

## **LEGISLATION AND REGULATION COMMITTEE REPORT**

Greg Lippe, CPA, Chairperson, Public Member

Lavanza Butler, RPh, Professional Member

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### **V. Regulations**

#### **a. Board Approved – Notice Period Pending or Completed**

##### **1. Amendment of Title 16 CCR sections 1715 and 1784 to Update Self-Assessment Forms 17M-13, 17M-14, and 17M-26**

On March 20, 2015, the board initiated a formal rulemaking process to amend the text of 16 California Code of Regulations sections 1715 and 1784 and to amend the Self-Assessment Forms incorporated by reference therein. Existing regulation requires a pharmacy, wholesaler and hospital to complete a self-assessment by July 1 of each odd-numbered year, and at other times, as specified in the regulation(s).

The rulemaking was open for two 45-day comment periods: the first from March 20 to May 6, 2015 – and then from May 29 through July 13, 2015. Thereafter, in November 2015, board staff compiled the final rulemaking documents and submitted the file to the Office of Administrative Law to begin the administrative review process.

The Office of Administrative Law returned the rulemaking to the board for the purpose of reviewing a comment on the Hospital Pharmacy Self-Assessment. Specifically, the board should determine if the self-assessment form should be modified to explain or further clarify what “personally registered with the federal Drug Enforcement Administration” means. Board staff determined this was a non-substantive issue and that clarification was not required; however, the Office of Administrative law requested that the board consider the comment before completing its review of the rulemaking record.

The two comments received to this rulemaking are provided in **Attachment 1**.

##### **2. Proposal to Add Title 16 CCR section 1730 related to Advanced Practice Pharmacist**

As directed by the board in June 2015, staff initiated a formal rulemaking to add Section 1730 to Title 16 of the California Code of Regulations related to Advanced Practice Pharmacist. Following the 45-day comment period, the board modified the proposed text

and thereafter, from October 9-23, 2015, issued a 15-day public comment period. A second 15-day public comment was initiated from November 20-December 5, 2015.

At this meeting, the board will consider comments receiving from the 15-day comment period that closed on December 5. These comments are provided in **Attachment 2**.

**3. Addition of Title 16 CCR section 1746.1 related to Self-Administered Hormonal Contraception**

In May 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations section 1746.1 related to Self-Administered Hormonal Contraception. The 45-day comment period concluded on June 22, 2016, and the board approved the final language at the September 2015 Board Meeting. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on October 13, 2015. On December 30, 2015, a 15-day comment period began to add several documents to the rulemaking file and to revise the economic impact assessment within the Initial Notice documents. The comment period closed January 14, 2016.

Staff will provide an update to this rulemaking at the board meeting. A copy of the comment received during the 15-day comment period is provided in **Attachment 3**.

**4. Proposal to Add Title 16 California Code of Regulations Section 1746.5 Related to Travel Medications**

On September 25, 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations Section 1746.5 related to Travel Medications. The 45-day comment period began closed on November 9, 2015.

At this meeting, the board will consider the comments received during the 45-day public comment period. The comments are provided in **Attachment 4**.

**5. Proposal to Add Title 16 CCR section 1746.4 related to Vaccinations**

On July 24, 2015, the board initiated a formal rulemaking to add Title 16 California Code of Regulations section 1746.4 related to Vaccinations. The 45-day comment period concluded on September 7, 2015. In response the comments received, the board approved modifications to the language and thereafter issued modified text for a 15-day comment period. Following the review of comments received, the board again modified the text of the regulation and issued a second 15-day comment period from November 20 through December 5, 2015.

**Attachment 5** contains copies of comments received during the 15-day public comment period that closed on December 15. At this meeting the board will review the comments received.

**6. Amendment of Title 16 CCR sections 1735 et seq., and 1751 et seq., related to Compounding**

On May 8, 2015, the board initiated a formal rulemaking related to Compounding. The 45-day comment period concluded on June 22, 2015. The board held a regulation hearing on June 25, 2015.

At the July 2015 Board Meeting, the board reviewed the 45-day comments received and modified the language of the rulemaking. A 15-day comment period ran from July 31 through August 15, 2015. Thereafter, at the October Board Meeting, the board reviewed the comments and again approved modified language for public comment. A second 15-day comment period concluded on December 5. The comments received during the second 15-day comment period are provided in **Attachment 6**.

At this Meeting, the board will review the regulation, the comments received and determine whether or not to adopt the language approved in October, or make further modifications and initiate another comment period.

**b. Awaiting Notice**

**1. Proposal to Add Title 16 California Code of Regulations Sections 1776 et seq. Related to Drug Take-Back**

At the October 2015 Board Meeting, the board approved proposed text to add Sections 1776 et seq. to Title 16 of the California Code of Regulations related to Drug Take-Back with specific modifications. The modified proposed text will be reviewed at the Board meeting.

A copy of the board-approved language (not yet noticed) is provided in **Attachment 7**.

**c. Board Approved – Submitted for Administrative Review by the Department of Consumer Affairs or the Office of Administrative Law**

Copies of all board-approved rulemakings undergoing review by the Office of Administrative Law can be viewed on the board's website:  
[http://www.pharmacy.ca.gov/laws\\_regs/regulations.shtml](http://www.pharmacy.ca.gov/laws_regs/regulations.shtml)

**1. Addition of Title 16 CCR section 1746.2 related to Nicotine Replacement Products**

At the January 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to add text to 16 California Code of Regulations section 1746.5 for Nicotine Replacement Products. The 45 day comment period began on May 8, 2015 and ended on June 22, 2015. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process at the end of July 2015. On December 15, 2015, the file was submitted for final review by the Office of Administrative Law for final approval, pursuant to the Administrative Procedures Act. The estimated date of completion is January 29, 2016. Board staff has requested an immediate effective date upon completion of the review.

**2. Addition of Title 16 CCR section 1746.3 related to Naloxone Hydrochloride (Non-Emergency)**

At the April 2015 Board Meeting, the board directed staff to initiate the formal rulemaking process to amend the emergency regulation text of 16 California Code of Regulations Section 1746.3. The 45 day comment period began on May 22, 2015 and ended on July 13, 2015. A 15 day comment period was required due to an error made with the incorrect proposed text being noticed in May 2015. The 15-day comment period began on September 4, 2015 and ended September 19, 2015. The Board approved the final language at the September 2015 Board Meeting. Board staff compiled the final rulemaking documents and submitted it to the Department of Consumer Affairs to begin the administrative review process on the October 16, 2015. As of December 15, 2015, the file is being reviewed by the Office of Administrative Law for final approval, pursuant to the Administrative Procedures Act. The estimated date of completion is January 29, 2016. Board staff has requested an immediate effective date upon completion of the review.

# **Attachment 1**

# **Self-Assessment**

**17M-13,**

**17M-14,**

**And**

**17M-26**

**Self-Assessment**

**45-Day Comments**

**Comment Period Closed July 13, 2015**

Code Section	Commenter	Comment
Pharmacy Self-Assessment 17M-13 Page 2	Dale Neuls	Needs a legend. It is not clear to me what APP# is. Why would an intern or technician have a DEA#? If Pharmacist does not prescribe, then why would they need a DEA#? What about an NPI#?
Pharmacy Self-Assessment 17M-13 Section 21.12 Page 22	Dale Neuls	"21.12. Electronic prescriptions (e-scripts) for controlled substances that are received by the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)" <u>Is this supposed to be received from the prescriber?</u>
Hospital Self-Assessment 17M-14 Section 8.1 Page 9	Rosemarie Hicks	<p>"8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&amp;PC 4052[b])".</p> <p>This needs clarification, what does "personally registered with the federal Drug Enforcement Administration" mean? Does this mean that the pharmacist must have their own DEA number, or can they use the hospital pharmacies DEA number, or can they use the DEA of the physician they have a collaborative agreement with. Is this required for every pharmacist, or only those that have been deemed as "Advanced Practice Pharmacist". You may want to provide the link to the form that a pharmacist may need to register. Or is this just referring to registration for CURES? Can you provide some insight regarding this?</p>

# **Self-Assessment**

## **Form 17M-13**



## COMMUNITY PHARMACY SELF-ASSESSMENT HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

**Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, a this Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. 10/14). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. ~~4/11~~ 02/12).**

**Each self-assessment must be kept on file in the pharmacy for three years after it is performed.**

Pharmacy Name: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

Ownership: Sole Owner  Partnership  Corporation  LLC   
 Non-Licensed Owner  Other (please specify)  \_\_\_\_\_

Permit #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_ Other Permit #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Licensed Sterile Compounding Permit # \_\_\_\_\_ Expiration: \_\_\_\_\_

~~or~~ Accredited by (optional): \_\_\_\_\_ From: \_\_\_\_\_ To: \_\_\_\_\_

DEA Registration #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_ Date of DEA Inventory: \_\_\_\_\_

Hours: Weekdays ~~Daily~~ \_\_\_\_\_ Sat \_\_\_\_\_ Sun. \_\_\_\_\_ 24 Hours \_\_\_\_\_

PIC: \_\_\_\_\_ RPH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Website address (optional): \_\_\_\_\_

**Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):**

{Please use an additional sheet if necessary} . APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1.	_____	RPH # _____ APP # _____ DEA # _____	Exp. Date: _____ Exp. Date: _____ Exp. Date: _____
2.	_____	RPH # _____ APP # _____ DEA # _____	Exp. Date: _____ Exp. Date: _____ Exp. Date: _____
3.	_____	RPH # _____ APP # _____ DEA # _____	Exp. Date: _____ Exp. Date: _____ Exp. Date: _____
4.	_____	RPH # _____ APP # _____ DEA # _____	Exp. Date: _____ Exp. Date: _____ Exp. Date: _____
5.	_____	RPH # _____ APP # _____ DEA # _____	Exp. Date: _____ Exp. Date: _____ Exp. Date: _____
6.	_____	INT # _____	Exp. Date: _____
7.	_____	INT # _____	Exp. Date: _____
8.	_____	INT # _____	Exp. Date: _____
9.	_____	TCH # _____	Exp. Date: _____
10.	_____	TCH # _____	Exp. Date: _____
11.	_____	TCH # _____	Exp. Date: _____

12. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

13. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

14. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

15. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

**COMMUNITY PHARMACY SELF-ASSESSMENT**  
**HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT**

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

**1. Facility**

Yes No N/A

- 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)
  
- 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)
  
- 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
  
- 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition-, properly lighted and free from rodents and insects. (CCR 1714)
  
- 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)
  
- 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)
  
- 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)
  
- 1.8. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])
  
- 1.9. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)
  
- 1.10. Does the pharmacy compound sterile injectable drugs?  
(If yes, complete ~~section 24~~ section 27 – "Compounding.")

Yes No N/A

1.11. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

1.12. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

1.13. The pharmacy reports to the board within 14 ~~30~~ days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

1.14. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: \_\_\_\_\_

E-mail address registered with the board: \_\_\_\_\_

1.15. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: \_\_\_\_\_

E-mail address registered with the board: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

**2. Delivery of Drugs**

Yes No N/A

2.1. Dangerous drugs and dangerous devices are only delivered to the licensed ~~premise~~ premises, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 11209(a))

2.2. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

- 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 2.2.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**3. Drug Stock**

Yes No N/A

3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q], CCR 1714[b])

3.2. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

- 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.
- 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.
- 3.2.3. Are not expired.

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**4. Voluntary Drug Repository and Distribution Program (H&SC 150200)**

Yes No N/A

4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 29 of this Self-Assessment.)

**4. 5. Pharmacist-in-Charge (PIC)**

Yes No N/A

4.1. 5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

Yes No N/A

4.2. 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (CCR 1709.1[b])

4.3. 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

4.4. 5.4. Is the PIC in charge of another pharmacy?

4.5. 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy \_\_\_\_\_

4.6. 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

4.7. 5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])

If yes, name the wholesaler or veterinary food-animal retailer. \_\_\_\_\_

5.8. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (H&SC 1206, 1265)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

**5. 6. Duties of a Pharmacist**

Yes No N/A

6.1. The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)

~~5.1.~~ 6.2. The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))

~~5.2.~~ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

6.4. Pharmacists are able to access information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

~~5.3.~~ 6.5. The pharmacist dispenses emergency contraceptive pursuant to the statewide protocol found in 16 CCR 1746.

6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (H&SC 1206[a])

\_\_\_\_\_  
PIC  
Initials

Yes No N/A

6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (H&SC 1206.6)

CDPH (CLIA) Registration #: \_\_\_\_\_ Expiration: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**7. Duties of an Advance Practice Pharmacist**

Yes No N/A

7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

7.2. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)

- 7.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers;
- 7.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers;
- 7.2.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient’s primary care provider or diagnosing provider; (B&PC 4052.6[b])
- 7.2.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient’s diagnosing prescriber or enters the appropriate information in a patient’s record system shared with the prescriber; (B&PC 4052.6[b])
- 7.2.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- 7.2.6 Ordering of tests is done in coordination with the patient’s primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

**6- 8. Duties of an Intern Pharmacist**

Yes No N/A

~~6-1.~~ 8.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

Yes No N/A

~~6.2.~~ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

~~6.3.~~ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**7. 9. Duties of a Pharmacy Technician**

Yes No N/A

~~7.1.~~ 9.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

~~7.2.~~ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

~~7.3.~~ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

~~7.4.~~ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**8. 10. Duties of Non-Licensed Personnel**

Yes No N/A

~~8.1.~~ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

~~8.2.~~ 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist’s responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**PHARMACY PRACTICE**

**9. 11. Consultation/Patient Profile/Review of Drug Therapy**

Yes No N/A

~~9.1.~~ 11.1. Pharmacists provide oral consultation: (B&PC 4052[a][7], CCR 1707.2):

- ~~9.1.1.~~ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ~~9.1.2.~~ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ~~9.1.3.~~ 11.1.3. upon request; and
- ~~9.1.4.~~ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.

~~9.2.~~ 11.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

~~9.3.~~ 11.3. The pharmacist reviews a patient’s drug therapy and medication record prior to consultation. (CCR 1707.3)

~~9.4.~~ 11.4. Consultation is performed in a manner that protects the patient’s protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

~~9.5.~~ 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

~~9.6.~~ 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**10. 12. Prescription Requirements**

Yes No N/A

~~10.1.~~ 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)

~~10.2.~~ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the ~~direction~~ direct supervision of a pharmacist. (B&PC 4070, CCR 1717)

~~10.3.~~ 12.3. If a prescription is orally or electronically transmitted by the prescriber’s agent, the pharmacist makes a reasonable attempt to verify that the prescriber’s agent is authorized to do so, and the agent’s name is recorded. (B&PC 4071)

~~10.4.~~ 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

~~10.5.~~ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

~~10.6.~~ 12.6. Facsimile prescriptions are received only from a prescriber’s office. (B&PC 4040[c])

~~10.7.~~ 12.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

~~10.8.~~ 12.8. With the exception of those prescriptions written under H&SC 11159.2 and H&SC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], H&SC 11167.5)

~~10.9.~~ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11120[e])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**11. 13. Prescription Labeling, Furnishing and Dispensing**

Yes No N/A

~~11.1.~~ 13.1. The prescription label contains all the required information. (B&PC 4076)

~~11.2.~~ 13.2. The prescription label is formatted in accordance with CCR\_1707.5.

~~11.3.~~ 13.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR\_1707.5[a])

Yes No N/A

13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])

- 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.
- 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.3.1; (CCR 1707.5[a][22])
- 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])

~~11.4.~~ 13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.

Exemption approved by board from: \_\_\_\_\_ to \_\_\_\_\_

~~11.5.~~ 13.6. Expiration dates of drugs' effectiveness are consistent with those of the manufacturer if the information is required on the original manufacturer's label. (B&PC 4076)

~~11.6.~~ 13.7. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

~~11.7.~~ 13.8. Generic substitution is communicated to the patient. (B&PC 4073)

~~11.8.~~ 13.9. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label. (B&PC 4115, CCR 1793.7, CCR 1712)

~~11.9.~~ 13.10. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

~~11.10.~~ 13.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

~~11.11.~~ 13.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

~~11.12.~~ 13.13. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

~~11.13.~~ 13.14. This The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership .

~~11.14.~~ 13.15. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

Yes No N/A

~~11.15-~~ 13.16. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200)

13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug (other than controlled substances, or psychotropic medication or drugs): (B&PC 4064.5)

13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (B&PC 4064.5[a])

13.17.1.1 The prescriber has not indicated “no change to quantity” or words of similar meaning; (B&PC 4064.5[d])

13.17.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

13.17.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

13.17.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

13.18. The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**~~12.~~ 14. Refill Authorization**

Yes No N/A

~~12.1-~~ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

~~12.2-~~ 14.2. Refills are documented. (CCR 1717)

~~12.3-~~ 14.3. Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient’s ongoing care and have a significant adverse effect on the patient’s well-being. (B&PC 4064)

~~12.4-~~ 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

Yes No N/A

~~12.5.~~ 14.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**~~13.~~ 15. Quality Assurance and Medication Errors**

Yes No N/A

~~13.1.~~ 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

~~13.2.~~ 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

~~13.3.~~ 15.3. The pharmacist communicates with the patient or patient’s agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

~~13.4.~~ 15.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

~~13.5.~~ 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

~~13.6.~~ 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ~~13.6.1.~~ 15.6.1. Date, location, and participants in the quality assurance review;
- ~~13.6.2.~~ 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ~~13.6.3.~~ 15.6.3. Findings and determinations; and
- ~~13.6.4.~~ 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

~~13.7.~~ 15.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

~~13.8.~~ 15.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**14. 16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions**

Yes No N/A

~~14.1.~~ 16.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

Yes No N/A

~~14.2.~~ 16.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

~~14.3.~~ 16.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b])

16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])

16.5. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**15. 17. Prescription Transfer**

Yes No N/A

~~15.1.~~ 17.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

~~15.2.~~ 17.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

**a. Schedule III, IV and V Controlled Substance Prescription Transfers**

~~15.3.~~ 17.3. For the **transferring pharmacy**: the prescription hard copy is pulled and “void” is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber’s authorization. (CFR 1306.25, CCR 1717[f])

Yes No N/A

~~15.4.~~ 17.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**~~16.~~ 18. Confidentiality of Prescriptions**

Yes No N/A

~~16.1.~~ 18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

~~16.2.~~ 18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

Yes No N/A

~~16.3.~~ 18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

~~16.4.~~ 18.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

~~16.5.~~ 18.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

~~16.6.~~ 18.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**~~17.~~ 19. Record Keeping Requirements**

Yes No N/A

~~17.1.~~ 19.1. A completed biennial pharmacy self -assessment is on file in the pharmacy and maintained for three years. (CCR 1715)

~~17.2.~~ 19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

- ~~17.2.1.~~ 19.2.1. Prescription records (B&PC 4081[a])
- ~~17.2.2.~~ 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
- ~~17.2.3.~~ 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ~~17.2.4.~~ 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

- ~~17.2.5.~~ 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
- ~~17.2.6.~~ 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ~~17.2.7.~~ 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
- ~~17.2.8.~~ 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

Yes No N/A

~~17.3.~~ 19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC ~~4140, 4149~~ 4145.5)

- ~~17.3.1.~~ 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- ~~17.3.2.~~ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- ~~17.3.3.~~ 19.3.3. The sale of ~~10 or fewer~~ hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145.5)
- ~~17.3.4.~~ 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)
- ~~17.3.5.~~ 19.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

19.4. When hypodermic needles and syringes are furnished by a pharmacy or hypodermic needle and exchange program without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e][f])

- 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.
- 19.4.2. Furnish or make available mail-back sharps containers.
- 19.4.3. Furnish or make available sharps containers.

~~17.4.~~ 19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

19.6. The pharmacy dispenses epinephrine auto-injector to a prehospital emergency medical care person or lay rescuer for the purpose of rendering emergency care in accordance with H&SC 1797.197a (B&PC 4119.3)

- 19.6.1.A physician/surgeon provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed (B&PC 4119.3[a][1])

- 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only", the dosage, use and expiration date. (B&PC 4119.3[a][1])
- 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**18. 20. DEA Controlled Substances Inventory**

- Inventory:
- | Yes                      | No                       | N/A                      |  |
|--------------------------|--------------------------|--------------------------|--|
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.1.</del> <u>20.1.</u> Is completed biennially (every two years).<br>Date completed: _____ (21 CFR 1304.11[b])  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.2.</del> <u>20.2.</u> Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.3.</del> <u>20.3.</u> Is available for inspection for three years. (CCR 1718)  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.4.</del> <u>20.4.</u> Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (CFR 1304.11[a])  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.4.</del> <u>20.5.</u> Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (CFR 1304.04[h])   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.5.</del> <u>20.6.</u> Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2]) |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.6.</del> <u>20.7.</u> Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)  |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.7.</del> <u>20.8.</u> U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)   |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <del>18.8.</del> <u>20.9.</u> When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)   |

Yes No N/A

- ~~18.9.~~ 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form 222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)
- ~~18.10.~~ 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503. B&PC 4160)
- ~~18.11.~~ 20.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7<sup>th</sup> day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])
- ~~18.12.~~ 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.
- ~~18.13.~~ 20.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)
- ~~18.14.~~ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or
- ~~18.15.~~ 20.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])
- ~~18.16.~~ 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])
- 20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**19. 21. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions**

Yes No N/A

~~19.1. 21.1.~~ A faxed prescription for a Schedule II controlled substance is dispensed **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

~~19.2. 21.2.~~ An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form. form, and: The licensed facility provides the pharmacy with a copy of the prescriber signed order when available. (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

21.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.

21.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.

21.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.

21.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], H&SC 11167.5)

~~19.3.~~ An electronically transmitted order for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed after the pharmacist produces, signs and dates the hard copy prescription on a form of the pharmacy's design. The licensed facility forwards to the dispensing pharmacist a copy of the order signed by the prescriber when available. (21 CFR 1306.11[f], H&SC 11167.5)

~~19.4. 21.3.~~ If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

~~19.5. 21.4.~~ The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill." (21 CFR 1306.13[b], CCR 1745)

~~19.6. 21.5.~~ The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

~~19.7. 21.6.~~ All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

Yes No N/A

~~19.8.~~ 21.7. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

~~19.9.~~ 21.8. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

Yes No N/A

~~19.10.~~ 21.9. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

21.10. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

21.11. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

21.12. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**~~20.~~ 22. Automated Dispensing/Delivery Devices**

Yes No N/A

~~20.1.~~ 22.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

~~20.2.~~ 22.2. The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B&PC 4342)

~~20.3.~~ 22.3. For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

- ~~20.3.1.~~ 22.3.1. Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H&SC 1261.6[d][1])
- ~~20.3.2.~~ 22.3.2. A pharmacist reviews the order and patient's profile prior to the drug being removed. (H&SC 1261.6[e][2])

- ~~20.3.3.~~ 22.3.3. Stocking of the automated drug delivery system is done by a pharmacist. (H&SC 1261.6[f])

Yes No N/A

~~20.4.~~ 22.4. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

- ~~20.4.1.~~ 22.4.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H&SC 1261.6[f][1])
- ~~20.4.2.~~ 22.4.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H&SC 1261.1[f][2])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

### ~~21.~~ 23. Repackaging by the Pharmacy

Yes No N/A

~~21.1.~~ 23.1. Drugs are repackaged (precouneted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B&PC 4342, H&SC 110105, 111430, CCR 1707.5)

~~21.2.~~ 23.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

~~21.3.~~ 23.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B&PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

### ~~22.~~ 24. Refill Pharmacy

Yes No N/A

~~22.1.~~ 24.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies \_\_\_\_\_

~~22.2.~~ 24.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

~~22.3.~~ 24.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) \_\_\_\_\_

If the answer to both questions above is "no" or "not applicable" go to section 23.

**Yes No N/A**

~~22.4.~~ 24.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

~~22.5.~~ 24.5. Refill prescription label meets requirements of B&PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

~~22.6.~~ 24.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

~~22.7.~~ 24.7. Both pharmacies maintain complete and accurate records ~~of~~ of refill. (CCR 1707.4[a][4])

~~22.8.~~ 24.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

~~22.9.~~ 24.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

## **25. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)**

**Yes No N/A**

25.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

25.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])

25.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])

25.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])

25.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

25.2. The pharmacy meets the following requirements:

25.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])

25.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])

25.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])

- 25.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])
- 25.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])
- 25.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])
- 25.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])
- 25.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])
- 25.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])
- 25.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])
- 25.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])
- 25.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

**23- 26. Policies and Procedures**

Yes No N/A

23.1. 26.1. There are written policies and procedures in place for:

- ~~23.1.1.~~ 26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order; (B&PC 4052.1[a][3])
- ~~23.1.2.~~ 26.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it ~~effects~~ affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[a],[c])

- ~~23.1.3.~~ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[b],[c])
- ~~23.1.4.~~ 26.1.4. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])
- ~~23.1.5.~~ 26.1.5. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])
- ~~23.1.6.~~ 26.1.6. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])
- ~~23.1.7.~~ 26.1.7. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present;- (B&PC 4059.5[f][1])
- ~~23.1.8.~~ 26.1.8. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;
- ~~23.1.9.~~ 26.1.9. Reporting requirements to protect the public; (B&PC 4104)
- ~~23.1.10.~~ 26.1.10. Preventing the dispensing of a prescription drug that is contrary to the law;- (B&PC 733)
- ~~23.1.11.~~ 26.1.11. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (B&PC 733)
- ~~23.1.12.~~ 26.1.12. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR\_1707.5)

Yes No N/A

~~23.2.~~ 26.2. Does your pharmacy employ the use of a common electronic file?

- 23.2.1. 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][2]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

- 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)
- 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

- 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)
- 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)
- 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)
- 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])
- 26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)
- 26.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

□□□

26.2. Does your pharmacy employ the use of a common electronic file?

- 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

□□□

26.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][2]? (B&PC 4052, CCR 1746) If yes, does the pharmacy:

- 26.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)
- 26.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)
- 26.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)
- 26.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)
- 26.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)
- 26.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])

26.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)

26.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a])

26.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

26.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

## COMPOUNDING

### 27. Compounding

Yes No N/A

27.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. ~~01/11~~, 02/12) (CCR 1735.2[j])

### ~~25.~~ 28. NUCLEAR PHARMACY Nuclear Pharmacy

Yes No N/A

~~25.1.~~ 28.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

~~25.2.~~ 28.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

~~25.3.~~ 28.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. ~~01/11~~ 02/12.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**29. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**

Yes No N/A

29.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

29.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)

29.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

29.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

29.3. No controlled substances shall be donated. (H&SC 150204[c][1])

29.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

29.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

29.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

29.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])

29.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

29.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

**30. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program**

Yes No N/A

30.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H&SC 150201[a][1])

30.1.1.1 Is county owned (H&SC 150201[a][1]) or

30.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[a][1], 150200)

30.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

**Yes No N/A**

30.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: \_\_\_\_\_ Date: \_\_\_\_\_

30.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: \_\_\_\_\_ (H&SC 150204[a][3])

30.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: \_\_\_\_\_

30.5. The pharmacy complies with the county's established written procedures. (H&SC 150204[b])

**Drugs and Maintenance of Drug Stock**

30.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H&SC 150204[j])

30.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H&SC 150204[k])

30.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

30.9. Donated medications received are unused, unexpired and meet the following requirements: (H&SC 150202, 150202.5, 150204[c])

30.9.1. Are received from authorized sources. (H&SC 150202, 150203)

30.9.2. No controlled substances are received. (H&SC 150204[c][1])

30.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H&SC 150204[c][2])

30.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H&SC 150204[c][3])

30.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 150204[d])

30.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H&SC 150204[i])

30.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

**Yes No N/A**

30.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H&SC 150204[d], 150204[h])

**Transferring Donated Drugs From One Participating Entity to Another**

30.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H&SC 150204[g][4])

30.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H&SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

\_\_\_\_\_

30.13. Donated medication is not transferred by any participating entity more than once. (H&SC 150204[g][4][B])

30.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H&SC 150204[g][4][C])

30.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H&SC 150204[g][4][C])

**Dispensing to Eligible Patients**

30.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H&SC 150204[i])

30.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H&SC 150204[f])

**PHARMACIST-IN-CHARGE CERTIFICATION:**

I, (please print) \_\_\_\_\_, RPH # \_\_\_\_\_ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Pharmacist-in-Charge)

**ACKNOWLEDGEMENT BY PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:**

I, (please print) \_\_\_\_\_, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature \_\_\_\_\_ Date \_\_\_\_\_

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24  
Business and Professions Code (B&PC), Chapter 9, Division 2  
Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act  
California Code of Regulations (CCR), Chapter 1, Division 5, Title 22  
Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration  
([www.dea.gov](http://www.dea.gov))

**California Board of Pharmacy**

1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834  
Phone: (916) 574-7900  
Fax: (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

**Pharmacy Law** may be obtained by contacting:

Law-Tech Publishing Co.  
1060 Calle Cordillera, Suite 105  
San Clements, CA 92673  
Phone: (800) 498-0911 Ext. 5  
[www.lawtechpublishing.com](http://www.lawtechpublishing.com)

**Pharmacist Recovery Program**  
(800) 522-9198 (24 hours a day)

**Atlantic Associates, Inc. (CURES)**  
Prescription Collection  
8030 S. Willow Street, Bldg 3 Unit 3  
Manchester, NH 03103  
Phone: (888) 492-7341  
Fax: 877-508-6704

**CURES**  
4949 Broadway  
Sacramento, CA 95820  
Phone: (916) 319-9062  
Fax: (916) 319-9448  
<http://www.ag.ca.gov/bne>

**CURES Patient Activity Report Request Forms:**  
<http://www.ag.ca.gov/bne/trips.php>

**PRESCRIBER BOARDS:**

**Medical Board of California**  
2005 Evergreen St., Suite 1200  
Sacramento, CA 95815  
Phone: (800) 633-2322  
Phone: (916) 263-2382  
Fax: (916) 263-2944  
<http://www.mbc.ca.gov>

**Dental Board of California**  
2005 Evergreen St., Suite 1550  
Sacramento, CA 95815  
Phone: (916) 263-2300  
Fax: (916) 263-2140  
<http://www.dbc.ca.gov>

**Board of Registered Nursing**  
1625 N. Market Blvd., Suite N217  
Sacramento, CA 95834  
Phone: (916) 322-3350  
Fax: (916) 574-7697  
<http://www.rn.ca.gov/>

**Board of Optometry**  
2420 Del Paso Road, Suite 255  
Sacramento, CA 95834  
Phone: (916) 575-7170  
Fax: (916) 575-7292  
<http://www.optometry.ca.gov/>

**Osteopathic Medical Board of California**  
1300 National Drive, Suite 150  
Sacramento, CA 95834  
Phone: (916) 928-8390  
Fax: (916) 928-8392  
<http://www.ombc.ca.gov>



# **Self-Assessment**

## **Form 17M-14**

## HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year.** The pharmacist-in-charge must also complete a self-assessment within 30 days whenever (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

The self-assessment must be completed in its entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

**Notes: If dispensing prescriptions for outpatient use, a Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. 04/14 10/14) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 04/14 02/12.)**

**Each self-assessment must be kept on file in the pharmacy for three years after it is performed.**

Pharmacy Name: \_\_\_\_\_

Address: \_\_\_\_\_ Phone: \_\_\_\_\_

Ownership: Sole Owner  Partnership  Corporation  LLC   
Non-Licensed Owner  Other (please specify)  \_\_\_\_\_

Permit #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_ Other Permit #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Licensed Sterile Compounding Permit # \_\_\_\_\_ Expiration: \_\_\_\_\_

~~or~~ Accredited by (optional): \_\_\_\_\_ From: \_\_\_\_\_ To: \_\_\_\_\_

Centralized Hospital Packaging Permit #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

DEA Registration #: \_\_\_\_\_ Exp. Date: \_\_\_\_\_ Date of DEA Inventory: \_\_\_\_\_

Hours: ~~Daily~~ Weekdays \_\_\_\_\_ Sat \_\_\_\_\_ Sun. \_\_\_\_\_ 24 Hours \_\_\_\_\_

PIC: \_\_\_\_\_ RPH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Pharmacy staff (pharmacists, interns, technicians):

APP=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
2.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
3.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
4.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
5.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
6.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
7.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
8.	_____	RPH # _____	Exp. Date: _____
		APP # _____	Exp. Date: _____
		DEA # _____	Exp. Date: _____
9.	_____	INT # _____	Exp. Date: _____
10.	_____	INT # _____	Exp. Date: _____
11.	_____	INT # _____	Exp. Date: _____
12.	_____	INT # _____	Exp. Date: _____
13.	_____	TCH # _____	Exp. Date: _____
14.	_____	TCH # _____	Exp. Date: _____
15.	_____	TCH # _____	Exp. Date: _____
16.	_____	TCH # _____	Exp. Date: _____

17. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

18. \_\_\_\_\_ TCH # \_\_\_\_\_ Exp. Date: \_\_\_\_\_

# HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If “NO,” enter an explanation on “CORRECTIVE ACTION or ACTION PLAN” lines below. If more space is needed, you may add additional sheets.

## 1. Pharmacy

Yes No N/A

- 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)
- 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])
- 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])
- 1.4. The pharmacy reports to the board within ~~30~~ 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])
- 1.5. The pharmacy maintains “night stock” medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])
- 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
- 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)
- 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)
- 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

Yes No N/A

1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

1.12. Does the pharmacy compound sterile injectable drugs?  
(If yes, complete section 24 – “Compounding Sterile Injectable Drugs”)

1.13. The pharmacy is subscribed to the board’s e-mail notifications. (B&PC 4013)

Date Last Notification Received: \_\_\_\_\_

E-mail address registered with the board: \_\_\_\_\_

1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board’s e-mail notifications through the owner’s electronic notice system. (B&PC 4013[c])

Date Last Notification Received: \_\_\_\_\_

E-mail address registered with the board: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**2. Nursing Stations**

Yes No N/A

2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

2.2. The pharmacist, intern, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (B&PC 4119.7[c], 4115[i], 22 CCR 70263[q][10])

2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

### 3. Delivery of Drugs

Yes No N/A

3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

Yes No N/A

3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

- 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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### 4. Drug Stock

Yes No N/A

4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

**Yes No N/A**

- 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)
- 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**

**Yes No N/A**

- 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)
  - 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (H&SC 150202.5)
  - 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)
- 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])
- 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])
  - 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
  - 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])
  - 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])
  - 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
  - 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])
- 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

**5. 6. Pharmacist-in-Charge (PIC)**

Yes No N/A

- ~~5.1.~~ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 709, 1709.1)
- ~~5.2.~~ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (~~CCR 1709.2[b]~~) (CCR 1709.1[b])
- ~~5.3.~~ 6.3. Is the PIC in charge of another pharmacy?  
If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])  
If yes, name of other pharmacy \_\_\_\_\_
- ~~5.4.~~ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)
- ~~5.5.~~ 6.5. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 [d])  
If yes, name the wholesaler or veterinary food-animal retailer. \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

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**6. 7. Duties of a Pharmacist**

Yes No N/A

- ~~6.1.~~ 7.1. Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4052, 4052.2, CCR 1793.1)
- ~~6.2.~~ 7.2. Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2. (B&PC 4027, 4051, 4052, 4052.2)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

## **8. Duties of an Advanced Practice Pharmacist**

Yes No N/A

- 8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])
- 8.2. The advance practice pharmacist has received an advance practice pharmacist recognition by the board and may do the following: (B&PC 4016.5, 4210)
- 8.2.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers;
  - 8.2.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers;
  - 8.2.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
  - 8.2.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 405.26[b])
  - 8.2.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[01])
  - 8.2.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

## **7. 9. Duties of an Intern Pharmacist**

Yes No N/A

- ~~7.1.~~ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)
- 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)
  - 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c])
- ~~7.2.~~ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])
- 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

Yes No N/A

~~7.3.~~ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned. (B&PC 4209, CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

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## **8- 10. Duties of a Pharmacy Technician**

Yes No N/A

~~8.1.~~ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2)

~~8.2.~~ 10.2. The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, when prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115, CCR 1793.7[f])

~~8.3.~~ 10.3. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

~~8.4.~~ 10.4. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her self as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

~~8.5.~~ 10.5. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

Yes No N/A

~~8.6.~~ 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)

10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])

~~8.7.~~ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

~~8.7.1.~~ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.

~~8.7.2.~~ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist-pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.

~~8.7.3.~~ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.

- ~~8.7.4.~~ 10.8.4. The pharmacy technician ~~check~~ checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ~~8.7.5.~~ 10.8.5. There is an ongoing evaluation of the program that uses ~~specially~~ specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

Yes No N/A

10.9. Pharmacy technician duties include the following:

- 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

## **9. 11. Duties of Non-Licensed Personnel**

Yes No N/A

~~9.1.~~ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&P 4007,CCR 1793.3)

~~9.2.~~ 11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

## **PHARMACY PRACTICE**

### **~~10.~~ 12. Pharmaceutical Service Requirements**

Yes No N/A

~~10.1.~~ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- ~~10.1.1.~~ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ~~10.1.2.~~ 12.1.2. Repackaging and compounding records;
- ~~10.1.3.~~ 12.1.3. Physician orders;
- ~~10.1.4.~~ 12.1.4. Wards, nursing stations and night stock medications;

- ~~10.1.5.~~ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ~~10.1.6.~~ 12.1.6. Bedside medications;
- ~~10.1.7.~~ 12.1.7. Emergency drug supply;
- ~~10.1.8.~~ 12.1.8. Pass medications;
- ~~10.1.9.~~ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ~~10.1.10.~~ 12.1.10. Routine distribution of inpatient medications;
- ~~10.1.11.~~ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ~~10.1.12.~~ 12.1.12. Handling of medication when pharmacist not on duty; and
- ~~10.1.13.~~ 12.1.13. Use of electronic image and data order transmissions.

