreyWhitney@pwprx.com>  
**Sent:** Wednesday, May 07, 2014 11:43 AM  
**To:** Damoth, Debbie@DCA; Herold, Virginia@DCA  
**Cc:** RPT Consulting - Paige Talley; stanweisser@aol.com; Dang, Janice@DCA; Sodergren, Anne@DCA; Art Whitney  
**Subject:** Re: Comment for proposed Patient-Centered Labeling Requirements  
**Attachments:** Letter to the board - label.pdf

To the Board of Pharmacy,

Please find the attached comment regarding the proposed language for Patient-Centered Labeling. I understand that this proposed language is an amendment to the already passed bill regarding Patient – Centered labeling and that the decision on the amendment is at the sole discretion of the board. I sincerely hope that the board understands the challenges and costs this amendment will create for the future of the Long Term Care industry while providing no benefit to patient safety.

Please contact me with any questions.

Sincerely,  
Corey Whitney  
Vice President

*Cell:* 916-416-0156  
*Office:* 916-630-4963  
*Fax:* 916-630-4965

**Pacific West Pharmacy**  
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May 7, 2014

California State Board of Pharmacy  
Attention: Debbie Damoth  
1625 N. Market Blvd  
N219  
Sacramento, CA 95834

Re: Title 16 Proposal to Amend Section 1707.5 Patient-Centered Labeling

To Whom It May Concern,

I am writing to comment on the proposal to amend section 1705.5 Patient-Centered Labeling and how it will directly impact our current and future business.

We are the longest running independent Long Term Care Pharmacy in Northern California and perhaps all of California. My father started Pacific West Pharmacy in 1987 as a “closed door” pharmacy to service the challenging needs of patients in a Skilled Nursing Facility. Through the years we have been able to maintain our excellent reputation and remain a family run pharmacy while directing the Long Term Care industry through many challenges brought on by government and economical forces. One of the challenges that we are currently creating solutions for is medication waste.

Medication waste is costing the government \$1.25 billion dollars annually in Long Term Care. The environmental impact for disposing of millions of tons of pharmaceutical waste is serious and there is no way to quantify the health risks for the nation’s general public. Patients in a SNF or Post Acute facility have multiple changes in medication throughout their stay due to the acute nature of their condition. Dispensing 30 day supply of each medication will ultimately result in 30% to 50% being wasted due to change in dosage or change in therapy.

There are developments in technology that can greatly reduce waste in a Skilled Nursing or Post-Acute facility setting. By limiting the medication supplied to the patient in the facility to a daily dispense, there is virtually zero waste. The packager in the facility automatically packages the medications for the patient needed for that particular day, so if anything has changed since the day before, the packager makes that change and therefor nothing has been wasted. This means that there is only a one day supply of medicine in the facility at any given time, a patient would in no way have a supply to take out of the facility. Currently PRN (As Needed Medication) is dispensed in 30 day supply containers. If the patient never needs the medication, the entire medication is wasted rather than when using the remote dispensing technology the medication would never have been dispensed and therefor never wasted. The technology

also creates efficiencies in nursing labor by packaging medications together that are given at the same time, ie; 8am medications are packaged in the same packet.

The down side of this technology is that the packets that which the medication is dispensed in is small due to the fact that it is only dispensing medications for a specific dosing time for the individual patient. The packet measures 2.5" x 2.25" (please see photo attached). When (3) prescriptions are in the same packet (the maximum number of prescriptions currently able to fit using font less than 12pt) the entire printable space is consumed on the packet.

The proposed changes to section 1707.5 will negatively impact this technology. Increasing the font size will limit the number of prescriptions in a packet and greatly reduce the efficiency of using the system. The proposed changes will also distort the information on the packet due the narrow nature of the packet that would cause a "wrap around" text. By increasing the font size, which would increase the amount of packets used for a medication pass, the cost of the packaging would increase. This is a cost currently absorbed by the pharmacy which is already reducing revenue for the benefit of reducing waste for the Federal and State government medication programs.

#### **The proposed changes will have NO benefit in our practice setting**

The patients never see the label as they are all administered by licensed nurses who compare every prescription to their Medication Administration Record before administering. When patients are discharged from the facility they will not have any remaining supply to be discharged with, since it is packaged daily on demand. Our pharmacy is currently notified before a patient is discharged and will fill a prescription that has outpatient friendly labeling and packaging.

The packets are considered "**unit of use**", meaning that each packet has prescription(s) for only a single dispensing and to be given together at the specified time/date on the packet. Current regulations exclude "**unit dose**" prescription packaging from the labeling requirement, which is packaging with a single medication.

#### **The proposed changes will negatively impact our current and future business**

By limiting the number of prescriptions in a packet to (1) prescription, the technology would become too cumbersome for the facility staff to efficiently use and the cost of packets/ink would be too much for the pharmacy to incur. We currently have over \$500,000 dollars invested in equipment and machines to provide onsite remote dispensing. We anticipate we will have over a million dollars invested



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by next year and have devised our future business plans based on this technology. There are new pharmacies starting in California who base their entire business model on this type of technology. They are bringing new jobs and careers to California. This will have a significant impact on LTC Pharmacies in California and the future of LTC Healthcare. If this proposed language is approved, California will be limiting the use of technology that benefits Federal and State medication programs financially, while adding no benefit to patient safety.

The proposed language has NO benefit to the consumer or to the State of California with regards to labeling of prescriptions for an LTC patient. I adamantly oppose the proposed amendment and hope it is rejected or revisions be made to exclude prescriptions for patients in a licensed facility setting. Determination of terminology to include "unit of use" as a form of "unit dose" would be an option that we would not oppose.

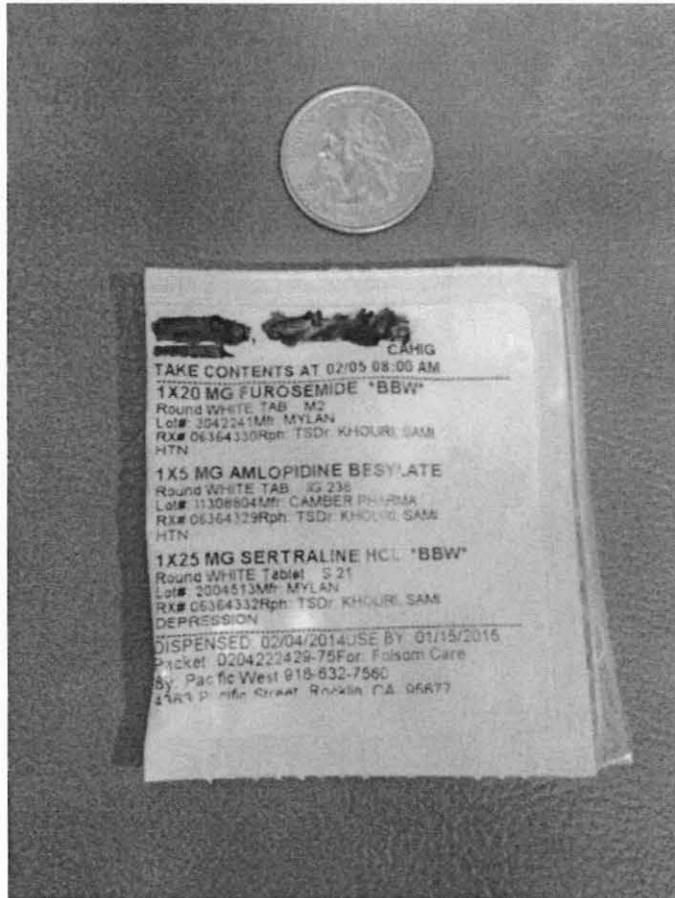
Sincerely,

Corey Whitney  
Vice President

Office: 916-630-4963

### Medication strip example

(Shown) A packet containing 3 prescriptions for an 8am med administration on February 5<sup>th</sup>. The efficiency is achieved when the packets are multipacked to include the medications for a specified medication pass, ie; all 8am medications would be in one packet. The pharmacy incurs the cost of the packaging and therefor by increasing the number of packets for a medication pass you would be significantly increasing the cost of this technology to the pharmacy.



Comment 1b

**Damoth, Debbie@DCA**

**From:** Klein, Carolyn@DCA  
**Sent:** Wednesday, May 07, 2014 4:55 PM  
**To:** Damoth, Debbie@DCA  
**Subject:** Comment for proposed Patient-Centered Labeling Requirements  
**Attachments:** Letter to the board - label.pdf

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**From:** Dang, Janice@DCA  
**Sent:** Wednesday, May 07, 2014 3:24 PM  
**To:** Klein, Carolyn@DCA  
**Subject:** FW: Comment for proposed Patient-Centered Labeling Requirements

FYI , Corey Whitney from Pacific West Pharmacy forward his comments on the regulations for patient centered labeling.