Yes No N/A

- ~~10.2.~~ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:
- ~~10.2.1.~~ 12.2.1. Destruction of controlled substances; and
  - ~~10.2.2.~~ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

### **11. 13. Medication/Chart Order**

Yes No N/A

- ~~11.1.~~ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)
- ~~11.2.~~ 13.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])
- ~~11.3.~~ 13.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)
- 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**~~12.~~ 14. Labeling and Distribution**

Yes No N/A

- ~~12.1.~~ 14.1. Unit dose medication and parenteral admixtures are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076, CCR 1751.2)
- ~~12.2.~~ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).
- ~~12.3.~~ 14.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to ~~received~~ receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
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**~~13.~~ 15. Duration of Drug Therapy**

Yes No N/A

- 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber’s specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**~~14.~~ 16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information**

Yes No N/A

- ~~14.1.~~ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)
- ~~14.2.~~ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)
- ~~14.3.~~ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

Yes No N/A

- ~~14.4.~~ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

### **~~15.~~ 17. Quality Assurance and Medication Errors**

Yes No N/A

- ~~15.1.~~ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)
- ~~15.2.~~ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])
- ~~15.3.~~ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])
- ~~15.4.~~ 17.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

Yes No N/A

- ~~15.5.~~ 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])
- ~~15.6.~~ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);
- ~~15.6.1.~~ 17.6.1. Date, location, and participants in the quality assurance review;
  - ~~15.6.2.~~ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
  - ~~15.6.3.~~ 17.6.3. Findings and determinations;
  - ~~15.6.4.~~ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.
- ~~15.7.~~ 17.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])
- ~~15.8.~~ 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

## **16. 18. Record Keeping Requirements**

Yes No N/A

- ~~16.1.~~ 18.1. A completed biennial pharmacy self -assessment is on file in the pharmacy and is maintained for three years. (CCR 1715)
- ~~16.2.~~ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:
- ~~16.2.1.~~ 18.2.1. Prescription records (B&PC 4081[a])
  - ~~16.2.2.~~ 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])
  - ~~16.2.3.~~ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
  - ~~16.2.4.~~ 18.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)
  - ~~16.2.5.~~ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)
  - ~~16.2.6.~~ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
  - ~~16.2.7.~~ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)
  - ~~16.2.8.~~ 18.2.8. Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)
  - 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1])
- ~~16.3.~~ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503, B&PC 4160)

Yes No N/A

- ~~16.4.~~ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, PDMA 503, B&PC 4160)
- ~~16.5.~~ 18.5. A controlled substances inventory is completed biennially (every two years).  
Date completed: \_\_\_\_\_ (21 CFR 1304.11)
- ~~16.6.~~ 18.6. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)
- ~~16.7.~~ 18.7. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)
- ~~16.8.~~ 18.8. DEA Forms 222 are properly executed. (21 CFR ~~1305.09~~ 1305.12)
- ~~16.9.~~ 18.9. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR ~~1309.09~~ 1305.13)
- ~~16.10.~~ 18.10. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

Yes No N/A

- ~~16.11.~~ 18.11. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)
- ~~16.12.~~ 18.12. Do pharmacy staff hand initial prescription records and prescription labels, OR
- ~~16.13.~~ 18.13. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

### **17. 19. After-Hours Supply of Medication**

Yes No N/A

- 19.1. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

### **18. 20. Drug Supplies for Use in Medical Emergencies**

Yes No N/A

- ~~18.1.~~ 20.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])
- ~~18.2.~~ 20.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])
- ~~18.3.~~ 20.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])
- ~~18.4.~~ 20.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the written policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

**19. 21. Schedule II-V Controlled Substances Floor Stock Distribution Records**

Yes No N/A

21.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

**20. 22. Emergency Room Dispensing**

Yes No N/A

~~20.1.~~ 22.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (B&PC 4068[a]):

- ~~20.1.1.~~ 22.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ~~20.1.2.~~ 22.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ~~20.1.3.~~ 22.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ~~20.1.4.~~ 22.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;
- ~~20.1.5.~~ 22.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ~~20.1.6.~~ 22.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

Yes No N/A

~~20.2.~~ 22.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

~~20.3.~~ 22.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

Yes No N/A

- ~~20.4.~~ 22.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
- ~~20.5.~~ 22.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (CFR 290.5)
- ~~20.6.~~ 22.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)
- ~~20.7.~~ 22.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

### **21. 23. Discharge Medication/Consultation Services**

Yes No N/A

- ~~21.1.~~ 23.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)
- ~~21.2.~~ 23.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)
- ~~21.3.~~ 23.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)
- ~~21.4.~~ 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])
- ~~21.5.~~ 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.  
Exemption approved by board from: \_\_\_\_\_ to \_\_\_\_\_

Yes No N/A

- ~~21.6.~~ 23.6. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)
- ~~21.7.~~ 23.7. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)
- ~~21.8.~~ 23.8. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)
- ~~21.9.~~ 23.9. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)
- ~~21.10.~~ 23.10. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

Yes No N/A

~~21.11.~~ 23.11. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (25 USC 1473 section 4[b], 16 CFR 1700.15, CCR 1717)

~~21.12.~~ 23.12. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_  
\_\_\_\_\_

**22. 24. Central Fill—Central Filling of Patient Cassettes For Other Hospital Pharmacies**

Yes No N/A

~~22.1.~~ 24.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is “yes,” name of hospital: \_\_\_\_\_

~~22.2.~~ 24.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is “yes,” name of supplying pharmacy: \_\_\_\_\_

If the answer to this and the previous question is “no” or “not applicable” go to Section ~~23.~~ 25.

~~22.3.~~ 24.3. Prescription information is electronically transferred between the two pharmacies (CCR 1710[b][6])

~~22.4.~~ 24.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

~~22.5.~~ 24.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

~~22.6.~~ 24.6. Each cassette or container meets the requirements of Business and Professions Code section 4076 (CCR 1710[b][3])

~~22.7.~~ 24.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

**25. Centralized Hospital Packaging Pharmacy**

Yes No N/A

25.1. The pharmacy packages unit dose medication for inpatients of one or more hospitals under common ownership within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

25.1.1. \_\_\_\_\_ Distance (miles): \_\_\_\_\_

25.1.2. \_\_\_\_\_ Distance (miles): \_\_\_\_\_

25.1.3. \_\_\_\_\_ Distance (miles): \_\_\_\_\_

25.1.4. \_\_\_\_\_ Distance (miles): \_\_\_\_\_

- 25.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)
- 25.3. All unit dose medications produced by a centralized hospital packaging pharmacy are barcoded and readable at the inpatient's bedside. The barcode information contains: (B&PC 4128.4)
- 25.3.1. The date the medication was prepared.
  - 25.3.2. The components used in the drug product.
  - 25.3.3. The lot number or control number.
  - 25.3.4. The expiration date.
  - 25.3.5. The National Drug Code Directory number.
  - 25.3.6. The name of the centralized hospital packaging pharmacy.
- 25.4. The label for each unit dose medication produced by a centralized hospital packaging pharmacy contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements. (B&PC 4128.5)
- 25.5. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

## ~~23.~~ 26. Policies and Procedures

Yes No N/A

- ~~23.1.~~ 26.1. There are written policies and procedures in place for:
- ~~23.1.1.~~ 26.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.
  - ~~23.1.2.~~ 26.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])
  - ~~23.1.3.~~ 26.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (B&PC 4104[b])
  - ~~23.1.4.~~ 26.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])
  - ~~23.1.5.~~ 26.1.5. Reporting to the board within ~~30~~ 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].

- ~~23.1.6.~~ 26.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])
- ~~23.1.7.~~ 26.1.7. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist’s responsibilities for checking all work performed by ancillary staff, and pharmacist’s responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])
- ~~23.1.8.~~ 26.1.8. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])
- ~~23.1.9.~~ 26.1.9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient’s language, including the selected means to identify the patient’s language and providing interpretive services in the patient’s language. (CCR 1707.5)

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

\_\_\_\_\_

**24. 27. Compounding**

**Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the “Compounding Self-Assessment” Form 17M-39 (Rev. ~~01/11~~ 02/12). (CCR 1735.2[j])**

**PHARMACIST-IN-CHARGE CERTIFICATION:**

I, (please print) \_\_\_\_\_, RPH # \_\_\_\_\_ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Pharmacist-in-Charge)

**ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:**

I, (please print) \_\_\_\_\_, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature \_\_\_\_\_ Date \_\_\_\_\_

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

California Code of Regulations (CCR), Title 16 and Title 24

Business and Professions Code (B&PC), Chapter 9, Division 2

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration ([www.dea.gov](http://www.dea.gov))

### **California Board of Pharmacy**

1625 N. Market Blvd., Suite N219

Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

<http://www.pharmacy.ca.gov>

**Pharmacy Law** may be obtained by contacting:

*LawTech Publishing Co.*

1060 Calle Cordillera, Suite 105

San Clements CA 92673

(800) 498-0911 Ext. 5

<http://www.lawtechpublishing.com>

### **Pharmacist Recovery Program**

(800) 522-9198 (24 hours a day)

### **Atlantic Associates, Inc. (CURES)**

Prescription Collection

8030 S. Willow Street, Bldg 3 Unit 3

Manchester, NH 03103

Phone: (888) 492-7341

Fax: (877) 508-6704

CURES

P.O. Box 160447

Sacramento, CA 95816-1089

Phone: (916) 319-9062

Fax: (916) 319-9448

<http://www.ag.ca.gov/bne>

CURES Patient Activity Report Request Forms:

<http://www.ag.ca.gov/bne/trips.php>

### **PRESCRIBER BOARDS:**

#### **Medical Board of California**

2005 Evergreen St., Suite 1200

Sacramento, CA 95815

Phone: (800) 633-2322

Phone: (916) 263-2382

Fax: (916) 263-2944

<http://www.mbc.ca.gov>

#### **Dental Board of California**

2005 Evergreen St., Suite 1550

Sacramento, CA 95815

Phone: (877) 729-7789

Phone: (916) 263-2300

Fax: (916) 263-2140

<http://www.dbc.ca.gov>

#### **Board of Registered Nursing**

1625 N. Market Blvd., Suite N217

Sacramento, CA 95834

Phone: (916) 322-3350

Fax: (916) 574-7697

<http://www.rn.ca.gov>

#### **Board of Optometry**

2420 Del Paso Road, Suite 255

Sacramento, CA 95834

Phone: (916) 575-7170

Fax: (916) 575-7292

<http://www.optometry.ca.gov>

#### **Osteopathic Medical Board of California**

1300 National Drive, Suite #150

Sacramento, CA 95834

Phone: (916) 928-8390

Fax: (916) 928-8392

<http://www.ombc.ca.gov>

**Physician Assistant Committee**

2005 Evergreen St., Suite 1100  
Sacramento, CA 95815  
Phone: (916) 561-8780  
Fax: (916) 263-2671  
<http://www.pac.ca.gov>

**Board of Podiatric Medicine**

2005 Evergreen St., Suite 1300  
Sacramento, CA 95815  
Phone: (916) 263-2647  
Fax: (916) 263-2651  
<http://www.bpm.ca.gov>

**Veterinary Medical Board**

2005 Evergreen St., Suite 2250  
Sacramento, CA 95815  
Phone: (916) 263-2610  
Fax: (916) 263-2621  
<http://www.vmb.ca.gov>

**FEDERAL AGENCIES:****Food and Drug Administration****– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

**DEA Website:** <http://www.deadiversion.usdoj.gov>

**Online Registration – New Applicants:**

[http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.deadiversion.usdoj.gov/drugreg/change\\_requests/index.html](http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html)

**DEA Registration Support (all of CA):**

(800) 882-9539

**Online DEA 106 Theft/Loss Reporting:**

<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>

**Online DEA 222 Controlled Substance Ordering System (CSOS):** <http://www.deaecom.gov/>**DEA - Fresno**

2444 Main Street, Suite 240  
Fresno, CA 93721  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (559) 487-5406

**DEA - Los Angeles**

255 East Temple Street, 20th Floor  
Los Angeles, CA 90012  
Registration: (888) 415-9822 or (213) 621-6960  
Diversion or Investigation: (213) 621-6942

**DEA – Oakland**

1301 Clay Street, Suite 460N  
Oakland, CA 94612  
Registration: (888) 304-3251  
Diversion or Investigation: (510) 637-5600

**DEA – Redding**

310 Hensted Drive, Suite 310  
Redding, CA 96002  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (530) 246-5043

**DEA - Riverside**

4470 Olivewood Avenue  
Riverside, CA 92501-6210  
Registration: (888) 415-9822 or (213) 621-6960  
Diversion or Investigation: (951) 328-6200

**DEA - Sacramento**

4328 Watt Avenue  
Sacramento, CA 95821  
Registration: (888) 304-3251 or (415) 436-7900

**DEA – San Diego and Imperial Counties**

4560 Viewridge Avenue  
San Diego, CA 92123-1637  
Registration: (800) 284-1152  
Diversion or Investigation: (858) 616-4100

**DEA – San Francisco**

450 Golden Gate Avenue, 14<sup>th</sup> Floor  
San Francisco, CA 94102  
Registration: (888) 304-3251  
Theft Reports or Diversion: (415) 436-7900

**DEA – San Jose**

One North First Street, Suite 405  
San Jose, CA 95113  
Registration: (888) 304-3251  
Diversion or Investigation: (408) 291-2631

# **Self-Assessment**

## **Form 17M-26**

# WHOLESALE DANGEROUS DRUGS & DANGEROUS DEVICES SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 18 ~~18~~ 21.

All references to “drugs” throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022. ([http://www.pharmacy.ca.gov/laws\\_regs/lawbook.pdf](http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf)).

Wholesaler Name \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Wholesaler E-mail address (~~optional~~) \_\_\_\_\_

Ownership: Please mark one

- sole owner       partnership       corporation       LLC  
 non- licensed owner       Other (please specify) \_\_\_\_\_

CA Wholesaler Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Other Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_  
*(Use additional sheets if needed.)*

DEA Registration # \_\_\_\_\_ Expiration Date \_\_\_\_\_

**VAWD Accreditation # \_\_\_\_\_ Expiration Date \_\_\_\_\_**

Date of most recent DEA Inventory \_\_\_\_\_

Hours: ~~Daily~~Weekdays \_\_\_\_\_ Sat \_\_\_\_\_ Sun \_\_\_\_\_ 24 Hours

Designated representative-in-charge (DRIC) / pharmacist (RPH) \_\_\_\_\_

DRIC License # / RPH License # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Website Address (optional): \_\_\_\_\_

**Licensed Wholesaler Staff (designated representative (DR), pharmacist):**

- 1. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 2. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 3. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 4. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 5. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 6. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 7. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 8. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 9. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_
- 10. \_\_\_\_\_ DR#/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_

Please mark the appropriate box for each question. If “NO,” enter an explanation on the “CORRECTIVE ACTION OR ACTION PLAN” lines at the end of the section. If more space is needed, add additional sheets.

### 1. Ownership/Location

Yes No N/A

- 1.1. Review the current wholesaler permit for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B&PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**
  
- 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

**Note:** Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B&PC 4082)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_  
\_\_\_\_\_

### 2. Facility

#### 2.1. Premises, fixtures and equipment:

Yes No N/A

- 2.1.1. Are clean and orderly
- 2.1.2. Are well ventilated
- 2.1.3. Are free from rodents and insects
- 2.1.4. Are adequately lit
- 2.1.5. Have plumbing in good repair
- 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22<sup>nd</sup> Edition) (CCR 1780[b])

- 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

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---

---

Yes No N/A

2.5. Does this business operate only when a designated representative or pharmacist is on the premises? (CCR 1781)

2.6. The wholesale premises is equipped with the following specific security features:

2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (~~CCR~~ CCR 1780[c][2]).

Explain how your security system complies with these requirements.

---

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Yes No N/A

2.7. Is this business a “reverse distributor”, that is, does the business act as an agent for pharmacies, drug wholesalers, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Yes No N/A

2.8. The facility is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: \_\_\_\_\_

E-mail address registered with the board: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

---

Yes No N/A

2.9. The facility receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: \_\_\_\_\_

E-mail address registered with the board: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~H~~ 12 of this document.

### 3. Designated Representative-in-Charge / Owner Responsibilities

Yes No N/A

3.1. The owner and the designated representative-in-charge are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

3.2. Is the designated representative-in-charge at least 18 years of age and is responsible for the wholesaler's compliance with all state and federal laws for the wholesale distribution of drugs? The designated representative-in-charge may be a pharmacist. (B&PC 4160[d])

3.3. The owner must notify the board within 30 days of termination of the designated representative-in-charge or pharmacist. (B&PC 4305.5[a])

3.4. The owner must identify and notify the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge. (B&PC 4160[d], 4331[c]) The appropriate form for this notification is a "Change of Designated Representative-in-Charge," which is available on the board's website.

Yes No N/A

- 3.5. The designated representative-in-charge who ends his or her employment at a wholesaler, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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#### 4. Designated Representative/Pharmacist

Yes No N/A

- If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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#### 5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

- 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

~~Yes No N/A~~

- 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

- 5.3. For license verification, the wholesaler may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

## 6. Receipt of Drugs by this Business

Yes No N/A

- 6.1. When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B & P 4059.5[a])
- 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

## 7. Drug Stock

Yes No N/A

- 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])
- 7.2. Are all drugs you order maintained in a secure manner at your licensed wholesale premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)
- 7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])
- 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)
- 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)
- 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

Yes No N/A

- 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs’ safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

**8. Sale or Transfer of Drugs by this Business**

Yes No N/A

- 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a] [b][d], B&PC 4169)

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8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

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\_\_\_\_\_

Yes No N/A

- 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

- 8.5.1. the pharmacy originally purchased the drugs from you?
- 8.5.2. your business is a “reverse distributor”?
- 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

Yes No N/A

8.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

8.6.1. transacted with a business licensed with this board as a wholesaler or pharmacy?

8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

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8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

8.8.2. comply with the pharmacy law of the receiving state within the United States?

8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

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Yes No N/A

8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987). ~~Commencing on July 1, 2017, an electronic pedigree must accompany all drugs (B&PC 4163), even those for which your business is an authorized distributor.~~

Yes No N/A

8.11. If preferentially priced drugs are sold by your business, that sale complies with the Prescription Drug Marketing Act of 1987 and CA Pharmacy Law. (B&PC 4380)

Yes No N/A

8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

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Yes No N/A

8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

**9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)**

Yes No N/A

9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

Yes No N/A

9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

- 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])
- 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

**9. 10. Outgoing Shipments of Drugs**

Yes No N/A

~~9.1.~~ 10.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

~~9.2.~~ 10.2. Does your business use a common carrier (a shipping or delivery company —UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

~~9.3.~~ 10.3. List the common carriers (shipping or delivery companies) you use.

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~4~~ 12 of this document.

**10. 11. Delivery of Drugs**

Yes No N/A

~~10.1.~~ 11.1. Are all drugs ordered by a pharmacy or another wholesaler delivered to the address of the buyer’s licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

Yes No N/A

~~10.2.~~ 11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (~~B&PC 4059[d]~~) (B&PC 4059.5[d])

~~10.3.~~ 11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

~~10.4.~~ 11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

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## **~~11.~~ 12. Controlled Substances**

Yes No N/A

~~11.1.~~ 12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

~~11.2.~~ 12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

~~11.3.~~ 12.3. Are DEA requirements for storage of Schedule ~~III~~ III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

Yes No N/A

~~11.4.~~ 12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a][c][e])

~~11.5.~~ 12.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

12.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

~~11.6.~~ 12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

~~11.7.~~ 12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

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Yes No N/A

~~11.8.~~ 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

~~11.9.~~ 12.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

~~11.10.~~ 12.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (H & S 11153.5[a][b][c])

~~11.11.~~ 12.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

~~11.12.~~ 12.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

~~11.13.~~ 12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

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Yes No N/A

~~11.14.~~ 12.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. —(CFR 1301.74[f])

~~11.15.~~ 12.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

~~11.16.~~ 12.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

Yes No N/A

- ~~11.17.~~ 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 form? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])
- ~~11.18.~~ 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)
- ~~11.19.~~ 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (~~CFR 1309.13[b]~~) (CFR 1305.13[b])
- ~~11.20.~~ 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])
- ~~11.21.~~ 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)
- ~~11.22.~~ 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))
- ~~11.23.~~ 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, ~~CFR 1305.09[d]~~, CFR 1305.17[c], 1305.17[a] [b], and ~~H&S~~ H&SC 11252, 11253, 1304.03)
- ~~11.24.~~ 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])
- ~~11.25.~~ 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])
- ~~11.26.~~ 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])
- ~~11.27.~~ 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (~~CFR 1305.16~~) (CFR 1305.17[d])

Yes No N/A

~~11.28.~~ 12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

~~11.29.~~ 12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**~~12.~~ 13. Policies and Procedures**

~~12.1.~~ 13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

~~12.1.1.~~ 13.1.1. Receipt of drugs?  
   ~~12.1.2.~~ 13.1.2. Security of drugs?  
   ~~12.1.3.~~ 13.1.3. Storage of drugs?(including maintaining records to document proper storage)

~~12.1.4.~~ 13.1.4. Inventory of drugs?(including correcting inaccuracies in inventories)

~~12.1.5.~~ 13.1.5. Distributing drugs?

~~12.1.6.~~ 13.1.6. Identifying, recording and reporting theft or losses?

~~12.1.7.~~ 13.1.7. Correcting ~~errors?~~ errors and inaccuracies in inventories?

Physically quarantining and separating:

~~12.1.8.~~ 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs?

~~12.1.9.~~ 13.1.9. drugs that have been partially used?

~~12.1.10.~~ 13.1.10. drugs where the outer or secondary seals on the container have been broken?

~~12.1.11.~~ 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug?

~~12.1.12.~~ 13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity?(CCR 1780[e][f])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**13. 14. Training**

Yes No N/A

- ~~14.1~~ 15.1 Is Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**14. 15. Dialysis Drugs**

Yes No N/A

- ~~14.1.~~ 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B&PC 4054) (4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~15.~~ 16.
- ~~14.2.~~ 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])
- ~~14.3.~~ 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a][b][c])
- ~~14.4.~~ 15.4. Does your business provide an “expanded invoice” for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)
- ~~14.5.~~ 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

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**15. 16. Record Keeping Requirements**

Yes No N/A

- ~~15.1.~~ 16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])
  
- ~~15.2.~~ 16.2. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4081[a], 4105[c], 4081, 4332, 4059.5[a]) Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.
  
- ~~15.3.~~ 16.3. Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])
  
- ~~15.4.~~ 16.4. Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, 1718)
  
- ~~15.5.~~ 16.5. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])
  
- ~~15.6.~~ 16.6. Are required records stored off-site only if a board issued written waiver has been granted?

~~15.7.~~ 16.7. If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date \_\_\_\_\_ Address \_\_\_\_\_

~~Yes No N/A~~

- ~~15.8.~~ 16.8. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])
  
- ~~15.9.~~ 16.9. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])
  
- ~~15.10.~~ 16.10. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])
  
- ~~15.11.~~ 16.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

Yes No N/A

- ~~15.12.~~ 16.12. Has this licensed premises, or the designated representative-in-charge or pharmacist, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):
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Yes No N/A

- ~~15.13.~~ 16.13. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)
- ~~15.14.~~ 16.14. Has this business received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])
- ~~15.15.~~ 16.15. If this business dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~H~~ 12 of this document.

### **16. 17. Reporting Requirements to the Board**

Yes No N/A

- ~~16.1.~~ 17.1. A designated representative-in-charge who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c]).
- ~~16.2.~~ 17.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or pharmacist (B&PC 4305.5[a])
- ~~16.3.~~ 17.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)
- ~~16.4.~~ 17.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

- ~~16.5.~~ 17.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)
- ~~16.6.~~ 17.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])
- ~~16.7.~~ 17.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])
- ~~16.8.~~ 17.8. Effective January 1, 2006 your business will develop and maintain a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:
1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
  2. identify purchases of any dangerous drugs at preferential or contract prices
  3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B&PC 4164[b])
- ~~16.9.~~ 17.9. I understand that this wholesaler license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])
- ~~16.10.~~ 17.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)
- ~~16.11.~~ 17.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

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**17. 18. Additional Licenses/Permits Required**

18.1. List all licenses and permits required to conduct this business, including local business licenses, wholesale licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

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**DESIGNATED REPRESENTATIVE-IN-CHARGE / PHARMACIST CERTIFICATION:**

I, (please print) \_\_\_\_\_, DRIC# / RPH # \_\_\_\_\_  
hereby certify that I have completed the self-assessment of this wholesale business of which I am the designated representative-in-charge (DRIC) / pharmacist (RPH). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
Designated Representative-in-Charge (DRIC) / Pharmacist (RPH)

**ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:**

I, (please print) \_\_\_\_\_, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature \_\_\_\_\_ Date \_\_\_\_\_

## Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

### California Board of Pharmacy

1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834  
Phone: (916) 574-7900  
Fax: (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

### Board of Registered Nursing

1625 N. Market Blvd., Suite N217  
Sacramento, CA 95834  
Phone: (916) 322-7697  
Fax: (916) 574-8637  
<http://www.rn.ca.gov/>

*Pharmacy Law* may be obtained by contacting:

LawTech Publishing Co.  
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### Board of Optometry

2420 Del Paso Road, Suite 255  
Sacramento, CA 95834  
Phone: (916) 575-7170  
Fax: (916) 575-7292  
<http://www.optometry.ca.gov/>

### Pharmacist Recovery Program

Phone: (800) 522-9198 (24 hours a day)

### Osteopathic Medical Board of California

1300 National Drive, Suite 150  
Sacramento, CA 95834  
Phone: (916) 928-8390  
Fax: (916) 928-8392  
<http://www.ombc.ca.gov>

### Prescriber Boards:

#### Medical Board of California

2005 Evergreen St., Suite 1200  
Sacramento, CA 95815  
Phone: (800) 633-2322  
Phone: (916) 263-2382  
Fax: (916) 263-2944  
<http://www.mbc.ca.gov>

#### Physician Assistant Committee

2005 Evergreen St., Suite 1100  
Sacramento, CA 95815  
Phone: (916) 561-8780  
Fax: (916) 263-2671  
<http://www.pac.ca.gov>

#### Dental Board of California

2005 Evergreen St., Suite 1550  
Sacramento, CA 95815  
Phone: (916) 263-2300  
Fax: (916) 263-2140  
<http://www.dbc.ca.gov>

#### Board of Podiatric Medicine

2005 Evergreen St., Suite 1300  
Sacramento, CA 95815  
Phone: (916) 263-2647  
Fax: (916) 263-2651  
<http://www.bpm.ca.gov>

**Veterinary Medical Board**

2005 Evergreen St., Suite 2250  
Sacramento, CA 95815  
Phone: (916) 263-2610  
Fax: (916) 263-2621  
<http://www.vmb.ca.gov>

**Federal Agencies:****Food and Drug Administration****– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

**DEA Website:**

<http://www.deadiversion.usdoj.gov>

**Online Registration – New Applicants:**

[http://www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.deadiversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.deadiversion.usdoj.gov/drugreg/change\\_requests/index.html](http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html)

**Online DEA 106 Theft/Loss Reporting:**

<https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp>

**Controlled Substance Ordering System**

**(CSOS):** <http://www.deacom.gov/>

**DEA Registration Support (all of CA):**

(800) 882-9539

**DEA - Los Angeles**

255 East Temple Street, 20th Floor  
Los Angeles, CA 90012  
Registration: (888) 415-9822 or (213) 621-6960  
Diversion or Investigation: (213) 621-6942

**DEA – San Francisco**

450 Golden Gate Avenue, 14<sup>th</sup> Floor  
San Francisco, CA 94102  
Registration: (888) 304-3251  
Theft Reports or Diversion: (415) 436-7900

**DEA - Sacramento**

4328 Watt Avenue  
Sacramento, CA 95821  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (916) 480-7250

**DEA - Riverside**

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Riverside, CA 92501-6210  
Registration: (888) 415-9822 or (213) 621-6960  
Diversion or Investigation: (951) 328-6200

**DEA - Fresno**

2444 Main Street, Suite 240  
Fresno, CA 93721  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (559) 487-5406

**DEA – San Diego and Imperial Counties**

4560 Viewridge Avenue  
San Diego, CA 92123-1637  
Registration: (800) 284-1152  
Diversion or Investigation: (858) 616-4100

**DEA – Oakland**

1301 Clay Street, Suite 460N  
Oakland, CA 94612  
Registration: (888) 304-3251  
Diversion or Investigation: (510) 637-5600

**DEA – San Jose**

One North First Street, Suite 405  
San Jose, CA 95113  
Registration: (888) 304-3251  
Diversion or Investigation: (408) 291-2631

**DEA – Redding**

310 Hensted Drive, Suite 310  
Redding, CA 96002  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (530) 246-5043

# **Attachment 2**

**Advanced Practice  
Pharmacist –  
1730, 1730.1, and  
1749**

**Advanced Practice Pharmacist –  
Second 15-Day Comments  
Comment Period Closed December 5, 2015**

Code Section	Commenter	Comment
1730.1(c)	<b>Joseph Woelfel</b>	Recommend removing "one year of" to read "Additionally, the experience must be composed....."
1730.1(c)(2)	<b>Joseph Woelfel</b>	Recommend removing "at least one year of" and change to "no fewer than 1,500 hours"
1730.1(c)	<b>Robert Stein</b>	<p>1. With respect to the collaborative practice experience required under 1730.1(c), it is inherently discriminatory to require the clinical experience be within ten years while 1730.1(b) contains no similar time limit on qualifying based on a residency program. As pointed out in the public comments at the Board and SB493 Committee meetings, a pharmacist with a (one year) residency 30 years ago qualifies, yet a clinical pharmacist working under protocols and collaborative agreements for 20 consecutive years where such experience happened to be more than ten years ago does not qualify. This is inconsistent and 1730.1(c) should omit the "within 10 years" requirement. There was no evidence presented during public proceedings indicating that a pharmacist with a one year residency earned 15 years ago is inherently more qualified than the clinical pharmacist working under protocols and collaborative practice agreements for five years (that happened to end 15 years ago).</p> <p>2. Further, as currently written, there is nothing to prevent a pharmacist with a one year residency, assuming 1500 hours working in collaborative practice environments from meeting 1730.1(b) and 1730.1(c). Therefore, 1730.1(c) should specifically preclude any experiential hours earned during a residency that qualifies under 1730.1(b). Such hours should not be able to be "double dipped" to meet two criteria that were clearly intended to be mutually exclusive.</p>

**Advanced Practice  
Pharmacist –  
Second Modified Text**

**Title 16. BOARD OF PHARMACY**  
**Second Modified Text**

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and **bold and dashed underline** for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the modified proposed language are shown by ~~double strikethrough and bold underline~~ for deleted language and **bold and double underline** for added language. (Additionally, the modified text is listed in blue for color printers.)

**Proposal to add** new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

**Article 3.5. Advanced Practice Pharmacist**

**Proposal to add** §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1730 Acceptable Certification Programs**

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

**Proposal to add** §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure**

For purposes of **Business and Professions Code section 4210** an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, ~~and must be earned within four consecutive years.~~ The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, **modifying or ~~and~~** discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210(a)(2)(C), which includes initiating, adjusting, **modifying or ~~and~~** discontinuing drug therapy of patients; and

(i) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

**Proposal to amend** §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1749 (Fee Schedule)**

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, ~~4210~~, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is ~~two hundred seven dollars (\$207)~~ **one hundred ninety-five dollars (\$195)**. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

- (l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).
- (m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).
- (n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325) . The penalty for failure to renew is one hundred fifty dollars (\$150).
- (p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).
- (r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).
- (s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).
- (t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

Advanced Practice Pharmacist

15-Day Comments

Comment Period Closed October 23, 2015

Code Section	Commenter	Comment
1730.1(c)(1)(B)	<b>Lori Hensic</b> Kaiser	1) Recommend modifying 1730.1(c)(1)(B): "...which includes initiating, adjusting, <u>modifying or</u> <del>and</del> discontinuing drug therapy..." To be consistent with proposed language as stated in 1730.1(c).
1730.1(c)(1)(B)	<b>Brian Warren</b> CPHA	(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, <u>modifying or</u> <del>and</del> discontinuing drug therapy of patients; and  For consistency with modifications made to 1730.1(c) to add "modifying" and replaced the "and" with an "or" in the requirement that experience include "initiating, adjusting, and discontinuing."
<b>The Comments Below are Outside the Scope of the Comment period and are Rejected</b>		

Code Section	Commenter	Comment
1730.1(b)	<p><b>Douglas Barcon</b> Barcon &amp; Associates</p>	<p>Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:</p> <p>(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or</p> <p>(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty. For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).</p> <p>SB 493 states:</p> <p>4210. (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:</p> <p>(2) Satisfy any two of the following criteria:</p> <p>(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.</p> <p>Paragraph 4210(a)(2)(B) does not specify whether the residency is a one-year or a two-year postgraduate residency. For a one-year PGY1 residency, SB 493 requires a minimum of six-months (50%) providing direct patient care services with interdisciplinary teams. This is held to be a valid qualifying criterion for advanced practice pharmacist licensure regardless of the number of years between the postgraduate residency and the date of application for licensure as an advanced practice pharmacist. Moreover, the minimum six-months providing direct patient care services in a residency during the first postgraduate year could overlap the collaborative practice experience specified in 4210(a)(2)(C), which would result in a total of one-year of collaborative practice experience from the combining of 4210(a)(2)(B) and 4210(a)(2)(C). However, it would be required under this law for a pharmacist without a postgraduate residency but who has a minimum of one-year of collaborative practice experience to obtain a certification as specified in 4210(a)(2)(A), while a pharmacist with a postgraduate residency is not required to obtain a certification. Thus the law is discriminatory and validates that the collaborative practice experience gained during a postgraduate residency is superior to any collaborative practice experience obtained outside of a postgraduate residency without any documentation supporting that validation. SB 493 made the assumption that the minimum six-months of qualifying post-graduate residency experience could replace all collaborative practice experience outside of the postgraduate residency should the pharmacist choose to obtain a certification. Additionally, SB 493 itself does not address whether the collaborative practice experience specified in 4210(a)(2)(C) could be applied to meeting both the equivalent qualifying experience of a post-graduate residency and the collaborative practice experience requirement.</p>

Code Section	Commenter	Comment
1730.1(c)	<b>Douglas Barcon</b> Barcon & Associates	<p>Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law.</p> <p>SB 493 states: 4210. (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements: (2) Satisfy any two of the following criteria: (C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.</p> <p>As proposed, Board of Pharmacy regulation 1730.1(c) adds a further burden on pharmacists who do not have a postgraduate residency because it eliminates any collaborative practice experience that occurred more than 10 years prior to the date of application for licensure as an advanced practice pharmacist from the qualifying criteria, while accepting collaborative practice experience gained during the one-year period of a postgraduate residency without regard to when it occurred prior to the application. The board of pharmacy is further validating that collaborative practice experience obtained during a postgraduate residency is superior to any collaborative practice experience gained outside of a postgraduate residency and is doing so without documentation supporting that validation.</p> <p>As currently proposed in 1730.1(c), pharmacists that have collaborative practice clinical pharmacy experience more than 10 years ago but do not have a residency gain nothing in regard to qualifying for advanced practice pharmacist licensure by acquiring a certification, because the experience specified in 4210(a)(2)(C) is excluded. Thus many pharmacists are prevented from seeking licensure as an advanced practice pharmacist regardless of their experience and skills by this exclusionary law and regulation. Further, a postgraduate residency is not a requirement for licensure as a pharmacist nor is it a requirement to practice clinical pharmacy or collaborative practice within current pharmacy law and regulations.</p> <p><b>Continued Next Row</b></p>

Code Section	Commenter	Comment
1730.1(c)	Douglas Barcon Barcon & Associates	<p><b>Continued Previous Row</b></p> <p>Pharmacists are not required to document their clock hours in regard to specific services among all functions and service provided throughout each day of work. Consequently, it is not practical or possible for a pharmacist to verify they have no fewer than 1,500 hours of experience providing clinical services to patients. This is not a requirement of SB 493 and should be removed from the proposed 1730.1(c).</p> <p>In further narrowing the qualifying criteria specified by SB 493, the board of pharmacy has created a barrier to practice and a restraint of trade. Further, without any grandfather clauses, the board of pharmacy has promoted age discrimination and has made a postgraduate residency of paramount importance regardless of when it occurred or its quality over any collaborative practice experience. The board of pharmacy and SB 493 both support that the minimum six months (50%) experience obtained during a postgraduate residency meets the qualifying criteria in perpetuity for applying for advanced practice pharmacist.</p> <p>If experience in collaborative practice pharmacy is not acceptable as a qualifying criterion for advanced practice pharmacist if it occurred more than 10 years prior to filing the application, then a post-graduate residency with collaborative practice experience should not be acceptable if it occurred more than 10 years prior to filing the application for consistency. The board should rethink the time limitation. The criteria specified in SB 493 and the proposed 1730.1 are unreasonable and unjustifiable barriers to seasoned pharmacists with practical experience who would like to pursue licensure as advanced practice pharmacists and do not help relieve the shortage of primary care practitioners.</p>
1730.1	Mitchell Pelter	<p>The proposed qualification language is not completely consistent with the language of Senator Hernandez's Chaptered Senate bill number 493. Under the legislation I would easily qualify as well as will many of my ambulatory care colleagues. Under the proposed regulation very few will qualify. We have very few board certified ambulatory care pharmacists. We have many residency qualified pharmacists. While many will also qualify under the hours requirement it is this requirement in particular I wish to address.</p> <p>Our Residency program has supported the Free Clinic of Simi Valley for about eight years. During that time we have served countless indigent, under insured and underserved patients that otherwise would not have access to quality care. I have personally treated these patients as well as precept our PGY 1 pharmacy residents of Woodland Hills and Panorama City. My volunteer time is roughly 10-15 hours/month. This equates to about 720 hours for four years which is well below the proposed regulations of at least 1500 hours. I use myself as an example but none of the six preceptors at the Free Clinic will meet the Board's requirements (four of which are current, full time ambulatory care pharmacists). Thus we will have no choice but to eliminate our service to this Clinic once the regulations go into effect.</p> <p>To give you an idea of the Free Clinic program and I am sharing with you the learning statement we provide our residents: "You will assume primary care responsibility for a panel of patients with chronic conditions to provide pharmaceutical care that includes physical assessment, laboratory testing, prescriptive authority, and patient education and counseling. Patients are often followed by the pharmacy resident for the entire residency year, permitting the resident to observe over time the evolution of a chronic disease and the impact of drug therapy. Our ACP service accepts referrals from the clinic's Family Medicine service for the patients with diabetes mellitus, hypertension, dyslipidemia, and hypothyroidism. During the course of the year, residents also conduct a FCSV project in collaboration with the clinic staff and preceptors. Our clinics are held two evenings per week, and provide an invaluable opportunity to work with skilled preceptors and develop direct patient care skills."</p>

Code Section	Commenter	Comment
1730.1	Mitchell Pelter	<p>I served as a military medic, then completed college and graduated from USC with a PharmD. I completed a clinical pharmacy residency at a very large, academic medical center in New England. My first position was providing acute care on a medical-surgical floor at the UCLA Medical Center. I then spent 6 years pioneering a critical care service at a medium size community hospital. I have been with my health care organization for over 25 years. For the first 11 years I was charged with educating our medical staff on pharmacotherapy as well as developing evidence based clinical practice guidelines. There were no ambulatory pharmaceutical care programs at my medical center prior to my arrival. I created all the programs! We now employ 68 pharmacists in this capacity and provide care to literally thousands of patients with serious chronic illnesses. All the services are under collaborative practice protocols (which I developed). I was also the one that pioneered the legislation in the mid-1990s that lead to the portion section of Business and Professions Section 4052.2 allowing collaborative practice in California in the ambulatory care setting. I have numerous publications and studies in peer reviewed pharmacy and medical journals, a few books chapters, and numerous scientific posters at national and state meetings. I have spoken to large and small groups of pharmacists, nurses and physicians on pharmacotherapeutic topics. Yet, despite spending my entire career moving our profession and patient care forward I will not qualify for the new licensure. Was it the intent of the Board to make older pharmacists obsolete?</p> <p>I have lined up the chaptered legislation with the proposed regulations by BOP (please see table below). Based upon the language of the chaptered legislation, the BOP language is inconsistent with some aspects of legislated language. While some might consider BOPs language to be clarification of ambiguities in the legislation, in terms of the criteria for APP the legislation is extremely and abundantly clear to the "common man".</p> <p>I am particularly troubled by the definition proposed for experience required. Amongst other problems it appears to set up a sort of Catch 22. One must acquire the hours needed for APP. However, one cannot acquire those hours without being an APP (since experience past 10 years and residency presumably past 10 years does not count). It is also a stagnant requirement in that one might obtain the needed hours of experience, then obtain the APP license then never practice direct patient care again for years. In fact, it appears that both the 10 year look back and the 4 year interval of experience is purely arbitrary. Why not consider moving the look back to the introduction of laws allowing pharmacist to perform collaborative practice in California (mid-1990s) and elimination of the 4 year consecutive period? Let me personalize this a bit with the following scenario</p>

Code Section	Commenter	Comment
1730.1	Mitchell Pelter	<p>1. I volunteer at a free clinic about 15 hours/month for the last eight years. I deliver direct patient care (patient assessment, prescribing, etc...). Additionally, I teach residents and students at the same clinic. The diseases we see are all cardiovascular related (primarily HTN, DM, dyslipidemia, hypothyroidism and others). I have completed a residency but am not board certified. My normal position is in charge of an assortment of ambulatory care programs in a large health care organization; all the programs of which I created. I also participate on clinical guidelines development, drug use management and have been a member of the regional hypertension leadership committee for years. I am adjunct faculty at two Universities and also a PGY 1 Pharmacy Residency Program Director. Based upon the proposed experience requirement I do not have the minimum hours needed within a four year period over the last 10 years to qualify for APP. However, I have an abundance of hours under protocol during my career (however, not within the last 10 years).</p> <p>2. We have a number of new people that are also managers of ambulatory care programs in the exact position as myself. A few of these individuals are likely to have the needed 4 years of experience by virtue of their past staff positions within the 10 year period. Several of the people that I am referring to have all their experience in anticoagulation services which is generally restricted to warfarin, enoxaparin, heparin, and possibly TSOAs. These people will likely acquire the APP license.</p> <p>Now let us fast forward 10 years. Both myself and the managers listed above have been in our management positions for 10 more years doing the exact same work. While these individuals will retain their APP I will still not be eligible for this licensure despite my broader experience in CVD. This despite my being one of the pioneers of ambulatory care practice in our large institution! While I can certainly understand the Board's vital mission in protecting patient's health I believe that mission is not exclusive. I too have a professional and personal mission to not only protect my patients' health at all costs but also to provide needed care to alleviate suffering, extend life and the quality of that life. In other words, the oath I took when I graduated pharmacy school. I take this very seriously to the point that I committed my entire life to the practice of pharmacy. Yet the proposed regulations will de facto place me in the same category as if I were a product oriented pharmacist my entire career. I should be allowed to acquire the new license! You should have a grandfather clause to allow those of us that pioneered these programs to continue to practice alongside those that are younger</p>

Code Section	Commenter	Comment
1730.1	Mitchell Pelter	<p>BOP Proposed Language – must meet 2/3 criteria Possession of current certification as specified in 4210(a)(2)(A)</p> <p>Chaptered SB 493 (Section 15, 4210.(a))– must meet 2/3 criteria Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.</p> <p>BOP Proposed Language – must meet 2/3 criteria Completion of a postgraduate residency.</p> <p>Chaptered SB 493 (Section 15, 4210.(a))– must meet 2/3 criteria Complete postgraduate residency of which at least 50% of the experience includes direct patient care services with interdisciplinary teams.</p> <p>BOP Proposed Language – must meet 2/3 criteria Experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for APP. Additionally, the one year of experience must be composed of no fewer than 1500 hours of experience providing clinical services to patients, and must be earned within four consecutive years.</p> <p>Chaptered SB 493 (Section 15, 4210.(a))– must meet 2/3 criteria Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.</p>

**Advanced Practice  
Pharmacist –  
First Modified Text**

**Title 16. BOARD OF PHARMACY**  
**Modified Text**

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and bold and dashed underline for added language. (Additionally, the modified text is listed in red for color printers.)

**Proposal to add** new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

**Article 3.5. Advanced Practice Pharmacist**

**Proposal to add** §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1730 Acceptable Certification Programs**

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

**Proposal to add** §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure**

For purposes of **Business and Professions Code section 4210** an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, **modifying or ~~and~~** discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(1) A written statement from the applicant attesting under penalty of perjury that he or she has:

(A) Earned the clinical experience within the required time frame;

(B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210 (a)(2)(C), which includes initiating, adjusting, and discontinuing drug therapy of patients; and

(i) The applicant shall provide a copy of the collaborative practice agreement or protocol.

(ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients. **For an applicant that cannot satisfy this document requirement, the board may, for good cause shown, grant a waiver for this subsection (2).**

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

**Proposal to amend** §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1749 (Fee Schedule)**

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, ~~4210~~, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is ~~one hundred ninety-five dollars (\$195)~~ **one hundred ninety-five dollars (\$195)** ~~two hundred seven dollars (\$207)~~. The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325) . The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

# **Advanced Practice Pharmacist – 45-day Comments**

Code Section	Commenter	Comment
BP 4210	<b>Sarah Loentz</b> UCSD	<p>I wanted to get clarification regarding 2.B. and the meaning of the statement <sup>3</sup>accredited postgraduate institution<sup>2</sup>. Does that mean the the site where the resident received their training need to be accredited, or does the residency program need to be accredited by ASHP? There are many pharmacists who have competed excellent residency programs over the years which were not accredited by ASHP. Would those pharmacists not qualify based on that criteria?</p> <p>4210. Advanced Practice Pharmacist License</p> <p>(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:</p> <p>(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.</p> <p>(2) Satisfy any two of the following criteria:</p> <p>(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.</p>
1730	<b>Brian Lawson</b> Board of Pharmacy Specialties	<p>BPS appreciates efforts by the California State Board of Pharmacy to develop proposed regulations that address the creation of a new pharmacist licensure category. BPS is supportive of the Board's recognition of pharmacy patient care certification programs that are accredited by the National Commission for Certification Agencies (NCCA) as described in Section 1730 Acceptable Certification Programs. NCCA accreditation helps to ensure the health, welfare, and safety of the public through accreditation of a variety of certification programs/organizations that assess professional competence.</p> <p>The NCCA standards require demonstration of a valid and reliable process for development, implementation, maintenance, and governance of certification programs. NCCA uses a rigorous peer review process to establish accreditation standards; evaluate compliance with the standards; recognize organizations/programs which demonstrate compliance; and serve as a resource on quality certification. The NCCA Standards are comprehensive and cover all aspects of the certification program(s), including administration, assessment development and recertification. NCCA standards are consistent with The Standards for Educational and Psychological Testing (AERA, APA, &amp; NCME,1999) and are applicable to all professions and industries.</p>

Code Section	Commenter	Comment
1730	<b>Sarah Mcbane</b> UCSD	<p>My comments center around the regulatory requirements to become an Advanced Practice Pharmacist. The currently language requires that a pharmacist have gained clinical experience within 10 years of submitting application to become an Advanced Practice Pharmacist, and that 1500 hours of that experience must be earned in four consecutive years. The ten year requirement would limit pharmacists who are seasoned experts in clinical pharmacy care – the pharmacists we look up to and seek expert advice from – who have now moved into supervisory roles where they oversee other pharmacy practitioners. These pharmacists are the individuals we would most want to become Advanced Practice Pharmacists, so they could continue to utilize that expertise in providing care to the people of California, while training other pharmacists to provide excellent clinical care. Additionally, there is no evidence to support that direct patient care experience is better if gained within a short period of time (ie – 4 years). In fact, Harvard has shown that occasional, repeated activity translates into better learning and we can extrapolate that to say that occasional but repeated direct patient care makes someone an excellent clinician.</p> <p>I would ask the board to strike the specific time requirements, and consider language such as:            Demonstrate that experience earned under a collaborative practice agreement or protocol consists of no fewer than 1,500 hours of experience providing clinical services to patients.</p> <p>Additionally, I would ask the board to strike the requirement for a written statement from a supervisory or other individual at the facility attesting the pharmacist’s experience. Some pharmacists may have gained their experience at facilities which are now closed, or have merged with facilities, and there may not be someone who could attest to the pharmacist’s experience. The pharmacist should attest to his or her own experience (under penalty of perjury).</p> <p>Lastly, I would like to take this opportunity to remind the board that SB 493 was written and passed in the spirit of improving access to care for Californians. Would limiting the number of Advanced Practice Pharmacists – particularly experienced pharmacists – compromise the intent of the legislation, and the health of our state.</p>
1730	<b>Tasneem Vazifdar</b>	<p>A and C are unclear to me. Does A refer to BCPS certification Also, how many hours are needed for C and in what time frame?</p>

Code Section	Commenter	Comment
1730	<b>Brian Warren</b> California Pharmacist Association	<p>Acceptable Certification Program:            The California Pharmacists Association (CPhA), California Retailers Association (CRA), and the National Association of Chain Drug Stores (NACDS) appreciate and support the Board of Pharmacy's (BOP) recognition of National Commission of Certifying Agencies (NCCA) accredited programs as one pathway for pharmacists to satisfy the requirements in Business and Professions Code section 4210(a)(2)(A).</p> <p>We also strongly encourage the Board of Pharmacy (BOP) not to limit the recognition of NCCA programs in the regulations. Rather, we believe the BOP is also required to recognize those programs that are statutorily authorized under Business and Professions Code section 4210(a)(2)(A) being offered "...from an organization recognized by the Accreditation Council for Pharmacy Education... ."</p> <p>Further, the BOP should include language in the draft regulations that requires all programs and/or providers seeking to offer certification of pharmacists to do so consistent with the clinical authorities of an Advanced Practice Pharmacist authorized under Section 4210. Specifically, these programs should be required to ensure that pharmacists are certified to deliver the following services: Patient Assessments; Ordering Tests; Patient Referrals; Collaborative Drug Therapy; Effective Communication; and Documentation. By articulating these services in the regulation the BOP is ensuring that any program seeking recognition by the BOP is required to align their certification programs with the authorized authorities.</p> <p>Ensuring multiple pathways and programs for pharmacists to achieve the certification criterion in section 4210(a)(2)(A) is critical for expanding quality patient care programs. We encourage the BOP is include these recommendations in the final regulations.</p>
1730.1	<b>Brian Warren</b> California Pharmacist Association	<p>CPhA, CSHP, and NACDS have strongly advocated for the full implementation of SB 493, including provisions relating to APPs. The public policy goal of SB 493 has always been to better utilize pharmacists' clinical knowledge and skills to improve patient care. This intent is carried out through ensuring that the greatest number of pharmacists who can practice under the bill's expanded authorities with a minimum level of competency are allowed to do so.</p> <p>Business and Professions Code Section 4210 establishes the application requirements for pharmacists seeking recognition as APPs. Among these requirements, applicants must meet two out of three prerequisite "pathways": certification, completion of a residency, or specified practice experience. Proposed Section 1730.1 establishes the specific elements that the Board intends to require for demonstration of each of these pathways.</p> <p>As you are aware, very few pharmacy resident openings are available to graduating pharmacists—less than 300 in the entire state. As a result, very few new graduate pharmacists applying for APP licensure will qualify using the residency pathway. Furthermore, pharmacists have practically no opportunity to enter a residency after beginning practice, essentially eliminating this pathway for experienced pharmacists who have not already completed a residency. It is therefore imperative that the requirements for satisfying the experiential and certification prerequisite pathways be carefully constructed so as to ensure that applicants for APP licensure meet minimum qualifications and levels of competency without creating unnecessary barriers to entry that would hinder the efficacy of the Legislature's intent in enacting SB 493.</p>

Code Section	Commenter	Comment
1730.1	<p><b>Brian Warren</b> California Pharmacist Association</p>	<p>One of the three pathways for qualifying for APP licensure is to “have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.” Proposed Section 1730.1(c) outlines, in detail, what the Board believes should be required to demonstrate this one year of experience.</p> <p>We are concerned that some of the requirements that would be established by proposed Section 1730.1(c) would unintentionally limit the number of pharmacists who would be able to qualify for APP licensure. We therefore propose the following modifications to Section 1730.1 to ensure that the greatest number of competent pharmacists can obtain APP licensure.</p> <p><b>1. Remove the requirement in subsection (c) that the one year of experience be completed within 10 years of the time of application for APP licensure.</b></p> <p>This requirement unnecessarily excludes pharmacists with extensive clinical practice experience but who do not engage in clinical practice a majority of the time. This includes pharmacists who previously engaged in clinical practice on a regular basis but who have moved on to supervisory or managerial roles, as well as pharmacists who engage in clinical practice a minority of the time but over a long period of time. Ironically, this time limitation excludes some of the most experienced pharmacists and favors pharmacists with perhaps less experience</p>
1730.1	<p><b>Brian Warren</b> California Pharmacist Association</p>	<p><b>2. Remove the requirement in subsection (c) that the one year of experience be completed within four consecutive years.</b></p> <p>Much like the above requirement, this unnecessarily excludes pharmacists who engage in clinical practice but not as a majority of their job. No evidence supports a specific timeframe for development and mastery of clinical skills. Establishing an arbitrary timeframe here would only serve to enact an unnecessary barrier to entry to APP licensure and would harm patient access to APP-licensed pharmacists.</p> <p><b>3. Modify the wording in subsection (c) and in subsection (c)(1)(B) of “initiating, adjusting, and discontinuing” to read “modifying, adjusting, or discontinuing.”</b></p> <p>Many pharmacists who engage in clinical practice actively manage drug therapy under a collaborative practice agreement or protocol but do not necessarily do all three of these authorities. In fact, prior to SB 493’s enactment, California’s collaborative drug therapy management statutes did not include the authority to discontinue medications (see B&amp;P Code Sections 4052.1 and 4052.2, which authorize initiating and adjusting but not discontinuing). More importantly, the exercise of only some of these authorities does not indicate an absence of the ability to practice all three.</p> <p><b>4. Remove the requirement in subsection (c)(2) that a written statement be made by the supervising practitioner, program director, or health facility administrator overseeing the collaborative practice agreement or protocol.</b></p> <p>Depending on the duration of time passed since a pharmacist practiced under a given collaborative therapy agreement or protocol, that pharmacist may no longer have contact with the provider or facility. This requirement particularly affects pharmacists with a longer career. The requirement also seems duplicative of the requirements in subsection (c)(1) for the pharmacist to file the application under penalty of perjury and to provide a copy or description of the protocol.</p>

Code Section	Commenter	Comment
1730.1	<b>Brian Warren</b> California Pharmacist Association	<p>Among the above four areas of commentary, one overarching theme among these comments exists: that pharmacists should be trusted to use their professional judgment.</p> <p>It is well-known that the majority of pharmacists go underutilized; greater utilization of pharmacists is after all the central goal of SB 493. This underutilization means that despite expert knowledge and skills, many pharmacists spend the majority of their time in a strictly dispensing role. By only allowing those pharmacists who already practice to a significant extent in a clinical nature to qualify for APP licensure, these proposed regulations exclude precisely the pharmacists SB 493 was intended to better utilize</p>
1730.1	<b>Brian Lawson</b> Board of Pharmacy Specialties	<p>BPS Specialty Certification Programs in Ambulatory Care Pharmacy, Nuclear Pharmacy, Nutrition Support Pharmacy, Oncology Pharmacy, Pharmacotherapy and Psychiatric Pharmacy are recognized as accredited certification programs by the National Commission for Certifying Agencies, (NCCA). Per NCCA policies and procedures, the Critical Care Pharmacy and Pediatric Pharmacy specialty certification programs will be eligible for accreditation in 2016.</p> <p>BPS is also supportive of the documentation described in subsection (a) listed under Section 1730.1 Application Requirements for Advanced Practice Pharmacists Licensure. BPS is comfortable working with the California Board of Pharmacy to confirm the status of BPS Board Certified Pharmacists.</p>
1730.1	<b>Douglas Barcon</b> Barcon & Associates	<p>A certification is a single qualifying criteria. A post-graduation residency is a single qualifying criteria. Experience practicing under a collaborative practice agreement can be at the minimum level, or it can be at a level much greater than the minimum level and for a significant length of time, yet it is considered the same under the terms of the application for an Advanced Practice Pharmacist without regard for the length of that practice beyond the minimum. Some pharmacists gained more practical experience in their first year or two post graduation than in an ASHP PGY1 residency, yet that experience does not count toward licensure as an Advanced Practice Pharmacist without a time frame limitation.</p> <p>Depending on the experience and the duration of experience (perhaps more than 5 years) practicing under collaborative practice agreements, there should be a provision to allow pharmacists who have practiced under collaborative practice agreements to split that experience and petition the board to accept that experience both as a substitute for a residency and as qualifying experience practicing under a collaborative practice agreement.</p>

Code Section	Commenter	Comment
1730.1(b)	<b>Douglas Barcon</b> Barcon & Associates	<p>In 1730.1(b) and in SB 493, there is no time limitation placed upon the qualifying residency regardless of whether it was completed in 2015 or 30 years ago. An ASHP PGY1 residency is a one-year residency that is typically completed in the first post-graduation year following graduation from the school of pharmacy.</p> <p>However, in the proposed 1730.1 (c), experience in a collaborative practice agreement is not acceptable as a qualifying criteria if it occurred more than 10 years prior to filing the application as an Advanced Practice Pharmacist regardless of the length of time the pharmacist practiced under such an agreement.</p> <p>Why should an ASHP PGY1 residency completed 30 years ago, let alone more than 10 years ago, be an acceptable qualifying criteria, while the experience gained by a pharmacist who practiced under a collaborative practice agreement for more than one year not be acceptable if it occurred more than 10 years prior to the application? Many pharmacists have practiced under collaborative practice agreements for more than 10 years and do not have residencies.</p> <p>The board needs to reassess the time limitation, which is not even specified in SB 493, so as not to exclude pharmacists who have practiced under a collaborative practice agreement but do not have a residency.</p>
1730.1(c)	<b>Steven Gray</b> Kaiser Permanente	<p>contrary to the general intent and the explicit statutory language of the Legislature's passage of SB 493, in the 2013 session of the California Legislature.</p> <p>The intent of the legislation was to change the scope of practice and increase the number of California pharmacists providing specified medication management clinical services to alleviate the current and anticipated shortage of primary care providers as California residents seek more access to health care subsequent to the Affordable Care Act implementation in California, the expansion of Medi-Cal enrollment and the increases in population - especially the senior population.</p> <p>Specifically the Proposed regulation provision 1730.1(c) would narrow the eligibility specified in Business and Professions Code Section 4210(a)(2)(C) to clinical services experience performed only in the ten years prior to the application. Pharmacists in California have been performing such clinical service very successfully for over twenty years under the provisions of Business and Professions Code 4052.2. Many such pharmacists have gone on to train, supervise and manage pharmacists performing such clinical services. They perform the services personally as part of that training, supervision and management and are actually high performing models of competency, maturity and performance for the development of new APP pharmacists urgently needed to alleviate the shortage of Primary Care Providers by performing non-diagnostic medication therapy management and thus relieving physicians, nurse practitioners and other Primary Care Providers for diagnostic and other roles. However the proposed requirement that the 1500 hours of clinical experience must be earned in four consecutive years of a 10 year period prior to application is not realistic in their current roles as Professors in Schools of Pharmacy, trainers, supervisors and managers in clinical care organizations and other situations where they function in personal clinical experience on an intermittent basis.</p>

Code Section	Commenter	Comment
1730.1(c)	<b>Steven Gray</b> Kaiser Permanente	<p>Thus the Board of Pharmacy's proposed establishment of a 1500 hour requirement in 4 consecutive years in the past 10 years will inappropriately and unnecessarily limit the number of highly qualified and experienced pharmacists that would qualify for the new Advanced Practice Pharmacist licensed category and thus prevent their participation in alleviating the shortages of primary care providers. It will frustrate the Legislator's intent by adding restrictions without demonstration of any clinical care cases to support such restrictions.</p> <p>Recommended Changes</p> <p>We respectfully recommend the following changes to subsection "(c)":</p> <p><del>"(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of prior to the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, and discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:"</del></p>
1730.1(c)	<b>Joseph Woelfel</b> University of the Pacific	<p>pharmacist and works in a part-time collaborative practice, the 10 year period would be very restrictive. This 10 year provision may favor recent graduates vs senior practicing consultant pharmacists with numerous years of experience. Same thing applies to the one year/1500 hours. This excludes those working part-time. Additionally, the four year requirement is very restrictive and favors those who have primary consulting as their full-time position or recent graduates with residencies.</p>
1730.1(c)	<b>Douglas Barcon</b> Barcon & Associates	<p>As in 1730.1(b), the 10-year limitation should be reconsidered and removed from the proposal. Such a limitation is not specified in SB 493. The 10-year limitation places an unfair burden on pharmacists who have practiced under collaborative practice agreements compared to pharmacists who completed an ASHP PGY1 or similar residency and can effectively preclude that pharmacist from becoming an Advanced Practice Pharmacist regardless of whether he or she completed a certification program and became certified in a specialty. For example, a pharmacist who practiced under collaborative practice agreements for 20 years but has not for the last 10 years would not qualify if he or she did not complete an ASHP PGY1 residency. That intent was not specified in SB 493.</p> <p>The duration of experience practicing under one or more collaborative practice agreements has more value than a date limitation.</p>

Code Section	Commenter	Comment
1730.1(c)(2)	<b>Douglas Barcon</b> Barcon & Associates	<p>In 1730.1(c)(1), the applicant pharmacist has already attested under penalty of perjury that he or she has complied with the clinical services and collaborative practice experience requirement.</p> <p>In 1730.1(c)(2), the applicant pharmacist is asked to prove what he or she attested to in 1730.1(c)(1) by providing a written statement by the supervising practitioner, program director or health facility administrator that the applicant has completed at least one year of providing clinical services to patients. It would appear that the board of pharmacy does not trust the applicant to answer truthfully by requiring (c)(2).</p> <p>What happens if the director of pharmacy is or was both the program director and the applicant?</p> <p>SB 493 became law in 2013. Pharmacists have been providing clinical services and collaborative practice in health-system pharmacy practice for many years. Requiring an Advanced Practice Pharmacist applicant to provide written statements as specified in 1730.1(c)(2) may not be possible because health facilities have closed, supervising practitioners may have passed away or are otherwise not able to be reached, or health facility administrators may have passed away or are otherwise not able to be reached.</p> <p>As written, the current proposal favors pharmacists with less than 10 years of experience and excludes others.</p>
Overall Comment	<b>Daniel Robinson</b> Western University	<p>A Sample Preamble to the Guidelines for Expanded Scope of Practice – Post-SB 493 including Advanced Practice Pharmacist Background</p> <p>Passage of SB 493 was an endorsement of the important role pharmacists can play in addressing the health care needs of the people of California. There is broad agreement that pharmacists are highly trained professionals who have been underutilized in providing team-based care. In the interest of public safety, it is incumbent on the Board of Pharmacy to work with the pharmacy profession to ensure that a critical number of pharmacists are fully engaged in providing services according to BPC Chapter 469 to have a meaningful impact on medication-related health care outcomes state-wide. Up to this point, the Board of Pharmacy has dealt with episodes of misconduct by pharmacists that are considered violations of pharmacy law. With the advent of Advanced Practice Pharmacists, pharmacists will be providing patient specific care that requires professional judgement that utilizes the full scope of pharmacy training and is in the best interest of the patient. In the event of a quality of care complaint, which may not be a violation of pharmacy law, the complaint should be reviewed by a pharmacy consultant with expertise in the area of consideration to determine if the pharmacist was acting within the acceptable standard of pharmacy care.</p> <p>SB 493 was signed into law by the Governor nearly two years ago and supported by a broad base of health care organizations and patient advocacy groups. In the interest of public safety we should do everything possible to provide immediate access to the additional services allowed under BPC Chapter 469. Our problem is not that we would qualify too many pharmacists, but that we would qualify too few.</p> <p>Daniel Robinson, September 2015</p>

Code Section	Commenter	Comment
Overall Comment	<b>Daniel Robinson</b> Western University	<p>Guidelines for Expanded Scope of Practice – Post SB 493            California Board of Pharmacy            Sample Preamble</p> <p>Protection of the public is the highest priority for the California Board of Pharmacy (Board) in exercising its licensing, regulatory, and disciplinary functions. The Board recognizes that principles of high-quality pharmacy practice and California law dictate that the people of California have access to appropriate, safe, and effective pharmacist services. These guidelines are intended to help pharmacists improve outcomes of patient care through modifications to the BPC (Chapter 469) that improve access to pharmacist services with respect to travel health, immunizations, self-administered hormonal contraception, nicotine replacement products, ordering and interpreting tests for the purpose of monitoring and managing drug therapies, including improved access to services provided by the Advanced Practice Pharmacist.</p> <p>These guidelines are not intended to mandate the standard of care. The Board recognizes that deviation from guidelines will occur and may be appropriate depending upon the unique needs of individual patients. Pharmacy, like the other healing arts, is practiced one patient at a time and each patient has individual needs. Pharmacists are encouraged to document their rationale for each patient management decision. Pharmacists should understand that if one is ever the subject of a quality of care complaint, peer expert review will be sought by the Board that will consider the totality of circumstances surrounding the pharmacist’s practice decisions. Specifically, experts are instructed to define the standard of care in terms of the level of skill, knowledge, and care in pharmacy practice ordinarily possessed and exercised by other reasonably careful and prudent pharmacists in the same or similar circumstances at the time in question.</p> <p>These guidelines may be updated from time to time based on evolving knowledge, research and understanding of subject matter. It is the pharmacist’s responsibility to remain current with referenced standards, resources, and professional skills.</p>

**Advanced Practice  
Pharmacist –  
Initial Proposed Text**

**Title 16. BOARD OF PHARMACY**  
**Proposed Regulation**

**Proposal to add** new Article 3.5 of Division 17 of Title 16 of the California Code of Regulations and a new Article title as follows:

**Article 3.5. Advanced Practice Pharmacist**

**Proposal to add** §1730 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1730 Acceptable Certification Programs**

The board recognizes the pharmacy patient care certification programs that are accredited by the National Commission for Certifying Agencies for purposes of satisfying the requirements in Business and Professions Code section 4210(a)(2)(A).

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Sections 4052.6, 4210 and 4400, Business and Professions Code.

## Title 16. BOARD OF PHARMACY

### Proposed Regulation

**Proposal to add** §1730.1 of Article 3.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **§1730.1 Application Requirements for Advanced Practice Pharmacist Licensure**

For purposes of 4210 an applicant for advanced practice pharmacist licensure must satisfy two of the following subdivisions.

(a) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210(a)(2)(A), an applicant shall provide either:

(1) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(2) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(b) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210(a)(2)(B), an applicant shall provide either:

(1) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(2) A letter of completion of a postgraduate residency signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution that lists the name of the applicant pharmacist, the dates of participation and completion, and area(s) of specialty.

(c) Demonstrate that experience earned under a collaborative practice agreement or protocol has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must be composed of no fewer than 1,500 hours of experience providing clinical services to patients, and must be earned within four consecutive years. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, and discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

- (1) A written statement from the applicant attesting under penalty of perjury that he or she has:
- (A) Earned the clinical experience within the required time frame;
  - (B) Completed the required number of hours of clinical services to patients, as specified in this subdivision and in Business and Professions Code section 4210(a)(2)(C), which includes initiating, adjusting, and discontinuing drug therapy of patients; and
    - (i) The applicant shall provide a copy of the collaborative practice agreement or protocol.
    - (ii) If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.
- (2) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least one year of experience providing clinical services to patients.

Note: Authority cited: Section 4005, 4210 and 4400, Business and Professions Code. Reference: Section 4052.1, 4052.2, 4052.6, 4210 and 4400, Business and Professions Code.

## Title 16. BOARD OF PHARMACY

**Proposal to amend** §1749 of Article 6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

### **§1749 (Fee Schedule)**

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.5, 4128.2, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license is five hundred twenty dollars (\$520). The fee for the annual renewal of pharmacy license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(b) The fee for the issuance of a temporary license is three hundred twenty-five dollars (\$325).

(c) The fee for the issuance of a pharmacy technician license shall be one hundred five dollars (\$105). The fee for the biennial renewal of a pharmacy technician license shall be one hundred thirty dollars (\$130). The penalty for failure to renew a pharmacy technician license is sixty-five dollars (\$65).

(d) The fee for application and examination as a pharmacist is two hundred sixty dollars (\$260).

(e) The fee for regrading an examination is one hundred fifteen dollars (\$115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars (\$195).

(2) The fee for application of an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.

(g)(1) The fee for the biennial renewal of a pharmacist's license is two hundred seven dollars (\$207). The penalty fee for failure to renew is ninety-seven dollars fifty cents (\$97.50).

(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance or renewal of a wholesaler's license is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is one hundred sixty five dollars (\$165). The penalty for failure to renew is eighty two dollars fifty cents (\$82.50).

(j) The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred ninety-five dollars (\$195). The penalty for failure to renew is ninety seven dollars and fifty cents (\$97.50).

(k) The fee for the issuance or renewal of a license as a nonresident wholesaler is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for an intern pharmacist license is one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(o) The fee for the issuance of a clinic license is five hundred twenty dollars (\$520). The fee for the annual renewal of a clinic license is three hundred twenty-five dollars (\$325). The penalty for failure to renew is one hundred fifty dollars (\$150).

(p) The fee for the issuance of a nongovernmental license, or renewal of a license, to compound sterile drug products is seven hundred eighty dollars (\$780). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred thirty dollars (\$330). The fee for the annual renewal of a license as a designated representative shall be one hundred and ninety-five dollars (\$195). The penalty for failure to renew is ninety-seven dollars and fifty cents (\$97.50).

(r) The fee for a veterinary food-animal drug retailer license is four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug retailer is three hundred twenty-five dollars (\$325). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred twenty-five dollars (\$125).

(s) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).

(t) The fee for the issuance of a centralized hospital packaging pharmacy license shall be \$800. The annual renewal fee for a centralized hospital packaging pharmacy license shall be \$800. The penalty for failure to renew is one hundred fifty dollars.

Note: Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4128.2, 4196, 4200, 4210, 4400, 4401 and 4403, Business and Professions Code.

# **Attachment 3**

**Self-Administered  
Hormonal  
Contraception  
1746.1**

# **Self-Administered Hormonal Contraception**

## **15- Day Comments**

**To be Provided as Board Meeting**

**(Revised Initial Statement of Reasons)**

**Comment Period Closes January 14, 2016**

**Martinez, Lori@DCA**

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**From:** starship1980s@aol.com  
**Sent:** Wednesday, December 30, 2015 2:40 PM  
**To:** Martinez, Lori@DCA  
**Subject:** Title 16 CCR § 1746.1,

I disagree with the proposed aforementioned. Pharmacists should not be allowed to dispense hormonal contraceptives without an rx. An rx should be required. This will cause undue and unnecessary hardship on pharmacists as they are already loaded up with more than their share of work. I would like a hearing to be set forth FORTHWITH.

**Self-Administered  
Hormonal  
Contraception  
Revised Initial  
Statement of Reasons**

**BOARD OF PHARMACY**

**REVISED INITIAL STATEMENT OF REASONS**

**Changes made to the originally proposed language are shown by ~~single strike-through~~ for deleted language and double underline for added language.**

Hearing Date: No hearing is presently planned unless one is requested no later than 15 days before the close of the 45-day comment period.

Subject Matter of Proposed Regulations: Self-administered hormonal contraception.

Section Affected: 16 CCR Section 1746.1.

Specific Purpose of Adoption: Business & Professions (“B&P”) Code section 4052.3 authorizes pharmacists to dispense self-administered hormonal contraception under a protocol adopted by the Board of Pharmacy (“Board”) in collaboration with other entities. The Board seeks to adopt the collaboratively developed and approved protocol as 16 CCR Section 1746.1.

The problem to be addressed by these regulations is that women’s access to self-administered hormonal contraception has been limited in that it requires a doctor’s prescription. B&P section 4052.3 instructed the Board to develop a protocol for pharmacists to follow to dispense self-administered hormonal contraception without a doctor’s prescription; proposed 16 CCR Section 1746.1 is that protocol.

The anticipated benefits from this regulatory action are that women will have increased access to self-administered hormonal contraception, resulting in fewer unplanned pregnancies. Pharmacists will have a protocol to follow to dispense self-administered hormonal contraception.

**Factual Basis/Rationale**

This proposal seeks to adopt 16 CCR Section 1746.1, which is a protocol for pharmacists to follow when dispensing self-administered hormonal contraception. This adoption is necessary to carry out the purpose of B&P section 4052.3. By following the proposed protocol, pharmacists will be able to dispense, where medically appropriate, self-administered hormonal contraception without a doctor’s prescription.

In 2013, the Legislature enacted, and the Governor signed, Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) which enabled pharmacists to serve as health care providers to the public in certain enumerated areas (including dispensing contraception as described herein). The Board, following the instructions set out in Business & Professions (“B&P”) Code section 4052.3, worked with the Medical Board of California and in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association and other appropriate entities to develop the proposed protocol. The protocol was approved as amended by the Medical Board on January 30, 2015, and the Board accepted those amendments and re-approved the protocol with the Medical Board’s amendments on March 9, 2015. Under the protocol, pharmacists provide patients with a self-screening tool (available in English and

alternative languages) to identify risk factors for the use of self-administered hormonal contraceptives, and pharmacists must keep a copy of that tool for at least three (3) years from the date of dispensing. If self-administered combined hormonal contraceptives are requested or appropriate to furnish, the pharmacist must measure and record the patient's seated blood pressure. The pharmacist must ensure the patient is appropriately trained in taking the requested or recommended contraceptive medicine, including dosage, effectiveness, potential side-effects, safety, the importance of receiving recommended preventative health screenings and is told self-administered hormonal contraceptives do not protect against sexually transmitted infections or diseases. Pharmacists must provide patients with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, a current customer-friendly comprehensive birth control guide and a copy of an administration-specific factsheet.

The patient must be referred to the patient's primary care provider, or if the patient doesn't have one, to nearby clinics, for appropriate follow-up care whether or not a self-administered hormonal contraception product is furnished. The pharmacist must notify the patient's primary care provider, when possible. When not possible, the pharmacist must provide the patient with a written record of the drug or device furnished. The pharmacist must maintain a record of having furnished self-administered hormonal contraception for three years from the date of dispensing. If self-administered hormonal contraceptive services aren't available or if the pharmacist declines to furnish them due to a conscience clause, the patient shall be referred to another appropriate health care provider. The protocol requires that a pharmacist complete a training program specific to self-administered hormonal contraception, application of the United States Medical Eligibility Criteria for Contraceptive Use developed by the federal Centers for Disease Control (CDC) and other CDC guidance on contraception prior to attempting to furnish self-administered hormonal contraception pursuant to the protocol.

Specific Benefits Anticipated: Self-administered hormonal contraceptives are among the most effective contraceptive medications and devices available to women. This regulation increases women's access to these effective forms of birth control by reducing both the time required and the overall cost of obtaining self-administered hormonal contraception. Unintended pregnancies are linked to many maternal and child health problems. Using effective birth control to increase the time between pregnancies improves both women's and children's health. Effective birth control use reduces unplanned pregnancies, which reduces the number of pregnancy terminations and maternal deaths. Increasing women's access to self-administered hormonal contraception contributes to public health and safety by reducing unwanted pregnancies.

B&P Code section 4001.1 mandates that the protection of the public shall be the highest priority for the Board and that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public comes first. This self-administered hormonal contraceptive protocol provides protection to the public by setting out clear dispensing procedures and guidelines for pharmacists, while increasing women's access to self-administered hormonal contraception.