Janice

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**From:** Corey Whitney [<mailto:CoreyWhitney@pwprx.com>]  
**Sent:** Wednesday, May 07, 2014 11:43 AM  
**To:** Damoth, Debbie@DCA; Herold, Virginia@DCA  
**Cc:** RPT Consulting - Paige Talley; [stanweisser@aol.com](mailto:stanweisser@aol.com); Dang, Janice@DCA; Sodergren, Anne@DCA; Art Whitney  
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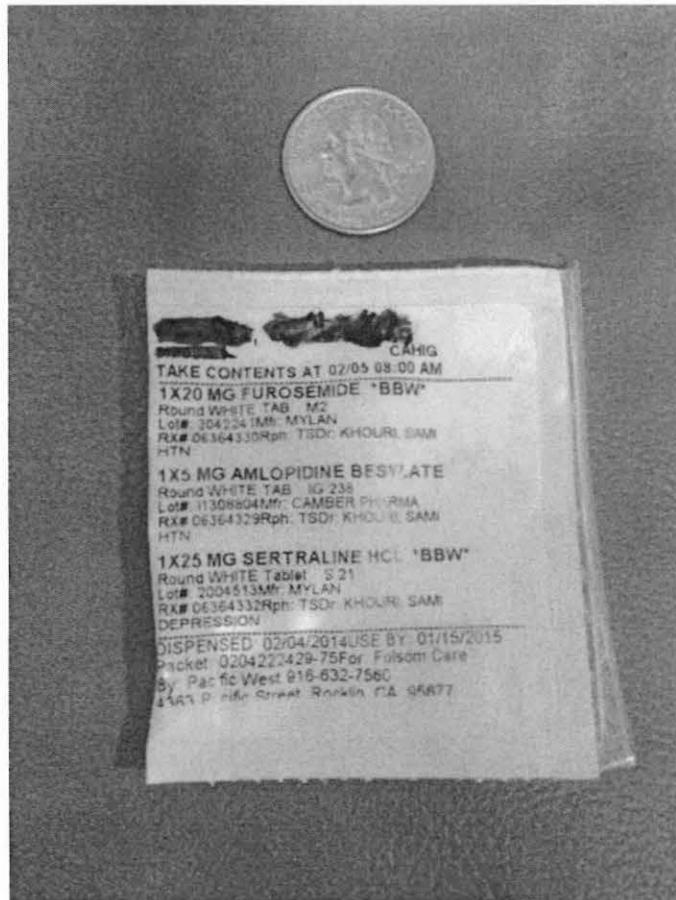
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Corey Whitney  
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**Damoth, Debbie@DCA**

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**From:** Barry Solomon <barry.solomon@verizon.net>  
**Sent:** Monday, May 19, 2014 7:42 AM  
**To:** Damoth, Debbie@DCA  
**Subject:** proposed labeling

I would make a suggestion to the labeling proposals.  
I am still working at 78 years and sometimes labels have  
the following instructions:

Take 1 tablet at bedtime. If you are not asleep after 1 hour  
take a second tablet.

I did not see this type of labeling in the materials sent from/by the  
board and would like them at their next meeting to consider  
the label/type I have noted.

Many thanks

Barry Solomon, R.Ph M.Ed  
[barry.solomon@verizon.net](mailto:barry.solomon@verizon.net)

**Damoth, Debbie@DCA**

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**From:** Anandi Law <alaw@westernu.edu>  
**Sent:** Friday, May 23, 2014 2:48 PM  
**To:** Damoth, Debbie@DCA  
**Subject:** RE: Notice of Proposed Action to Amend Section 1707.5 to Title 16 of the California Code of Regulations Related to Patient-Centered Labels for Prescription Drug Containers  
**Attachments:** Rx label BOP Presentation 0103.pptx

Debbie

I am writing comments to address the Board of Pharmacy's proposal on new Rx labels based on my experience with redesigning and testing labels since 6 years. Our labels align with USP standardization parameters and CA state proposed parameters. I also presented my work at the BOP in January this year.

The area that I would respectfully suggest change:

Directions – as seen in the attached, our redesigned labels included a “table of administration times”, which specify ranges of time instead of at bedtime or in the morning which have a wide range - this helps with adjusting times and receiving correctly spaced doses of medications for optimal effects.

Please let us know if you would like our redesigned label as a template.

Thanks for the opportunity

--Anandi

Anandi V. Law, B.Pharm., MS, PhD, FAACP, FAPhA  
Professor and Chair  
Department of Pharmacy Practice and Administration  
Director, ACCP-peer reviewed Fellowship in Health Outcomes  
College of Pharmacy  
Western University of Health Sciences  
309 E. Second Street, Pomona, CA 91766  
Tel: (909) 469-5645  
Fax: (909) 469-5428  
Email: [alaw@westernu.edu](mailto:alaw@westernu.edu)

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**From:** Damoth, Debbie@DCA [mailto:Debbie.Damoth@dca.ca.gov]  
**Sent:** Friday, April 11, 2014 2:03 PM  
**To:** Damoth, Debbie@DCA  
**Subject:** Notice of Proposed Action to Amend Section 1707.5 to Title 16 of the California Code of Regulations Related to Patient-Centered Labels for Prescription Drug Containers

The Board of Pharmacy has released a Notice of Proposed Action to amend Section 1707.5 to Title 16 of the California Code of Regulations related to Patient-Centered Labels for Prescription Drug Containers.

The Board of Pharmacy will accept comments to the proposed text until 5:00 p.m. on Monday, May 26, 2014.

[http://www.pharmacy.ca.gov/laws\\_regs/1707\\_5\\_notice.pdf](http://www.pharmacy.ca.gov/laws_regs/1707_5_notice.pdf)

[http://www.pharmacy.ca.gov/laws\\_regs/1707\\_5\\_proposed.pdf](http://www.pharmacy.ca.gov/laws_regs/1707_5_proposed.pdf)

Please click on the link below to view all documents associated with this proposed regulatory action and other pending regulations or newly approved regulations.

[http://www.pharmacy.ca.gov/laws\\_regs/regulations.shtml](http://www.pharmacy.ca.gov/laws_regs/regulations.shtml)

Debbie Damoth  
Administration and Regulations Manager  
California State Board of Pharmacy  
(916) 574-7935

DD:pell

## Redesigned Prescription Label: Evidence for patient preference and improved comprehension

Anandi V. Law, B.Pharm., MS, PhD, FAACP, FAPhA  
Professor and Chair  
Pharmacy Practice and Administration  
College of Pharmacy,  
Western University of Health Sciences

## Acknowledgments:

Outcomes Research Fellows—  
Drs. Amir Zargarzadeh, Prashant  
Sakharkar & Bik-Wai Tai  
and Student Pharmacists

## Prescription Label

- › Rx labels serve as an immediate and important source of medication information for patients
- › Prescription (Rx) labels are used to communicate key information
  - Medication name
  - Dosage
  - Directions
  - Precautions



## What is a GOOD Prescription Label?

- › Easy to use
  - Simple
  - Convenient
- › Without need for assistance
- › Intended to supplement provider counseling
- › Communicates to patient:
  - What is the med
  - When to take the med
  - How to take the med
  - How much to take
  - WHY to take the med

## Some facts about Rx Labels

- › Differences in Rx label formats and instructions among pharmacies
- › Patients often do not receive adequate medication counseling from healthcare providers (e.g. physicians, pharmacists)<sup>1-4</sup>
- › Vulnerable populations show difficulty in understanding Rx and auxiliary labels.<sup>5-7</sup>
  - Elderly
  - People with low health literacy
  - People with low English proficiency (LEP)

## Issues with Rx labels<sup>8-9</sup>

- Difficult to read and/or understand
  - Complex labeling language
  - Unclear administration times
  - Confusing label layout
  - Small font size
  - Auxiliary labels

## Impact of Misunderstanding Rx labels

- Institute of Medicine (IOM) report in 2006 cited Rx labeling as **"the cause of a large proportion of outpatient medication errors and adverse drug events."**<sup>10</sup>
- **Misunderstanding Rx label instructions has led to inadvertent patient-initiated errors in med use**<sup>11-13</sup>
  - Under or overdosing
  - Preventable adverse drug reactions
  - Emergency room visits
  - Hospital admissions
  - Morbidity and mortality
  - Economic burden in healthcare system

## Impact of Misunderstanding Rx labels

### Some statistics<sup>14-15</sup>:

- 63% of patients misunderstand one or more dosage instructions on the prescription label
- 12% of emergency room visits are drug related
- 1.5 million preventable adverse drug events occur every year
- Medication errors and adverse drug reactions result in an estimated annual cost of \$50 billion

## Our previous studies

- Our study 'How do patients read, understand, interpret and use prescription drug labels? An exploratory study examining patient and pharmacist perspectives.'<sup>16</sup> showed that patients desire Rx labels with the following characteristics:
  - Better content organization of labels
  - Use of bigger fonts
  - Color backgrounds
  - Inclusion of indication and precautions on the labels
- We therefore initiated our next study 'Design and test of preference for a new prescription medication Label'<sup>17</sup> to measure preference for newly designed Rx labels compared to the existing labels from different perspectives

## How was label redesigned?

- **Content, convenience, and cosmetic appearance (3Cs)**
  - **Content:**
    - Use of simple language (5th grade level)
    - A time-table for medication administration
    - Indication of medication
    - 2008 CA State law requirements for Rx drug labels (section 4076)
  - **Convenience:**
    - Bigger font size (patient name, medication name and dosage and directions)
    - Size of label (5.715 x 9.525 cm) fits a 13 dram size bottle
    - Delete aux label: Warnings/ Precautions as part of the Rx label
  - **Cosmetic appearance**
    - Use of color backgrounds and adequate white space

## Study Methodology

"Design and test of preference for a new prescription medication Label"

- Two new labels were designed based on literature and results from our previous study.
- A structured interview study design was used to test the preference for a new Rx label from perspective of patients, pharmacists and physicians
- 444 patient participants were sampled from 20 community pharmacies and 2 hospital outpatient pharmacy departments
- 115 pharmacists and 69 physicians was sampled from professional association meetings held in California

### Study Methodology

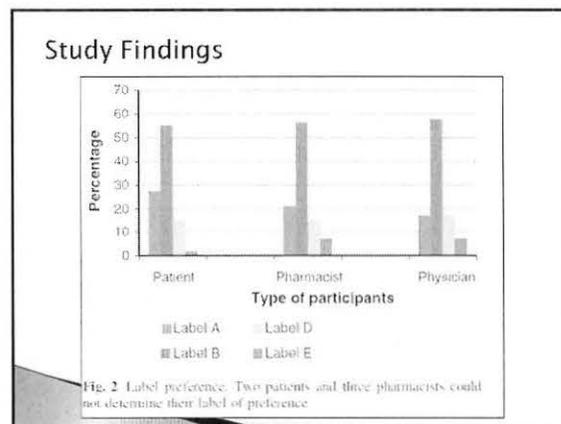
Label A, Label B, Label C, Label D

### New Label A

Use of color backgrounds and adequate white space - Bigger font size  
 Indication included  
 Table of administration times included  
 Auxiliary information as part of the Rx label

### New Label B (Versus Label A)

More space for directions  
 Minimized the need to turn the bottle in order to view the directions and table of administration times



### 2012 USP labeling standards<sup>18</sup>

- Provide a universal approach to the format, appearance, content and language of instructions for a 'patient-centered Rx label' used by pharmacists and prescribers.
  - High-contrast print
  - Familiar fonts and large font size for critical information (e.g. 12-point Times Roman or Arial)
  - Punctuated like a sentence (e.g. initial capital followed by lower-case words)
  - Horizontal text only
  - Highlighting, bolding, and other typographical cues
  - Include indication of the medication
  - Emphasize patient-centric information or information that facilitates adherence (e.g. refill ordering)
  - Avoid vague instructions for dosing intervals
  - Minimize the need to turn the container to read lines of text
  - Limit auxiliary information