**Underlying Data:**

1. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held March 9, 2015.
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2015.
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 29-30, 2014.
4. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held July 30-31, 2014.
5. Centers for Disease Control and Prevention, "United States Medical Eligibility Criteria for Contraceptive Use," (2010) *available at* <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>. (*This resource served as the basis for self-administered hormonal contraception medications from which a pharmacist may select*).
6. Centers for Disease Control and Prevention, "U.S. Selected Practice Recommendations for Contraceptive Use, 2013," *available at* <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6205a1.htm>. (*This document from the CDC offers guidance on how to use contraceptive methods most effectively. It is adapted from a World Health Organization (WHO) publication, and was endorsed by the American College of Obstetricians and Gynecologists (ACOG)*).
7. S. Shotorbani, et al., "Agreement Between Women's and Providers' Assessment of Hormonal Contraceptive Risk Factors," 73 CONTRACEPTION 501, 501-506 (2006). (*This article provided a Medical History Questionnaire that was used in the development of the protocol's self-assessment tool. The article's research found 96% agreement between women's self-administered risk factor questionnaire and their providers' evaluation of their medical eligibility for hormonal contraceptive use.*)
8. CPhA/CSHP, "Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraceptives." (*This draft protocol was consulted in development of the Board's recommended protocol.*)
9. Food and Drug Administration Office of Women's Health, "HPV, HIV, Birth Control" (last updated June 24, 2014), *available at* <http://www.fda.gov/ForConsumers/ByAudience/ForWomen/WomensHealthTopics/ucm117971.htm> (*This site contains a consumer-friendly birth control guide recommended for patient education.*)
10. Office on Women's Health, U.S. Department of Health and Human Services, "Birth Control Methods" (last updated Nov. 21, 2011), *available at* <http://www.womenshealth.gov/publications/our-publications/fact-sheet/birth-control-methods.pdf>. (*This fact sheet was consulted in development of the Board's recommended fact sheet.*)
11. Division of Reproductive Health, Centers for Disease Control and Prevention, "Contraception" (last updated Oct. 14, 2014), <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/contraception.htm>. (*This website, especially the chart, is recommended as a resource for pharmacists choosing to provide additional user-friendly information on various birth control methods.*)
12. The American College of Obstetricians and Gynecologists, "Birth Control - Especially

- for Teens,” FAQ112 (Dec. 2013), *available at* <http://www.acog.org/Patients/FAQs/Birth-Control-Especially-for-Teens>. (*This fact sheet was consulted in development of the Board’s recommended fact sheet.*)
13. J. McIntosh et al., “Changing Oral Contraceptives from Prescription to Over-the-Counter Status: An Opinion Statement of the Women’s Health Practice and Research Network of the American College of Clinical Pharmacy,” *Pharmacotherapy* Vol. 31, Number 4, 424-437 (2011). (*This opinion paper discusses pharmacist training on page 432. Both pharmacists and pharmacy students generally expressed interest in more education specifically on appropriate product selection.*)
  14. Fatim Lakha, et al., “The Acceptability of Self-Administration of Subcutaneous Depo-Provera,” *72 CONTRACEPTION* 14-18 (2005). (*This research finds that subcutaneous self-injectable hormonal contraception is beneficial for many women with appropriate training and reminder system.*)
  15. Nicole J. Monastersky Maderas & Sharon Cohen Landau, “Pharmacy and Clinic Partnerships To Expand Access to Injectable Contraception,” *47 J. AM. PHARM. ASSOC.* 527-531 (2007). (*This research finds that pharmacy reinjection of contraception is a viable option for many women, and is most successful when combined with primary care provider support and integration.*)
  16. Sujatha Prabhakaran & Ashley Sweet, “Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate for Contraception: Feasibility and Acceptability,” *85 CONTRACEPTION* 453-457 (2012). (*This research article finds that self-administration injections were easy and convenient for women with training from two Planned Parenthood health centers.*)
  17. Sharon T. Cameron, et al., “Pilot Study of Home Self-Administration of Subcutaneous Depo-Medroxyprogesterone Acetate for Contraception,” *85 CONTRACEPTION* 458-464 (2012). (*This research concludes that self-administration is feasible and has similar continuation and satisfaction rates to clinician-administration injections.*)
  18. Rebekah L. Williams, et al., “Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate by Adolescent Women,” *88 CONTRACEPTION* 401-407 (2013). (*This research concludes that many adolescents are interested in and capable of self-administration with brief education and minimal assistance.*)
  19. S. Vinker, et al., “The Effect of Drug Information Leaflets on Patient Behavior,” *ISR. MED. ASSOC. J.* 9(5) 383-4386 (May 2007). (*This research concludes that reading the leaflet did not greatly affect adherence but caused anxiety and decreased adherence in some patients.*)
  20. 21 C.F.R §§ 201 “Labeling,” *available at* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201> *These FDA regulations require manufacturers to include comprehensive patient leaflets in both prescription-only and OTC products.*
  21. 21 C.F.R. § 310.501 “Patient Package Inserts for Oral Contraceptives,” (Apr. 1, 2014), *available at* <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=310.501>. (*These FDA regulations are specific to leaflet requirements for oral contraceptives.*)
  22. Economic Impact Analysis

**Business Impact:** The Board does not believe this regulation will have a significant adverse economic impact on businesses. Adopting this regulation simply provides pharmacists, who choose to dispense self-administered hormonal contraception without a doctor's prescription, with a protocol to follow.

The Board has made an initial determination that the proposed regulatory action would have no significant adverse economic impact directly affecting businesses or individuals because this proposal provides an additional outlet where women can receive hormonal contraception. According to the Centers for Disease Control and Prevention (CDC), approximately 61.7% of women, aged 15-44 use contraception in the United States. Of this, 16.0% use hormonal contraception.

According to the 2010 United States Census, California had a population of 37,253,956. Of that population, approximately 8,556,578 are women between the ages of 18 and 50 years old. Using the CDC estimate of approximately 61.7%, approximately 5,279,470 women in California use some method of contraception. Sixteen percent of that population, or 844,715, would be estimated to use hormonal contraception based on the CDC's study.

According to the research article, "Birth Control within reach: a national survey of women's attitudes toward and interest in pharmacy access to hormonal contraception," an estimated 68% of women using hormonal contraception would be willing to utilize a pharmacy for access if it was available. Using this figure, approximately 574,406 women in California would be willing to utilize a pharmacy to obtain hormonal contraception. During the study conducted in Washington State, the women who reported interest in utilizing a pharmacy for hormonal contraception also reported that they would want to have a gynecologic exam during the recommended three-year intervals.

As such, the Board does not believe that all these women will immediately begin utilizing a pharmacy to obtain hormonal contraception. The Board expects that patients will continue to see their primary care physician for other health related matters. The Board also expects that patients will continue to seek gynecologic exams every three years, as recommended by the American Congress of Obstetricians and Gynecologists, and will continue to receive the hormonal contraception prescription as part of that exam.

Additionally, the Board believes that the use of pharmacies will be slow to begin and utilization by women may take several years. In order to provide hormonal contraception, pharmacists wishing to participate will be required to complete a one hour continuing education program and pharmacies also have to develop and implement the procedures for each location and ensure compliance with the standardized protocol.

The cost of the hormonal contraception itself will likely remain the same irrespective of how the patient receives the prescription. The cost to the patient may vary based upon whether they receive the prescription from their doctor versus from a pharmacy. During the study conducted in Washington State, pharmacists were paid a fee of \$25.00 for screening and prescribing services and according to the Agency of Healthcare Research and Quality, in 2012 the average co-payment for a doctor's visit was approximately \$24.00.

Assuming that 10% of women elect to utilize a pharmacy for hormonal contraception or approximately 57,500 women will utilize a pharmacy during the first year of implementation. At an estimated cost of \$25.00, the total expense in the first year of implementation would be \$1,437,500.

### **Economic Impact Assessment:**

This regulatory proposal will have the following effects:

- It will not create or eliminate jobs in the State of California because pharmacists already dispense self-administered hormonal contraception with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing self-administered hormonal contraception without a doctor's prescription.
- It will not create new businesses or eliminate existing businesses within California because pharmacists already dispense self-administered hormonal contraception with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing self-administered hormonal contraception without a doctor's prescription.
- It would not affect the expansion of businesses currently operating in California because pharmacists already dispense self-administered hormonal contraception with a doctor's prescription; the proposed regulation simply sets out a protocol for dispensing self-administered hormonal contraception without a doctor's prescription.
- This regulatory proposal benefits the health and welfare of California residents because it increases women's access to safe and highly effective forms of contraception that will reduce unplanned pregnancies, resulting in positive impacts on women's and children's health. This regulatory proposal ensures that pharmacists, that so choose to provide hormonal contraception, have a standardized protocol to follow to furnish women with self-administered hormonal contraceptive products for the prevention of unintended pregnancy. By providing an additional option to obtain hormonal contraception, it will make it easier for members of the public to obtain self-administered hormonal contraceptive products which may reduce the number of unintended pregnancies, and the negative public health impacts of unintended pregnancies. When members of the public no longer need a doctor's prescription to purchase self-administered hormonal contraceptive products, there may be an increase in sales of self-administered hormonal contraceptive products.
- This regulatory proposal will have no impact on worker safety because pharmacists have dispensed doctor-prescribed self-administered hormonal contraceptives for decades, and the Board has not received any information about impacts on worker safety.
- This regulatory proposal will have no impact on the state's environment because pharmacists have dispensed doctor-prescribed self-administered hormonal contraceptives for decades, and the Board has not received any information about environmental impacts.

**Specific Technologies or Equipment:** This regulation would not mandate the use of specific technologies or equipment.

**Consideration of Alternatives:** The Board of Pharmacy has determined that no reasonable alternative considered by the Board, or otherwise identified and brought to the Board's attention, would either be more effective in carrying out the purpose for which the actions are proposed, or would be as effective and less burdensome to affected private persons than the proposals described herein, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law. ~~The Board found taking no action an unacceptable alternative in the face of the specific charge in the law that the Board enforce B&P section 4052.3(a) for its licensees.~~ This proposed regulation implements B&P section 4052(a)(10), B&P section 4052.3(a) and B&P section 4052.3(c). The only alternative would be to not implement the standardized procedures and protocols. This is not reasonable as the Board would not be in compliance with current law, which requires the development of the procedures and protocols. This determination was made during the development and regulatory process and with consultation with experts in the field.

# **Self-Administered Hormonal Contraception**

## **45-Day Comments**

**Comment Period Closed June 22, 2015**

## Hormonal Contraception

<u>Person/Organization Commenting</u>	<u>Section</u>	<u>Comment/Proposed Language</u>
Mary Staples, National Association of Chain Drug Stores	§1746.1	"There is a public health benefit to expanded patient access to self-administered hormonal contraception. These benefits include improved maternal health, safe pregnancies, and reduced unwanted pregnancies."
Brian Warren, California Pharmacists Association	§1746.1(b)(4)(B)	"CPhA supports all elements contained in the Board's protocol, including the requirement to measure and record a patient's seated blood pressure prior to furnishing estrogen-progestin combination products."
Bonnie Zell, MD, MPH, FACOG, Icebreaker Health	§1746.1(b)(4)(B)	1- "Requiring seated blood pressure will limit access to hormonal contraception." 2- Blood pressure can be adequately obtained and communicated to the health care provider through self-reporting tools." 3- Other comparable health care providers are not required to obtain a seated blood pressure before providing hormonal contraceptives." 4- other organizations do not recommend a seated blood pressure, and these other organizations call for hormonal contraception to be classified as over-the-counter."
Beth H. Parker, Planned Parenthood Affiliates of California	§1746.1(b)(4)(B)	"1 - Blood pressure can be adequately obtained through self-reporting tools. 2 - Hormonal contraception is very safe and promotes women's health. 3 - Self-reporting of blood pressure will increase access to contraception for women. 4 - access to contraception is crucial for women's economic opportunity and equality."

**Person/Organization Commenting**

Mitchell D. Crenin, MD, Catherine Cansino, MD, MPH, Melody Hou, MD, MPH, and Juliana Melo, MD, MSCS, Division of Family Planning, Dept. of Obstetrics and Gynecology, University of California, Davis

**Section**

§1746.1(b)(4)(B)

**Comment/Proposed Language**

"1 - Requiring an evaluation of blood pressure for women seeking progestin-only pills is beyond CDC recommendations. 2 - Blood pressure can be adequately obtained and communicated to a pharmacist through self-reporting tools, and blood pressure reporting can be "optional" if the pharmacist feels it is indicated based on other factors such as obesity. 3 - Seated blood pressure requirement is beyond the recommendation of the ACOG's over-the-counter initiative."

**Self-Administered  
Hormonal  
Contraception  
Proposed Text**

**BOARD OF PHARMACY**  
Proposed Regulation

Adopt §1746.1 of Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1746.1 Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception.**

(a) A pharmacist furnishing self-administered hormonal contraception pursuant to Section 4052.3 of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Self-Administered Hormonal Contraception

(1) Authority: Section 4052.3(a)(1) of the California Business and Professions Code authorizes a pharmacist to furnish self-administered hormonal contraceptives in accordance with a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol in this section satisfies that requirement.

(2) Purpose: To provide timely access to self-administered hormonal contraception medication and to ensure that the patient receives adequate information to successfully comply with therapy.

(3) Definition of Self-Administered Hormonal Contraception: Hormonal contraception products with the following routes of administration are considered self-administered:

- (A) Oral;
- (B) Transdermal;
- (C) Vaginal;
- (D) Depot Injection.

(4) Procedure: When a patient requests self-administered hormonal contraception, the pharmacist shall complete the following steps:

- (A) Ask the patient to use and complete the self-screening tool;
- (B) Review the self-screening answers and clarify responses if needed;
- (C) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.
- (D) Before furnishing self-administered hormonal contraception, the pharmacist shall ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.
- (E) When a self-administered hormonal contraceptive is furnished, the patient shall be provided with appropriate counseling and information on the product furnished, including:

- (i) Dosage;
- (ii) Effectiveness;
- (iii) Potential side effects;
- (iv) Safety;
- (v) The importance of receiving recommended preventative health screenings;
- (vi) That self-administered hormonal contraception does not protect against sexually transmitted infections (STIs).

(5) Self-Screening Tool: The pharmacist shall provide the patient with a self-screening tool containing the list of questions specified in this protocol. The patient shall complete the self-screening tool, and the pharmacist shall use the answers to screen for all Category 3 and 4 conditions and characteristics for self-administered hormonal contraception from the current United States Medical Eligibility Criteria for Contraceptive Use (USMEC) developed by the federal Centers for Disease Control and Prevention (CDC). The patient shall complete the self-screening tool annually, or whenever the patient indicates a major health change.

A copy of the most recently completed self-screening tool shall be securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense.

This self-screening tool should be made available in alternate languages for patients whose primary language is not English.

(6) Fact Sheet: The pharmacist shall provide the patient with the FDA-required patient product information leaflet included in all self-administered hormonal contraception products, as required by the Business and Professions Code Section 4052.3(c). The pharmacist shall answer any questions the patient may have regarding self-administered hormonal contraception.

Pharmacists should provide the patient with a copy of a current consumer-friendly comprehensive birth control guide such as that created by the FDA, and a copy of an administration-specific factsheet; examples of appropriate guides and factsheets are available on the Board of Pharmacy's website.

(7) Follow-Up Care: Upon furnishing a self-administered hormonal contraceptive, or if it is determined that use of a self-administered hormonal contraceptive is not recommended, the pharmacist shall refer the patient for appropriate follow-up care to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics. A patient who is determined not to be an appropriate candidate for self-administered hormonal contraception shall be advised of the potential risk and referred to an appropriate health care provider for further evaluation.

(8) Notifications: The pharmacist shall notify the patient's primary care provider of any drug(s) or device(s) furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drug(s) or device(s) furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

(9) Referrals and Supplies: If self-administered hormonal contraception services are not immediately available or the pharmacist declines to furnish pursuant to a conscience clause, the pharmacist shall refer the patient to another appropriate health care provider.

The pharmacist also shall comply with all state mandatory reporting laws, including sexual abuse laws.

(10) Product Selection: The pharmacist, in consultation with the patient, may select any hormonal contraceptive listed in the current version of the USMEC for individuals identified as Category 1 or 2, based on the information reported in the self-screening tool and the blood pressure (if recorded by the pharmacist). The USMEC shall be kept current and maintained in the pharmacy or health care facility, and shall be available on the Board of Pharmacy's website.

Generic equivalent products may be furnished.

(11) Documentation: Each self-administered hormonal contraceptive furnished by a pharmacist pursuant to this protocol shall be documented in a patient medication record and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. A patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 16, sections 1717 and 1707.1 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(12) Training: Prior to furnishing self-administered hormonal contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of a board-approved continuing education program specific to self-administered hormonal contraception, application of the USMEC, and other CDC guidance on contraception. An equivalent curriculum-based training program completed on or after the year 2014 in an accredited California school of pharmacy is also sufficient training to participate in this protocol.

(13) Patient Privacy: All pharmacists furnishing self-administered hormonal contraception in a pharmacy or health care facility shall operate under the

pharmacy or facility's policies and procedures to ensure that patient confidentiality and privacy are maintained.

(14) Self-Screening Tool Questions

**HORMONAL CONTRACEPTION SELF-SCREENING TOOL QUESTIONS**

1	What was the first date of your last menstrual period?	/ /	
2	Have you ever taken birth control pills, or used a birth control patch, ring, or shot/injection? (If no, go to question 3)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Are you currently using birth control pills, or a birth control patch, ring, or shot/injection?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
3	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4	Do you smoke cigarettes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
5	Do you think you might be pregnant now?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
6	Have you given birth within the past 6 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
7	Are you currently breastfeeding an infant who is less than 1 month of age?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
8	Do you have diabetes?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9	Do you get migraine headaches, or headaches so bad that you feel sick to your stomach, you lose the ability to see, it makes it hard to be in light, or it involves numbness?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10	Do you have high blood pressure, hypertension, or high cholesterol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12	Have you ever had a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
13	Have you ever been told by a medical professional that you are at a high risk of developing a blood clot in your leg or in your lung?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
14	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
15	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
16	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
18	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		
20	Do you have any other medical problems or take regular medication?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If yes, list them here:		

Authority: Sections 4005, 4052(a)(10), and 4052.3, Business and Professions Code.  
 Reference: Sections 4052(a)(10) and §4052.3, Business & Professions Code.

# **Attachment 4**

# **Travel Medications**

**1746.5**

# **Travel Medications**

## **45-Day Comments**

**Comment Period Closed November 9, 2015**

Code Section	Commenter	Comment
1746.5(a)	<b>Scott Clark</b> CA Medical Assoc.	<p>CMA believes that amendments are needed to clarify that travel medications do not include controlled substances, given prior Board discussion that suggested Ambien (zolpidem) might be dispensed for jet lag. The law specifies that a pharmacist may furnish prescription medications “for individuals traveling outside of the United States.” The intent is to allow furnishing of medications for illnesses not typically experienced during travel within the United States, such as malaria, and not meant to encompass more general conditions, such as jet-lag. There are non-controlled substances available for more general travel needs, including over-the-counter medications such as mild sedatives and sleep aids for jet-lag, as recommended in the referenced CDC Yellow Book.</p> <p>In further support of a cautious approach, the CDC Yellow Book’s discussion “Self-Treatable Conditions” includes the following statements:            “To minimize the potential negative effects of a self-treatment strategy, the recommendations should follow a few key points:</p> <ul style="list-style-type: none"> <li>• Drugs recommended must be safe, well tolerated, and effective for use as self-treatment.</li> <li>• A drug’s toxicity or potential for harm, if used incorrectly or in an overdose situation, should be minimal.”</li> </ul> <p>Controlled substances by definition imply concerns about safe use and potential for harm and should not be allowed to be furnished by pharmacists in the regulation.</p> <p><b>Vaccinations</b></p> <p>A second issue is that some prophylactics may require an injection, such as the vaccine for Yellow Fever. Any vaccines provided as travel medications should be administered according to the rules set out in the yet-to-be finalized proposed regulation on Pharmacists Initiating and Administering Vaccines (§1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations). This would help ensure the safety of consumers by requiring completion of an approved immunization training program and continuing education focused on immunizations and vaccines. Clarifying language to this effect would address the potential ambiguity regarding regulatory authority that was raised in a previous Board discussion.</p> <p><b>Continued on Next Row</b></p>

Code Section	Commenter	Comment
1746.5(a)	<b>Scott Clark</b> CA Medical Assoc.	<p><b>Continued from Previous Row</b></p> <p><b>Prophylactic Use</b>            While CMA agrees with the Board that the term “prophylactic” refers to a medication or treatment used to prevent a disease from occurring, we believe the broad term potentially captures medications for medical conditions that are unlikely to be encountered during international travel and should not be furnished by pharmacists under this section.</p> <p>The above issues can be addressed with the following combined edits:</p> <p>(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications “not requiring a diagnosis” means a <del>prescription medication</del> <u>non-controlled substance</u> that is either:</p> <p>(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or</p> <p>(2) A prophylactic <u>for infectious disease that may be encountered in international travel, with all prophylactic vaccinations administered by injection pursuant to section 1746.4.</u></p>

Code Section	Commenter	Comment
1746.5(c)	<b>Brian Warren,</b> CPHA <b>Mary Staples,</b> NACDS <b>Angie Manetti,</b> CRA	<p>The California Pharmacists Association (CPhA), California Retailers Association (CRA), and National Association of Chain Drug Stores (NACDS) thank the Board of Pharmacy (Board) for moving forward in the implementation of SB 493. Our organizations do, however, have concerns with the proposed regulations intended to place requirements on pharmacists who furnish travel medicines pursuant to Business and Professions Code Section 4052(a)(10). The Board’s proposed regulations establish training requirements that all pharmacists would have to meet in order to furnish travel medicines. As currently published, these requirements mandate completion of a program that is, in fact, impossible to meet using any travel medicine training program currently in existence.</p> <p>Based on the discussions that took place during the Board’s SB 493 Implementation Committee meetings, the general consensus among Board members and public stakeholders was that pharmacists furnishing travel medicines should have an immunization certificate, complete training specific to travel medicine, and have completed the CDC’s Yellow Fever Vaccine Course. The Board’s public materials for the February 25, 2015, SB 493 Implementation Committee meeting note that “APhA has a training module of 20 hours for immunizations plus a second 10 hours for travel medication.” At that meeting, the committee discussed draft regulations that specifically referenced the APhA program, but the drafting of these regulations seems to have erroneously combined the 20-hour immunization program and the 10-hour travel medicine program into a single requirement for completion of a 30-hour travel medicine program (the 30-hour requirement was presented to the full Board at its April 22, 2015, board meeting, but the motion referenced in the minutes from that meeting included a 20-hour requirement).</p> <p>It is essential to include completion of an immunization certificate program and completion of a travel medicine program as separate requirements because they are two distinct programs. Most pharmacists are immunization certified in the first year of pharmacy school. Pharmacists who complete a travel medicine program do so at a later time. We therefore recommend modifying the proposed regulation to require (1) completion of an immunization certificate program and (2) completion of a travel medicine program consistent with the APhA program, which is 10 hours.</p> <p><b>Continued on Next Row</b></p>

Code Section	Commenter	Comment
1746.5(c)	<b>Brian Warren,</b> CPHA <b>Mary Staples,</b> NACDS <b>Angie Manetti,</b> CRA	<p><b>Continued from Previous Row</b></p> <p>We further recommend the following technical modifications:</p> <ul style="list-style-type: none"> <li>• Remove the word “approved” from the reference to a travel medicine program, because the Board is not proposing to approve such programs and no other approval body exists.</li> <li>• Specify what the 10 hours in the required program are in reference to, i.e., it must consist of 10 hours of training.</li> <li>• Modify the requirement that the training cover “each element” of ISTM’s Body of Knowledge to refer to “relevant elements” of the ISTM’s Body of Knowledge. This is necessary because the ISTM Body of Knowledge includes items such as recommended precautions regarding accidents and violence.</li> </ul> <p>A mock-up of these modifications is included below. Modify the training requirements contained in subsection (c), as follows:</p> <p>(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:</p> <p>(1) Completion of an <u>immunization certificate program that meets the requirements of Section 1746.4,</u></p> <p><u>(2) Completion of a <del>approved</del> travel medicine training program, which must consist of at least <u>10 20</u> hours of <u>training</u> and cover <u>each relevant</u> elements of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),</u></p> <p><del>(2)</del> <u>(3)</u> Completion of the CDC Yellow Fever Vaccine Course, and</p> <p><del>(3)</del> <u>(4)</u> Current basic life support certification.</p>

Code Section	Commenter	Comment
1746.5(c)	<b>Jeff Goad</b> Chapman University	<p>Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:</p> <p>(1) Completion of an approved travel medicine training program, which must consist of at least 20 hours <u>of an approved immunization training course and 10 hours of an approved travel health training course</u> <del>and</del> that covers each element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (<del>2012</del>),</p> <p>(2) Completion of the CDC Yellow Fever Vaccine Course, and</p> <p>(3) Current basic life support certification.</p> <p>Notes on these suggested changes:</p> <ul style="list-style-type: none"> <li>• In (1)           <ul style="list-style-type: none"> <li>o 20 hours is the length of time that was previously approved for the immunization training requirement and immunization training is a pre-requisite for Travel Health.</li> <li>o 10 hours, which is the current length of time for the APhA travel health course, can only be taken after pharmacists have completed the immunization training.</li> <li>o Suggest removing 2012 as it gets updated every couple of years. Whatever is posted is always the most current version</li> </ul> </li> </ul>
1746.5(f)	<b>Jeff Goad</b> Chapman University	<p>Notifications: The pharmacist shall notify the patient’s primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of dispense furnishing, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient’s choice.</p> <p>Notes on suggested change:</p> <ul style="list-style-type: none"> <li>• If pharmacists are providing medications “by other means” under the furnishing provisions in an Ambulatory Care setting instead of “dispensing” from a pharmacy, it may not be possible to know when or if the medication was dispensed.</li> <li>• Furnished is used everywhere else in this section.</li> </ul>

# **Travel Medications**

## **Initial Proposed Text**

**BOARD OF PHARMACY**  
**Proposed Text**

**Add** §1746.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

**§1746.5 Pharmacists Furnishing Travel Medications.**

(a) For purposes of Business and Professions Code section 4052(a)(10)(A)(3), prescription medications “not requiring a diagnosis” means a prescription medication that is either:

(1) For a condition that is both self-diagnosable and recognized as self-treatable by the federal Center for Disease Control and Prevention’s (CDC) Health Information for International Travel (commonly called the Yellow Book), or

(2) A prophylactic.

(b) A pharmacist furnishing prescription medications not requiring a diagnosis that are recommended by the CDC for individuals traveling outside the 50 states and the District of Columbia pursuant to section 4052(a)(10) of the Business and Professions Code shall follow the requirements of this section.

(c) Training: A pharmacist who furnishes travel medications shall keep documentation of the following on site and available for inspection by the Board:

(1) Completion of an approved travel medicine training program, which must consist of at least 20 hours and cover each element of the International Society of Travel Medicine’s Body of Knowledge for the Practice of Travel Medicine (2012),

(2) Completion of the CDC Yellow Fever Vaccine Course, and

(3) Current basic life support certification.

(d) Continuing Education: Pharmacists must complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunizations and vaccines, from an approved provider once every two years.

(e) Prior to furnishing travel medication, a pharmacist shall perform a good faith evaluation of the patient, including evaluation of a patient travel history using destination-specific travel criteria. The travel history must include all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. An example of an appropriate and comprehensive travel history is available on the Board’s website.

(f) Notifications: The pharmacist shall notify the patient's primary care provider of any drugs and/or devices furnished to the patient within 30 days of the date of dispense, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with written record of the drugs and/or devices furnished and advise the patient to consult a physician of the patient's choice.

(g) Documentation: For each travel medication furnished by a pharmacist, a patient medication record shall be maintained and securely stored in physical or electronic manner such that the information required by title 42, section 300aa-25 of the United States Code and title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a progress note, which fully documents the clinical assessment and travel medication plan. An example of an appropriate and comprehensive progress note is available on the Board's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052, Business and Professions Code.

# **Attachment 5**

# **Vaccinations**

**1746.4**

# **Vaccinations**

## **Second 15-Day Comments**

**Comment Period Closed December 5, 2015**

Code Section	Commenter	Comment
1746.4(d)	Anonymous	The pharmacist or his/her agent SHOULD NOT BE Required to report vaccinations to a state immunization registry or to the doctor for that matter. it SHOULD BE OPTIONAL. I would like a regulatory hearing to be had FORTHWITH
1746.4(e)	Valley Children's Hospital	<p>Comments:</p> <ol style="list-style-type: none"> <li>1. Would the board consider changing the word "shall" on page 2 (e) immunization registry to "may" until such time as the Section 120440(c) language is changed from may and/or the CAIR becomes mandatory for provider participation.</li> <li>2. Would the board consider adding language regarding an option for a waiver of the requirement to inform the patient's primary care provider of any vaccines administered by a pharmacist, when the pharmacist is administering vaccines to employees within an acute care hospital.</li> <li>3. Can the pharmacists be exempted (of informing primary providers) when administering flu shots as part of the organization's flu vaccine program under the oversight of an MD within Employee Health Services?</li> </ol> <p>Section 120440(c) includes the verbiage below: health care providers, and other agencies, including, but not limited to, schools, child care facilities, service providers for the California Special Supplemental Food Program for Women, Infants, and Children (WIC), health care plans, foster care agencies, and county welfare departments, may disclose the information set forth in paragraphs (1) to (10), inclusive, from the patient's medical record, or the client's record, to local health departments operating countywide or regional immunization.</p> <p>The current California Immunization Registry (CAIR) is voluntary for Providers participation. With the registry being voluntary for providers but mandatory for pharmacists it has set up a dichotomy of requirements between vaccinations given to employees by a pharmacist vs. those given by employee health RNs, NP and MDs.</p>

# **Vaccinations**

## **Second Modified Text**

## Title 16. BOARD OF PHARMACY

### Second Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and **bold and dashed underline** for added language. (Additionally, the modified text is listed in red for color printers.)

Changes made to the modified proposed language are shown by ~~double strikethrough and bold underline~~ for deleted language and **bold and double underline** for added language. (Additionally, the modified text is listed in blue for color printers.)

**Proposal to add** §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **§1746.4 Pharmacists Initiating and Administering Vaccines.**

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an approved immunization training program, and
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within ~~30~~ **14** days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. ~~If known, notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.~~

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~30~~ 14 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient [vaccine administration medication](#) record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the ~~initiation and administration of any~~ [vaccines administered by the pharmacist](#). An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

# **Vaccinations**

## **First 15-Day Comments**

**Comment Period Closed October 22, 2015**

Code Section	Commenter	Comment
1746.4(d)	<b>Lauren Berton</b> CVS Health	<p>(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 14 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.</p> <p>CVS Health would like to add language to the end of the last sentence so that it may read "Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine, <u>if the prenatal care provider is known or was provided by the pregnant patient.</u>" The prenatal care provider may not always be known to the Pharmacy and it should allow the patient a choice to provide this information, should they want the pharmacy to report to this provider</p>
1746.4(f)	<b>Lori Hensic</b> Kaiser	<p>1) Regarding notifying providers of those vaccinated: Recommend the same stipulation for primary care providers be added, such that if a pregnant patient does not have a prenatal care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice.</p> <p>2) Regarding documentation/1746.4(f): The requirement to maintain a patient medication record may not be feasible in all pharmacist practice settings where pharmacists initiate and/or administer vaccines (i.e., outside of a pharmacy, and/or if a patient receives a vaccine at a pharmacy at which the patient does not receive prescriptions). Recommend changing to: "For each vaccination administered by a pharmacist, a patient <del>medication</del> <u>vaccination</u> record shall be maintained in an automated data processing or manual record mode such that the required information under Title 42, Section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours."</p> <p>3) Recommend modifying 1746.4(f): "A pharmacist shall provide the patient with a vaccine administration record, which fully documents the <del>initiation and administration of any</del> <u>vaccines initiated and administered by the pharmacist.</u>" Given a pharmacist may not have access to the patient's vaccine administration record/history at their site, the regulation should clarify which vaccines must be included within the vaccine administration record. Pharmacists should only be responsible for providing this documentation only for those vaccines initiated and administered under their care.</p>

Code Section	Commenter	Comment
Overall Comment	<b>San Diego County Pharmacists Association</b>	<p>We fully support expanded access to routine vaccinations in pharmacies. However, we are concerned that requiring pharmacies to report to immunization registries may prohibit some pharmacies from participating. The pharmacy systems used by some of our local pharmacies do not support reporting. Without an electronic interface to facilitate efficient reporting, pharmacies will be unable to participate. This is further restricted with a 14-day notification requirement for vaccines initiated for and/or administered to pregnant women.</p> <p>This proposed regulation was shared with the Registry Manager of our local San Diego Regional Immunization Registry earlier this month. He was unaware of this regulation. In order to operationalize this locally, he communicated that either an interface or electronic data export will need to be developed for each pharmacy system. The registry staff are currently unable to process the volume of data expected to be exported and sent to them by pharmacies. Until the system is able to effectively use this data, it seems futile and an inefficient use of resources for pharmacies to prepare and submit this data. Our local registry manager estimates that it will take 2 – 3 months to build an interface for each system and the pharmacy systems, among other clinic systems, will be prioritized by volume of immunizations. With over 20 pharmacy systems in use in our county alone, it will be several years before the system is ready for use in a meaningful way. The registry is only of value if users can use it as a history and screening tool.</p> <p>Other health care providers who immunize are not required to report to immunization registries. While this should be a best practice recommendation to all immunizing health care providers, we ask that it be removed as a requirement. Registry reporting was not included in the senate bill text. To realize the full public benefit of this protocol, we request that this barrier be removed. We urge the California Board of Pharmacy to reconsider this requirement in light of the burden it will cause and the lack of benefit for the foreseeable future. If the Board insists on this requirement, perhaps it would be more reasonable to include a deadline of 3 or 5 years from now to comply with the reporting requirement.</p>
Overall Comment	<b>Julia Heinzerling</b> LA County Dept. Public Health	<p>The Los Angeles County Department of Public Health (LAC/DPH) supports the adoption of California Code of Regulations, Title 16, Division 17, Article 5, Section §1746.4, as amended by the California State Board of Pharmacy on October 7, 2015. Please accept the following comments in support of this revised regulation.</p> <p>The proposed regulation establishes standards for pharmacists to initiate and administer vaccines and sets training, continuing education, notification, and reporting requirements. The LAC/DPH supports this regulation's adoption on the basis of its potential to improve vaccine reporting, access to vaccinations, and pharmacist adherence to recommended immunization practices. LAC/DPH also strongly supports the proposed requirement to report vaccination data to an immunization registry. Such registries help providers identify appropriate vaccinations, reduce missed opportunities to vaccinate, and prevent duplicate vaccine doses. They also provide local health departments with access to data for surveillance, program planning, evaluation, and outbreak investigations. For these reasons, LAC/DPH supports enactment of the proposed regulation.</p> <p><b>Continued Next Row:</b></p>

Code Section	Commenter	Comment
Overall Comment	<b>Julia Heinzerling</b> LA County Dept. Public Health	<p><b>Continued Previous Row:</b></p> <p>LAC/DPH also supports the following amendments to the regulation, as proposed by the California State Board of Pharmacy on October 7, 2015:</p> <ul style="list-style-type: none"> <li>• Require Pharmacists to Notify Prenatal Care Providers of Vaccine Doses Administered to Pregnant Women: Section §1746.4 (d)- Notifications</li> <li>• Require Notification and Reporting within 14 Days of Vaccination: Section §1746.4 (d)- Notifications and Section §1746.4 (e)- Immunization Registry</li> </ul> <p>There is clear rationale for both of these amendments, which also reflect changes suggested by LAC/DPH in its letter to the California State Pharmacy Board on September 4, 2015. For instance, requiring notification of prenatal care providers of doses administered will help these providers identify needed vaccines for pregnant women, vaccinate at appropriate intervals and avoid duplicate vaccine doses. Requiring reporting to providers and an immunization information system within 14 days is consistent with registry best practice standards and will benefit patients, providers, and local health departments. For instance, patients will have better access to vaccination records for employment, child care entry, or school entry and providers will be able to better assess for minimum intervals between vaccine doses and avoid duplicate doses. Local health departments will also benefit from more complete vaccination records when conducting outbreak, case, and contact investigations. For these reasons, LAC/DPH supports both proposed changes to the reporting requirements under this regulation.</p>

# **Vaccinations**

## **First Modified Text**

## Title 16. BOARD OF PHARMACY

### Modified Text

Changes made to the originally proposed language are shown by ~~double strikethrough~~ for deleted language and **dashed underline** for added language. (Additionally, the modified text is listed in red for color printers.)

**Proposal to add** §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **§1746.4 Pharmacists Initiating and Administering Vaccines.**

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

- (1) Completion of an approved immunization training program, and
- (2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within ~~30~~ **14** days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice. **Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine.**

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within ~~30~~ **14** days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

# **Vaccinations**

## **Initial Proposed Text**

## Title 16. BOARD OF PHARMACY

### Proposed Text

**Proposal to add** §1746.4 of Article 5 of Division 17 of Title 16 of the California Code of Regulations as follows:

#### **§1746.4 Pharmacists Initiating and Administering Vaccines.**

(a) A pharmacist initiating and/or administering vaccines pursuant to section 4052.8 of the Business and Professions Code shall follow the requirements specified in subdivisions (b) through (f) of this section.

(b) Training: A pharmacist who initiates and/or administers any vaccine shall keep documentation of:

(1) Completion of an approved immunization training program, and

(2) Basic life support certification.

This documentation shall be kept on site and available for inspection.

(c) Continuing Education: Pharmacists must complete one hour of ongoing continuing education focused on immunizations and vaccines from an approved provider once every two years.

(d) Notifications: The pharmacist shall notify the patient's primary care provider of any vaccines administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. Primary care provider notification must take place within 30 days of the administration of any vaccine. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall advise the patient to consult an appropriate health care provider of the patient's choice.

(e) Immunization Registry: A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 30 days of the administration of any vaccine. The pharmacist shall inform the patient or the patient's guardian of immunization record sharing preferences, detailed in Section 120440(e) of the Health and Safety Code.

(f) Documentation: For each vaccine administered by a pharmacist, a patient medication record shall be maintained in an automated data processing or manual record mode such that the required information under title 42, section 300aa-25 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide

the patient with a vaccine administration record, which fully documents the initiation and administration of any vaccine. An example of an appropriate vaccine administration record is available on the Board of Pharmacy's website.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.8, Business and Professions Code.