### A Currently Existing Rx label

Local Pharmacy  
 100 MAIN STREET  
 ANYTOWN, USA 11111 (800) 555-5555

JANE SMITH  
 855 MAIN STREET, ANYTOWN, USA 11111 (DATE FILLED: 05/27/13)

SIMVASTATIN 20 MG TABLET  
 TAKE ONE TABLET BY MOUTH IN THE EVENING

RX # 0238385-07070 (RX REFILL: 05/27/14)  
 QTY: 30 (C. JONES, MD)  
 RESULTS: B

Round red tablet / MFL Mark  
 Side 1: MFL 720 Side 2: 20 RPN: NLF

DO NOT USE EXPIRED OR  
 UNUSUAL APPEARANCE  
 TABLETS OR CAPSULES  
 PREGNANT

### A Newly Designed Rx label

No separate auxiliary labels and abstract icons

- Familiar font and large font size (12-point Times Roman)  
- Highlighting  
- Bolding

Punctuated like a sentence

Indication included

Horizontal text only for the whole Rx label

The need to turn the container is minimized

Table of administration times provides clear instructions for dosing intervals

Test Pharmacy (909) 555-5555  
111 Main Street, Anaheim, CA 92701

RX 0238385-07070

Round red tablet  
Front side: M3D \*26  
MR. Merck  
Prescribed by: C. Jones, MD  
Fill Date: 01/28/2013

Use Before: 01/23/2014

Warnings

1. Avoid grapefruit products  
2. Contact your pharmacist or physician if you experience muscle pain or weakness.  
3. Avoid pregnancy or breast feeding.

Directions:  
Take 1 tablet by mouth in the evening for lowering cholesterol.

When to take:

6-11 am	
12-2 pm	
5-8 pm	✓
9-11 pm	

QTY: 30 tabs 3 Refills

CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS TABLET TO ANY PERSON OTHER THAN THE PATIENT.

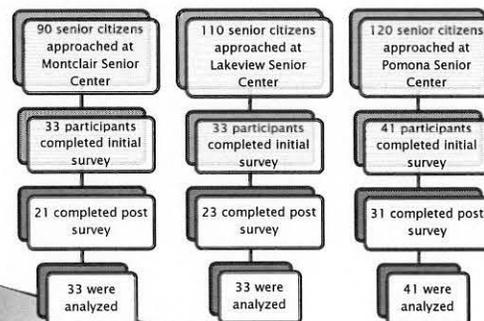
### Current Study - Label Comprehension

- ▶ We needed to slightly modify our redesigned labels to meet the USP standards
- ▶ We are currently testing their usefulness in comprehension
- ▶ Study purpose:
  - To examine
    - (1) Patients' Rx label comprehension with the new and old Rx label designs,
    - (2) The effect of pharmacist intervention on their Rx label comprehension ability

### Study Design

- ▶ A multi-site, pre-post, randomized, controlled trial is in progress
- ▶ Conducted at 3 community senior centers in So. Cal.
  - Irvine - *new label*
  - Pomona - *new label*
  - Montclair - *old label*
- ▶ Participants inclusion criteria:
  - Adults who are above 55 years of age
  - Currently taking 2 or more Rx medications daily
  - Are able to read, speak, and understand English
- ▶ Participants exclusion criteria:
  - Visual, hearing, or cognitive impairment

### Study Design



### Data collection

- ▶ The 107 participants from the 3 senior centers were randomized to control (N=47) or intervention group (N=60)
- ▶ 5 Rx labels on actual physical Rx bottles
  - Metformin, Glipizide, Lisinopril, Simvastatin, acetaminophen/hydrocodone
- ▶ Baseline and post-assessment Rx label comprehension levels were measured using modified LaRue Medical Literacy Tool
- ▶ During the 1-month study period, the intervention group received focused education (individual counseling and printed material) on Rx label comprehension from our research team

### Tools

#### Modified LaRue Medical Literacy Tool

- ▶ Has established face and content validity
- ▶ Contains 25 open-ended free-text and multiple choice questions central to the appropriate use of Rx medications:
  - Medication name
  - Indication of the medication
  - Time and direction to take the medication,
  - Original and remaining number of pills in the bottle
  - Number of refills available
  - Expiration date
  - Precautions/warnings on how to take the medication
- ▶ Score range of 0 to 25; participant scored 1 point for a correct answer, 0 point for an incorrect answer

### Study Findings

- Baseline characteristics (e.g. age, gender, ethnicity, education level, annual income) of intervention and control groups were not significantly different across the 2 label groups.
- Post-intervention showed differences

Current Rx Label	Rx Label Comprehension	Pre-Score	Post-Score	P-value
	Intervention		21.6 ± 4.2	23.4 ± 2.1
Control		18.9 ± 6.1	21.0 ± 4.5	0.786
Redesigned Rx label	Rx Label Comprehension	Pre-Score	Post-Score	P-value
	Intervention		23.0 ± 2.2	24.3 ± 1.0
Control		23.0 ± 2.8	23.3 ± 2.0	0.409

### How about Cost?

- Label change in surface area: 1.7% to 100% => 0-2cents
- Vial change in size: 13 to 60 drams => 0-29.2 cents
- Amount of ink used: 1.7% to 100% => 0-4.0 cents
- Cost of label change = 0-35.2 cents
  - Additional costs annually for a community pharmacy filling an average of
    - 100 prescriptions/day = (100x5x52) x (0-35.2) = 0-9,152 USD
    - 200-500 prescriptions/day = 0-(18,304-45,760) USD
- Cost MAY increase if label area is increased.

### Key Messages

- Rx labels need to be extremely simple, easy to use and understand, given that they are a routine part of self-care.
- Certain populations consistently find it difficult to read and understand existing Rx labels, leading to adverse health outcomes and economic burden on the health system.
- Our redesigned labels were favored over existing labels by all stakeholders.
- Rx Label comprehension improved significantly following educational intervention with the redesigned labels compared to existing labels in our current study.
- The new Rx label is showing promise in acceptability and comprehension.

### When Reading Your Prescription Label, Do you Feel Like You're Reading Another Language?



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**Damoth, Debbie@DCA**

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**From:** Herold, Virginia@DCA  
**Sent:** Friday, May 23, 2014 4:37 PM  
**To:** 'ppsi'  
**Cc:** Damoth, Debbie@DCA  
**Subject:** RE: Notice of regulatory hearing May 27, 2014 at 9:30 AM  
  
**Importance:** High

1. Here is the link to the notice: [http://www.pharmacy.ca.gov/laws\\_regs/regulations.shtml](http://www.pharmacy.ca.gov/laws_regs/regulations.shtml)
2. Q ? Is it 6 or 12 languages on the poster and what languages are they ? Poster # at bottom is OSP 13129747, if that helps. The website is [http://www.pharmacy.ca.gov/publications/point\\_to\\_your\\_language.pdf](http://www.pharmacy.ca.gov/publications/point_to_your_language.pdf)

A: As you state: "translation of prescription drugs will be available into at least 5 (five) languages other than English." We have on our website translations for the standardized directions (that are listed in the regulation in section 1707.5 in English (a)) for use in 5 top languages in use in California. These translations were done and vetted by a group through a grant. There is no requirement to use these translations, but they are available on our website. This is referenced in 1707.5(b)

However, all pharmacies are required to have oral interpreters available in at least 12 languages by requirements in sections 1707.5(d) and 1707.6(c)

---

**From:** ppsi [mailto:ppsi@aol.com]  
**Sent:** Friday, May 23, 2014 3:20 PM  
**To:** Damoth, Debbie@DCA  
**Cc:** Herold, Virginia@DCA; Brown, Debra (CDPH-LNC-HQ); Mason, Marc@DCA; jstein@advanstar.com; jtalsma@advanstar.com; fgebhart@pobox.com; mlowery@advanstar.com; jodi Reid; henekelly@aol.com  
**Subject:** Notice of regulatory hearing May 27, 2014 at 9:30 AM

Debbie:

It says to give you a call if we have problems and we cannot seem to find this Notice of regulatory hearing May 27, 2014 at 9:30 AM on the website.

Can you send it along-perhaps it has not been added to the website yet ?

It is my understanding as a CARA affiliate member, that at this hearing, patient center labels will or have been approved for 12 point font on all prescriptions in California and that translation of prescription drugs will be available into at least 5 (five) languages other than English.

Drug Topics magazine (circ. 190,000) is interested in doing a article on this new "bellweather" regulation, that is establishing standards for pharmacy practice in the United States for

pharmacy. Their email is above and the editor is Julia Talsma. Would you be kind enough to email your reply before/after the May 27 hearing, along with the agenda and notice of regulatory hearing, that I received in the mail last week.

There seems to be some confusion in that the California Board of Pharmacy (Calif) put out a poster at the CPhA Annual meeting last month in Palm Desert, that spells out 12 languages, with the 8 1/2 x 11 poster "point to your language. It's your right. Interpreter Services will be provided at no cost". In the regulation, it says at least 5 languages, other than English".

Q ? Is it 6 or 12 languages on the poster and what languages are they ? Poster # at bottom is OSP 13129747, if that helps. The website is [http://www.pharmacy.ca.gov/publications/point\\_to\\_your\\_language.pdf](http://www.pharmacy.ca.gov/publications/point_to_your_language.pdf)

Please advise.

Thanks for all your help and assistance to our consumer groups and CARA, for all you do.

Ginny-since you are setting national standards for pharmacy and California is a "bellweather" state for doing this, would you be kind enough to send this along to USP in Washington, DC, who I understand is setting national standards for both of these important consumer issues ?

Best-Fred

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Website: [www.ppsinc.org](http://www.ppsinc.org)



## Regulation Hearing Minutes

The hearing was held to consider the board's proposal to Amend Title 16, California Code of Regulations, Section 1707.5 related to patient-centered label for prescription drug containers. The hearing began at 9:30 a.m. on May 27, 2014, and was facilitated by Debbie Damoth, Administration and Regulations Coordinator for the Board of Pharmacy. Ms. Damoth presented the following information for the attendees.