**Vaccinations –  
45-day Comments  
1746.4**

Code Section	Commenter	Comment
1746.4(d)	<b>Karen Smith</b> CDPH	<p>Change #1. (d) Add a requirement for the pharmacist to notify the prenatal care provider (if the patient is pregnant)</p> <p>Rationale. The Advisory Committee on Immunization Practices (ACIP) currently recommends all pregnant women receive an influenza vaccine during the flu season and Tdap (during the third trimester of every pregnancy). If prenatal care providers do not administer these vaccines in their offices and refer to pharmacists, the prenatal care providers need a routine mechanism to confirm immunization of their patients.</p>
1746.4(d)	<b>Karen Smith</b> CDPH	<p>Change #2. (d) Shorten the notification period to within 14 days of the administration of any vaccine.</p> <p>Acceptable Alternatives:</p> <p>... Notification to the prenatal care provider of immunizations provided to pregnant women must take place within 14 days of the administration of any vaccine. Notification to the primary care provider must take place within 30 days of the administration of any vaccine.</p> <p>...Notification to the prenatal care provider and primary care providers of immunizations other than influenza vaccine must take place within 14 days of the administration of any vaccine. Notification to the primary care provider must take place within 30 days of the administration of influenza vaccine.</p> <p>Rationale. A longer interval of 30 days between immunization and notification may negatively impact patient care, especially for prenatal Tdap vaccine, which should be administered between 27 and 36 weeks of the pregnancy. A 30-day lag is too long for prenatal care providers to take timely action to follow up with women not yet vaccinated during the window. While a provider can call a pharmacist to request the fax of an immunization record, this is time consuming and inefficient. Timely notification from pharmacies to providers will optimize patient care.</p>

Code Section	Commenter	Comment
1746.4(d)	<b>Karen Smith</b> CDPH	<p>Change #3. (e) Enter vaccines into the Immunization Registry within 14 days of the administration of any vaccine.</p> <p>Acceptable Alternatives:</p> <p>A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any immunization given to a pregnant woman and within 30 days for all other immunizations.</p> <p>A pharmacist shall fully report the information described in Section 120440(c) of the Health and Safety Code into one or more state and/or local immunization information systems within 14 days of the administration of any immunization other than influenza vaccine and within 30 days for all influenza immunizations.</p> <p>Rationale. See Change #2 regarding the importance of timely notification for patient care. We understand that the 30 day time interval was a compromise developed during the public hearings. However, pharmacies in California are already using electronic systems to promptly report doses to California's immunization information system, the California Immunization Registry (CAIR). For example, CAIR receives messages from Walgreens within 24 hours of date of administration of the vaccine, and other pharmacy chains report at least weekly. The following additional pharmacies are already sharing their immunization data electronically with CAIR: Albertson's/Savon; SafewayNons/Pavilions; Walmart; and RiteAid. CVS is in process in sharing their immunization data.</p> <p>The California Board of Pharmacy reports that 60% of the state's 7000 community pharmacies are in large chains. Some of the remaining 40% of pharmacies (those that are a single site or less than eight stores in a chain) may also have electronic systems. Even for those that will manually enter into CAIR because they have no electronic upload yet, 14 days is reasonable given that data entry into CAIR takes only five minutes per patient</p>
1746.4(d)	<b>Jeffrey Gunzenhauser</b> LAC/DPH	<p>Recommendation 1: Require Pharmacists to Notify Prenatal Care Providers of Vaccine Doses Administered to Pregnant Women</p> <p>Pertussis and influenza vaccines are recommended for pregnant women to prevent complications during pregnancy and spread of disease to newborn infants, who are at high risk for complications. The CDC and American Congress of Obstetricians and Gynecologists encourage prenatal care providers to recommend, assess the need for, and/or offer vaccines to pregnant women. This requires access to a complete vaccination record, including vaccine doses administered in complementary settings. Thus, DPH recommends that the regulation be amended to require in situations where a woman's prenatal care provider is different from her primary care provider, that the pharmacist will also notify her prenatal care provider.</p>

Code Section	Commenter	Comment
1746.4(d) & (e)	<b>Jeffrey Gunzenhauser</b> LAC/DPH	<p>Recommendation 2: Require Notification and Reporting within 14 Days            DPH recommends that the required timeframe for reporting vaccine doses to an immunization information system (Subsection e) and the provider (Subsection d) be shortened from 30 to 14 days.</p> <p>Timely reporting benefits patients, providers, and local health departments. A 14-day reporting period is better aligned with the CDC's immunization schedule, which allows some vaccine doses to be administered less than 30 days following a previous dose. If amended, providers will be better able to assess for minimal intervals between doses to ensure vaccine delivery according to recommended schedules and to avoid duplicate doses. Patients will also benefit from better access to vaccination records needed for employment, child care entry, or school entry. Local health department response during outbreak, case, and contact investigations will also be aided by having more complete vaccination records.</p> <p>Additionally, the proposed amendment is consistent with registry best practice standards. The American Immunization Registry Association, for example, recommends that vaccine records be submitted within 14 days of the encounter date, as a best practice for improving data quality. (Source: American Immunization Registry Association, Available at <a href="http://www.immregistries.org/resources/aira-mirow_dga_selected_aspects_best_practice_guide_05-17-2013.pdf">www.immregistries.org/resources/aira-mirow_dga_selected_aspects_best_practice_guide_05-17-2013.pdf</a>)</p>
Overall Comment	<b>Jeffrey Gunzenhauser</b> LAC/DPH	<p>The LAC/DPH supports adoption of the proposed regulation on the basis of its potential to increase vaccine reporting and participation in the California Immunization Registry (CAIR), improve access to vaccinations, and encourage pharmacist adherence to recommended immunization practices.</p> <p>DPH also strongly supports the proposed requirement to report vaccination data to an immunization information system, such as CAIR. Systems like CAIR can improve patient care, as they allow providers to view, update, and store consolidated records of vaccines given in and outside of their clinic. They are recommended by the United States Task Force on Community Preventive Services based on strong evidence of effectiveness in increasing vaccination rates. At the point of clinical care, they provide decision support and help providers identify appropriate vaccinations, reduce missed opportunities to vaccinate, and prevent duplicate vaccine doses. Local health departments benefit from aggregate data for surveillance, program planning, and evaluation purposes and patient-level data during outbreaks. For these reasons, DPH supports the proposed reporting requirement.</p> <p>By establishing standards by which pharmacists can initiate and administer vaccines without a doctor's prescription, this regulation supports increased access to vaccinations and is supported by DPH.</p> <p>Vaccine storage, handling, and administration errors can lead to serious problems including patient harm, impotent or ineffective vaccines, and wasted vaccine doses. Formal immunization training may minimize vaccine errors and encourage adherence to the CDC's Advisory Committee on Immunization Practices' immunization schedule. Thus, DPH supports the proposed requirement for pharmacists to complete an accredited training program that includes hands-on injection technique, vaccine indications and contraindications, and vaccine reactions. This requirement is consistent with the National Vaccine Advisory Committee's Standards for Immunization Practices, which recommend that providers are knowledgeable about immunizations and receive ongoing immunization education.</p>

Code Section	Commenter	Comment
Overall Comment	<b>San Diego County Pharmacists Assoc Board</b>	<p>We fully support expanded access to routine vaccinations in pharmacies. However, we are concerned that requiring pharmacies to report to immunization registries may prohibit some pharmacies from participating. The pharmacy systems used by some of our local pharmacies do not support reporting. Without an electronic interface to facilitate efficient reporting, pharmacies will be unable to participate.</p> <p>Other health care providers who immunize are not required to report to immunization registries. While this should be a best practice recommendation to all immunizing health care providers, we ask that it be removed as a requirement. Registry reporting was not included in the senate bill text. To realize the full public benefit of this protocol, we request that this barrier be removed.</p>

# **Attachment 6**

**Compounding**  
**1735 et seq. and**  
**1751 et seq.**

# **Compounding**

## **Second 15-Day Comments**

Code Section	Commenter	Comment
1735.1(e)(1)	<b>Rheta Sandoval &amp; James McNulty</b>	<p>Deleting the word “minimum” creates a pressure requirement that is different than current and proposed USP Chapter &lt;797&gt;. At is reads in the current USP Chapter &lt;797&gt;, the pressure differential range is a source of confusion. I believe the intent is that a minimum positive pressure be established at 0.02-inch water column relative to adjacent spaces, and not to keep the positive pressure differential in a range between 0.02-to 0.05-inch water column.</p> <p>In the proposed revisions to USP Chapter &lt;797&gt;, (see section “ESTABLISHING AND MAINTAINING PRESSURE DIFFERENTIALS” lines 557 – 563, the proposed verbiage is “The pressure differential between the ISO Class 7 area and the general pharmacy area must not be less than 0.02-inch water column.</p> <p>Please consider not deleting the word “minimum”.</p>
1735.1(e)(1)	<b>Bruce Lepley</b>	<p>Reason for Concern: USP 797 makes the stipulation of 12 air changes per hour as the air displacement requirement when compounding hazardous drugs. In addition, this is a contradiction to the same proposed BOP regulations in 1735.6 (e) (1) where it states that for hazardous drug compounding, 12 air changes per hour are sufficient.</p> <p>Solution: Replace the 30 ACPH with 12 ACPH in this section in accordance with USP 797 and in accordance with these same proposed BOP regulations in 1735.6 (e) (1).</p>
1735.1(f)	<b>Douglas Barcon</b>	<p>Correct spelling to “recirculated”</p> <p>Add “within the work area” after “recirculated” because some PECs recirculate a portion of the exhaust air outside of the work area and send it back through the HEPA filter into the work area. Such recirculated air is twice HEPA filtered. This is different in meaning than air that is recirculated as loops or circles within the work area due to eddies created by poor design, compounding equipment placement, and isolator glove sleeves which may affect the ability of the isolator to maintain clean unidirectional air at the critical sites and direct compounding area, and is turbulent. Clarification is needed.</p>
1735.1(f)	<b>Douglas Barcon</b>	<p>Maintaining non-turbulent air in the entire work area within the CACI is difficult with the placement of anything in the work area, including an IV hanging bar. A pattern smoke test will show this. A TPN compounder or a bag or bottle hanging are examples. Proper aseptic technique, air flow, and placement of TPN compounders minimize turbulence.</p> <p>Is this paragraph addressing static, dynamic, or both conditions of operation? Clarification is needed.</p> <p>Consider modifying this sentence to state: “Air within the CACI shall not be recirculated nor turbulent within the work area as verified by pattern smoke test, and sources of turbulence corrected as necessary.”</p>

1735.1(g)	<b>Douglas Barcon</b>	<p>Correct spelling to “recirculated”</p> <p>Add “within the work area” after “recirculated” because some PECs recirculate a portion of the exhaust air outside of the work area and send it back through the HEPA filter into the work area. Such recirculated air is twice HEPA filtered. This is different in meaning than air that is recirculated as loops or circles within the work area due to eddies created by poor design, compounding equipment placement, and isolator glove sleeves which may affect the ability of the isolator to maintain clean unidirectional air at the critical sites and is turbulent. Clarification is needed.</p>
1735.1(g)	<b>Douglas Barcon</b>	<p>Maintaining non-turbulent air in the entire work area within the CAI is difficult with the placement of anything in work area, including an IV hanging bar. A pattern smoke test will show this. A TPN compounder or a bag or bottle hanging are examples. Proper aseptic technique, air flow, and placement of TPN compounders minimize turbulence.</p> <p>Is this paragraph addressing static, dynamic, or both conditions of operation? Clarification is needed.</p> <p>Consider modifying this sentence to state: “Air within the CAI shall not be recirculated nor turbulent within the work area as verified by pattern smoke test, and sources of turbulence corrected as necessary.”</p>
1735.1(k)	<b>Brian Warren and Joyce Sprinkles</b>	<p>Define “essentially a copy”</p> <p>Define “clinically significant difference”</p> <p>Clarify where “high particulate matter” can be compounded? In ISO 8 or ISO 7 area?</p> <p>Clarify where “sterile compounding” is required to be done?</p> <p>Both questions were asked during the first and second comment period but was never addressed. Both statements have several interpretations. Please advise.</p>
1735.1(k)	<b>Brian Warren and Joyce Sprinkles</b>	<p>If the prescriber writes for a different base, oil, or filler due to patient sensitivity, allergy, or intolerance or because the physician feels this a clinically significant difference, would we then be allowed to compound the preparation?</p> <p>Recommendation: If a different base, oil, or filler prevents a lapse in patient compliance with their medications, then this qualifies as a clinically significant difference determined by a prescribing practitioner to allow the patient to have continuity of care.</p> <p>Recommendation: Use the same verbiage as the Federal 503A definition to avoid confusion between Federal, NABP, and CaBOP. Many compounding pharmacies are licensed to various states, not just California. See below.</p> <p>Section 503A- Traditional Compounder: Shall not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product. For purposes of this Section, the term “essentially a copy of a commercially available drug product” does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.</p>

1735.1(m)	<b>Rheta Sandoval &amp; James McNulty</b>	<p>The added language is unclear and subject to interpretation. This may result in facility non-compliance and/or variability in expectations set by inspectors. Please consider clarifying language to give direction on how to “test” the airflow requirements are being met (i.e. are there a certain number of air velocity measurements and specific locations for measurements that the board feels are necessary to satisfy this requirement). Please clarify if the intent is to assess the air velocity across the line of demarcation, along an imaginary vertical plane from floor to ceiling and wall to wall on the line (when the displacement airflow method is employed).</p>
1735.1(m)	<b>Bruce Lepley</b>	<p>Reason for concern: The statement that the air velocity must be 40 feet per minute or more from floor to ceiling, wall to wall and from the clean area across the line of demarcation into the ante area may require clarification. If the intent is to have an air velocity of 40 feet per minute or greater from the clean area into the ante area at all measurable points (floor to ceiling, wall to wall), we would recommend rearranging the statement to make this clear. It otherwise could be read to require that the velocity be 40 feet per minute in every direction within the clean area.</p> <p>Solution: Please clarify the verbiage to make it clear that the velocity will only be measured in the direction from the clean area to the ante area, but that it must be 40 feet per minute at all measurable points in the clean area. If this is the case, please clarify how this should be documented/demonstrated during certification/environmental testing as it may not be feasible to provide measurements at every potentially measurable point across the line of demarcation.</p>
1735.1(t)	<b>Bill Jones</b>	<p>While performing sterile to sterile compounding it is possible an interruption may be required and may be appropriate. An interruption may be required to provide appropriate checks of the compounding process, gather additional supplies, or may be required for personal reasons. Also California labor requirements for hourly employee breaks for an eight hour shift (hourly employee) require a meal break to start prior to the fifth hour of the shift and for their to be two fifteen minute breaks one in the morning and one in the afternoon that can not be attached to the lunch break.</p> <p>Examples of when these interruption compounding may occur are:</p> <ul style="list-style-type: none"> <li>• An employee requires an unscheduled restroom break. Would we prefer the Technician rush through the completion of a batch or would we allow them to take a quick break and return?</li> <li>• A Pharmacist or a Technician may have a question that arises during compounding of a lot regarding any part of the compounding session, the functionality of the PEC, or the performance of the cleanroom. The employee should be encouraged to pause and make certain their concern is quickly addressed and make a decision on continuation with compounding rather than not ask questions.</li> <li>• A Technician discovers an issue with supplies required to compound a lot such as they dropped a vial on the floor, they are missing a tubing set which is required to compound this lot, or any situation where they are short of a required material. Sterile Compounding Pharmacies are discouraged from storing excess supplies in the cleanroom as they can become clutter, can become sources of contamination, and could be used inadvertently in a lot where they are not required. Our current wipe down process to introduce supplies into the compounding room takes at a minimum 35 minutes as there are two levels of decontamination so even if the supply issue is identified early in the compounding of a specific lot there could be a delay while awaiting introduction of the required supply into the cleanroom.</li> </ul> <p>Continues to Next Row.</p>

1735.1(t)	<b>Bill Jones</b>	<p>Continued from Previous</p> <p>Each of the situations described above are examples of when an interruption may be required and would be appropriate because they encourage employees to follow appropriate procedures for ensuring the safety of the preparations they are compounding and following appropriate procedures to minimize introduction of contaminants into the cleanroom. Under the proposed definition of a 'lot', the above examples of interruptions would require that the pre and post interruption CSPs would need to be labeled with two different lot numbers. This would require the Technician/Pharmacist to scrap the entire compounding process or to take the existing batch record they are using and create two separate records (after the fact), prepare a new set of labels for the post interruption batch to indicate the appropriate lot. This introduces an unnecessary source of potential error which could affect patient safety.</p> <p>Recommended Language:  (t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).</p>
1735.1(u)	<b>Douglas Barcon</b>	<p>"efficacy" does not appear to be the most appropriate term. Suggest changing it to "quality" or "competency."</p>
1735.1(u)	<b>Brian Warren and Joyce Sprinkles</b>	<p>Please clarify "evaluated for sterility", does that mean in-house sterility according to pharmacy's policy and procedures or does this mean sending it out to an independent laboratory for sterility results?</p> <p>Recommendation: In-house sterility evaluation for "Media-fill test" should be sufficient</p>
1735.1(u)	<b>Brian Warren and Joyce Sprinkles</b>	<p>(u) "Media-fill test" means a test <u>used to measure the efficacy of compounding personnel in aseptic techniques whereby that mimics compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility using in-house sterility evaluation.</u> <del>to demonstrate the competency of compounding personnel in aseptic techniques.</del> The media-fill test must mimic the most complex compounding procedures performed by the pharmacy <del>that aseptic techniques of compounding personnel or processes routinely employed to not result in microbial contamination.</del> <del>To be valid, media fill tests must be conducted on both the most routine and the most challenging compounding procedures performed.</del></p> <p>Specify how the BOP expects pharmacies to evaluate media-fill tests for sterility. This change is needed to ensure clarity in what "evaluated for sterility" means; specifically, in-house sterility according to pharmacy's policy and procedures, as opposed to sending it out to an independent laboratory for sterility results.</p>

<p>1735.1(y) <b>Marie Cottman</b></p>	<p>Comments: "...Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt..." But why exempt acute care facilities? What is the clinical and patient safety difference of an acute care facility compounding Vancomycin IV 50mg/ml in their cleanroom and my retail pharmacy compounding Vancomycin IV 50mg/ml for our local jail in our cleanroom? The issue is that this attempts to exempt a specific product (manufactured sterile pharmaceutical products) but actually exempts a facility.</p> <p>Recommendation: Revise by removing "...in a health care facility licensed under section 1250 of the Health and Safety Code..." Then the resulting statement would exempt the products from the potency requirement, only.</p> <p>New: "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.</p>
<p>1735.1(y) Incorrectly Identified as (z) <b>Bruce Lepley</b></p>	<p>Reason for Concern: USP 797 only describes potency in terms of ensuring potency by monitoring controlled storage areas. In addition, considering the many drugs that could be compounded (biosimilars, immune mediators, blood derivatives, etc) it may be too arbitrary to put such a hard limit on this definition.</p> <p>Solution: Remove section that defines "potency" altogether.</p>
<p>1735.1(ab) Incorrectly Identified as (ac) <b>Bruce Lepley</b></p>	<p>Reason for Concern: The inherent definition of a PEC is that it has the ability to produce/provide ISO Class 5 or better air environment. Many Sterile Compounding Automated Robots that are available and that are in production have no intention of being able to create/produce/provide an ISO Class 5 (or any air class for that matter). These automated robots are made to be simply put or placed in the appropriate air environment (ISO Class air).</p> <p>Solution: Remove sterile compounding automated robots from the PEC definition and just make the stipulation that they should be used in an appropriate ISO Class 5 or 7 environments.</p>
<p>1735.1(af) <b>Rheta Sandoval &amp; James McNulty</b></p>	<p>Typographical error change the word "meet" to "met"</p>
<p>1735.1(af) <b>Douglas Barcon</b></p>	<p>Delete the s in "its" and change "meet" to "meets"</p>

<p>1735.1(af) Incorrectly Identified as (ag)</p>	<p><b>Bruce Lepley</b></p>	<p>Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units). The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. If one were to believe that this is an unverified study then one would have to question most of the conclusions derived from USP 797 as many of the conclusions taken from there are not based on “randomized controlled trials”. We believe that we can remove the 3 foot no sink/drain requirement when CACIs are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model.</p> <p>Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.</p>
<p>1735.2(c)</p>	<p><b>Bill Jones</b></p>	<p>Section C appears to be in violation of the Federal Food Drug and Cosmetic act section 503A. There is no provision for distribution of drug products prior to receipt of a prescription in section 503A. The only instance of distribution of non patient specific drugs products (prescriptions) is by registering as a 503B pharmacy. FDA issued guidance on this in July 2014 (Pharmacy Compounding of Human Drug Products. Under Section 503A of the Federal Food, Drug, and Cosmetic Act) where they state: Under section 503A of the FD&amp;C Act, a compounded drug product is exempt from sections 501(a)(2)(B), 502(f)(1), and 505 of the FD&amp;C Act if it meets the conditions of section 503A of the FD&amp;C Act. Specifically, the compounded drug product qualifies for the exemptions if:</p> <ol style="list-style-type: none"> <li>1. The drug product is compounded for an identified individual patient based on the receipt of a valid prescription order, or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient (section 503A(a) of the FD&amp;C Act).</li> <li>2. The compounding of the drug product is performed: <ul style="list-style-type: none"> <li>• By a licensed pharmacist in a state licensed pharmacy or a Federal facility, or by a licensed physician on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs; or</li> <li>• By a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient and: <ul style="list-style-type: none"> <li>- is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product; and</li> </ul> </li> </ul> </li> </ol> <p>Continued to next row</p>

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1735.2(c) **Bill Jones**

- those orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order (sections 503A(a)(1) and (2) of the FD&C Act). There is no provision for distribution without first receiving a prescription. Further, the guidance states that: FDA expects state boards of pharmacy to continue their oversight and regulation of the practice of pharmacy, including pharmacy compounding. FDA also intends to continue to cooperate with state authorities to address pharmacy activities that may be violative of the FD&C Act, including section 503A. How does the CA Board of Pharmacy reconcile this apparent conflict with federal law, specifically Section 503A of the FD&C act? Does the Board intend to "not cooperate" with the FDA when they seek to enforce section 503A as indicated in FDA guidance?

Recommendation:

Do not eliminate the ability of pharmacies to compound for prescriber's office use by changing decades of vital history that has allowed a prescriber to dispense from the prescriber's office up to at least a 72-hour supply of pharmacy compounded medication. In fact, as the Board's rationale of acceptance for allowing "...a 120-hour supply for veterinary medical practices..." should be also allowed for human medical care.

Rationale:

1735.2(c)(1), (3) **Kaiser**

For over 30 years, the Legislature's authorization for pharmacists' ability to compound preparations for prescriber "for office use by the prescriber" (B&P Code 4052(1)(a) has been interpreted to include BOTH for administration in the office and for DISPENSING to a patient for up to a 72-hour supply. Under State law prescriber's are allowed to dispense prescription medications to their own patients. This Board proposed will effectively narrow the scope of practice of physicians and other prescribers without a discussion via the Legislature of that vital State policy.

The proposed regulation language will remove the allowance for pharmacists to compound for any prescriber for dispensing - except for veterinarians. [See Proposed regulation Section 1735.2(c)(3)]

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This change in pharmacy scope of practice could hinder appropriate and safe human therapy in some situations where, by definition, the prescriber has asked a pharmacy to compound a product to either keep on hand for a potential human need (just like the Board's rationale for allowing the compounding for animal therapy). It will also encourage medication compounding by practitioners or health professionals with less education and training in compounding than pharmacists, e.g. physicians, dentists, etc. and nurses, etc., respectively. These potential adverse consequences were exactly what the Legislature was trying to avoid when the Statute was enacted decades earlier after it was alerted to such tragedies. Some examples of the need for allowing prescriber dispensing of pharmacy-compounded products, include when medication is unavailable for a type of patient with special needs, (such as an eye drop without preservatives) or when a commonly available critical medication is in reality not available from usual sources.

1735.2(c)(1), (3) **Kaiser**

Another increasing reason for allowing a prescriber to dispense a reasonable supply of a pharmacy compounded drug is to avoid unnecessarily increasing the cost of care or increasing the waste of safe and effective medication and the avoidable adverse effects on the environment of its unnecessary disposal. One example, is when the prescriber could administer a few drops of a pharmacy—compounded eye solution in the office but under the regulation change would have to discard the remainder of the container instead of dispensing it to the patient even though the patient would only need a few day's therapy or who would be unlikely to procure a continuous supply directly from a compounding pharmacy in the remaining 72 to 120 hours of therapy.

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The Board's apparent intent will be to discipline the pharmacy, Pharmacist-In-Charge and dispensing pharmacist if they knew or should have known that the prescriber was going to dispense the remainder of the bottle to the patient. Consequently it won't be done and prescriber's and patients will be denied this option without discussion via the Legislature.

1735.2(c)(1), (3) **Kaiser**

Just as for animal treatment, which the Board intends to allow, the ability for prescribers to dispense pharmacy-compounded medications is also important to situations where a compounding pharmacy will not be reasonably available, e.g. because of holidays, distance, expertise, proper equipment for sterile compounding, etc.. The Regulation will delay or interrupt vital therapy, such as immediate and continuous treatment of infections or relief of suffering. Situations that most likely can be avoided with the dispensing of the 72 to 120 hour supply.

This change in statutory intent could also make care substantially more expensive for the patient whom would have to buy another supply of compounded medication at the pharmacy and/or for the organization responsible for the drug cost.

<p>1735.2(i) <b>Bruce Lepley</b></p>	<p>Reason for Concern: Many CSP's (e.g. reconstituted vials) that are a result of following manufacturer's directions have labeling (supported by the manufacturer) that exceeds what is listed in this section for water containing formulations and water containing topical/dermal formulations. Furthermore, to expect that stability studies will be provided by the manufacturer in lieu of a general statement by the manufacturer stating the stability/sterility is not feasible. Many generic manufacturers do not have the infrastructure to accommodate inquiries by many pharmacies to provide them stability studies.</p> <p>Solution: Retract the examples of water containing oral formulations and water containing topical/dermal formulations from this section and replace the language with what was in the previous version. In addition, add the stipulation that a later date may be used for a CSP if the manufacturer provides communication regarding stability and sterility to support that claim.</p>
<p>1735.2(i)(1)(E) <b>Douglas Barcon</b></p>	<p>USP 795 USP 37-NF 32 specifically states 14 days at controlled cold temperature for water-containing oral formulations. (D) and (F) are room temperature storage. Please clarify.</p>
<p>1735.2(i)(1)(A-F) <b>Marie Cottman</b></p>	<p>Comments: This section for BUDs is totally acceptable EXCEPT that it does NOT allow for extending the BUD with appropriate testing. There are several water containing creams and liquids that can meet requirements of potency, integrity, and quality well beyond 14 or 30 days. Additionally, the following section 1735.2 (i) 2 (D) 3 allows for extension of the beyond use date for sterile compounds when certain criteria are met.</p> <p>Recommendation: Add subsection (G) to 1735.2 (i) (1) to read: Extension of a beyond use date is only allowable when supported by stability studies to verify integrity of the compounded product.</p> <p>Reference: Please see Eagle Analytical BUD testing flow chart at <a href="https://www.eagleanalytical.com/sitecontent/598/beyond-use-dating-bud/category/462/about-testing.aspx">https://www.eagleanalytical.com/sitecontent/598/beyond-use-dating-bud/category/462/about-testing.aspx</a></p>

1735.2(i)

**Brian Warren and  
Joyce Sprinkles**

Are all of those tests required for both sterile and non-sterile compounds for the extension of beyond use dating? Please clarify/define "Method suitability test" for STERILE and NON-STERILE? The term is very different for a sterile compound versus a non-sterile compound. A true fully validated method development/suitability test per formula for a NON-STERILE compound is appropriately \$10,000 per formula. Typically independent laboratories don't have a library for non-sterile compounds to allow information to be extrapolated from. Many compounding pharmacies that have been in practice for 10 or more years have thousands of unique non-sterile formulas which would be extremely costly to accomplish. Most compounding pharmacies would not be able to afford this test for the many formulas that they have. A basic method suitability test per USP 61 (checking number of CFUs testing at time zero and testing at a desired end point) which already encompasses a closure integrity test for a 503A facility is ~ \$1000 per formula. Bracketing should be allowed (ie: Testing a high concentrated formula and a low concentrated formula) to apply to multiple formula strengths in between. Keep in mind, these laws are directed to 503A facilities therefore the tests required should be proportional to the facility. Please clarify/define "Container Closure Integrity Test" for STERILE and NON-STERILE? For cGMP, this test is usually used in lieu of a sterility/endotoxin at time zero and end date of when you would want your preparation to be tested? The cGMP test involves submerging your finished preparation in a microbial dye and the final test doesn't test for sterility or endotoxin. Many independent laboratories (ARL, Eagle, etc) that specialize in providing testing for compounding pharmacies are not set up for this type of test for sterile preparations. Or does the "Container Closure Integrity Test" mean to confirm that our compounded preparation remained sterile and endotoxin free at time zero and at our designated end date? For non-sterile preparations, is this test referring to testing an empty container without active product? And are all vials (5ml, 10ml) or containers (30gm pump, 60gm pump, 30gm topiclick) considered equal meaning we would only have to test one size of the same container so long as it's from the same manufacturer?

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1735.2(i)

**Brian Warren and  
Joyce Sprinkles**

Please clarify/define "Stability Studies" STERILE and NON-STERILE? A true cGMP stability study used in industry would cost \$50,000 per formula and again many of the independent laboratories that specialize in providing testing for compounding pharmacies are not set up for this type of test. Or does the "Stability Study" mean at various time points (time zero, end date time, etc), the compounded preparation had the appropriate potency, and confirmed sterility and endotoxin free?

The FDA allows testing to be done on a low and high concentration formula and the data can be applied to formulations in between

Recommendation:

Extension of a beyond use date is only allowable when supported by the following: (A) Method Suitability Test; (B) Stability Studies: defined as potency, sterility, and endotoxin testing at time zero and at a designated end date to confirm potency, sterility, and endotoxin testing over time remained the same in the container of choice. It is reasonable to test a low and high concentration formula and information may be applied to other formulations in between these strengths.

- (1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
- (A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation;
  - (B) the chemical stability of any one ingredient in the compounded drug preparation;
  - (C) the chemical stability of the combination of all ingredients in the compounded drug preparation; or
  - (D) in the absence of stability information that is applicable to the specific drug and preparation, beyond use dates shall not exceed:
- (1) 180 days for non-aqueous formulations,
  - (2) 14 days for water-containing oral formulations, and
  - (3) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

1735.2(i)(1) **Pamela Almeida**

USP <795> Pharmaceutical Compounding – Nonsterile Preparations – General Guidelines for Assigning Beyond-Use Dates states:

“In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for nonsterile compounded drug preparations...” then lists the BUDs as written in 1735.2(i)(1)(D through F).

The wording in the modified proposed language “any of the following” implies that it is inclusive even when stability data demonstrates a longer expiration date than those listed in D, E, F cannot be exceeded. For example stability for a water-containing oral formulation is known to be 30 days but per 1735.2 (i)(1)(E) only 14 days can be used. That contradicts USP <795> as quoted in the above paragraph.

1735.3(a)(2)

**Rheta Sandoval &  
James McNulty**

Please consider revising to:

“A record of compounding containing all of the following:”

Rationale: The proposed language is congruent with a paper-based recordkeeping process. As facilities are moving towards implementing IV workflow management systems, the information required for recordkeeping as described in 1735.3(a)(2)(A-J) is captured/stored electronically. The stored electronic information is readily retrievable in the pharmacy.

<p>1735.4(a)(3) <b>Bill Jones</b></p>	<p>This regulation will apply to 503A Compounding Pharmacies and 503B Outsourcing Facilities since both must register in the state of CA as Pharmacies and Sterile Compounding Pharmacies. 503B Facilities can not meet all of these label requirements specifically the infusion rate for admixed IV solutions as the drugs are distributed prior to receiving a patient specific prescription and as such any individual dose can have more than one possible rate of infusion depending on the final prescription at the time of dispensing. The 503B Outsourcing Facility would also not be able to label the sterile compounded preparation with the name of the dispensing pharmacy as this would require the 503B Outsourcing Facility to compound custom batches for each customer with custom labeling.</p> <p>Recommended Language:</p> <p>(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:</p> <ol style="list-style-type: none"> <li>(1) Name of the compounding pharmacy and dispensing pharmacy (if different);</li> <li>(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;</li> <li>(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included; For admixed IV solutions dispensed under Section 503A of the FD&amp;C act, the rate of infusion shall be included;</li> <li>(4) The beyond use date for the drug preparation;</li> <li>(5) The date compounded; and</li> <li>(6) The lot number or pharmacy reference number.</li> </ol>
<p>1735.4(a)(3) <b>Kaiser</b></p>	<p>Recommendations:</p> <ol style="list-style-type: none"> <li>1. Exempt sterile admixed IV solutions for patients in a health care facility licensed under section 1250 of the Health and Safe Code from the requirement that the rate of infusion shall be included on the label.</li> </ol> <p>Rationale: Numerous admixed IV solutions in the hospital setting are frequently titrated based upon the patient's changing condition. Some infusions of pressor agents in an intensive care setting are titrated literally on a minute-by-minute basis to achieve the desired hemodynamic parameters. Requiring the infusion rate on the label can result in confusion for the Nurse and lead to errors in programming infusion pumps and drug administration. The rate on the label may not be the actual rate that should be infused because of the rapidly changing condition of the patient.</p>
<p>1735.6(e) <b>Sandy Atwater</b></p>	<p>My organization uses a MIC negative pressure closed system isolator for compounding hazardous drugs. This PEC does not need to be vented according to the manufacturer, and is classified as a closed system isolator. According to the Containment Technologies Mobile Isolation Chamber (MIC) Owner's Manual, "The MIC utilizes a recirculating air system and does not require outside venting. An airlock allows access to the ISO Class 5 environment. Manipulations take place through gloves and sleeves, allowing the pharmacist to leave and re-enter the workstation without compromising the ISO Class 5 environment. The MIC workstation requires no special wiring, plumbing, or room-air filtration." How will closed system isolators be addressed in the regulations?</p>

1735.6(e)	<b>Bill Jones</b>	<p>Comment: The requirement for a seamless room would be difficult to meet. Interpretation of the 'seamless' requirement could change over time and between inspectors. The room's walls should be smooth and nonporous.</p> <p>Recommended Language: (e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements: (1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and (2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and (3) Each PEC in the room shall also be externally vented; and (4) All surfaces within the room shall be smooth, <del>seamless</del>, impervious, and non-shedding.</p>
1735.6(e)(1)	<b>Sandy Atwater</b>	<p>My organization uses a MIC negative pressure closed system isolator for compounding hazardous drugs. This PEC does not need to be vented according to the manufacturer, and is classified as a closed system isolator. According to the Containment Technologies Mobile Isolation Chamber (MIC) Owner's Manual, "The MIC workstation requires no special wiring, plumbing, or room-air filtration."</p>
1735.6(e)(2)	<b>Sandy Atwater</b>	<p>My organization uses a MIC negative pressure closed system isolator for compounding hazardous drugs. This PEC does not need to be vented according to the manufacturer, and is classified as a closed system isolator. According to the Containment Technologies Mobile Isolation Chamber (MIC) Owner's Manual, "The MIC workstation requires no special wiring, plumbing, or room-air filtration." The MIC is maintained at a negative pressure of -0.2 to -0.5 for hazardous drug compounding.</p>
1735.6(e)(3)	<b>Sandy Atwater</b>	<p>According to the Containment Technologies Mobile Isolation Chamber (MIC) Owner's Manual, "The MIC utilizes a recirculating air system and does not require outside venting. An airlock allows access to the ISO Class 5 environment. Manipulations take place through gloves and sleeves, allowing the pharmacist to leave and re-enter the workstation without compromising the ISO Class 5 environment. The MIC workstation requires no special wiring, plumbing, or room-air filtration."</p>
1735.7(a)	<b>Douglas Barcon</b>	<p>This may be outside the scope of the modified text, however, environmental services, housekeeping, and maintenance cannot be expected to be trained in all aspects of policies and procedures, because this would include compounding processes which are beyond the scope of their job descriptions and training. Such staff are not pharmacy technicians or pharmacists.</p>

Recommendation: "The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, of compounded drug preparations. The criteria and frequency by which preparations would be tested for potency, quantitative analysis, and labeled strength analysis shall be described in the quality assurance plan as determined by the pharmacist-in-charge. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula.

1735.8(c) **Kaiser**

Rationale: This proposed language may be interpreted to encompass non-sterile compounding of preparations such as creams and ointments, for which quantitative testing methods do not exist or are exorbitantly expensive.

This language could be interpreted to require that quantitative and qualitative analysis be performed on compounded products regardless of cost, availability of the actual assay, or scientific validity.

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If one or two compounded drug preparations were tested annually, what is the value of those results to the pharmacist in charge? What are the benefits to the public?

Those test results would show that a compounded drug prepared at a specific time on a specific date by a specific pharmacist did (or did not) meet potency and labeled strength requirements.

Those test results can NOT be applied, however, to an identical compounded drug prepared the following day using the same master formula by another pharmacist, or even if it is prepared the following day by the same pharmacist (unless that product was tested as well – a highly unlikely occurrence).

1735.8(c) **Kaiser**

It seems like the Board is attempting to apply the systematic testing approach used in the pharmaceutical industry, in which large batches of finished products are systematically manufactured, and where samples from multiple batches are tested.

By its very nature – preparing a compounded drug based on an individual prescription - pharmacy compounding is an episodic process. Therefore, testing for potency and labeled strength must be approached differently.

It is important that there be a quality assurance plan, with criteria for end product examination in the master formula; as well as criteria and circumstances by which end products are tested for potency or labeled strength.