The hearing was opened to take oral testimony and/or documentary evidence by any person interested in these regulations for the record, which was being electronically recorded. All oral testimony and documentary evidence will be considered by the Board pursuant to the requirements of the Administrative Procedure Act before the Board formally adopts the proposed regulation or recommends changes which may evolve as a result of this hearing.

A record of this hearing, as well as testimony received, will become a part of the rulemaking file. A complete copy of the rulemaking file will be available for review at the Board's main office in Sacramento.

If any interested person desires to provide oral testimony there is a sign-up sheet in the front of the room. It will be appreciated if the person commenting comes forward and gives his or her name and address, and if he or she represents an organization, the name of such organization, so that we will have a clear record of all those who appear.

Please keep in mind the following when making comments:

1. This is a public forum to receive comments on the proposed regulations. It is not intended to be a forum for debate or defense of the regulations. Responses by the Board to all recommendations or objections will be included in the Final Statement of Reasons that is filed with the Office of Administrative Law.

2. Written testimony may be summarized but should not be read. The board will give equal consideration to written and oral testimony.
3. If you have a question about a proposed regulation, please re-phrase your question as a comment. For example, instead of asking what a particular subdivision means, you should state that the language is unclear, and explain why you find it to be unclear.

After all interested parties have been heard, the issue will stand submitted. Are there any questions concerning the nature of the proceedings or the procedure to be followed here before we begin?

A question was presented to Ms. Damoth from an unnamed member of the audience asking if this meant the Board is just going to review whatever is submitted today and the public will not have an opportunity or exchange with the Board. Ms. Damoth explained this hearing is a public forum to receive comments on the proposed regulation and is not intended to be a forum for debate or defense of the regulations. The Board is accepting your comments to be reviewed, discussed, and then addressed in the Final Statement of Reasons.

The unnamed member of the audience asked how long the process would take. Ms. Damoth responded that the comment period closed May 26, 2014. All mail must be opened to ensure all comments are received and then it would go through levels of review at the Department of Consumer Affairs, Agency, and Department of Finance before submission to the Office of Administrative Law.

Ms. Damoth then called on those persons wishing to testify regarding the board's proposed action.

#### **Oral Testimony #1 - Corey Whitney, Vice President of Pacific West Pharmacy (PWP)**

Mr. Corey Whitney explained his objective was to obtain written clarification on the current and proposed label requirements in regards to the patients residing in care facility. Mr. Whitney explained the language states the board may exempt the requirements if a licensed health care professional was the person administering the medication. Mr. Whitney requested clarification if the board has exempted that.

Mr. Whitney stated his second objective is to ensure long term care industry is represented in the decision making of any label requirements that can potentially negatively impact patient safety, the federal and state health care budget, innovation, and pharmacy industry. Mr. Whitney provided a physical sample of the

automated packets containing up to three prescriptions. Mr. Whitney stated under the proposed new regulations a 12-point font on the four crucial pieces of information on the packet would increase the size of the information which would not allow PWP to use these packets as the packets are not large enough. Mr. Whitney stated it can't be large enough because it is a single unit of use packet. A single unit of use packet means that this is for one dosing period at a time given by the nurse in a care facility. Mr. Whitney provided samples of the packets for patient Mickey Mouse taking three prescriptions for orange tic tacs. Mr. Whitney stated in essence by increasing the font size, PWP would not be able to put 2-3 prescriptions in a packet which would limit the use of this technology in a care facility.

### **Oral Testimony #2 – Art Whitney, Pacific West Pharmacy (PWP) and California Council for the Advancement of Pharmacy (CCAP)**

Pharmacist Art Whitney stated his comments and concerns with the regulation are that it will eliminate some dosing systems for much needed patients. Pharmacist Whitney stated he was referring to DDNs and DDHs. Pharmacist Whitney explained PWP provides services to a boy's ranch up in the wilderness outside of Grass Valley. PWP developed a delivery system to prevent drug errors there and have been working with them for 15-20 years. A system was developed that eliminates the errors, prevents abuse, and now will have to tell them they can't have that any more. Pharmacist Whitney stated it does a great disservice when packaging is limited. Pharmacist Whitney stated if the board would give exemptions for certain situations, that would be great but one size does not fit all. Pharmacist Whitney indicated it was bothersome that these organizations will have to rethink how they try to control drug delivery. Pharmacist Whitney concluded his testimony.

Pharmacist Whitney continued his testimony indicating there are two issues. The issue Pharmacist Whitney was trying to get better clarification on was what the regulation or ruling is going to be for this type of labeling in an institutional setting.

Mr. Corey Whitney requested clarification if the board would exempt this as the regulation provides for exemption and would like to see written documentation for the exemption.

Pharmacist Art Whitney continued it is institution and delivered by a licensed health care provider. Pharmacist Whitney clarified what he was speaking to was DDNs and DDHs where they don't have licensed administration of the medication; they are med techs or psychiatrists. Mr. Corey Whitney stated they aren't registered nurses. Pharmacist Art Whitney clarified they are med clerks for a better description and are not

licensed. Pharmacist Whitney stated if the regulation goes through it will eliminate these types, not institutions because they are not licensed as institutions, from having specific drug delivery systems.

Pharmacist Whitney continued there are two different issues. Pharmacist Whitney stated for the packets they were looking for an exemption to ensure they are exempt as they do not go home with the patient.

Pharmacist clarified his other comment was for those patients in home settings and that would eliminate the use of this type of packaging for those patients.

### **Oral Testimony #3 – Paige Talley, California Council for the Advancement of Pharmacy (CCAP)**

Ms. Talley wanted to clarify regarding the institutional meds with packets, the multi-unit dose packages they would not get into the patients hands because they are labeled at the time of dispensing through a specific machine. As technology advances, there will be lots of changes and might be challenging to always come back to the table to exempt those. Ms. Talley stated this was clearly a case where the patient won't have it and wanted to clarify that when they were talking about the institutionalized patients and with the ICF DDHs and DDNs which are considered like SNFs.

### **Questions from the Audience on the Regulation Process – Unnamed Audience Members**

An unnamed audience member asked for clarification of the process. Ms. Damoth explained the comment period ended May 26, 2014. Board staff is reviewing the mail to check for possible comments received postmarked by May 26, 2014. Ms. Damoth continued the final package will be forwarded through the Department for various levels of review before forwarded to the Office of Administrative Law. The unnamed audience member asked when the 45 day period start. Ms. Damoth explained the 45 day comment period ended May 26, 2014. The unnamed audience member asked if these are published again and if there were any more comments, would the 45 day comment period start again? Ms. Damoth clarified the 45 day comment period ended and the Board is taking comments now at the hearing. Ms. Damoth continued the board will move forward in submitting the regulation package for review and approval. Ms. Damoth stated all comments will be considered and responded to in the Final Statement of Reasons. The unnamed audience member queried if it would be heard at the Board's meeting in July. Ms. Damoth stated the Board noticed the regulation, the comment period has closed, the Board held the regulation hearing at the request of the public, the Board is taking comments and those comments will be addressed in the Final Statement of Reasons and the Board will move forward with submitting the regulation for approval. An unnamed member of the

audience asked at what meeting would the Board do that. An unnamed member of the audience asked it would take an action of the Board, if the Board would be required to adopt the regulation, or the final statement of reasons. Ms. Damoth stated not that she was aware. Board of Pharmacy Executive Officer Virginia Herold clarified that the Board will adopt at a Board Meeting. There are now two Board Meetings in June 26-27, 2014, will be one day meeting, June 26, 2014, and July 30-31, 2014, where it may be discussed at either but more than likely the July meeting.

**Oral Testimony #4 – Valerie Wiebe, University of California, Davis – Veterinary Medical Teaching Hospital**

Ms. Wiebe stated she has a lot of issues with labeling prescriptions for animals and now that regular pharmacies on the outside are also capable of selling veterinary labeled prescriptions for animals out of Costco, Walmart, etc. Ms. Wiebe stated she has concerns with labeling of all those products. Ms. Weibe indicated they kind of have unique drugs that don't have NDC numbers, a lot of different mnemonics that are used, different directions for use. Ms. Wiebe stated there is nothing in the veterinary law book except for referral back to the pharmacy law with regard to prescription labeling so she want to make sure that when the laws are written, they keep that in mind. Ms. Wiebe stated there are a lot of veterinary patients out there and a lot of veterinarians and as far as being able to label things according to big industry requirements, its be cost ineffective for them and they are not going to be able to comply. Ms. Wiebe wanted to confirm that is being kept in mind.

Ms. Damoth verified the Board is taking comments at this time.

Ms. Damoth asked for other comments or testimony. Ms. Damoth stated if no one else wished to speak, this hearing is now closed. The hearing ended at 9:46 a.m.

California State Board of Pharmacy  
**Comments on Proposed Amendment to Patient Centered Labeling**

---

**Presented By: Corey Whitney, Vice President of Pacific West Pharmacy**

**Objective 1:** To obtain written clarification on the current and proposed labeling requirements in regards to a patient residing in a licensed care facility.

**Objective 2:** Insure that the Long Term Care Pharmacy industry is represented in the decision making of any labeling requirements that can potentially have negative impacts on patient safety, the Federal & State healthcare budget, innovation, and the pharmacy industry.

---

**4076.5. Standardized, Patient-Centered Prescription Labels; Requirements**

(a) The board shall promulgate regulations that require, on or before January 1, 2011, a standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.

(b) To ensure maximum public comment, the board shall hold public meetings statewide that are separate from its normally scheduled hearings in order to seek information from groups representing consumers, seniors, pharmacists or the practice of pharmacy, other health care professionals, and other interested parties.

(c) When developing the requirements for prescription drug labels, the board shall consider all of the following factors:

- (1) Medical literacy research that points to increased understandability of labels.
- (2) Improved directions for use.
- (3) Improved font types and sizes.
- (4) Placement of information that is patient-centered.
- (5) The needs of patients with limited English proficiency.
- (6) The needs of senior citizens.
- (7) Technology requirements necessary to implement the standards.