<p>1735.8(c) <b>Bruce Lepley</b></p>	<p>Reason for concern: This section describes the requirement of a quality assurance plan including “written standards for qualitative and quantitative analysis of compounded drug preparations...including the frequency of testing”. The verbiage is not specific and appears to imply that all products compounded by a pharmacy must be tested for integrity, potency, quality and labeled strength at least annually. Given the wide range and various dosage forms of products compounded in any given hospital pharmacy, as well as the limitations of some end-product testing laboratories to only be able to test certain medications, we recommend that facilities should be allowed to adopt a methodology and frequency (at least annually) for testing specific products for potency.</p> <p>Solution: Reword the statement to use “shall include a program for routine testing and analysis of designated compounded drug preparations on at least an annual basis”.</p>
<p>1735.1(a)(5) <b>Douglas Barcon</b></p>	<p>Is this paragraph addressing static, dynamic, or both conditions of operation? Is it during certification only or done by trained pharmacy staff at other times? Are all smoke test videos, including those for training, open for inspection? Silence would indicate all studies are open for inspection. Is there a catalog or log for the videos? How are the videos stored? There are many factors to consider beyond just requiring a video.</p> <p>As currently written, video is required in all ISO certified spaces, which include the ISO class 8 ante area or ISO class 7 ante area, ISO class 7 buffer area, and ISO class 5 PEC. Video of smoke studies should be limited to the ISO class 5 PEC in this regulation.</p> <p>If background music is added to the video, are ASCAP/BMI and artist fees paid? Is credit given? Are board inspectors going to police the certifiers and pharmacy staff where failures are shown? Are these videos to show regulators, the PIC, and compounding staff where in the PEC there is some turbulence, where to place TPN compounders or other devices, and for training purposes? How often are smoke studies done? Please clarify.</p>
<p>1751.1(a)(5) <b>Valley Children's Hospital</b></p>	<p>Recommendations:</p> <ol style="list-style-type: none"> <li>1. Delete this from the record keeping requirements. Video created by a third party is of limited value given the current cybercrime and network security issues. Many facilities no longer allow employees to insert unencrypted devices or data storage devices (CD's or DVDs) into networked computers.</li> <li>2. Add to section 1751.4 (f) page 32: In-situ air pattern analysis (smoke studies) shall be performed in ISO Class 5 PECs under dynamic conditions by a CETA certifier at a minimum of every 6 months in accordance with CAG-003-2006-13.</li> <li>3. The findings of the smoke studies shall be recorded in the report provided to the organization which shall be readily retrievable by the pharmacy.</li> </ol> <p>Continued to Next Row</p>

<p>1751.1(a)(5) <b>Valley Children's Hospital</b></p>	<p>Continued From Previous</p> <p>Support for recommendation</p> <ul style="list-style-type: none"> <li>• Neither ASHP nor USP797 state that smoke studies must be done in all ISO certified spaces (i.e. ante rooms, buffer rooms etc.).</li> <li>• Smoke studies for certification are currently performed and test results are documented for the board of pharmacy and facility analysis.</li> </ul> <p>ASHP Drug Distribution and Control: preparation and handling-guidelines, Compounding Sterile Preparations mention smoke studies only once. On page 77 upper left column "Smoke tests of PECs assist a facility in verifying unidirectional airflow and lack of turbulence and reverse flows."</p> <p>According to USP Chapter &lt;797&gt;, " The airflow in the PEC shall be unidirectional (laminar flow) and because of the particle collection efficiency of the filter, the first air at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations. Proper design and control prevents turbulence and stagnant air in the critical area. In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions."</p> <p>USP &lt;797&gt; requires testing in all ISO Class 5 environments, including primary engineering controls (PECs), such as laminar airflow workstations (LAFWs), biological safety cabinets (BSCs), and compounding aseptic isolators (CAIs).</p>
<p>1751.1(a)(5) <b>Bruce Lepley</b></p>	<p>Reason for concern: We believe the language in USP 797 (current version) as well as the proposed revision requires smoke studies for the certification of PECs/ISO class 5 areas. It does not appear to require smoke studies for all ISO-classified areas. We believe it is appropriate to utilize airflow testing with objective measurements to certify other ISO-classified areas such as ante rooms and clean rooms (which are not ISO class 5).</p> <p>Solution: We recommend changing the verbiage to require smoke studies for PECs/ISO class 5 areas only.</p>
<p>1751.1(a)(5) <b>Rheta Sandoval &amp; James McNulty</b></p>	<p>Please revise to: documents indicating in situ air pattern analysis via smoke studies were conducted at the critical area (PEC) to assess for unidirectional airflow and sweeping action over and away from the preparation</p> <p>This language is consistent with current USP Chapter &lt;797&gt;.</p> <p>Rationale: 1. Proposed language is unclear as to specific location(s) where the smoke studies are to be performed. 2. Video documentation may add to the expense of certification and is not required for other recordkeeping such as daily monitoring of temperatures, air pressures, etc.</p>

<p>1751.1(a)(5) <b>Kaiser</b></p>	<p>Recommendation: Delete this verbiage</p> <p>Rationale: Hood certification experts conduct video smoke studies of Primary Engineering Controls, e.g. laminar flow hoods, during the certification process. Other testing methods are utilized to quantify particle counts and airflow dynamics when certifying buffer rooms and ante-rooms, i.e. other ISO certified spaces. There is no practical reason for the pharmacy to save videos of smoke studies if the primary engineering control is certified by a hood certification expert and has documentation that the hood met all requirements for certification.</p>
<p>1751.1(a)(8) Incorrectly identified as (a)(7) <b>Bruce Lepley</b></p>	<p>Reason for Concern: USP 797 allows for at least daily documentation or by using a continuous recording device. We would like to continue to allow the use of a continuous recording device as an alternative which would also give the facility better “real time” data.</p> <p>Solution: Reword the section to state “Documents indicating daily documentation or by continuous recording device of air pressure differentials...”</p>
<p>1751.1(b) <b>Marie Cottman</b></p>	<p>Comments: This section is confusing as 1735.2 references both patient specific and office use compounding in sub-sections (b) and (c) respectively. I believe this language is referencing ONLY section (c) regarding dispensing for office use and is NOT required nor relevant to section (b) which would have a patient specific prescription for documentation and tracking of the lot, etc.</p> <p>Recommendation: Add specific sub section to the text. If appropriate: “(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 (c) shall...”</p>
<p>1751.3(e) <b>Bruce Lepley</b></p>	<p>Reason for concern: We acknowledge that any material or significant changes to written policies and procedures for sterile compounding should be communicated to all personnel involved in compounding. However, this section implies that personnel must review all changes to all compounding policies and procedures, even if they do not directly impact their job duties in a material fashion. Additionally, our pharmacy and organization holds personnel responsible for abiding by all policies and procedures whether they are related to compounding or not; it is a standard expectation, and signature and date are not collected except in rare cases where the practice change is deemed significant. We believe a signature and date should only be required if there is a significant practice change being implemented as a result of any changes in policies and procedures.</p> <p>Solution: Change the first sentence to “...any material or significant additions, revisions and deletions...must be communicated to all personnel involved in sterile compounding”. Change the last sentence to “If changes to the written policies and procedures result in a significant change in practice for compounding personnel, the review must be documented by a signature and date”.</p>

<p>1751.4(d) <b>Bruce Lepley</b></p>	<p>Reason for Concern: USP 797 does not make any stipulation or requirement of mandatory use of a sterilizing agent (i.e. sporicidal: EPA definition). It only makes the stipulation of sanitizing and disinfecting. Furthermore, when sterilizing (i.e. killing spores) is mentioned as recommendation in the literature it is limited to general floor cleaning. The way it is written in this section could lend itself to believe that all items in the IV room have to be sterilized (i.e. use of a sporicide; EPA definition) at least monthly which is not a recommendation that cannot be found anywhere for a pharmacy that compounds sterile products (using sterile to sterile compounding methodology).</p> <p>Solution: Remove the requirement that the use of a sporicidal agent is required monthly and ensuring that there continues to be requirements for sanitizing and disinfecting at appropriate intervals. If the sporicidal requirement is not removed at least add verbiage that specifies that this requirement is for the cleaning of floors.</p>
<p>1751.4(d)(1) <b>Marie Cottman</b></p>	<p>Comments: We do not access our cleanroom on a daily basis, but use it approximately one or two times per week. As “daily” is defined in section 1735.1(l) as every day a pharmacy is operating, this regulation would require that my staff enter and clean the counters, work surfaces and floors even on days that the ISO Class 5 facility is not used! This, in my opinion, would increase the risk of contamination by excessive entry that is not necessary.</p> <p>Recommendation: Clarify the regulation by changing “at least daily” to “at least daily on each day of use.”</p>
<p>1751.4(e) <b>Bruce Lepley</b></p>	<p>Reason for Concern: The language in this sentence uses disinfectant and sterile agent in the same sentence which could be interpreted as the use of a sterilizing agent to disinfect. According to EPA and other regulatory standards disinfect and sterilize have two distinct meanings. There could be confusion if these two words are used in the same sentence.</p> <p>Solution: Remove the words “using a suitable sterile agent” to “using a suitable disinfecting agent” to mitigate the risk of confusion that the use of a sterilizing agent is required to disinfect the PEC.</p>
<p>1751.4(e) <b>Bruce Lepley</b></p>	<p>Reason for Concern: The language here states that disinfection should occur at least every 30 minutes. Please know that the Phenol and Quaternary Ammonia compounds used for disinfecting state that once these chemicals are used they are to be air dried for up to 10 minutes. If we are making the requirement to disinfect at least every 30 minutes then that means that the PEC can only be used for 40 minutes of every hour if you take into consideration the time to allow to dry when cleaning with disinfectants. In addition, if we are to disinfect upon spill, before each lot, etc... as stipulated in this same section this only further diminishes the time we can use our PEC. This could potentially mean that we could be disinfecting so often that we could only be using the PEC for less than 30 minutes for each hour the PEC is available when you consider the drying time needed after the application of the Phenol or Quaternary Ammonium compounds that are used. This would impair pharmacy’s ability to meet turnaround times for medications that are essential for a patient centered care model of service established for hospitals that produce “STAT” medications.</p> <p>Solution: Remove the requirement to disinfect (the PEC) at least every 30 minutes. Maintain the stipulations in this section that describe disinfecting at the beginning of each shift...items (1),(2),(3), and (4).</p>

<p>1751.4(e)(2) <b>Bruce Lepley</b></p>	<p>Reason for Concern: The most recent USP 797 regulations state that cleaning of the ISO 5 PEC should occur at the beginning of each work shift, before each batch (USP 797 only uses the word batch in referencing high-risk compounding) preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. With the new proposed definition of “lot,” interruption of workflow of hospital compounding in order to clean before and after each lot may impact the timeliness of medication delivery to patient and could introduce potential for medication errors.</p> <p>Solution: Remove “before and after each lot” and keep items (1), (2), (3), and (4) which will ensure proper intervals for disinfection are still in place.</p>
<p>1751.4(g) <b>Sandy Atwater</b></p>	<p>My organization uses a MIC negative pressure closed system isolator for compounding hazardous drugs. This PEC does not need to be vented according to the manufacturer, and is classified as a closed system isolator. According to the Containment Technologies Mobile Isolation Chamber (MIC) Owner’s Manual, “The MIC utilizes a recirculating air system and does not require outside venting. An airlock allows access to the ISO Class 5 environment. Manipulations take place through gloves and sleeves, allowing the pharmacist to leave and re-enter the workstation without compromising the ISO Class 5 environment. The MIC workstation requires no special wiring, plumbing, or room-air filtration.”</p>
<p>1751.4(g) <b>Bruce Lepley</b></p>	<p>Reason for Concern: We just want to be sure that when we use the definition of “hazardous” drugs we are referring to agents used to treat neoplasms. We want to be sure that we are not using the NIOSH definition of hazardous drugs that include non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug including those with manufacturers’ safe handling guidance (MSHG).</p> <p>Solution: Modify the definition of “hazardous” to mean “all anti-neoplastic agents <b>used to treat neoplasms</b> identified by the National Institute for Occupational Safety (NIOSH).....”</p>
<p>1751.4(g) <b>Bruce Lepley</b></p>	<p>Reason for Concern: This statement would include CACI’s that are used as PEC’s to compound hazardous drugs. USP 797 does not make it required that CACI’s that are used to compound hazardous drugs to be externally vented. In fact, USP 797 recognizes that many hazardous have sufficient vapor pressures that allow volatilization at room temperature and that environmental sampling in the CACI to detect uncontained hazardous drugs can be performed and analyzed to help determine if there is a need for a CACI to be externally vented.</p> <p>Solution: Add the stipulation that a PEC does not have to be externally vented if it is a CACI unless environmental sampling cannot be provided or proved that there is no detection of uncontained hazardous drugs on the CACI work surfaces.</p>

1751.4(i) <b>Douglas Barcon</b>	<p>Any equipment, such as a TPN compounder or bags, vials, bottles, or isolator glove sleeves placed in the CAI or CACI will disrupt unidirectional air flow downstream and create some turbulence. TPN compounders are placed to the left or right of the DCA central area where compounding occurs for this reason. The bag connection port of a TPN compounder must be in unidirectional air that is non-turbulent. The native CAI or CACI should not generate turbulent air flow. In actual compounding, turbulence should be minimized by proper compounding technique, air flow, and placement of equipment and devices. If this paragraph is addressing the native CAI or CACI without any equipment present in the work area, it should state so and it should also state expectations with devices present for clarification. Peripheral areas within the workspace may have low-level turbulence. Non-turbulent air flow throughout the workspace may not be possible. Please clarify.</p> <p>Note: This regulation specifically addresses a CAI and CACI, but does not address LAFW hoods. LAFW PECs must also provide unidirectional air flow patterns without turbulence especially in the work areas where actual compounding occurs. LAFWs should be added to this regulation and not be limited to 1735.1(ab).</p>
1751.5(a)(6) <b>Bruce Lepley</b>	<p>Reason for Concern: Prohibiting the use of nail polish in an ISO Class 5 or 7 area supersedes the nationally enforceable USP 797 regulation that only makes the stipulation that artificial nails or extenders are prohibited. In fact, there are studies that have reviewed nail polish used in these areas and have found no direct correlation that nail polish increases the number of particles shed from compounding personnel which lead to an increased risk of microbial contamination of critical sites of CSP's.</p> <p>Solution: Remove "nail polish" from this section.</p>
1751.6(e)(1)(E) <b>Bruce Lepley</b>	<p>Reason for concern: The statement "which contain the same amount or greater of volume transferred during the selected manipulations" implies that the media-fill test performed by personnel must involve a volume transfer the same size or greater than the largest volume transfer performed by the pharmacy when compounding sterile products. It would be difficult to establish this threshold; furthermore, media-fill test kits are commercially manufactured and designed with specific volume transfers and procedures to mimic the most complex manipulation performed by the pharmacy.</p> <p>Solution: Remove the portion of the sentence stating "and which contain the same amount or greater of volume transferred during the selected manipulations".</p>
1751.6(e)(2) <b>Rheta Sandoval &amp; James McNulty</b>	<p>Typographical error change the word "performs" to "performed"</p>
1751.6(e)(2) <b>Douglas Barcon</b>	<p>Change "performs" to "performed"</p>
1751.6(j)(2) <b>Kaiser</b>	<p>Recommendation: Clarify the exact intent of this verbiage.</p> <p>Rationale: It is unclear from the verbiage exactly what training is required for each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices.</p>

<p>1751.7(b)(1) <b>Judith Brosz</b></p>	<p>(b)(1) The pharmacy and each individual engaged involved in, or directly supervising and controlling the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations ...</p> <p>Emphasizes that the testing should be limited to people actually engaged in or directly supervising and controlling aseptic preparation. "Involved" is more vague, and has been demonstrated to be subject to misinterpretation.</p>
<p>1751.7(b)(1) <b>Bill Jones</b></p>	<p>Comment: The requirement for the volume of the media fill to be equal to or greater than the volume transferred during compounding should not be a requirement. The most important criteria is making certain that all compounding steps and aseptic manipulations or processes are simulated in the media fill. Emphasis should be placed on performing simulation of compounding steps and aseptic manipulations to truly assess individual's ability to safely compound and to confirm that the environment supports the process being performed.</p> <p>Recommend Language for volume issue: b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug 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 the types of manipulations, products containers/types, and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth prior to using it for a media-fill validation and post incubation of media-fill units. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, product impact assessment conducted, corrective action taken and documented, and the validation process repeated.</p>

1751.7(b)(3) **Bruce Lepley**

Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units). The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. If one were to believe that this is an unverified study then one would have to question most of the conclusions derived from USP 797 as many of the conclusions taken from there are not based on "randomized controlled trials".

We believe that we can remove the 3 foot no sink/drain requirement when CACIs are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model.

Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.

Comment:

The requirements for revalidation are too broad and sometimes inappropriate. Revalidation may be required in many circumstances but these should not be mandated in the regulation. Many of the specific scenarios listed should be reviewed by a qualified Quality Assurance Microbiology and Sterilization expert to assess and determine revalidation criteria, as necessary. Revalidation should be limited to critical changes in design, controls, and processes that can truly impact sterility assurance level of a product. An unacceptable quality assurance result could mean many things that are unrelated to an individual's aseptic technique or the ability of the environment to maintain appropriate levels of control. For some of the mechanical issues listed in the proposed text the appropriate quality assurance step would be to qualify the equipment by performing enhanced environmental monitoring prior to returning the equipment to service. We suggest that unacceptable results that would require revalidation be defined in the registrants required standard operating procedure.

Recommended Language:

If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

1751.7(b)(3) **Bill Jones**

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation procedure must address circumstances where the validation process on aseptic technique and aseptic area practices must be revalidated. Specifically the procedure should address revalidation requirements for the following situations: whenever:

(A) Identify which unacceptable the quality assurance program results will require revalidation, yields an unacceptable result,

(B) there is any change in the compounding process, the type of Primary Engineering Control (PEC), or the need to represent compounding in a different classification of compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved to a different room, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns. or when improper aseptic techniques are observed.

(C) Requirement for review of quality assurance program data including environmental monitoring results, direct observation, deviations in process, and reports of infection by a qualified quality assurance expert to determine if revalidation should be part of the investigation and corrective actions The investigation must be documented.

1751.7(e)(1) <b>John Voliva</b>	<p>Currently, USP &lt;797&gt; also allows for an alternate method of sterility testing. “A method not described in the USP may be used if verification results demonstrate that the alternative is at least as effective and reliable as the USP Membrane Filtration method or the USP Direct Inoculation of the Culture Medium method where the Membrane Filtration method is not feasible.” (USP38-NF33) As provided to the Board this past January and again attached to these comments, Laser Scanning Cytometry provides for a more rapid sterility test compared to compendial tests (namely USP &lt;71&gt;) and is also orders of magnitude more sensitive than the USP &lt;71&gt; test. We recommend adding in language to allow for these testing procedures to ensure quicker patient access to compounded sterile preparations as well as to provide for a more robust testing procedure than what is currently described in USP &lt;71&gt;. Recommended language is as follows: “Sterility testing shall be USP chapter 71 compliant and pyrogen testing shall confirm acceptable levels of pyrogens, per USP chapter 85 limits, before dispensing. An alternate sterility test method to USP chapter 71 may be used if verification results, consistent with USP chapter 1223, demonstrate the alternative is at least as effective and reliable as the USP chapter 71 Sterility Test Method.”</p> <p><b>Attachment Provided (Title: Eagle CA BOP Handout)</b></p>
1751.7(e)(1) <b>Douglas Barcon</b>	Change “preparation” to “preparations.”
1751.7(e)(1) <b>Marie Cottman</b>	<p>Comments:</p> <p>A) “...Sterility testing shall be USP chapter 71 compliant...” Is a cost prohibitive limitation (well over \$500 for a method suitability test from Eagle Analytical or ARL) when other sterility tests are available (and faster) such as the Rapid Scan RDI. This requirement for USP 71 compliance (when USP 71 is so far out of date to current technologies) will further reduce patient access to one of a kind sterile products because the cost of testing alone for method suitability and pyrogens will be greater than \$600.00.</p> <p>B) “...quarantined until the end product testing confirms sterility...” If the only method of testing is USP &lt;71&gt;, then your testing time is a minimum of 15 days (1 for transport and 14 for testing). What about batch preparations which have less than 15 days stability? What if the compounded preparation is only stable for 9 days? Even quarantining for an Rapid Scan RDI will use up a minimum of 5 of the possible 9 days of therapy..</p> <p>Continued on Next Row</p>

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Recommendations:

A) Return to previous language (from the Modified Text 15- Day Comment Period July 31, 2015 – August 15, 2015) stating "...preparations shall be subject to documented end product testing for sterility..." and remove reference to USP <71>. (see Rapid Scan RDI reference

1751.7(e)(1) **Marie Cottman**

<https://www.eagleanalytical.com/Uploads/Groups/117/DocumentGallery/The%20ScanRDI%20Sterility%20Test%20Suitability%20Considerations.pdf>)

B) In order to optimize patient care and access, consider allowing an exception for pharmacies to develop a validated process (whereby they verify sterility through testing before the 1st dispense to patients). Then once validated, allow the pharmacy to dispense without quarantine only with concurrent sterility testing of each batch.

1751.7(e)(2)(B) **John Voliva**

We are concerned that some compounded sterile preparations for inhalation may require a longer course of therapy than five days, thus requiring a pharmacy to make multiple batches of a compounded sterile preparation for inhalation in order to ensure an uninterrupted course of therapy for the patient. For example, if a prescribed course of treatment is for thirty days, the pharmacy would be required to prepare four different batches of the preparation to comply with this section. On the day the pharmacy receives the prescription, they would be required to prepare two different batches of the preparation: one being a five day supply to start the patient's treatment and a second batch to send out for sterility and pyrogen testing. On day five of the patient's treatment, the pharmacy would need to compound another five-day supply of the preparation. And again, on day 10, the pharmacy would need to compound another five-day supply of the preparation to allow the patient to continue treatment until the sterility and pyrogen testing results are returned. At day fifteen, assuming the second batch compounded on day one of the patient's treatment passes the sterility and endotoxin testing, the second batch prepared on day one can then be dispensed to the patient.

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<p>1751.7(e)(2)(B) <b>John Voliva</b></p>	<p>Continued from Previous</p> <p>Board staff has requested examples of compounded sterile preparations for inhalation that could fall into this type of situation. Following a non-exhaustive review, we believe that at least the following are examples where this situation could arise:</p> <ul style="list-style-type: none"> <li>• Vancomycin Inhalation Solution – course of therapy may last more than 5 days</li> <li>• Azithromycin Inhalation Solution – course of therapy may last more than 5 days</li> <li>• Glutathione / Acetylcysteine Inhalation Solution – usually used for cystic fibrosis</li> <li>• Sodium Chloride Inhalation Solution – usually used for cystic fibrosis – long term therapy</li> <li>• Gentamicin Inhalation Solution - course of therapy may last more than 5 days</li> <li>• Non-commercially available strengths of albuterol for inhalation - course of therapy may last more than 5 days</li> <li>• Morphine Inhalation Solution – typically used in the hospice setting, course of therapy may last more than 5 days</li> </ul> <p>We would recommend changing the proposed language to the following: “Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 15 days or less pursuant to a prescription. If the single patient requires a course of therapy longer than 15 days, the preparation for inhalation must undergo proper testing for sterility and pyrogens. A pharmacy may not continuously prepare a fifteen day supply of the preparation without the preparation undergoing the proper testing for sterility and pyrogens.”</p>
<p>1751.7(f) <b>Judith Brosz</b></p>	<p>(f) Personnel that are not directly engaged in sterile compounding, but are involved in other compounding activities such as remote checking of compounded products outside the controlled area, do not need to perform practical aseptic preparation tests, but shall otherwise complete all written competency examinations on the process.</p> <p>Added (f) to clarify that remote checking should not have identical training requirements to actual production of sterile drug preparations in the controlled environment. Written competency tests are appropriate, practical tests of cleaning and needle handling are not necessary.</p> <p>This permits disabled people to operate in the checking mode when using remote terminal checking systems.</p>
<p>1751.8(b)(1) <b>Marie Cottman</b></p>	<p>Comments: USP&lt;797&gt; uses the phrase “one or more of the following” when discussing Medium Risk CSPs. As this regulation is not directly referring to Medium Risk CSPs, I believe that sterile products should be subject to this beyond use dating if ANY (not ALL) of the following apply.</p> <p>Recommendation: Consider a clarification by changing the word “all” to the phrase “one or more” to remain consistent with the referenced USP &lt;797&gt;.</p> <p>... and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and one or more of the following apply: ...</p>

1751.8(a)(1)	<b>Douglas Barcon</b>	A CACI can be used in place of a CAI for non-hazardous compounding depending on air pressure configuration—usually positive pressure is used. A CACI should not be deleted from this paragraph.
1751.8(b)(1)	<b>Douglas Barcon</b>	A CACI can be used in place of a CAI for non-hazardous compounding depending on air pressure configuration—usually positive pressure is used. A CACI should not be deleted from this paragraph.
1751.8(c)(1)	<b>Douglas Barcon</b>	A CACI can be used in place of a CAI for non-hazardous compounding depending on air pressure configuration—usually positive pressure is used. A CACI should not be deleted from this paragraph.
1751.8(e)	<b>Bruce Lepley</b>	<p>Reason for Concern: Many large health care facilities already employ the use of an “immediate use only” label for reasons other than a 1 hour BUD (e.g. criticality of the drug, cost of the drug, etc.) In addition, other regulatory agencies (i.e. The Joint Commission) have stipulations in existence for labeling “immediate use” sterile products (i.e. medication name, strength, quantity, diluent and volume, expiration date when not used within 24 hours, and expiration time when expiration occurs in less than 24 hours). To avoid confusion, it would be beneficial to specifically remove the requirement of labeling the product for “immediate use only” and impose the existing regulation of the expiration time when expiration occurs in less than 24 hours.</p> <p>Solution: Replace the requirement of labeling for “immediate use only” with the exact one hour beyond use date and time.</p>
1751.8(e)	<b>Bruce Lepley</b>	<p>Reason for Concern: This section does not stipulate as to whether this applies to all healthcare professionals who are qualified to engage in immediate use sterile compounding drug preparation outside the profession of pharmacy.</p> <p>Solution: Please clarify and insert verbiage to make clear of whether or not this stipulation applies to all professions outside of pharmacy who are qualified to engage in immediate use sterile compounding (e.g. RN).</p>
1751.8(e)(1) Section does not exist	<b>Bruce Lepley</b>	<p>Reason for Concern: Other regulatory agencies (i.e. The Joint Commission) have stipulations in existence for one to compound immediate use sterile products which include: “...a delay could harm the patient ...or the products stability is short. To mitigate risk of confusion we recommend adopting similar language that would accomplish the intent of this section.</p> <p>Solution: Reword section to use “a delay could harm the patient” or “the products stability is short”.</p>

1751.9(b)(2)	<b>Bruce Lepley</b>	<p>Reason for concern: It can certainly be acknowledged that single-dose containers may be susceptible to air exposure after the initial puncture and should not be exposed to general room air. However, the stipulation that the containers must remain in an ISO class 5 area puts pharmacies at risk of maintaining excessive amounts of medication vials within the PECs in order to preserve their use. This can put personnel at risk of committing a medication error by selecting the wrong vial; it also creates the potential for clutter in PECs, disruption of airflow and the maintenance of items in the PEC that are not critical to the compounding being performed at any given time.</p> <p>Solution: We recommend allowing single-dose containers to be used for 6 hours (or per manufacturer recommendation) as long as the container was needled-punctured in ISO class 5 or better air and the container is then sealed with a sterile seal before removing it from the PEC. Upon returning the container to the PEC for further usage, the seal could be removed and the top swabbed with isopropyl alcohol. This would limit the exposure of the container to less than ISO 5 class air, while minimizing the risks associated with maintaining all single-dose containers in the PEC for the entire 6 hours.</p>
Overall Comments	<b>Brian Warren and Joyce Sprinkles</b>	<p>USP 795 Guidelines for Assigning Beyond-Use Dates: In the absence of stability information that is applicable to a specific drug and preparation, the following table presents maximum BUDs recommended for nonsterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature, unless otherwise indicated.</p> <p>NOTE: The only requirement from USP 795 to extend BUD is stability information and packaged in tight, light-resistant containers. There's no mention of method suitability tests, or container closure tests.</p>
Overall Comments	<b>Brian Warren and Joyce Sprinkles</b>	<p>Sterilization of solid dosage forms and location of sterilization. Is radiation acceptable or autoclaving? Important to note, sterilization via autoclaving was detrimental to many who were injured or died from the NECC tragedy. Guidance should be advised.</p> <p>For example an autoclave to be used to sterilize a solid dosage form should not be placed in an ISO 5 environment due to the amount of steam and humidity it would release which would potentially compromise your ISO 5 sterile environment. Yet there was no revision to the current section 1250.4(5.) Compounding Area for Parenteral Solutions which states:</p> <p>“Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments: 5.1 An ISO class laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas. 5.2 An ISO class 5 cleanroom. 5.3 A barrier isolator that provides an ISO class 5 environment for compounding</p>

# **Compounding**

## **Second Modified Text**

## Title 16. Board of Pharmacy

### Second Modified Text

Changes made to the originally proposed language are shown by ~~double strike through~~ for deleted language and double underline for added language. (The changes are also indicated in **red font**)

Changes made to the modified proposed language are shown by ~~double strike through/bold underline~~ for deleted language and curved underline for added language. (The changes are also indicated in **blue font**)

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 that is commercially available in the marketplace~~

~~(d)~~(c) 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” means an [area with ISO Class 8 or better air quality 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 or~~ cleanroom, and maintains air flows from clean to dirty areas. \[ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.\]\(#\)](#)

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not ~~be begun~~ [begin](#), the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compound~~ing~~ sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. ~~Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet ~~should~~ [shall](#) be appropriately removed by properly designed external building ventilation. [This external venting should be dedicated to one BSC or CACI.](#)~~

~~(d) “Buffer area” means an area which maintains segregation from the adjacent ante-area by means of specific pressure differentials. The principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the~~

~~buffer area across the line of demarcation into the ante area. The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.~~

~~(e)~~(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, ~~becomes is~~ an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

~~(f)~~(e) “Cleanroom ~~or clean area or buffer area~~” means a ~~physically separate~~ room ~~or area with walls and doors with HEPA-filtered air~~ that provides ~~at least an~~ ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a ~~A minimum differential~~ positive pressure ~~differential~~ of 0.02- to 0.05-inch water column ~~relative to all adjacent spaces~~ is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of ~~between at least 0.01 to 0.03 inches of water column~~ relative to all adjacent spaces is required.

~~(h)~~(f) “Compounding Aseptic Containment Isolator (CACI)” means a ~~unidirectional~~ HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where ~~volatile~~ hazardous drugs are prepared, the exhaust air from the isolator ~~should~~ shall be appropriately removed by properly designed external ~~building~~ ventilation. ~~This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be re-circulated nor turbulent.~~

(g) “Compounding Aseptic Isolator (CAI)” means a form of isolator specifically designed for ~~non-hazardous~~ compounding ~~of~~ pharmaceutical ingredients or preparations ~~while bathed with~~

unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be re-circulated nor turbulent.

~~(h)~~ “(h) ‘‘Controlled cold temperature’’ means 2 degrees to 8 degrees C (35-6 degrees to 46-4 degrees F).

~~(i)~~ “(i) ‘‘Controlled freezer temperature’’ means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

~~(j)~~ “(j) ‘‘Controlled room temperature’’ means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

~~(k)~~ “(k) ‘‘Copy or essentially a copy’’ of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

~~(l)~~ “(l) ‘‘Daily’’ means occurring every day that a the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

~~(m)~~ “(m) ‘‘Displacement airflow method’’ means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the

ingredient, or for hazardous compounds.

~~(n)(e)(n)~~ “Dosage unit” means a quantity sufficient for one administration to one patient,  
~~except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less~~  
~~shall be considered one dosage unit.~~

~~(a)(e)(e)(o)~~ “Equipment” means items that must be calibrated, maintained or periodically  
certified.

~~(e)(e)(p)~~ “First air” means the air exiting the HEPA filter in a unidirectional air stream that is  
essentially particle free.

~~(e)(e)(q)~~ “Gloved fingertip sampling” means a process whereby compounding personnel lightly  
press each fingertip and thumb of each hand onto appropriate growth media, which are then  
incubated at a temperature and for a time period conducive to multiplication of  
microorganisms, and then examined for growth of microorganisms.

~~(e)(e)(r)~~ “Hazardous” means all anti-neoplastic agents identified by the National Institute for  
Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any  
other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

~~(b)(e)(e)(s)~~ “Integrity” means retention of potency until the expiration beyond use date noted  
provided on the label, so long as the preparation is stored and handled according to the label  
directions after it is dispensed.

~~(e)(e)(t)~~ “Lot” means one or more compounded drug preparation(s) prepared during one  
uninterrupted continuous cycle of compounding from one or more common active  
ingredient(s).

~~(e)(e)(u)~~ “Media-fill test” means a test used to measure the efficacy of compounding personnel  
in aseptic techniques whereby that mimics compounding procedures are mimicked using a  
growth-based media and then the resulting preparation is evaluated for sterility. to demonstrate  
the competency of compounding personnel in aseptic techniques. The media-fill test must mimic the  
most complex compounding procedures performed by the pharmacy that aseptic techniques of  
compounding personnel or processes routinely employed do not result in microbial  
contamination. To be valid, media-fill tests must be conducted on both the most routine and the  
most challenging compounding procedures performed.

~~(w)(v)~~(v) “Non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

~~(w)(w)~~(w) “Parenteral” means a preparation of drugs administered in a manner other than through the digestive tract. ~~This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation.~~ It does not include topical, sublingual, rectal or buccal routes of administration.

~~(x)(x)~~(x) “Personal protective equipment” means clothing or devices that protect the employee from exposure to ~~drug products compounding ingredients and/or potential toxins~~ and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

~~(y)(y)~~(y) “Potency” means active ingredient strength within +/- 10% ~~(or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014)~~ of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range ~~may~~ shall be calculated and defined in the master formula.

~~(z)(z)~~(z) “Preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

~~(aa)(aa)~~(aa) “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. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber’s practice environment.

~~(ab)(ab)~~(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for ~~the exposure of critical sites when~~ compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic

containment isolators.

~~(ac)~~~~(ad)~~(ac) “Process validation” means demonstrating that when a process is repeated 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.

~~(ad)~~~~(ac)~~(ad) “Product” means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

~~(d)~~~~(ae)~~~~(af)~~(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, ~~and~~ the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula ~~record~~ document.

~~(af)~~~~(ag)~~(af) “Segregated sterile compounding area” means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile 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. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing ~~non-hazardous~~ of sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows its ~~meeting~~ the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d) ~~(b)~~.

~~(e)~~(ag) “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~~ preparation 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” ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

- (1) is ordered by the prescriber or the prescriber’s agent ~~and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation,~~ 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’s office and signed for by the prescriber or the prescriber’s agent; 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 for human medical practices, or~~ a 120-hour

supply for veterinary medical practices, solely to the prescriber's own ~~veterinary~~ patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~the quantity provided for office use is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) for With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, ~~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 an 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 commercially available 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, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

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

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps 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.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(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~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation 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 compendial 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 or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This “beyond use date” of the compounded drug product preparation~~ shall not exceed any of the following: 180 days ~~from preparation or~~

(A) the shortest expiration date or beyond use date of any component ingredient in the compounded drug product preparation, ~~nor shall it exceed 180 days~~

- (B) the chemical stability of any one ingredient in the compounded drug preparation;
- (C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
- (D) 180 days for non-aqueous formulations,
- (E) 14 days for water-containing oral formulations, and
- (F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations,  
~~from preparation~~

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

- (A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,
- (B) The chemical stability of any one ingredient in the sterile compounded drug preparation,
- (C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- (D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

- (A) Method Suitability Test,
- (B) Container Closure Integrity Test, and
- (C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be ~~using~~ the same identical ~~components in~~ ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

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

~~(k)~~(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 (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. 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.

~~(e)(1)~~ Packages of ingredients, both active and inactive, 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 and 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 and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions.~~

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~~ document.

(2) A compounding log consisting of a single document containing all of the following: ~~The compounding document shall include the following:~~

(A) Name and Strength of the compounded drug preparation.

~~(2)~~ (A)(B) The date the drug ~~product~~ preparation was compounded.

~~(3)~~ (B)(C) The identity of the ~~any~~ pharmacy personnel ~~who compounded the~~ engaged in compounding ~~the~~ drug ~~product~~ preparation.

~~(4)~~ (C)(D) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

~~(5)~~ (D)(E) The quantity of each ~~component~~ ingredient used in compounding the drug ~~product~~ preparation.

~~(6)~~ (E)(F) 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. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (k) shall apply.

(i) Exempt from the requirements in this paragraph ~~(1735.3(a)(2)(E))~~ are sterile ~~products~~ preparations compounded ~~on a one-time basis in a single lot~~ 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 (USP~~37~~-NF~~32~~) Through 2nd Supplement (35 37<sup>th</sup> Revision, Effective ~~May~~ December 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)(E)(G)~~ A pharmacy-assigned unique reference or lot number for the compounded drug ~~product preparation~~.

~~(8)(G)(H)~~ The expiration beyond use date or beyond use date and time of the final compounded drug ~~product preparation~~, expressed in the compounding ~~record~~ document in a standard date and time format.

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

(J) Documentation of quality reviews and required post-compounding process and procedures.

(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 ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). 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, either written in English or translated into English, for chemicals, bulk drug substances, and drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding ~~product chemical, bulk drug substance, or drug products~~ 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 last in effect. 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) ~~Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:~~

~~(1) Name of the compounding pharmacy and dispensing pharmacy (if different);~~

~~(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;~~

~~(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;~~

~~(4) The beyond use date for the drug preparation;~~

~~(5) The date compounded; and~~

~~(6) The lot number or pharmacy reference number.~~

~~In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s).~~

~~(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.~~

~~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. Exempt from the requirements of this paragraph are those sterile drug preparations compounded within a health care facility solely for administration, by a licensed health care professional, to a patient of the facility. To be treated as such, the "health care facility" must be licensed under Health and Safety Code section 1250.~~

~~(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a~~

~~statement that the drug has been compounded by the pharmacy. 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 of the preparation, pharmacy reference or lot number, and expiration beyond use date and shall not be subject to minimum font size requirements.~~

~~(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) 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), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).~~

~~(e) All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”~~

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 policies and procedures ~~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. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for

disciplinary action.

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

(c) The policies and procedures ~~manual~~ shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes or to the policies~~ or procedures ~~manual~~.

(2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product preparation~~ where subsequent ~~verification information~~ demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) ~~The p-P~~ 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.

(4) ~~The p-P~~ 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.

(45) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.

(56) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures manual by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures manual approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and

daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) 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 within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

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 compound~~ing of ed~~compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned 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, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded ~~in writing~~ in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-

contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of ~~12~~30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of ~~at least~~ 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the [insert effective date upon adoption] amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

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) A pharmacy engaged in compounding shall maintain documentation ~~that demonstrates demonstrating that~~ personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation ~~that demonstrating that all~~ personnel involved in compounding ~~was~~ are trained in all aspects of

~~polices and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the sterile compounding process. 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. Additionally, documentation demonstrating that staff have been trained on all polices and procedures shall be maintained.~~

(b) The pharmacy shall develop and maintain an ongoing 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 analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled

strength, including the frequency of testing, ~~analysis of compounded drug products~~  
~~preparations~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~  
~~preparations~~ shall be retained by the pharmacy and ~~collected~~ maintained along with the  
compounding ~~log record document~~ and master formula document. The quality assurance plan  
shall include a schedule for routine testing and analysis of specified compounded drug  
preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual  
basis.

(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 outside~~  
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 within the pharmacy ~~or~~ and within patient care areas of a hospital  
where furnished drug is returned for redispensing.

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 or~~ cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 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 505.5 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, 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. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

(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 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better ~~buffer area or~~ cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, ~~with the exception of emergency eye-rinsing stations.~~ A sink may be located in an ante-area. ~~(A) When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) they the sterile compounding area is are exempt from the room requirement listed in 1751(b)(3).~~

~~(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, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

~~(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, and 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), any pharmacy engaged in any compounding of for sterile drug products preparations compounded from one or more non-sterile ingredients, shall make and keep maintain the following records, which must be~~ must be made and kept by readily retrievable, within the pharmacy:

(1) ~~The Documents evidencing training and competency evaluations of employees in sterile product~~ drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments 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 tests.

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

(5) Video of smoke studies in all ISO certified spaces.

(2) ~~(5)~~(6) Documents indicating daily ~~recording~~ ~~documentation~~ of room, R refrigerator, and freezer temperatures appropriate for sterile compounded 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)~~(7) Certification(s) of the sterile compounding environment(s).

(7) ~~(8)~~ Documents indicating daily ~~documentation~~ ~~recording~~ of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

(4) ~~(9)~~(9) Other facility quality control logs-records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

(5) ~~(9)~~(10) Logs or other documentation of ~~I~~-inspections for expired or recalled pharmaceutical products or raw ingredients-chemicals, bulk drug substances, drug products, or other ingredients.

(6) ~~(10)~~(11) Preparation records including the master ~~formula document~~ ~~work sheet~~, the preparation ~~compounding log document~~ ~~work sheet~~, and records of end-product evaluation ~~testing and~~ 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, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, ~~and~~ license type and number of the 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 California Code of Regulations, title 16, sections ~~1707.5 and~~ 1735.4, a pharmacy ~~which that~~ compounds sterile ~~injectable drug products preparations~~ shall include the following information on the labels for each such those products preparation:

(a) ~~The~~ ~~Telephone~~ number of the pharmacy. ~~except~~ The telephone number is not required on the label for sterile injectable drug products preparations ~~dispensed administered~~ for to inpatients of a within the hospital pharmacy.

~~(b) Name (brand or generic) and concentration strength, volume, or weight of each active ingredients contained in the sterile injectable drug product preparation.~~

~~(c)~~ Instructions for storage, ~~and~~ handling, ~~and administration.~~

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

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 drug preparations shall maintain ~~a~~ written policies and procedures ~~manual~~ for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, ~~there shall be~~ written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling ~~=~~ and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

~~(9)~~(9) Facility management including certification and maintenance of controlled environments and related equipment.

~~(9)~~(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

~~(10)~~(11) Hand hygiene and garbing.

~~(11)~~(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

~~(12)~~(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations. ~~Media fill testing procedure.~~

~~(13)~~(14) Orientation, training, and competency evaluation of staff in all aspects of the

preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

~~(14)~~(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

~~(15)~~(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(16)~~(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(17)~~(18) Proper use of equipment and supplies.

~~(18)~~(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

~~(19)~~(20) Record keeping requirements.

~~(20)~~(21) Temperature monitoring in compounding and controlled storage areas.

~~(21)~~(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

~~(22)~~(23) Use of automated compounding devices (if applicable).

~~(23)~~(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products preparations shall maintain a written policies and procedures manual for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action, 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 product compounded drug preparations based on the~~

~~intended route of administration and recommended rate of administration.~~

~~(3) Proper use of E equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable drug products. Hand hygiene and garbing.~~

~~(5) Procedures for handling cytotoxic agents. Media-fill testing procedure.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(8) Compounded sterile drug preparation stability and beyond use dating.~~

~~(9) Visual inspection and other final quality checks of sterile drug preparations.~~

~~(10) Use of automated compounding devices (if applicable).~~

~~(11) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.~~

~~(12) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.~~

~~(13) Airflow considerations and pressure differential monitoring.~~

~~(14) Cleaning and maintenance of ISO environments and segregated compounding areas.~~

~~(15) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.~~

~~(16) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.~~

~~(17) Temperature monitoring in compounding and controlled storage areas.~~

~~(18) Facility management including certification and maintenance of controlled environments and related equipment.~~

~~(19) Action levels for colony forming units (CFUs) detected during viable surface testing, sampling, glove fingertip, and volumetric viable air sampling.~~

~~(b)(20) The determination and approval by a pharmacist of 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)(21) 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. Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(22) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(23) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.~~

(b) For lot compounding, the pharmacy shall maintain ~~a~~ written policies and procedures ~~manual~~ that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formulas ~~s documents~~ and compounding ~~logs documents work sheets~~.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain ~~a~~ written policies and procedures ~~manual~~ for compounding that includes, in addition to the elements required by section 1735.5, ~~and~~ 1751.3(a), ~~and 1751.7(e)~~, written policies and procedures regarding the following:

(1) ~~Process validation for chosen s sterilization methods and shall include sterilization method suitability testing for each master formula document.~~

(2) End-product evaluation, ~~quantitative~~, and ~~qualitative~~ testing.

(d)(1) ~~All written p~~ Policies and procedures ~~manuals and materials~~ shall be immediately available to all personnel involved in ~~these~~ compounding activities and ~~to~~ board inspectors.

~~(d)(2)(e)~~ All personnel involved must read the policies and procedures before compounding

~~sterile injectable products drug preparations, and any~~ All personal involved must read all additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding. This Each review must be documented by a signature and date.

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

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area.~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. 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.~~

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.**

(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: Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.~~

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently ~~(at least every 30 minutes)~~, including:

(1) At the beginning of each shift;

(2) ~~At least every 30 minutes when compounding involving human staff is occurring or~~ before ~~and after~~ each lot;

(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 daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent 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 air quality. 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-003-2006-131, Revised ~~January 31, 2012~~ May 20, 2015). Certification records must be retained for at least 3 years. Unidirectional ~~€~~compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 ~~buffer area or~~ cleanroom if the isolator is certified to 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 or are not located within an ISO Class 7 ~~buffer area cleanroom~~ 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 cytotoxic sterile hazardous agents shall do so in accordance with Section 505.125.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. ~~The hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-131, Revised ~~January 31, 2013~~ May 20, 2015). ~~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.~~ Certification records must be retained for at least 3 years. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, ~~complete with.~~ Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and ~~two layers of gloves with the outermost glove tested to meet two pairs of sterile~~ ASTM D6978-05 standard gloves. ~~Where the documentation provided by CAGI manufacturer does not require garbing, only the two glove requirement shall apply.~~

(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) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least ~~quarterly~~ every six months for all sterile-to-sterile compounding and ~~monthly~~ quarterly for all non-sterile-to-sterile compounding.

Volumetric Viable air sampling shall be done by ~~impaction~~ volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and ~~volumetric viable~~ air sampling shall be performed 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. Viable 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 pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area ~~is in the~~ pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-~~24~~ degrees Celsius (68-~~75~~ degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

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. ~~unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing is not required.~~ For hazardous compounding double shoe covers are required.~~

~~(2) Cleanroom garb Personal protective equipment must be donned and removed outside the designated area in an ante-area or 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 any wrist, hand, finger, and or wrist other visible jewelry or piercing must be eliminated. jewelry, piercing, headphones, earbuds, or personal electronic device. ~~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 or~~ cleanroom. 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 ~~exposed~~ rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections ~~or other communicable disease~~, or those wearing cosmetics, ~~nail polish, or artificial nails~~ shall be excluded from the ISO Class 5 and ISO Class 7 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 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). ~~Exceptions are as listed in 1751.4(g).~~

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 ~~drug 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 or greater of volume transferred during the selected manipulations.~~

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

(G) General conduct in the controlled area (aseptic area practices).

(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 using models that are comparable to the most complex manipulations to be performed by the

individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. 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 ~~Quality Assurance 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) Documentation justifying the chosen expiration beyond use dates for compounded sterile ~~injectable drug products~~ preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug 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 the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic 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 or greater 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 promote 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. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, 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.~~

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all compounding personnel each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug 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.

~~(c)-(e)~~(1) Batch-produced sterile ~~injectable~~ drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), ~~non-sterile-to-sterile batch drug preparations~~ shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogen, per USP chapter 85 limits, 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. Exempt from pyrogen testing are ~~non-injectable~~ topical ophthalmic and inhalation preparation.

~~(2)~~ The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

~~Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients. Non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, 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.~~

~~(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 conformity with and 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 does not exceed ~~the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation~~ ~~the expiration date or beyond use date provided by the manufacturer for any component in the preparation~~, and that, 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 (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify ~~a more an~~ extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area ~~or compounded entirely within a CAI or CAGI~~ which ~~meets the requirements in 1751.4(f)(1)-(3)~~, 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 ~~or spiked transfer devices~~, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature in solid frozen state~~, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area ~~or compounded entirely within a CAI or CAGI~~ ~~which meets the requirements in 1751.4(f)(1)-(3)~~, 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.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature in solid frozen state~~, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, ~~regardless of intervening sterilization of that ingredient and the following applies: 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.~~

~~For the purposes of this subdivision, "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.~~

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI ~~or CAG~~ which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile 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.

(e) 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. A PEC used solely to compound ‘immediate use’ preparations need not be placed within an ISO Class 7 ~~buffer area or~~ cleanroom, with an ante-area. (4) 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.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

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 ~~shall be labeled with a beyond use date BUD and~~ 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. ~~A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.~~

(3) ~~If the puncture time is not noted on the container, the container must immediately be discarded.~~

(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 shall be labeled with a beyond use date BUD and 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 storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

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 ~~injectable 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.

**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 1:1,000;

(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 policies 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~~ 1753.

(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~~ 1753.

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

# **Compounding**

## **First 15-Day Comments**

Code Section	Commenter	Comment
1735(b)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Add wording to indicate that the examples are not all inclusive and specifically the categories of "ophthalmic" and "otic" to the list of products where "Compounding" does not include "reconstitution". Use the following language :"(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), such as for ophthalmic otic, 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.</p> <p>Rationale: Several of the most popular products are ophthalmic products that only have to be reconstituted following manufacturer's instructions.</p> <p>The proposed language is missing some very common and important categories of products that the standards of practice do not call for extra specified conditions, such as Phospholine Iodide eye drops. Relying on the term "topical" to include such categories is unrealistic and adding some specific terms will reduce confusion.</p>
1735.1(a)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: "Ante-area" means and ISO Class 8 or better air quality for a positive pressure buffer area or ISO Class 7 or better air quality for a negative pressure buffer area....."</p> <p>Rationale: To be in alignment with USP Chapter 797, the Ante-area for a negative pressure buffer area must be ISO Class 7 or better air quality. The Ante-area for a positive pressure buffer area may be ISO Class 8 or better air quality.</p> <p>An ISO Class 8 Ante-area is inappropriate for a negative pressure buffer area.</p>
1735.1(c)	<b>Jeffrey Nehira</b> Dignity Health	<p>Recommend removing added text, "Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet should be appropriately removed by properly designed external building ventilation." This is currently not a requirement of USP&lt;797&gt; or current hazardous compounding regulation and does not have foundation in evidenced base practice.</p>
1735.1(c)	<b>Michael Tou</b> Providence Health	<p>Proposed Text: Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet should be appropriately removed by properly designed external building ventilation.</p> <p>Providence requests the board issue exemptions to hospital pharmacies which are unable to immediately comply with the requirements of section 1735.1(c).</p>
1735.1(d)	<b>Jeffrey Nehira</b> Dignity Health	<p>Recommend using USP&lt;797&gt; definition of buffer area, "Buffer Area-An area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.</p>
1735.1(d)	<b>Jeffrey Nehira</b> Dignity Health	<p>Recommend using USP&lt;797&gt; definition, "A container of a sterile preparation for parenteral use that contains many single doses."</p>
1735.1(e)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	<p>For hazardous compounding at least <del>30</del> 12 air changes per hour of HEPA- Filtered supply air and a negative pressure of at least 0.01inches of water column relative to all adjacent spaces is required.</p> <p>To remain consistent with 1735.6,e,1(p. 17) and USP 797, recommend changing number of air changes per hour required for hazardous drug preparation areas from 30 to 12.</p>
1735.1(e)	<b>Jeffrey Nehira</b> Dignity Health	<p>Recommend removing the requirement for HEPA-filtered air. This is not in USP&lt;797&gt; and is not required. If an IV room has lower particulate matter of ISO-7 or better, this in itself decreases the risk for contamination. ISO-5 areas where compounding occurs should have HEPA filtered air, as those are the locations of actual manipulation. HEPA filtration of the room will not necessarily reduce any incidence of contamination and is a costly upgrade for any compounding facility; especially hospitals which typically have low risk due to the short turn around times from the preparation of a medication to administration.</p>

1735.1(e)	<b>Doug O'Brien</b> Kaiser Permanente	Recommendations:  1. Adopt the USP Chapter 797 definition for buffer area, "An area where the primary engineering control is located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs."  2. Adopt the USP Chapter 797 definition for cleanroom: "A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class." This definition accommodates all acceptable cleanroom configurations including cleanrooms with the displacement airflow method design.  3. Allow the use of the displacement airflow method design for positive pressure buffer areas (1735.1(n)). This design utilizes a high airflow principle rather than a door and pressure differentials between the Buffer Area and the Ante Area.  4. Delay implementation of the requirement for a negative pressure buffer area for compounding hazardous drugs until USP Chapter 800 is finalized.  <b>Continued in Next Row</b>
1735.1(e)	<b>Doug O'Brien</b> Kaiser Permanente	<b>Continued from Previous Row</b>  5. If a negative pressure room requirement will be included in the Regulations, allow an adequate period for the phase-in of this design. For some facilities, this redesign process could take several years due to numerous factors including physical constraints within the facility, cost of the redesign, and time to obtain the appropriate permits from regulatory agencies such as OSHPD.  Rationale: Combining the definition of cleanroom and buffer area is non-standard, confusing, and inaccurate as the most common "cleanroom" designs include both a Buffer Area and an Ante-Area. For example, a cleanroom could also be a physically separate room that contains a buffer area, in which the air quality is ISO Class 7 or better; and an ante area, in which the air quality is ISO Class 8 or better. Displacement airflow concept described in 1735.1 (n) could be used.  USP Chapter 797 allows for the compounding of low volumes of hazardous drugs in a positive pressure buffer area with appropriate primary engineering controls.  Remodeling and construction costs exceeding \$75 million to convert existing cleanrooms in KFH hospitals and Ambulatory Oncology Infusion Centers to provide separate positive pressure and negative pressure buffer areas and eliminate all cleanrooms with the displacement airflow method of design
1735.1(e)(1)	<b>Jeffrey Nehira</b> Dignity Health	Pt1. This statement is confusing with regard to the addition of "buffer area" to the clean room definition. If a room has both a buffer area and a designated ante area the pressure differential would be between the ante area and the adjacent space.  Pt.2 The recommendation of the differential positive pressure of 0.02 to 0.05 inch is not standard practice. Recommend following USP<797> 2014 pg13, "The pressure between the ISO Class 7 (see Table1) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.

1735.1(e)(1-2)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	<p>(e) (1) References a minimum range of pressure. Implying anything outside of this range is not allowed. We recommend the following:  (1) For nonhazardous sterile compounding a minimum positive pressure differential of 0.02 inch water column relative to all adjacent spaces is required.</p> <p>(e) (1) and (2) Nothing in these sections references “sterile preparations” we recommend the following:</p> <p>(e) “Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located, typically utilized for sterile compounding.  (1) For nonhazardous sterile compounding a minimum positive pressure differential of 0.02 inch water column relative to all adjacent spaces is required.  (2) For hazardous sterile compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of at least 0.01 inches of water column relative to all adjacent spaces is required.</p>
1735.1(e)(2)	<b>Jeffrey Nehira</b> Dignity Health	This statement does not correspond with current CETA engineering requirements compared with USP<797>. The amount of Air Changes Per Hour (ACPH) required should be dependent upon the volume of hazardous compounding done as well as risk category (low, medium, versus high). Room pressure differentials should also be dependent on both compounding volume and risk category. Recommend reclassifying this requirement according to CETA flowchart of Engineering Control Requirements for Hazardous Drugs revised May 2009 (see attached document).
1735.1(e)(2)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: USP 797 makes the stipulation of 12 air changes per hour as the air displacement requirement when compounding hazardous drugs. In addition, this is a contradiction to the same proposed BOP regulations in 1735.6 (e) (1) where it states that for hazardous drug compounding, 12 air changes per hour are sufficient.</p> <p>Solution: Replace the 30 ACPH with 12 ACPH in this section in accordance with USP 797 and in accordance with these same proposed BOP regulations in 1735.6 (e) (1).</p>
1735.1(e)(2)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	<p>In the proposed USP Chapter &lt;800&gt;, alternate ACPH requirements are being offered that are fewer air changes than what is being proposed in this modified text depending upon the type of hazardous drug being compounded (nonsterile or sterile) and the facility configuration. Please consider adding alternate ACPH requirements that are consistent with the proposed USP Chapter &lt;800&gt;.</p> <p>If the BOP adopts the modified text as proposed, please consider establishing reasonable timelines and expectations for compliance so as not to severely limit patient access to needed care or place tremendous burdens on patients and those supporting their care to travel to a facility that is compliant with the regulation.</p> <p>Outside of the costs and time necessary to complete facility modifications to meet this requirement, there could be negative impacts if a pharmacy could not continue to provide the potentially life-saving “hazardous” medications needed as a facility works towards gaining compliance with the requirement. Some geographic areas of the State may not have a nearby health facility to provide this type of service or the ability to handle the order volume currently managed by the Pharmacy.</p>
1735.1(f)	<b>Jeffrey Nehira</b> Dignity Health	This statement does not correspond with current CETA engineering requirements compared with USP<797>. Recommend reclassifying this requirement according to CETA flowchart of Engineering Control Requirements for Hazardous Drugs revised May 2009 (see attached document).

1735.1(f)	<b>Douglas Barcon</b> Barcon & Associates	Between “unidirectional” and “compounding” insert: unidirectional HEPA-filtered airflow.  Consider strengthening (change should to must) and rewriting for clarity (not physical location of duct): “Where volatile hazardous drugs are prepared, the exhaust air from the isolator <del>should</del> <u>must</u> be vented externally by properly designed building ventilation.”
1735.1(g)	<b>Douglas Barcon</b> Barcon & Associates	Between “unidirectional” and “air” insert: HEPA-filtered
1735.1(i)	<b>Jeffrey Nehira</b> Dignity Health	Calculation of C to F does not take into account significant figures. Suggest 2-8 degrees C(35 to 46 degrees F) as this is typically the temperature range posted for refrigeration. This is consistent with the calculation of Controlled Freezer temperature and Controlled Room temperature following this definition in the regulation.
17351(l)	<b>University Compounding Pharmacy</b> Joe Grasela	Definition should be changed to keep it consistent with the Federal law section 503A which is what most typical compounding pharmacies are and follow.  “Copy or essentially a copy” of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change made for an individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.  503A regarding “essentially a copy”. (D) Does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.” Definition: For purposes of paragraph (1)(D), the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.'
17351(l)	<b>University Compounding Pharmacy</b> Joe Grasela	<b>Continued in Next Row</b>  <b>Continued from Previous Row</b>  Reasons for change: The Federal definition state “significant difference” only vs the proposed language of “clinically significant difference” (1) Most pharmacies do not have access to patient charts therefore to include “clinically significant difference, as determined by a prescribing practitioner” implies that for every compounded prescription the pharmacist is supposed to followup with the practitioner and document the clinical significance which will impose more issues. Issues include: (1) Contacting the physician for every single prescription. (2 &3)Which will delay the prescription from being compounded therefore delaying therapy to the patient. (4) Contacting physicians frequently for followup/notation of “clinically significant difference” will over burden the MD office (5)Was this cleared by the AMA or medical board to impose on a physician to notate/determine the clinical significance when using a compound that is “essentially of copy”? Is this included in medicine law? (6) Are we now interfering with the practice of medicine? (7) Overall, including that statement “clinically significant difference” will cause unnecessary burden on the physician, patient, and pharmacy. (8) The law is unenforceable for out of state pharmacies because they follow their state laws. BOP does not inspect out of state pharmacies for non-sterile compounded preparations which is the majority of the compounding business.
1735.1(m)	<b>Jeffrey Nehira</b> Dignity Health	Defining daily as every 24 hours is not correct and will provide future problems with definitions which conflict with national standards. Daily is defined within the 24 hours of a calendar day. 24 hours extremely restricts the use of the term daily and is confusing when defining standards of practice. If requirements are to be defined within 24 hours, they should state that in the regulation.

1735.1(m)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: remove “daily means every 24 hours” as this would imply within the hour of exact same time for measurement to be recorded each day. In the hospital setting, critical patient care issues may interrupt normal routines delaying the recording of the temperature if continuous or electronic monitoring not in place. Twice yearly time changes would also impact.
1735.1(n)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	<p>The verbiage in USP 797 specific to “displacement concept” reads, “The displacement concept shall not be used for high-risk compounding.” The reference cited “ISO 14644-4:2001 Cleanrooms and associated controlled environments-Design, construction, and start-up” includes section A.5.2 which describes the displacement concept. The displacement concept is described in this reference as a means to effectively separate clean and less clean adjacent zones without any mention of hazardous compounds or chemotherapy. As such, the term “high-risk” should be taken to mean high risk of microbial contamination as described in USP &lt;797&gt; and should not be taken to mean hazardous compounds.</p> <p>Some facilities are currently meeting the “low volume” exemption described in USP &lt;797&gt;, hazardous CSP prepared in an ISO 5 CACI using closed-system transfer devices. The PEC (CACI) is located in the ISO 7 buffer area (located in a positive pressure room where the buffer area is not physically separated from the ante-area and the principle of displacement airflow is employed. Adopting the language as proposed will put some facilities in this state out of compliance limiting patient access to needed cancer care or placing tremendous burdens on patients and those supporting their care to travel to a facility that is compliant with the regulation.</p> <p>Please consider the following remedies:</p> <ol style="list-style-type: none"> <li>1. If the modified text is adopted as proposed, please establish reasonable timelines and expectations for compliance and a process for waiver application that would allow facilities to continue to provide services out of their existing sterile compounding pharmacies as they work to gain regulatory compliance.</li> <li>2. Please delete the language “or for hazardous compounds” and consider reintroducing at a later time after fully assessing impacts to Pharmacies holding compounding licenses in this state and establishing reasonable timelines for gaining compliance.</li> <li>3. Please consider deleting 1735.1(n) in its' entirety. The term “displacement airflow method” is not used in 16 CCR Articles 4.5, 7 or 7.5 except in the proposed definition.</li> </ol>
1735.1(n)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: “Displacement airflow method: For buffer areas not physically separated from the ante-areas, this concept utilizes a low pressure differential, high airflow principle. The principle of displacement airflow shall require an airflow velocity of 40 ft per minute or more from the buffer across the line of demarcation into the ante-area.”</p> <p>Rationale: USP Chapter 797 allows the compounding of low volumes of hazardous drugs within a positive pressure buffer area with the displacement airflow method of design, with appropriate primary engineering controls.</p> <p>Remodeling and construction costs exceeding \$75 million to convert existing cleanrooms in KFH hospitals and Ambulatory Oncology Infusion Centers to provide separate positive pressure and negative pressure buffer areas and eliminate all cleanrooms with the displacement airflow displacement method of design.</p>
1735.1(s)	<b>Douglas Barcon</b> Barcon & Associates	Should include NIOSH hazardous drugs that are not anti-neoplastic to provide additional guidance for the pharmacist-in-charge and to help ensure that staff does not inadvertently handle a hazardous drug as non-hazardous because the PIC overlooked it. Suggest adding “or NIOSH” at end after “pharmacist-in-charge.”

1735.1(u)	<b>Doug O'Brien</b> Kaiser Permanente	<p>The wording of this definition is confusing and requires clarification. We believe "lot" could be interpreted two different ways.</p> <p>1. It could be interpreted to include different types of preparations that are prepared during one uninterrupted continuous cycle of compounding. A typical example of this interpretation in a hospital pharmacy: compounding four doses of azithromycin 500 mg/250mL dextrose 5% for four different patients, and two doses of famotidine 40 mg in 250mL dextrose 5% 250mL for one patient, and five doses of furosemide 100mg/100mL dextrose 5% for five different patients. All of these would be prepared in an uninterrupted continuous cycle of compounding.</p> <p>Recommendation: If the above example is the intended interpretation, then we recommend this language: "Lot" means one or more different compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s)."</p> <p>2. It could be interpreted to mean a single type of drug preparation compounded during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s). Using the example above, four doses of azithromycin 500 mg/250mL dextrose 5% for four different patients would be considered one lot.</p> <p>Recommendation: If interpretation #2 is correct, then we recommend this language: "Lot" means a single type of drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s)."</p>
1735.1(u)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	<p><del>"Lot" means one or more-</del> <b><u>"non-sterile to sterile batch" which means any compounded drug preparation containing two or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.</u></b> <del>compounded drug preparation(s) during one uninterrupted continuous cycle of compounding from one or more common active-ingredient(s).</del></p> <p>OR</p> <p>Alternatively, recommend changing definition of "lot" to "greater than one dose" in order to ensure timely preparation of compounded drugs to treat emergency patients' conditions where immediate administration of medications is essential. When medications are prepared as single doses, time is of the essence and documentation requirements for a lot would delay patient treatment.</p> <p><del>"Lot" means one or more-</del> <b><u>greater than one dose of compounded drug preparation prepared in anticipation of immediate patients needs.</u></b> <del>compounded drug preparation(s) during one uninterrupted continuous cycle of compounding from one or more common active-ingredient(s).</del></p>
1735.1(v)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	<p>Recommendation/ Comments: we had several people review this statement to determine the intent. The range in answers was an exact copy of the process to make a critical product which many not have complex manipulations versus a complex serial dilution for a neonate. The complexity changes in an ever changing environment and staff are tested throughout the year. We would like to update the process on an annual basis based on what we would determine to be complex and error prone.</p>
1735.1(x)	<b>Jeffrey Nehira</b> Dignity Health	<p>Suggest redefining this term. Confusion can result by defining the term "parenteral" other than what it actually is. For example, the transdermal route of administration was omitted. Suggest using a more common definition of the term parenteral and removing specifics added in the new language.</p>

1735.1(x)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	The phrase “. . . administration into the eye” can include ophthalmic drops. The phrase “. . . administration into the eye” should be changed to “injection into the eye”.
1735.1(z)	<b>Jeffrey Nehira</b> Dignity Health	Suggest adding an appendix of USP34-NG32, 37th Revision referencing "Potency" to the policy for easier referencing of USP version required in CA Pharmacy Law. This has changed since the last draft and should be reviewed through the BOP for adoption when changes are made.
1735.1(z)	<b>Doug O'Brien</b> Kaiser Permanente	Recommendation: “Sterile injectable preparations compounded solely from commercially manufactured sterile pharmaceutical products are exempt from this definition. For those exempt, the range may be calculated and defined in the master formula.”  Rationale: All pharmacies with sterile compounding permits should be able to benefit from the exemption  Consistency of the regulations
1735.1(z)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: USP 797 only describes potency in terms of ensuring potency by monitoring controlled storage areas. In addition, considering the many drugs that could be compounded (biosimilars, immune mediators, blood derivatives, etc) it may be too arbitrary to put such a hard limit on this definition.  Solution: Remove section that defines “potency” altogether.
1735.1(ab)	<b>Doug O'Brien</b> Kaiser Permanente	Recommendation: Eliminate from the Proposed Regulation this unsafe narrowing of the definition of a “Prescriber’s Office”. Rationale: Prescribers have not provided care for several decades in what once was a solo practitioner’s medical office facility. In fact for decades there have been many additional categories of “prescribers” that are authorized under State statutes to dispense or “furnish” and administer medications to their own patients in their practice sites, e.g. Nurse Practitioners. Such additional dispensing clinicians have not, however been trained in safe and appropriate compounding required by current standards. Also many categories of sites of clinician practice have come to rely on pharmacists to compounded products to provide medical care for special patient needs and or in special situations. These sites include but are not limited to Licensed Clinics and small hospitals (99 beds or less) such as rural and/or specialty hospitals that are not required to have a pharmacy or pharmacist. This proposed Regulatory definition would lead to dangerous compounding and/or sub-optimal care in such facilities by either compounding by less qualified personnel or deferral of the care provided by pharmacist-compounded products. The Board’s intent may be to force such facilities/clinicians to obtain such products that are not available from traditional suppliers (e.g. FDA registered manufacturers.), from FDA or State licensed “Outsourcing” facilities/entities. However there are and will be many situations when based on the cGMP rules such facilities or entities will have to follow, supplying these true “prescriber’s offices” will neither be a reality within the time needed nor a commercial practicality. Thus the ability of properly trained and qualified pharmacies in properly designed and equipped facilities to supply these clinician practice sites is vital to safe and effective patient care.  Decreases patient safety Encourages sub-optimal medication therapy.
1735.1(ac)	<b>Jeffrey Nehira</b> Dignity Health	Recommend removing the wording "...through the use of unidirectional HEPA filtered first air." from the definition as it also is not in USP797. Although it is implied that through the PEC directional flow would be one way, most negative pressure glove boxes can be configured for both positive and negative pressure.

1735.1(ac)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: The inherent definition of a PEC is that it has the ability to produce/provide ISO Class 5 or better air environment. Many Sterile Compounding Automated Robots that are available and that are in production have no intention of being able to create/produce/provide an ISO Class 5 (or any air class for that matter). These automated robots are made to be simply put or placed in the appropriate air environment (ISO Class air).</p> <p>Solution: Remove sterile compounding automated robots from the PEC definition and just make the stipulation that they should be used in an appropriate ISO Class 5 or 7 environments.</p>
1735.1(ag)	<b>Jeffrey Nehira</b> Dignity Health	<p>The USP 797 definition of a Segregated compounding area is "a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12 hour or less BUD". The proposed language does not correspond to standard of practice which exist and is defined.</p>
1735.1(ag)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Allow compounding of hazardous drugs in a segregated compounding area within a CACI by removing the language "non-hazardous". The applicable sentence would read, "The segregated sterile compounding area shall be restricted to preparing non-hazardous sterile to sterile compounded preparations."</p> <p>Rationale: The USP Chapter 797 definition of a segregated compounding area is "a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12 hour or less BUD".</p> <p>USP Chapter 797 allows placement of a CACI (used for hazardous drug compounding) in less clean than ISO Class 7 areas if the following conditions are met:</p> <ul style="list-style-type: none"> <li>-The isolator shall provide isolation from the room and maintain ISO Class 5 during the dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs</li> <li>-Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations</li> <li>-Not more than 3520 particles per m<sup>3</sup> shall be counted during material transfer, with the particle count probe located as near to the transfer door as possible without obstructing the transfer.</li> </ul> <p>Section 1735.6(e) delineates requirements for hazardous drug compounding facilities. The requirements described in this section are referring to a segregated compounding area as described in the draft language of USP Chapter 800. This section implies that it is appropriate to compound hazardous drugs within a segregated compounding area with the appropriate engineering controls.</p> <p>Concordance with USP Chapter 797 National Standards and the current version of USP Chapter 800 National Standards Consistency of the regulations</p>

1735.1(ag)	<b>Douglas Barcon</b> Barcon & Associates	<p>The current draft of USP 800 (C151881) permits hazardous sterile preparations in a containment segregated compounding area (C-SCA), which is a separate room with negative pressure and at least 12 air changes per hour. It further states that low- and medium-risk HD compounded sterile preparations may be prepared in a BSC or compounding aseptic containment isolator (CACI) located in a C-SCA, provided the BUD of the CSP does not exceed 12 hours.</p> <p>There is no reference to a CACI tested by the manufacturer to comply with USP 797 in air worse than ISO Class 7, ISO Class 8, or unclassified air quality permitting full USP 797 beyond-use-dates for low and medium risk HDs as is specified for non-HDs in USP 797. I discussed this with and submitted my comment on this to the USP 800 committee for review in the current revision (C151881) of USP 800 that closed for comments on May 31, 2015.</p> <p>There has been no reason given that a hazardous preparation should be given a 12-hour BUD, while a non-hazardous preparation can have the full BUD duration. Hazardous drug preparation compounding should be permitted in a CACI with manufacturer compliance with USP 797 when located in a segregated sterile compounding area provided the area is negative pressure, externally vented, and has at least 12 ACPH.</p>
1735.1(ag)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units). The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. If one were to believe that this is an unverified study then one would have to question most of the conclusions derived from USP 797 as many of the conclusions taken from there are not based on “randomized controlled trials”.</p> <p>We believe that we can remove the 3 foot no sink/drain requirement when CACIs are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model.</p> <p>Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.</p>
1735.1(ah)	<b>Douglas Barcon</b> Barcon & Associates	Paragraph needs to be relabeled as (ah) because the previous paragraph is labeled (ag).
1735.2(c)(1)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	<b>Recommendation/ Comments:</b> In the health system, purchase orders and payment is processed by the University accounts payable or other systems, not by the physician directly.
1735.2(c)(1)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	<p>The phrase “. . . and paid for by the prescriber” suggests that only the prescriber may pay for the medication. Many prescribers belong to a practice and as with any business entity the entity pays for purchases, not the individual member or employee. We suggest the following:</p> <p>(1) Is ordered by the prescriber or the prescriber’s agent and paid for by the prescriber or their practicing entity.</p>

<p>1735.2(c)(1) &amp; 1735.2(c)(3)</p>	<p><b>Doug O'Brien</b> Kaiser Permanente</p>	<p>Recommendation #1: Clarify that the prescriber does not have to personally pay for the medication supplied to the prescriber for office use by adding the phrase "or the prescriber's agent" as shown below. Rationale: Not all prescriber's are in private solo practice and the medications they use in the prescriber's office are actually paid for by either the prescriber's group entity or another entity that is responsible for the cost of the patient's care, e.g. a county or city government, the State or even a private health plan or clinic. "1) Is ordered by the prescriber or the prescriber's agent and paid for by the prescriber or the prescriber's agent..."</p> <p>Recommendation #2 Do not eliminate the ability of pharmacies to compound for prescriber's office use by changing decades of vital history that has allowed a prescriber to dispense from the prescriber's office up to at least a 72-hour supply of pharmacy compounded medication. In fact, as the Board's rationale of acceptance for allowing "...a 120-hour supply for veterinary medical practices..." should be also allowed for human medical care. Rationale: For over 30 years, the Legislature's authorization for pharmacists' ability to compound preparations for prescriber "for office use by the prescriber" (B&amp;P Code 4052(1)(a) has been interpreted to include BOTH for administration in the office and for DISPENSING to a patient for up to a 72-hour supply. Under State law prescriber's are allowed to dispense prescription medications to their own patients. This Board proposed will effectively narrow the scope of practice of physicians and other prescribers without a discussion via the Legislature of that vital State policy.</p> <p>The proposed regulation language will remove the allowance for pharmacists to compound for any prescriber for dispensing - except for veterinarians. [See Proposed regulation Section 1735.2(c)(3)]</p> <p><b>Continued in Next Row</b></p>
<p>1735.2(c)(1) &amp; 1735.2(c)(3)</p>	<p><b>Doug O'Brien</b> Kaiser Permanente</p>	<p><b>Continued from Previous Row</b></p> <p>This change in pharmacy scope of practice could hinder appropriate and safe human therapy in some situations where, by definition, the prescriber has asked a pharmacy to compound a product to either keep on hand for a potential human need (just like the Board's rationale for allowing the compounding for animal therapy). It will also encourage medication compounding by practitioners or health professionals with less education and training in compounding than pharmacists, e.g. physicians, dentists, etc. and nurses, etc., respectively. These potential adverse consequences were exactly what the Legislature was trying to avoid when the Statute was enacted decades earlier after it was alerted to such tragedies.</p> <p>Some examples of the need for allowing prescriber dispensing of pharmacy-compounded products, include when medication is unavailable for a type of patient with special needs, (such as an eye drop without preservatives) or when a commonly available critical medication is in reality not available from usual sources.</p> <p>Another increasing reason for allowing a prescriber to dispense a reasonable supply of a pharmacy compounded drug is to avoid unnecessarily increasing the cost of care or increasing the waste of safe and effective medication and the avoidable adverse effects on the environment of its unnecessary disposal. One example, is when the prescriber could administer a few drops of a pharmacy—compounded eye solution in the office but under the regulation change would have to discard the remainder of the container instead of dispensing it to the patient even though the patient would only need a few day's therapy or who would be unlikely to procure a continuous supply directly from a compounding pharmacy in the remaining 72 to 120 hours of therapy</p> <p><b>Continued in Next Row</b></p>