(d) **The board may exempt from the requirements** of regulations promulgated pursuant to subdivision

(a) prescriptions dispensed to a patient in a health facility, as defined in Section 1250 of the Health and Safety Code, if the prescriptions are administered by a licensed health care professional. Prescriptions dispensed to a patient in a health facility that will not be administered by a licensed health care professional or that are provided to the patient upon discharge from the facility shall be subject to the requirements of this section and the regulations promulgated pursuant to subdivision (a). Nothing in this subdivision shall alter or diminish existing statutory and regulatory informed consent, patients' rights, or pharmaceutical labeling and storage requirements, including, but not limited to, the requirements of Section 1418.9 of the Health and Safety Code or Section 72357, 72527, or 72528 of Title 22 of the California Code of Regulations.

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**1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements**

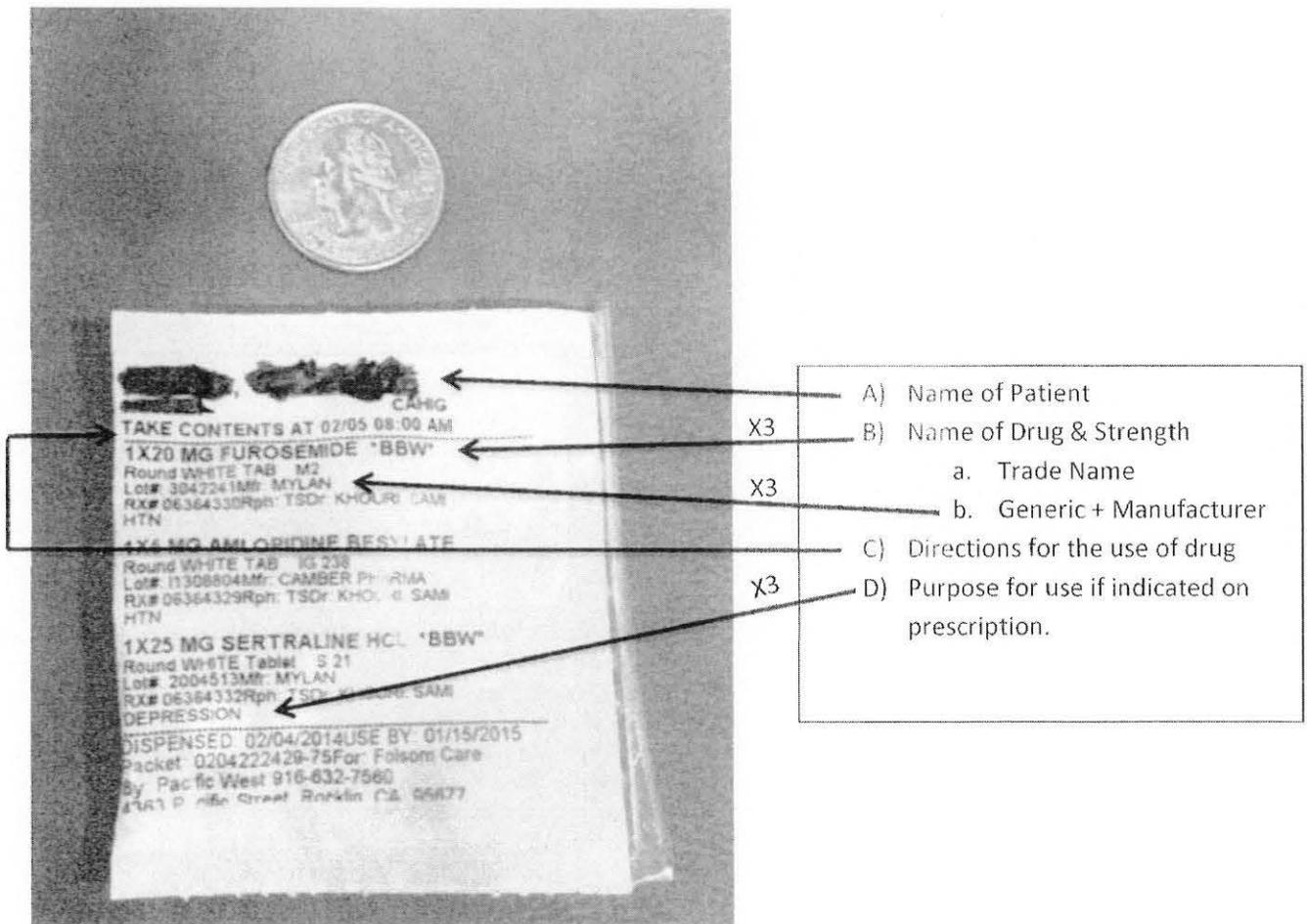
(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer. (C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.



**Board Considerations:**

The Board should consider that there are many other beneficial uses of this technology outside of a facility that administers meds by a licensed healthcare professional.

**Other Long Term Care facility settings**

- Developmentally Disabled / Habilitative Facilities
- Assisted Living Facilities

Due to the Patient Centered Labeling requirements, these healthcare facility settings are restricted from innovation and technology that increases patient safety and reduces Federal and State healthcare costs.





# **Attachment 5**

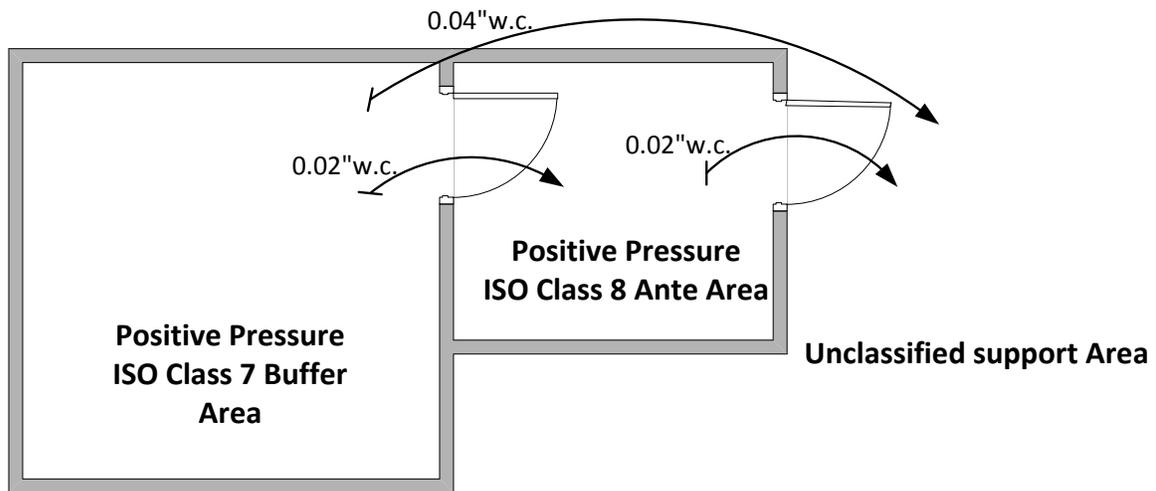
**Minimum Room Cleanliness and Pressure Requirements**

Room Type	ISO Classification	Minimum Room Pressure Requirement
<b>Non-hazardous buffer area</b>	ISO Class 7	0.02" w.c. positive
<b>Hazardous buffer area</b>	ISO Class 7	at least 0.01" w.c. negative
<b>Ante area to non-hazardous buffer area</b>	ISO Class 8	0.02" w.c. positive to all areas except 0.02" w.c. negative to the sterile compounding room
<b>Ante Room to hazardous buffer area</b>	ISO Class 7	0.02" w.c. positive to all areas except 0.01" w.c. positive to the sterile hazardous compounding room

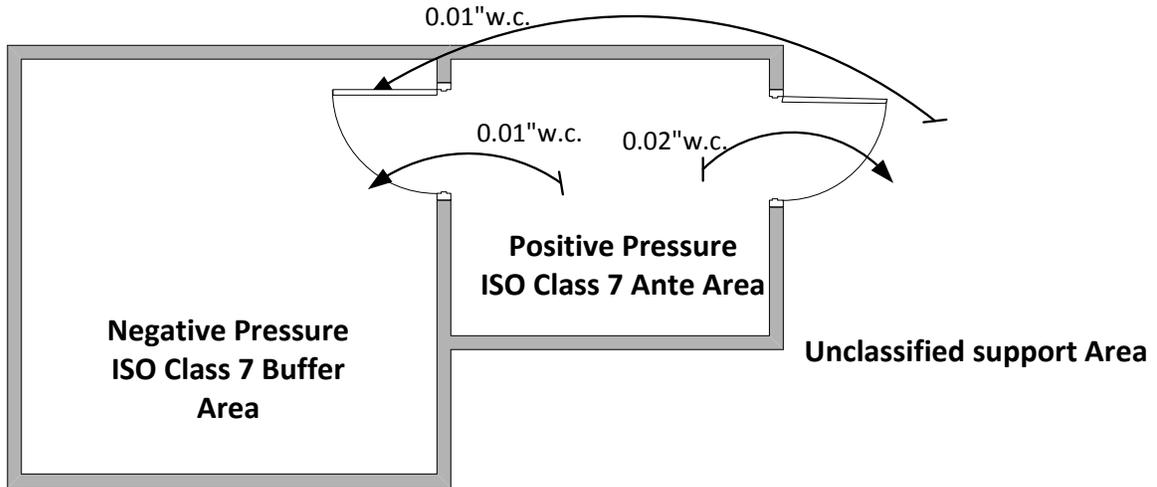
**Minimum Room Cleanliness and Displacement Airflow Requirements  
(Applies only to low to medium risk level non-hazardous sterile compounding areas)**

Room Type	ISO Classification	Minimum Room Pressure Requirement
<b>Non-hazardous buffer area</b>	ISO Class 7	Minimum 40 fpm from buffer to ante
<b>Ante Room to non-hazardous buffer area</b>	ISO Class 8	Minimum 40 fpm from buffer to ante and from ante room to all other areas (unless ante area at least 0.02" w.c. positive to all other areas)

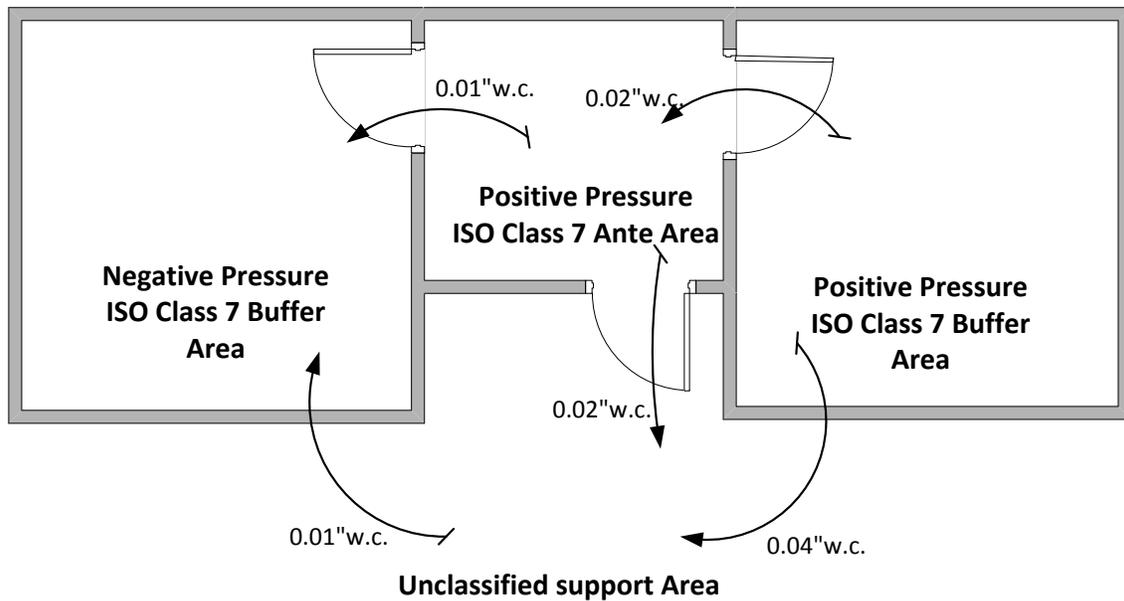
**Pressure relationship for a Non-Hazardous sterile compounding area**



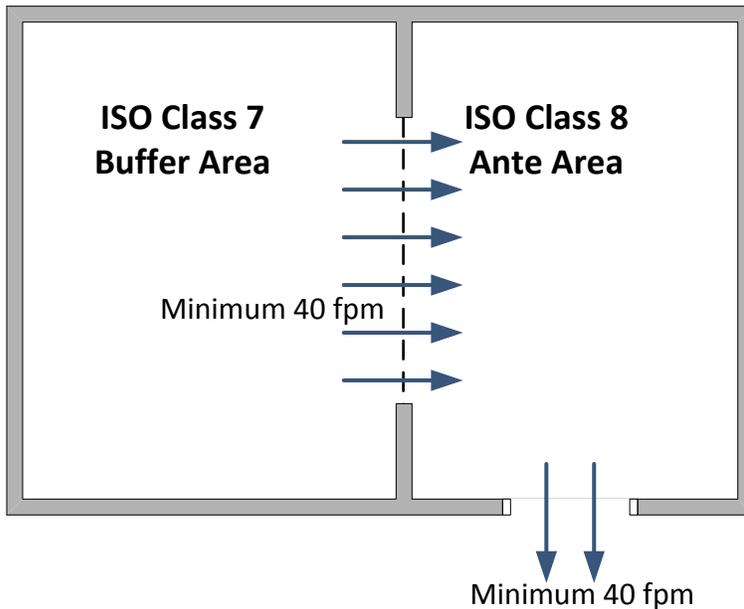
**Pressure relationship for a *Hazardous* sterile compounding area**



**Pressure relationship for a *Combination* sterile compounding suite**



**Optional displacement airflow relationship  
for a low or medium risk *Non-Hazardous*  
sterile compounding area**

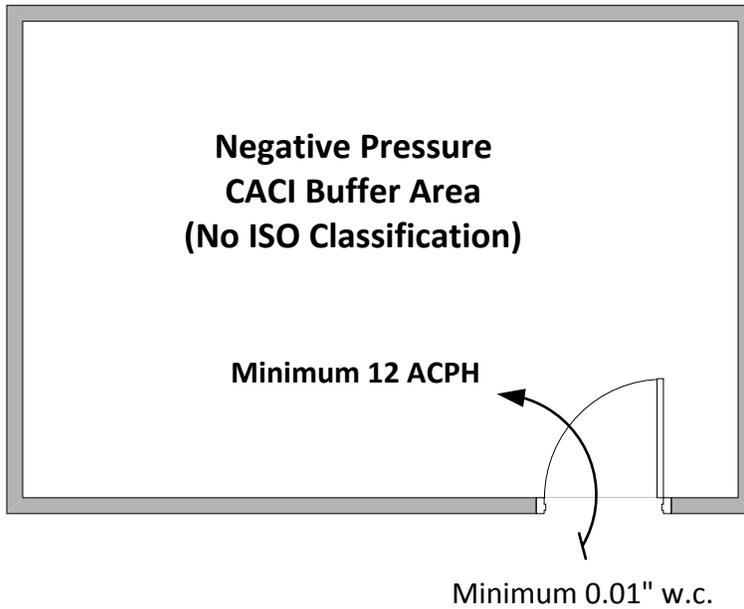


**Unclassified support Area**

**Placement of a unidirectional airflow isolator that passes tests outlined in CETA CAG-002**

Isolator Type	ISO Classification	Minimum Room requirements	External Venting
<b>CAI</b>	None	Room should have a sink for hand-washing. Finish materials should stand up to regular cleaning and disinfecting.	None required
<b>CACI</b>	None	Room should have a sink for hand-washing. Finish materials should stand up to regular cleaning and disinfecting.  Minimum of 12 ACPH  Minimum room negative pressure of 0.01" w.c.	CACI should be vented outside the building unless none of the drugs compounded volatilize.  Room needs adequate exhaust to achieve 12 ACPH.

**Placement of a unidirectional airflow CACI that passes tests outlined in CETA CAG-002**



**Unclassified support Area**

## Title 16. Board of Pharmacy

### Proposed Language

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

#### 1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

- (1) Altering the dosage form or delivery system of a drug
- (2) Altering the strength of a drug
- (3) Combining components or active ingredients
- (4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal, topical, or injectable administration, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug ~~product~~ preparation that is commercially available in the marketplace.

(d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.1. Compounding Definitions.**

(a) "Ante-area" (also called ante-room) means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the buffer area and maintains air flows from clean to dirty areas.

(b) "Batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient.

(c) "Beyond use date" means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.

(d) "Buffer area" means an area providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located.

(e) "Cleanroom" (which may also be referred to as a buffer area) means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials.

(f) "Controlled cold temperature" means 2.2 degrees to 7.7 degrees C (36 degrees to 46 degrees F).

(g) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F).

(h) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

~~(a)~~ (i) "Equipment" means items that must be calibrated, maintained or periodically certified.

- (j) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
- (k) "Gloved fingertip sampling" means a process where, compounding personnel lightly press each fingertip and thumb onto appropriate growth media, that are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.
- ~~(b)~~ (l) "Integrity" means that all aspects of quality including sterility, packaging, chemical stability and potency, handling, and transport and storage are maintained throughout the drug preparation process, and retention of potency until the expiration beyond use date noted provided on the label.
- (m) "Media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic technique of compounding personnel or processes routinely employed do not result in microbial contamination. Media fill tests are conducted on the most challenging and routine compounding procedures performed.
- (n) "Parenteral" means a sterile preparation of drugs for injection or implantation through one or more layers of skin.
- (o) "Personal protective equipment" means clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
- ~~(e)~~ (p) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Effective May 1, 2014) of the labeled amount.
- (q) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not contain sterile products.
- (r) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment.
- (s) "Process validation" means demonstrating that when a process is operated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

(t) "Product" means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

(u) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air.

~~(d)~~ (v) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active and inactive ingredients other than those noted on the label.

(w) "Segregated compounding area" means a designated space where a device that provides unidirectional airflow of ISO Class 5 air quality, including compounding aseptically, is located within either a demarcated area (three to six foot perimeter) or room. Such area shall contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation, and shall not have a sink located within three to six feet of the ISO Class 5 PEC. This sterile compounding area will be restricted to preparing sterile-to-sterile compounded preparations .

(x) "Smoke test" means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.

~~(e)~~ (y) "Strength" means amount of active ingredient per unit of a compounded drug ~~product~~ preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.2. Compounding Limitations and Requirements; Self-Assessment.**

(a) Except as specified in (b) and (c), no drug ~~product preparation~~ shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product preparation~~ either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product preparations~~ in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” furnished to a prescriber for office use by the prescriber as authorized by ~~as used in~~ Business and Professions Code section 4052 subdivision (a)(1) means that amount of compounded drug ~~product preparation~~ that:

(1) is ordered and paid for by the prescriber, using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for either office administration ~~or application to patients in the prescriber’s office, or for distribution of not more than~~ or furnishing of a 72-hour supply ~~to the prescriber’s patients, as estimated by the prescriber~~; and

(2) is delivered to the prescriber office and signed for by the prescriber; and

(3) is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 72-hour supply solely to the prescriber's own patients seen as part of regular treatment in the prescriber's office, as estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy; and

(4) is reasonable considering the intended use of the compounded medication and the nature of the prescriber’s practice; and

~~(3)~~ (5) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug ~~product preparation~~; and

(6) does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) is classified by the FDA as demonstrably difficult to compound;  
(2) appears on a FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or  
(3) is a copy or essentially a copy of one or more drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense. The pharmacy shall retain a copy of the documentation of the shortage in the pharmacy records for three years.

~~(d e)~~ A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

- (1) Active ingredients to be used.
- (2) Equipment to be used.
- (3) ~~Expiration dating requirements.~~ The rationale or reference source for determining the maximum allowable beyond use date for this preparation.
- (4) Inactive ingredients to be used.
- (5) ~~Process and/or Specific compounding steps procedure~~ used to prepare the drug.
- (6) Quality reviews required at each step in preparation of the drug.
- (7) Post-compounding process or procedures required, if any.

~~(e f)~~ Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f g)~~ The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until it is dispensed.

~~(g h)~~ All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h i) Every compounded drug product preparation shall be given an ~~expiration~~ beyond use date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun. This “beyond use date” of the compounded drug product preparation shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product preparation, unless a longer date is supported by stability studies of finished drugs or compounded drug products preparations using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product preparation.

(j k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. ~~(Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.)~~ That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(l) Packages of ingredients that lack a supplier’s expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy unless either appropriate

documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and  
(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

**To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.3. ~~Records~~ Recordkeeping of for Compounded Drug ~~Products~~ Preparations.**

(a) For each compounded drug ~~product preparation~~, ~~the~~ pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug ~~product preparation~~ was compounded.
- (3) The identity of ~~the any~~ pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product preparation~~.
- (4) The identity of the pharmacist reviewing the final drug ~~product preparation~~.
- (5) The quantity of each component used in compounding the drug ~~product preparation~~.
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile ~~products preparations~~ compounded on a one-time basis for administration within seventy-two (72) hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) (~~35~~ 37<sup>th</sup> Revision, Effective May 1, ~~2012~~

2014), hereby incorporated by reference, ~~to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.~~

(7) A pharmacy-assigned reference or lot number for the compounded drug ~~product~~ preparation.

(8) The ~~expiration beyond use~~ date of the final compounded drug ~~product~~ preparation.

(9) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing.

(10) Storage preparation for the drug preparation.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, ~~bulk drug substances, drug products, and components used in compounding.~~

(c) Active pharmaceutical ingredients shall be obtained from a FDA registered supplier. All other ~~C~~chemicals, bulk drug substances, and drug products, ~~and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from reliable FDA-registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis for chemicals, and bulk drug substances, ~~drug products, and components~~ used in compounding. ~~Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration. Certificates of purity or analysis are to be matched to the product received.~~

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.**

(a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug ~~product~~ preparation shall contain the generic name(s) of the principal active ingredient(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.

(c) Drug ~~products~~ preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and ~~expiration~~ beyond use date.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

**To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.5. Compounding Policies and Procedures.**

(a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. The pharmacy shall follow its policies and procedures and failure to follow these policies and procedures shall constitute grounds for disciplinary action.

(b) The policy and procedure manual shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.

(c) The policy and procedure manual shall include the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.

- (2) Evidence that staff have been educated and trained on all policies and procedures.
- ~~(2 3)~~ Documentation of a ~~A~~ written plan for recall of a dispensed compounded drug ~~product~~ ~~preparation~~ where subsequent verification demonstrates the potential for adverse effects with continued use. All affected doses can be accounted for as part of the recall.
- ~~(3 4)~~ The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- (5) The procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- ~~(4 6)~~ Documentation of the methodology appropriate to compounded drug preparations used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.
- ~~(5 7)~~ Documentation of the methodology used to determine appropriate ~~expiration beyond use~~ dates for compounded drug ~~products~~ preparations.
- (8) Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.
- (9) Dates of any revisions to the policy and procedure manual approved by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.
- (10) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures.
- (11) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

**To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### **1735.6. Compounding Facilities and Equipment.**

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug ~~products~~ preparations. Where applicable, this shall include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, and maintained in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, per manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### **1735.7. Training of Compounding Staff.**

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1735.8. Compounding Quality Assurance.**

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug ~~products~~ preparations. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and collated with the compounding record and master formula.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations, including for preparations furnished to patient care areas.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

**To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**Article 7. Sterile ~~injectable~~ Compounding**

**1751. Sterile ~~injectable~~ Compounding; Compounding Area; Self-Assessment.**

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated compounding~~ area designated for the preparation of sterile ~~injectable drug products-preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The buffer area, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. which shall meet the following standards: The environments within the pharmacy shall meet the following standards:~~

~~(1) Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified annually at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations. Certification records must be retained for at least 3 years.

~~(5) (2) The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile injectable drug products preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6) (3)~~ A sink shall be included in accordance with Section 1250 of Title 24, Part 2, of the California Code of Regulations. Sinks and drains shall not be present in an ISO Class 7 or better buffer area, nor within three feet of an ISO Class 5 PEC or better located in segregated compounding areas. A sink may be located in an ante-area.

~~(7) (4)~~ There shall be a refrigerator and ~~for~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing.

(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; Sections 1735, 1735.1,-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of Regulations; and Section 18944, Health and Safety Code.

**To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.1. Sterile Injectable Compounding Recordkeeping Requirements.**

~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b)~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, for sterile ~~compounded drug products preparation compounded from one or more non-sterile ingredients~~, the following records must be made and kept by the pharmacy:

(1) The training and competency evaluation of employees in sterile ~~product preparation~~ procedures.

~~(2) Results of hand hygiene and garbing assessment with integrated gloved fingertip testing.~~

~~(3) Results of assessments of personnel for aseptic techniques including results of media fill tests and gloved fingertip testing performed in association with media fill testing.~~

~~(4) Results of viable volumetric air and surface sampling.~~

~~(2) (5) Daily documentation of room, R refrigerator, and freezer temperatures appropriate for drug preparations consistent with the temperatures listed in section 1735.1 for:-~~

~~(A) Controlled room temperature.~~

~~(B) Controlled cold temperature.~~

~~(C) Controlled freezer temperature.~~

~~(3) (6) Certification(s) of the sterile compounding environment.~~

~~(7) Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO rooms or areas, including those associated with compounding aseptic (containment) isolators.~~

~~(4) (8) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~

~~(5) (9) Logs or other documentation of inspections for expired or recalled pharmaceutical products or raw ingredients.~~

~~(6) (10) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name of the compounded drug preparation, lot number, amount, and date on which the preparation was provided to a prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.2. Sterile ~~Injectable Compounding~~ Labeling Requirements.**

In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile ~~injectable drug products preparations~~ shall include the following information on the labels for those ~~products preparations~~:

(a) Telephone number of the pharmacy, except for sterile ~~injectable drug products preparations~~ dispensed ~~for to~~ inpatients ~~of by~~ a hospital pharmacy.

(b) Name and concentrations of ingredients contained in the sterile ~~injectable drug product preparation~~.

(c) Instructions for storage and handling.

(d) All ~~cytotoxic hazardous~~ agents shall bear a special label which states ~~“Chemotherapy– Dispose of Properly” or “Cytotoxic Hazardous – Dispose of Properly”~~ or “Chemotherapy - Dispose of Properly,” if applicable.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:  
Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

**To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.3. Sterile Injectable Compounding Policies and Procedures.**

(a) Any pharmacy engaged in compounding sterile injectable drug products preparations shall maintain a written policy and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

- (1) Compounding, filling, and labeling of sterile injectable compounds drug preparations.
- (2) Labeling of the sterile injectable drug product preparations based on the intended route of administration and recommended rate of administration.
- (3) Proper use of Equipment and supplies.
- (4) Training of staff in all aspects of the preparation of sterile injectable drug products preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; cleaning and disinfection of controlled compounding areas and proper aseptic technique.
- (5) Hand hygiene and garbing.
- (6) Cleaning and maintenance of ISO environments and segregated compounding areas.
- (7) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- (8) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- (9) Media fill testing procedure.
- (10) Compounded sterile drug preparation stability and beyond use dating.

(11) Visual inspection and other final quality checks of sterile drug preparations.

~~(5) (12)~~ Procedures for handling, compounding and disposal of cytotoxic hazardous agents.

~~(6) (13)~~ Quality assurance program.

~~(7) (14)~~ Record keeping requirements.

(b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.

(c) Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(d) Pharmacies compounding sterile injectable drug products preparations from one or more non-sterile ingredients must have written policies and procedures that comply with the following:

(1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.

(2) All personnel involved must read the policies and procedures before compounding sterile injectable drug products preparations, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.

(3) Policies and procedures must address at least the following:

(A) Orientation, training, and competency evaluation of compounding personnel.

(B) Storage and handling of products and supplies.

(C) Storage and delivery of final products.

(D) Media fill testing and Process validation.

(E) ~~Personnel access and movement of materials into and near the controlled area~~ Conduct of personnel in controlled areas and aseptic technique overview.

(F) Use and maintenance of ~~environmental control devices~~ PECs used to create the critical direct compounding area for ~~manipulation of sterile products~~ compounding of sterile drug

~~preparations (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~

~~(G) Regular Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants as specified in section 1751.4. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area. Non-viable particle testing.~~

~~(I) For sterile batch compounding; written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation. Viable air sampling.~~

~~(J) Sterilization. Surface sampling.~~

~~(K) End-product evaluation and testing. Airflow considerations and pressure differential monitoring.~~

~~(L) Temperature and humidity monitoring in compounding and controlled storage areas.~~

~~(M) Facility management including certification and prevention maintenance of controlled environments and related equipment.~~

~~(N) Gloved fingertip sampling.~~

~~(O) Compounded sterile product stability and assignment of beyond use dating~~

~~(P) Use of automated compounding devices (if applicable).~~

~~(Q) Hazardous drug compounding (if applicable).~~

~~(i) Hazardous drug employee training and safety program.~~

~~(ii) Hazardous drug handling, storage, labeling and transport.~~

~~(iii) Hazardous drug compounding techniques.~~

~~(iv) Hazardous drug spill, deactivation and waste management.~~

~~(R) Preparing sterile solutions from nonsterile components (if applicable).~~

~~(S) Hand hygiene and garbing.~~

(4) Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subparagraph.

(A) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

(B) For sterile batch compounding:

(i) use of master formulas and compounding work sheets;

(ii) appropriate documentation; and

(iii) appropriate sterility and bacterial endotoxin testing.

(C) For non-sterile to sterile compounding:

(i) Sterilization methods

(ii) End-product evaluation and testing.

(D) Action levels for colony-forming units (CFUs) detected during viable surface testing, glove fingertip and volumetric air sampling.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding ~~[from Non-Sterile Ingredients].~~**

(a) No sterile ~~injectable drug product preparation~~ shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile ~~injectable drug products preparations.~~

(b) During the compounding of preparation of sterile ~~injectable drug products preparations~~, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated ~~area or cleanroom~~ for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:

(1) at the beginning of each shift;

(2) before and after each batch;

(3) after each spill; and

(4) when surface contamination is known or suspected.

~~(d) (e) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination. Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.~~

~~(e) (f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 buffer area if the isolator meets the following criteria:~~

~~(1) particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.~~

(2) not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators or compounding aseptic containment isolators that do not meet the requirements as outlined in this subdivision and are not located within an ISO Class 7 buffer area may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing ~~parenteral sterile cytotoxic hazardous~~ agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications.~~ CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). ~~Certification records must be retained for at least 3 years.~~ Pharmacies that primarily compound hazardous drugs but also routinely compound non-hazardous drugs, even if used with antineoplastic chemotherapy regimens, must install a compounding aseptic isolator in a pharmacy location that is not located within the negative pressure hazardous drug buffer area or install a laminar flow hood on the clean side of the line of demarcation from the ISO Class 7 ante-room, at least six feet from the sink. Any drug preparation that is compounded in a hazardous drug PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, complete with hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Viable surface and volumetric air sampling by impaction shall be done at least monthly for low and medium risk-level compounding and weekly for high-risk compounding by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management.

(j) The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. Humidity levels should be consistent ASHRAE Standard 55 (30-65% RH).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1751.5. Sterile ~~Injectable~~ Compounding Attire.**

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b) (a)~~ When compounding sterile drug products preparations from one or more non-sterile ingredients the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low non-~~shedding ~~coverall gown~~, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed in an ante-area or outside the designated area immediately outside the segregated compounding area.

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

~~(3) (4)~~ Compounding personnel shall not wear Hhand, finger, and or wrist jewelry ~~must be eliminated~~. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.

~~(4) Head and facial hair must be kept out of the critical area or be covered.~~

~~(5) Gloves made of low-shedding materials are required. Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or buffer area. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.~~

~~(6) Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from the compounding areas until their conditions are remedied.~~

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

~~(b) When preparing cytotoxic hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.6** ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver. Sterile Compounding Consultation; Training of Sterile Compounding Staff.~~

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile injectable drug products preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile injectable drug products preparations ~~shall~~ have training and

demonstrated competence in the safe handling and compounding of sterile injectable drug products preparations, including cytotoxic hazardous agents if the pharmacy compounds products with cytotoxic hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable drug products preparations.

(e) Pharmacies that compound sterile products from one or more non-sterile ingredients preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile product preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures using media fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the selected manipulations.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area.

(H) Cleaning, sanitizing, and maintaining of the equipment and used in the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices.

Evaluation must include written testing and a written protocol of periodic routine performance

checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.**

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

(1) Procedures for Cleaning and sanitization of the ~~parenteral medication~~ sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~ (2) Actions to be taken in the event of a drug recall.

~~(4)~~ (3) Written justification of Documentation justifying the chosen ~~expiration beyond use~~ dates for compounded sterile ~~injectable drug products~~ preparations.

(b) Each individual involved in the preparation of sterile ~~injectable drug products~~ preparations must first successfully demonstrate competency by successfully performing aspect media fill tests ~~complete a validation process on technique~~ before being allowed to prepare sterile

~~injectable drug products preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount of volume transferred during the compounding process.~~ The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promoted growth. Completed ~~medium media~~ samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the ~~validation process media fill testing~~ repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile ~~injectable drug products preparations~~ is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented. Three media fill tests per day for three consecutive days must be included in annual revalidation.

(c) All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug products preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients.

~~(e)~~ (e) Batch-produced sterile ~~injectable drug products preparations~~ compounded from one or more non-sterile ingredients ~~shall be subject to documented end product testing for sterility~~

that are exposed longer than 12 hours at 2 to 8 degrees and longer than 6 hours at warmer than 8 degrees before they are sterilized shall meet the sterility test in accordance with methodologies and processes found in Chapter 71 of the United States Pharmacopeia – National Formulary (USP37-NF32) (37<sup>th</sup> Revision, Effective May 1, 2015), and testing for pyrogens in accordance with the methods of Chapters 85 and 151 of the United States Pharmacopeia – National Formulary (USP37-NF32) (37<sup>th</sup> Revision, Effective May 1, 2014), hereby incorporated by reference, and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile.

In a circumstance where a batch-produced sterile drug preparation compounded from one or more non-sterile ingredients is necessary for immediate dispensing where failure to dispense could result in loss of life or intense suffering, the drug preparation may be dispensed before receipt of test results so long as the pharmacy complies with a written procedure included in the pharmacy's policies and procedures that includes:

(1) Prior to dispensing:

- (A) Notifying the prescriber of the inability to conduct testing;
- (B) Suggesting an available alternative product to the prescriber; and
- (C) Securing the prescriber's written consent to dispense.

(2) And subsequent to dispensing:

- (A) Daily observation of the incubating test specimens; and
- (B) Immediate recall of the dispensed compounded sterile preparation's when there is any evidence of microbial or pyrogen growth in the test specimens.

Any such dispensing shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist in charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:  
Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

**To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.**

In addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that conforms to the following limitations, except that the beyond use date shall not exceed any expiration date or beyond use date provided by the manufacturer for any component in the preparation.

(a) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using only sterile ingredients, products, components, and devices; and

(2) the compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature.

(b) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) the compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature.

(c) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives, in the

absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature. For the purposes of this paragraph, “non-sterile” includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.

(d) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations

(1) entirely within an ISO Class 5 PEC that is located in a segregated compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) the compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer’s original containers; and

(3) the compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device

in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013) hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet.

(e) Where the sterile compounded drug preparation was compounded

(1) using or containing hazardous drugs or components; and

(2) using two tiers of containment (e.g., a closed system transfer device within a biological safety cabinet or a laminar air flow workbench that is located in a non-negative pressure room with at least 12 air changes per hour)

the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.

(f) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled “for immediate use only” and administration shall begin no later than one hour following the start of the compounding process. Unless the “immediate use” preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an “immediate use” preparation.

Such “immediate use” preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use**

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such condition.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:

Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1751.8. 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.**

In any pharmacy engaged in compounding sterile drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:  
Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

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To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

**Article 7.5 Furnishing for Home Administration**

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1751.10, 1752. Furnishing to Parenteral Patient at Home.**

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1751.11, 1753. Furnishing to Home Health Agencies and Licensed Hospices.**

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

- (1) furnished by a registered pharmacist;
- (2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;
- (3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;
- (4) labeled on the outside of the container with a list of the contents;
- (5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

- (1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;
- (2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;
- (3) two vials of urokinase 5000 units;
- (4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:
  - (A) heparin sodium lock flush 100 units/mL;
  - (B) heparin sodium lock flush 10 units/mL;
  - (C) epinephrine HCl solution 1:1000;
  - (D) epinephrine HCl solution 1:10,000;
  - (E) diphenhydramine HCl 50mg/mL;
  - (F) methylprednisolone 125mg/2mL;
  - (G) normal saline, preserved, up to 30 mL vials;
  - (H) naloxone 1mg/mL 2 mL;
  - (I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policy and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the

furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

**To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.**

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section 1751.11.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section 1751.11.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

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To Amend §1250.4 in Chapter 12 of Part 2 of Title 24 of the California Code of Regulations to read as follows:

**1250.4 Sterile** compounding area ~~for parenteral solutions~~. The pharmacy shall have a designated area for the compounding of sterile preparations for dispensing which shall:

1. In accordance with ~~Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 ISO 14644-1 Cleanrooms and associated controlled environments – Part 1 Classification of air cleanliness the environment inside the PECs must meet the standards for ISO Class 5 and buffer areas (cleanrooms) must meet ISO Class 7 through~~ HEPA (high efficiency particulate air) filtered air ~~such as laminar airflow hood or clean room resulting in less than 3520 and 352,000 respectively of particles less than 0.5 µm and larger per cubic meter measured under dynamic operating conditions.~~
2. Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.
3. The pharmacy shall be arranged in such a manner that the ~~laminar flow hood is~~ PECs are located in ~~an area which is~~ exposed to minimal traffic flow, and ~~is~~ separate from any area used for bulk storage of items not related to the compounding of ~~parenteral~~ solutions. There shall be sufficient space, well separated from the ~~laminar flow hood area~~ buffer area (cleanroom) for the storage of bulk materials, equipment and waste materials.
4. A sink with hot and cold running water must be ~~within the parenteral solution compounding area or adjacent to it~~ located adjacent to the sterile compounding area, however not inside the buffer area or immediately adjacent to the PEC located within the segregated compounding area.

5. Any pharmacy that compounds sterile ~~injectable drug products preparations from one or more nonsterile ingredients~~ must compound the medication in one of the following environments:

- 5.1 An ISO class 5 ~~laminar airflow hood PEC(s)~~ within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential of at least 0.02" water column positive relative to each adjacent areas.
- 5.2 ~~An ISO class 5 cleanroom.~~ The cleanroom must have a positive air pressure differential relative to adjacent areas.
- ~~5.3 A barrier isolator that provides an ISO class 5 environment for compounding.~~
- 5.3 A compounding isolator (either compounding aseptic isolator or compounding aseptic containment isolator) that provides an ISO Class 5 environment for compounding within an ISO Class 7 cleanroom unless documentation from the manufacturer of the barrier isolator permits operation of the barrier isolator in an environment that exceeds ISO Class 7.

6. When compounding hazardous drugs, the surrounding environment must provide at least 0.01 water column negative air pressure and 12 air changes per hour.

**To Amend §505.5 in Chapter 5 of Part 4 of Title 24 of the California Code of Regulations to read as follows:**

**505.5 Pharmacies – Primary Engineering Controls for Non-Hazardous Sterile Compounding Area of Parenteral Solutions.** [CA – Board of Pharmacy] In all pharmacies preparing non-hazardous sterile drug preparations, all compounding shall be conducted within a certified laminar air flow workbench or compounding aseptic isolator. The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall be ventilated in a manner not interfering with laminar air flow.

To Amend §505.5.1 in Chapter 5 of Part 4 of Title 24 of the California Code of Regulations to read as follows:

505.5.1 Pharmacies: ~~Laminar Flow Biological Safety Cabinet.~~ Primary Engineering Controls for Hazardous Drug Compounding. [CA – Board of Pharmacy]

In all pharmacies preparing ~~parenteral cytotoxic~~ hazardous agents, all compounding shall be conducted within a certified Class II Type A2 ~~or~~ Class II Type B2 or compounding aseptic containment isolator. ~~vertical laminar airflow hood with bag in bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight.~~

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