1735.2(c)(1) & 1735.2(c)(3)	<b>Doug O'Brien</b> Kaiser Permanente	<p><b>Continued from Previous Row</b></p> <p>The Board's apparent intent will be to discipline the pharmacy, Pharmacist-In-Charge and dispensing pharmacist if they knew or should have known that the prescriber was going to dispense the remainder of the bottle to the patient. Consequently it won't be done and prescriber's and patients will be denied this option without discussion via the Legislature.</p> <p>Just as for animal treatment, which the Board intends to allow, the ability for prescribers to dispense pharmacy-compounded medications is also important to situations where a compounding pharmacy will not be reasonably available, e.g. because of holidays, distance, expertise, proper equipment for sterile compounding, etc.. The Regulation will delay or interrupt vital therapy, such as immediate and continuous treatment of infections or relief of suffering. Situations that most likely can be avoided with the dispensing of the 72 to 120 hour supply.</p> <p>This change in statutory intent could also make care substantially more expensive for the patient whom would have to buy another supply of compounded medication at the pharmacy and/or for the organization responsible for the drug cost.</p>
1735.2(d)(2)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	<p>Subdivision (2) does not reference "human" drugs. As such, this would not allow veterinary preparations to be compounded that have been removed for human use, but are not necessarily unsafe or not effective for veterinary use.</p> <p>We recommend the following:</p> <p>(2) Appears on an 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 for human use; or</p>
1735.2(d)(3)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	<p>Subdivision (3) does not take into consideration medications needed for veterinary use. While some medications may appear on the ASHP list, the FDA list of veterinary drugs includes five drugs and is not updated on a regular bases. There is no other formal list of short supply or backordered veterinary drugs.</p> <p>We recommend the following:</p> <p>(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists), FDA list of drugs that are in short supply at the time of compounding, or for veterinary products the pharmacy shall document unavailability by the wholesaler or manufacturer, and at the time of dispensing, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.</p>

1735.2(i)	<b>University Compounding Pharmacy</b> Joe Grasela	<p>Definition should be changed to the following: This "beyond use date" of the compounded drug preparation shall not exceed the shortest expiration date of any ingredient in the compounded drug preparation, nor shall it exceed 180 days for non-aqueous formulations, 14 days for water-containing oral formulations, and 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations, unless a later date is supported by stability studies of finished drugs or compounded drug preparations using similar ingredients, specific and essential compounding steps, quality reviews, and similar packaging made from the same materials (ie: plastic, glass, etc).</p> <p>Reasons: (1) The extreme number of variations in customized, yet similar preparations, would prevent us from providing an adequate supply of compounds to the patient. This wording removes pharmacists judgment and is unnecessarily restrictive to the patient, affecting continuity of therapy. (2) This would inhibit our ability to compound for anticipatory prescriptions which we have on record that these patients are using for routine therapy. (3) Increased delay in therapy to the patient. (4) Patients will have to come back every 30 days for their prescriptions (5) Overall, unnecessary burden to the patient, and affects continuity of therapy/care. (6) The law is unenforceable for out of state pharmacies because they follow their state laws. BOP does not inspect out of state pharmacies for non-sterile compounded preparations which is the majority of the compounding business. (7) Patients that prefer their medications mailed to them (~5-7 days to mail), the drug would be expired if we sent a 30 day supply with a 30 day expiration date by the time they receive in in the mail. In effect they would get a 21 day supply and have to get their prescription filled every 21 days due to mailing delay</p>
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1735.2(i)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	<p>The use of the word “identical” in the phrase “. . . unless a later date is supported by stability studies of finished drugs or compounded drug preparations using identical ingredient, specific and essential compounding steps, quality reviews and packaging” is extremely limiting.</p> <p>USP states the following regarding BUDs:</p> <p>“BUDs should be assigned conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:</p> <ul style="list-style-type: none"> <li>• the nature of the drug and its degradation mechanism</li> <li>• the dosage form and its components</li> <li>• the potential for microbial proliferation in the preparation</li> <li>• the container in which it is packaged</li> <li>• the expected storage conditions</li> <li>• the intended duration of therapy (see General Notices and Requirements, Preservation, Packaging, Storage, and Labeling, Labeling, Expiration Date and Beyond-Use Date).</li> </ul> <p>We recommend the following:</p> <p>“. . . unless a later date is supported by stability studies of finished drugs or compounded drug preparations. The pharmacy shall assign BUDs conservatively. When assigning a BUD, compounders shall consult and apply drug-specific and general stability documentation and literature when available and should consider:</p> <ol style="list-style-type: none"> <li>(1) the nature of the drug and its degradation mechanism</li> <li>(2) the dosage form and its components</li> <li>(3) the potential for microbial proliferation in the preparation</li> <li>(4) the container in which it is packaged</li> <li>(5) the expected storage conditions, and;</li> <li>(6) the intended duration of therapy</li> </ol>
1735.2(i)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many CSP’s (e.g. reconstituted vials) that are a result of following manufacturer’s directions have labeling (supported by the manufacturer) that exceeds what is listed in this section for water containing formulations and water containing topical/dermal formulations. Furthermore, to expect that stability studies will be provided by the manufacturer in lieu of a general statement by the manufacturer stating the stability/sterility is not feasible. Many generic manufacturers do not have the infrastructure to accommodate inquiries by many pharmacies to provide them stability studies.</p> <p>Solution: Retract the examples of water containing oral formulations and water containing topical/dermal formulations from this section and replace the language with what was in the previous version. In addition, add the stipulation that a later date may be used for a CSP if the manufacturer provides communication regarding stability and sterility to support that claim.</p>
1735.3(a)(2)(E)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	<p>(a) (2) (E) Requires that if an expiration date is not provided by the manufacturer the pharmacy shall document the date of receipt on the compounding document. Section 1735.2 subdivision (k) restricts when the said component cannot be used. Requiring both the expiration and acquisition date of components on documents will lead to confusion and inconsistent record keeping.</p> <p>We recommend the following:</p> <p>(E) If the manufacturer does not supply an expiration date for any component, the records shall include the date beyond which the component shall not be used as the limitations of section 1735.2, subdivision (k) shall apply.</p>

1735.3(a)(2)(E)(i)	<b>Doug O'Brien</b> Kaiser Permanente	Recommendation: Include ambulatory oncology clinic pharmacies in the seventy-two (72) hour exception language, in a manner similar to inpatient pharmacies.  Rationale: Ambulatory oncology clinic pharmacies compound preparations in a similar manner to inpatient pharmacies
1735.3(a)(2)(H)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: Drugs are stored according to USP or manufacturer recommendations. We do not record the storage of each drug. This would be a labor intensive requirement to maintain these records and is not provided by electronic pharmacy inventory management systems in a readily retrievable format.
1735.3(c)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	The term "supplier" implies "wholesaler" consequently excluding manufacturers. We recommend the following: (c) Active ingredients shall be obtained from a wholesaler or manufacturer registered with the Food and Drug Administration (FDA).
1735.4(b)	<b>Douglas Barcon</b> Barcon & Associates	Should also include sterile drug preparations compounded in a centralized hospital packaging pharmacy for use with patients at affiliated health care facilities under common ownership as per B&PC regulation 4128.
1735.4(c)	<b>Jeffrey Nehira</b> Dignity Health	With regard to drug labeling I believe this regulation requiring both the names of the compounding pharmacy and dispensing pharmacy, if different, should also state, "if not apparent from the container". Products may come from multiple sources and this requirement currently states that the pharmacy label should have both names. This is impracticable if the original pharmacy label is apparent from the product and has the information required. (ex. TPN formulations prepared at an outsourced facility)
1735.4(e)	<b>Candace Fong</b> <b>Clara Evans</b> Dignity Health	Add: Alternate cleaning schedules may be submitted to the Board for fully automated robots  CHA appreciates the addition of robotics into the regulations and now requests to add alternate cleaning schedules to address their specific disinfecting needs. Cleaning at 30 minute intervals is unobtainable with robots that are totally contained.
1735.4(e)	<b>BJ Bartleson</b> California Hospital Association	Add: Alternate cleaning schedules may be submitted to the Board for fully automated robots  Dignity Health appreciates the addition of robotics into the regulations and requests to add alternate cleaning schedules to address specific disinfecting needs. Cleaning the robots at 30 minute intervals is unrealistic with robots that are totally contained
1735.5(a)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: Change shall to may or eliminate as unnecessary as regulations give the Board authority to take disciplinary actions.
1735.5(a)	<b>Douglas Barcon</b> Barcon & Associates	Suggest defining "material" and "material failure." The definitions used by the board in disciplinary actions would suffice, or alternatively the definitions from Black's Law Dictionary 6th and 9th Editions including such terms as significant, substantial, important, necessary, and essential.
1735.5(c)(4)	<b>Jeffrey Nehira</b> Dignity Health	Reference to "disinfecting the facility (physical plant) used for compounding" needs clarification. Regulations already exist for the requirements of cleaning walls, ceilings, etc. The reference to "the facility (physical plant)" is not defined in the definitions at the beginning of the document.
1735.5(c)(7-8)	<b>Jeffrey Nehira</b> Dignity Health	Recommend removal of the requirement for annual review. Although this is in current policy, this differs from other regulatory body requirements for hospitals. Request review, "at least every 3 years" or to similar verbiage in Title 22. Reference to "signed and dated by the pharmacist-in-charge" should be updated to include electronic signatures.
1735.5(c)(9)	<b>Douglas Barcon</b> Barcon & Associates	Suggest adding at end after the word pharmacy: "and as specified in 1735.8 (e) for health care facilities" for continuity

1735.5(c)(9)	<b>Jeffrey Nehira</b> Dignity Health	Need further clarification regarding room temperature storage. Currently regulation state that medications are stored at controlled room temperature, but there is no requirement for daily monitoring. Request an extended implementation date is this is now required for hospital settings.
1735.5(c)(10)	<b>Jeffrey Nehira</b> Dignity Health	Suggest and exemption for health care settings with a facility services policy regarding appropriate function of refrigeration devices.
1735.5(c)(10)	<b>Douglas Barcon</b> Barcon & Associates	Suggest adding at end after the word pharmacy: "and as specified in 1735.8 (e) for health care facilities" for continuity
1735.6(e)	<b>Rachel Taggs</b> <b>Shauna Doherty</b> Precision Pharmacies	Subdivision (e), including points (1), (2) and (3), are all included in the USP <800> draft, which has yet to be published. We ask that this section is removed until the new chapter has been made effective and no changes can occur.
1735.6(e)	<b>Jeffrey Nehira</b> Dignity Health	A physically separate room for low risk, low volume hazardous compounding is not required according to current standards of practice and does not take into account the use of CASis. This statement does not correspond with current CETA engineering requirements compared with USP<797>. Recommend ceiling, reclassifying this requirement according to CETA flowchart of Engineering Control Requirements for Hazardous Drugs revised May 2009 (see attached document).
1735.6(e)	<b>Brian Warren</b> California Pharmacist Association	<p>(e) <u>Beginning no later than January 1, 2020</u>, Hazardous drug compounding shall be completed in a physically separate room with the following requirements:</p> <p>(1) Minimum of 12 air changes per hour; and</p> <p>(2) Maintained at a negative pressure of at least 0.01 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and</p> <p>(3) All surfaces with the room shall be smooth, seamless, impervious, and non-shedding.</p> <p>During discussion by the Board of Pharmacy of the proposed modifications that added these requirements, the Board expressed an interest in an exemption process or delayed implementation of the hazardous room requirements.</p> <p>We support requirements that will protect pharmacy personnel and others from potential contact with hazardous drugs, though we would like to reiterate that USP &lt;800&gt; is still in draft form and caution against enacting regulations before USP finalizes the standard. Promulgating a separate rulemaking package to enact USP &lt;800&gt; standards after they are finalized would be a more prudent process.</p> <p>If the Board is intent on moving forward with these requirements as part of this rulemaking package, we recommend placing delayed implementation in the regulation until 2020. Given the extensive changes that these requirements could necessitate for some hospitals and pharmacies, some time will be necessary to allow for compliance. Delayed implementation is preferable to some sort of exemption process, because the latter would require detailed parameters that exemptions would have to be granted or denied based upon. Delayed implementation, on the other hand, allows pharmacies to begin compliance over a period of time, with a deadline of January 1, 2020</p>
1735.6(e)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: This would require physical plant alterations and would need a lead time of a minimum of 3-5 years to implementation given space and cost considerations and extent of mechanical systems to handle the venting and negative pressure requirements. We started an evaluation based on USP 800 proposed regs and are in active architect level design work and estimated completion is currently out 2-3 years if space and funding can be secured. There is equipment available that allows for containment and protection of staff which, if allowed by the board, provide an alternative either short or long term.

1735.6(e)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendations:</p> <ol style="list-style-type: none"> <li>1. Delay implementation of the requirement for a negative pressure buffer area for compounding hazardous drugs until USP Chapter 800 is finalized.</li> <li>2. If a negative pressure room will continue to be included in the Regulation, allow an adequate period for the phase-in of this design. For some facilities, this redesign process could take several years due to numerous factors including physical constraints within the facility, cost of the redesign, and time to obtain the appropriate permits from regulatory agencies such as OSHPD.</li> <li>3. Eliminate or reword item(3)</li> </ol> <p>Rationale: USP Chapter 797 allows the compounding of low volumes of hazardous drugs within a positive pressure buffer area with appropriate primary engineering controls.</p> <p>The language of Item(3) is ambiguous and confusing.</p>
1735.6(e)	<b>Douglas Barcon</b> Barcon & Associates	(1), (2), and (3) are fine, but should add an additional numbered line to include the proposed requirement in USP 800 for the room to be externally vented and the PEC to be externally vented. May want to shift current (3) to (4) to accommodate change.
1735.6(e)(1)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	As proposed, appears to conflict with 1735.1(e)(2). Is this section addressing sterile hazardous drug compounding in a segregated compounding area that is negative pressure?
1735.6(e)(2)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	Please strike the words within the parenthesis or provide guidance on how the pressure differential is monitored between the negative pressure room and the ceiling above it.
1735.6(e)(3)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	Typographical error change the word "with" to "within"
1735.6(e)(1-3)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	<p>If the BOP adopts the modified text as proposed, please consider establishing reasonable timelines and expectations for compliance so as not to severely limit patient access to needed cancer care or place tremendous burdens on patients and those supporting their care to travel to a facility that is compliant with the regulation. Additionally, please establish a process for waiver application that would allow compounding pharmacies to continue to provide services out of their existing pharmacies as they work to gain regulatory compliance.</p> <p>Outside of the costs and time necessary to complete facility modifications to meet this requirement, there could be negative impacts if a pharmacy could not continue to provide the potentially life-saving "hazardous" medications needed as a facility works towards gaining compliance with the requirement. Some geographic areas of the State may not have a nearby health facility to provide this type of service or the ability to handle the order volume currently managed by the Pharmacy.</p>
1735.6(e)(1)	<b>Michael Tou</b> Providence Health	<p>Proposed Text: (e) Hazardous drug compounding shall be completed in a physically separate room with the following requirements: (1) Minimum of 12 air changes per hour; and</p> <p>Providence requests the board issue exemptions to hospital pharmacies which are unable to immediately comply with the requirements of section 1735.6(e)(1)(2)(3).</p>

1735.6(e)(2)	<b>Michael Tou</b> Providence Health	Proposed Text: (2) Maintained at a negative pressure of at least 0.01 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and  Providence requests the board issue exemptions to hospital pharmacies which are unable to immediately comply with the requirements of section 1735.6(e)(1)(2)(3).
1735.6(e)(3)	<b>Michael Tou</b> Providence Health	Proposed Text: (3) All surfaces with the room shall be smooth, seamless, impervious, and non-shedding.  Providence requests the board issue exemptions to hospital pharmacies which are unable to immediately comply with the requirements of section 1735.6(e)(1)(2)(3).
1735.6(e)(1-3)	<b>Lauren Berton</b> CVS Health	Rule language proposed in 1735.6(e)(1-3) reflects draft language found in USP 800 – Hazardous Drugs – Handling in Healthcare Settings. USP Chapter 800 draft language was released on 10/31/14 with a comment submission period until 5/31/15 and is currently pending final draft. It is our understanding that this particular USP chapter will undergo significant language changes due to comments received. It is recommended that the Board remove the proposed language found in 1735.6(e)(1-3) for Compounding Facilities and Equipment and await the final language release for USP Chapter 800 before amending the regulation in regards to hazardous drug compounding.
1735.7	<b>Jeffrey Nehira</b> Dignity Health	Time frame for the record keeping requirement should be specified and further clarification should be included specifying the training of pharmacy staff, as this is a BOP requirement. Pharmacies do not have direct oversight of the training of personnel with institutional contracts; outsourced cleaning services are not taken into account with this added language. Request exemption of institutions with contracts for environmental cleaning services as the outsourced companies should maintain documentation of their assigned staff. Pharmacies should have oversight of the processes and contracts themselves.
1735.8(c)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for concern: This section describes the requirement of a quality assurance plan including “written standards for qualitative and quantitative analysis of compounded drug preparations...including the frequency of testing”. The verbiage is not specific and appears to imply that all products compounded by a pharmacy must be tested for integrity, potency, quality and labeled strength at least annually. Given the wide range and various dosage forms of products compounded in any given hospital pharmacy, as well as the limitations of some end-product testing laboratories to only be able to test certain medications, we recommend that facilities should be allowed to adopt a methodology and frequency (at least annually) for testing specific products for potency.  Solution: Reword the statement to use “shall include a program for routine testing and analysis of designated compounded drug preparations on at least an annual basis”.
1735.8(c)	<b>Doug O'Brien</b> Kaiser Permanente	Recommendation: “The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, of compounded drug preparations. The criteria by which preparations would be tested for potency, quantitative analysis, and labeled strength analysis shall be described in the quality assurance plan. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding record and master formula. Rationale: This proposed language would encompass non-sterile compounding of preparations such as creams and ointments, for which quantitative testing methods do not exist or are exorbitantly expensive.  This language could be interpreted to require that quantitative and qualitative analysis be performed on all compounded products regardless of cost, availability of the actual assay, or scientific validity. Or, it could be interpreted to mean that one or two compounded drug preparations could be tested annually.  <b>Continued in Next Row</b>

1735.8(c)	<b>Doug O'Brien</b> Kaiser Permanente	<p><b>Continued from Previous Row</b></p> <p>Let's consider the latter scenario, since the former scenario is completely unrealistic.</p> <p>If one or two compounded drug preparations were tested annually, what is the value of those results to the pharmacist in charge? What are the benefits to the public?</p> <p>Those test results would show that a compounded drug prepared at a specific time on a specific date by a specific pharmacist did (or did not) meet potency and labeled strength requirements.</p> <p>Those test results can NOT be applied, however, to an identical compounded drug prepared the following day using the same master formula by another pharmacist, or even if it is prepared the following day by the same pharmacist (unless that product was tested as well – a highly unlikely occurrence).</p> <p>It seems like the Board is attempting to apply the systematic testing approach used in the pharmaceutical industry, in which large batches of finished products are systematically manufactured, and where samples from multiple batches are tested.</p> <p>By its very nature – preparing a compounded drug based on an individual prescription - pharmacy compounding is an episodic process. Therefore, testing for potency and labeled strength must be approached differently.</p> <p>It is important that there be a quality assurance plan, with criteria for end product examination in the master formula; as well as criteria and circumstances by which end products are tested for potency or labeled strength.</p>
1735.8(e)	<b>Jeffrey Nehira</b> Dignity Health	Suggest and exemption for health care settings with a facility services policy regarding appropriate function of refrigeration devices.
1735.8(e)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	1735.8(e) Agree with Doug O'Brien of Kaiser written comments in 45 Comment document. Additionally could create a push for increased use of 503B facility produced products due to the substantial increase in cost for implementing this onerous of a program as defined and left to interpretation by inspectors.
1751(b)	<b>Jeffrey Nehira</b> Dignity Health	This requirement for venting may provide a challenge for DSH and rural hospitals. Request exemption for these settings. Referencing this code of regulations as an appendix in the CA law book would be helpful as the referenced chapter may change.

1751(b)(3)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units). The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. If one were to believe that this is an unverified study then one would have to question most of the conclusions derived from USP 797 as many of the conclusions taken from there are not based on “randomized controlled trials”.</p> <p>We believe that we can remove the 3 foot no sink/drain requirement when CACIs are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model.</p> <p>Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.</p>
1751(b)(3)(A)	<b>Douglas Barcon</b> Barcon & Associates	<p>Current proposed text does not include manufacturer documentation of Chapter 797, USP-38 NF-33, 38th Revision, Effective May 1, 2015 compliance in air quality worse than ISO Class 7. The text in (A) should be amended to include this depending on whether the BUD is 12-hours or longer.</p> <p>Suggest adding after 1751.4(f)(1)-(3): “in air quality worse than ISO Class 7 or is non-ISO classified air quality ”</p>
1751(b)(4)	<b>Douglas Barcon</b> Barcon & Associates	Suggest adding: “products or” before “compounded drug preparations
1751.1(a)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: Please amend length of time within the pharmacy versus outside of the department or offsite storage. If 3 years within the pharmacy for personnel (>100 staff members) and compounding records would impact critical space available for operational and distributive needs.
1751.1(a)(5)	<b>Jeffrey Nehira</b> Dignity Health	<p>Need further clarification regarding room temperature storage.</p> <p>Currently regulations state that medications are stored at controlled room temperature but there is no requirement for daily monitoring. Request an extended implementation date if this is now required for hospital settings.</p>
1751.1(a)(7)	<b>Jeffrey Nehira</b> Dignity Health	<p>Currently the technology does not exist for mobile isolation chambers and barrier isolators to measure the pressure differential of the 150-7 area of the devices. Only the pressure associated with the 150-5 compounding area. Clarification needs to be made regarding this requirement. For areas/rooms utilizing laminar flow hoods, it is impractical for daily monitoring of the pressure differential between areas. There has been no studies done indicating that a drop in pressure leads to an increase in contaminated preparations. Recommend removing the requirement for MICs/Barrier Isolators and changing the requirement for testing to every 6 months for room compliance.</p>
1751.1(a)(7)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: USP 797 allows for at least daily documentation or by using a continuous recording device. We would like to continue to allow the use of a continuous recording device as an alternative which would also give the facility better “real time” data.</p> <p>Solution: Reword the section to state “Documents indicating daily documentation or by continuous recording device of air pressure differentials...”</p>
1751.1(b)	<b>Douglas Barcon</b> Barcon & Associates	Suggest adding: “license type” before or after “license number” and shifting placement of “and.”

1751.2(c)	<b>Douglas Barcon</b> Barcon & Associates	Suggest adding protection from light at end to read: "Instructions for storage and handling, including protection from light."
1751.2(d)	<b>Douglas Barcon</b> Barcon & Associates	Insert between hazardous agents and shall:" "and non-hazardous preparations compounded in a PEC that is also used for compounding hazardous preparations" to bring into harmony with 1751.4(g).
1751.2(a)(2) Incorrect Section listed. Should be 1751.2(d)	<b>Jeffrey Nehira</b> Dignity Health	Cytotoxic and Hazardous drugs have very specific definitions not necessarily interchangeable. The NIOSH list 2014 states refer to Antineoplastic medications while other Hazardous agents are to be evaluated at each facility setting. Recommend leaving the comment, "if applicable" at the end of the statement that was removed.
1751.3	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: Change shall to may or eliminate as unnecessary as regulations give the Board authority to take disciplinary actions.
1751.3(a)	<b>Douglas Barcon</b> Barcon & Associates	Consider adding definition of "material" or "material failure" as in suggestion for 1735.5(a).
1751.3(a)(2)	<b>Jeffrey Nehira</b> Dignity Health	Currently the technology does not exist for mobile isolation chambers and barrier isolators to measure the pressure differential of the 150-7 area of the devices. Only the pressure associated with the 150-5 compounding area. Clarification needs to be made regarding this requirement. For areas/rooms utilizing laminar flow hoods, it is impractical for daily monitoring of the pressure differential between areas. There has been no studies done indicating that a drop in pressure leads to an increase in contaminated preparations. Recommend removing the requirement for MICs/Barrier Isolators and changing the requirement for testing to every 6 months for room compliance.
1751.3(a)(7)	<b>Jeffrey Nehira</b> Dignity Health	Language should state, "Cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4." as the frequency is specified elsewhere regulations.
1751.3(a)(9)	<b>Jeffrey Nehira</b> Dignity Health	Purge time for some CACI's is indicated by an LED light or lockout mechanism. An exemption should be written in, "if applicable"
1751.3(a)(16)	<b>Jeffrey Nehira</b> Dignity Health	Infection control policies in health care institutions cover procedures around infectious materials. An exemption should be written for institutions, such as hospitals, with mandatory Infection Control and Safety policies. Most pharmacies do not handle infectious materials; so "if applicable" should be added to the verbiage.
1751.3(a)(20)	<b>Jeffrey Nehira</b> Dignity Health	Need further clarification regarding room temperature storage. Currently regulations state that medications are stored at controlled room temperature but there is no requirement for daily monitoring. Request an extended implementation date if this is now required for hospital settings. Monitoring of medications at room temperature is also not required from distribution centers or during transport. Daily monitoring is impractical and does not correspond to current industry practice. Room temperature monitoring should first go to the FDA and manufacturers/distributors for consistency of practice. To require this at a local pharmacy level does not take into account any chain of custody until the final storage location.
1751.3(c)	<b>Douglas Barcon</b> Barcon & Associates	Change text: "section 1735.5 and 1751.3(a)" to "section 1735.5, 1751.3(a), and 1751.7(e)"
1751.3(e)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: Please amend to allow for electronic capture. We use an online learning system to manage distributing to employees and documenting their learning.

1751.3(e)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for concern: We acknowledge that any material or significant changes to written policies and procedures for sterile compounding should be communicated to all personnel involved in compounding. However, this section implies that personnel must review all changes to all compounding policies and procedures, even if they do not directly impact their job duties in a material fashion. Additionally, our pharmacy and organization holds personnel responsible for abiding by all policies and procedures whether they are related to compounding or not; it is a standard expectation, and signature and date are not collected except in rare cases where the practice change is deemed significant. We believe a signature and date should only be required if there is a significant practice change being implemented as a result of any changes in policies and procedures.</p> <p>Solution: Change the first sentence to "...any material or significant additions, revisions and deletions...must be communicated to all personnel involved in sterile compounding". Change the last sentence to "If changes to the written policies and procedures result in a significant change in practice for compounding personnel, the review must be documented by a signature and date".</p>
1751.4(d)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: USP 797 does not make any stipulation or requirement of mandatory use of a sterilizing agent (i.e. sporicidal: EPA definition). It only makes the stipulation of sanitizing and disinfecting. Furthermore, when sterilizing (i.e. killing spores) is mentioned as recommendation in the literature it is limited to general floor cleaning. The way it is written in this section could lend itself to believe that all items in the IV room have to be sterilized (i.e. use of a sporicide; EPA definition) at least monthly which is not a recommendation that cannot be found anywhere for a pharmacy that compounds sterile products (using sterile to sterile compounding methodology).</p> <p>Solution: Remove the requirement that the use of a sporicidal agent is required monthly and ensuring that there continues to be requirements for sanitizing and disinfecting at appropriate intervals. If the sporicidal requirement is not removed at least add verbiage that specifies that this requirement is for the cleaning of floors.</p>
1751.4(d)(1-2)	<b>Jeffrey Nehira</b> Dignity Health	<p>Use of a sporicidal agent is not required or standard of practice for surfaces other than ISO-5 environments in institutional settings, and is not mentioned in USP&lt;797&gt;. This regulation implies that a sporicidal agent is used on all surfaces and floors daily, which is not based on practice or evidenced based infection control practices. Frequency of cleaning also goes beyond/contradicts the requirements of weekly cleaning as specified in earlier regulation. Recommend removing this requirement of, "work table surfaces, carts, counters, and the clean room floor" as well as "walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment." Fungal contamination takes weeks of incubation, and through monitoring of surface sampling and standard infection control practices risk is minimal.</p>
1751.4(d)(4)	<b>Jeffrey Nehira</b> Dignity Health	<p>An exemption should be made for institutions regarding storage of cleaning supplies in a clean room or ante-area as there are conflicting regulatory requirements for the storage of cleaning products under safety and environment of care. Suggest removal of the last statement, " and shall not be removed from these areas except for disposal."</p>
1751.4(e)	<b>Jeffrey Nehira</b> Dignity Health	<p>This requirement is not listed in USP&lt;797&gt; and not based in evidence practice. Implementation of this practice would severely impede workflow, especially in an institutional setting where there are requirements of timely delivery of monthly... Disinfection, using a suitable sterile agent, shall also occur on administration. This requirement encourages the all surfaces in the ISO Class 5 PEC frequently (at least every 30 minutes): preparation of compounded products by non-pharmacy personnel as delays patient care. If this requirement of every 30 minute cleaning is implemented in the hospital pharmacy practice setting, it would severely compromise the integrity of the pharmacy profession.</p>

1751.4(e)	<b>William Stuart</b> Hartley Medical	<p>Recommend:</p> <p>(d) Disinfection of the ISO Class 5 PEC, using a suitable sterile agent, shall also occur frequently, including:</p> <ol style="list-style-type: none"> <li>(1) At the beginning of each work shift;</li> <li>(2) Before each batch preparation is started;</li> <li>(3) Every 30 minutes during continuous compounding periods of individual CSPs;</li> <li>(4) After each spill; and</li> <li>(5) When surface contamination is known or suspected.</li> </ol> <p>Rationale:</p> <p>The proposed language does not differentiate between different compounding activities.</p> <p>A "lot" that requires longer than 30 minutes to complete would force an operator complying with this policy to cease compounding and disinfect the PEC. This would require unnecessary interventions into the PEC, therefore greatly increasing the risk of contamination of the lot either by moving the components outside of the PEC (biological contamination risk) or by cleaning while the components are inside the PEC (chemical contamination risk).</p> <p>The definition of lot "means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s)." would could classify each patient specific prescription as a lot. This would require an operator to disinfect the entire PEC before the start of every prescription. Disinfecting the PEC before the start of every single prescription would be an unreasonable burden for the operators and would decrease productivity significantly. We recommend introducing the definition of a "batch" to differentiate between patient specific prescriptions and larger quantity compounded preparations.</p> <p>Our recommendation to the proposed legislation follows USP &lt;797&gt; more closely to accurately represent the intent of the guideline. (Source: Cleaning and Disinfecting Compounding Area, February 2015 USP Compounding Compendium)</p>
1751.4(e)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Delete 1751.4(e)(2)</p> <p>Rationale: Consider a typical scenario in a clean room in a hospital pharmacy. During a 15-minute period of compounding operations, pharmacy personnel could compound four doses of azithromycin 500 mg/250mL dextrose 5% for four different patients, two doses of famotidine 40 mg in 250mL dextrose 5% 250mL for one patient, and five doses of furosemide 100mg/100mL dextrose 5% for five different patients. Under the definition of "lot", pharmacy personnel would be required to clean and disinfect the ISO Class 5 PEC before each lot – four times in 15 minutes. If one considers the number of lots that would be compounded in four hours, the PECs would need to be cleaned and disinfected 50 to 60 times.</p> <p>Subsections 1751.4(e)(1) , 1751.4(e)(3), and 1751.4(e)(4) are sufficient.</p>
1751.4(e)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	<p>Please consider inserting the verbiage "when ongoing compounding activities are occurring" after the word "minutes". This verbiage is consistent with USP Chapter &lt;797&gt;.</p> <p>Rational: some sterile compounding pharmacies are not open 24-7.</p>

1751.4(e)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: The language in this sentence uses disinfectant and sterile agent in the same sentence which could be interpreted as the use of a sterilizing agent to disinfect. According to EPA and other regulatory standards disinfect and sterilize have two distinct meanings. There could be confusion if these two words are used in the same sentence.  Solution: Remove the words "using a suitable sterile agent" to "using a suitable disinfecting agent" to mitigate the risk of confusion that the use of a sterilizing agent is required to disinfect the PEC.
1751.4(e)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: The language here states that disinfection should occur at least every 30 minutes. Please know that the Phenol and Quaternary Ammonia compounds used for disinfecting state that once these chemicals are used they are to be air dried for up to 10 minutes. If we are making the requirement to disinfect at least every 30 minutes then that means that the PEC can only be used for 40 minutes of every hour if you take into consideration the time to allow to dry when cleaning with disinfectants. In addition, if we are to disinfect upon spill, before each lot, etc... as stipulated in this same section this only further diminishes the time we can use our PEC. This could potentially mean that we could be disinfecting so often that we could only be using the PEC for less than 30 minutes for each hour the PEC is available when you consider the drying time needed after the application of the Phenol or Quaternary Ammonium compounds that are used. This would impair pharmacy's ability to meet turnaround times for medications that are essential for a patient centered care model of service established for hospitals that produce "STAT" medications.  Solution: Remove the requirement to disinfect (the PEC) at least every 30 minutes. Maintain the stipulations in this section that describe disinfecting at the beginning of each shift....items (1),(2),(3), and (4).
1751.4(e)(2)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: The most recent USP 797 regulations state that cleaning of the ISO 5 PEC should occur at the beginning of each work shift, before each batch (USP 797 only uses the word batch in referencing high-risk compounding) preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. With the new proposed definition of "lot," interruption of workflow of hospital compounding in order to clean before and after each lot may impact the timeliness of medication delivery to patient and could introduce potential for medication errors.  Solution: Remove "before and after each lot" and keep items (1), (2), (3), and (4) which will ensure proper intervals for disinfection are still in place.
1751.4(f)	<b>Jeffrey Nehira</b> Dignity Health	Recommend updating the second sentence to state, "Certification and testing of primary and secondary engineering controls shall be performed no less than every six months. Certification and testing will also occur when ver the device or area designated for compounding is altered or a service to the facility is performed that would impact the device or area." Barrier isolators are self-contained by definition and manufacturer specification and should not require recertification if moved.
1751.4(f)(1)	<b>Jeffrey Nehira</b> Dignity Health	This section requires clarification and exemption should be made for Barrier Isolators for this requirement as the airflow displacement is different than laminar flow hoods. The requirements for measuring the particle counts apply to lamnar flow hoods.
1751.4(f)(2)	<b>Jeffrey Nehira</b> Dignity Health	Recommend clarification of this requirement. If this is requiring testing of Barrier Isolators during material transfer this is impracticle and not part of testing for recertification of the hoods.
1751.4(f)(3)	<b>Jeffrey Nehira</b> Dignity Health	Recommend clarification of this requirement. CACI's are by definition contained isolators that should not need to be located in an ISO-7 cleanroom. If this is requiring testing of in Barrier Isolators during material transfer this is impracticle and also not part of testing for recertification of the hoods. Barrier isolators have manufacturer recommended purge times prior to aseptic manipulation. Perhaps this regulation should defer to manufacturer specifications.

1751.4(g)	<b>Jeffrey Nehira</b> Dignity Health	Request exemption of the labeling requirement for DSH hospitals and rural hospitals as this places a tremendous cost on the organization/facility. The third sentence states that during hazardous compounding performed using a compounding aseptic containment isolator full garbing must occur, which includes two layers of gloves... this contradicts some manufacturers recommendation of mobile isolation chamber use. This also does not correspond to the ASHP recommendations of Hazardous Drug Preparation. Clarification needs to be made since manufacturers recommend an intermediary cloth glove that allows for easy removal of the hand from the containment glove. Please note that most sterile gloves do not meet ASTM D6978-05 standards and those that are used for chemotherapy handling that most facilities utilize are typically the non-sterile nitrile gloves. The non-sterile gloves are then sterilized with the appropriate disinfecting agent. Recommend adding that non-sterile nitrile gloves that meet ASTM D6978-05 standard can be used if sterilized with the appropriate disinfecting agent. This statement does not correspond with current CETA engineering requirements compared with USP<797>. Recommend reclassifying this requirement according to CETA flowchart of Engineering Control Requirements for Hazardous Drugs revised May 2009 (see attached document).
1751.4(g)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: We just want to be sure that when we use the definition of “hazardous” drugs we are referring to agents used to treat neoplasms. We want to be sure that we are not using the NIOSH definition of hazardous drugs that include non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug including those with manufacturers’ safe handling guidance (MSHG).  Solution: Modify the definition of “hazardous” to mean “all anti-neoplastic agents used to treat neoplasms identified by the National Institute for Occupational Safety (NIOSH).....”
1751.4(g)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. <del>Additionally, each PEC used to compound hazardous agents shall be externally vented.</del>  Include timeframe (ex.5 years) to allow facility changes to be made for external venting of PEC before enforcing.
1751.4(g)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: This statement would include CACI's that are used as PEC's to compound hazardous drugs. USP 797 does not make it required that CACI's that are used to compound hazardous drugs to be externally vented. In fact, USP 797 recognizes that many hazardous have sufficient vapor pressures that allow volatilization at room temperature and that environmental sampling in the CACI to detect uncontained hazardous drugs can be performed and analyzed to help determine if there is a need for a CACI to be externally vented.  Solution: Add the stipulation that a PEC does not have to be externally vented if it is a CACI unless environmental sampling cannot be provided or proved that there is no detection of uncontained hazardous drugs on the CACI work surfaces.
1751.4(g-l)	<b>University Compounding Pharmacy</b> Joe Grasela	It is unnecessary to have the gown close in the back so long as the employee is fully covered, front closure with zippers or snaps should be allowed Gloves tested to meet ASTM 6978-05 are standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs. Double gloves should only be required when working with NIOSH Anti-neoplastics and shouldn't be a requirement for NIOSH NON Anti-neoplastics. USP 800 doesn't require or propose a double glove when working with hazardous compounds non-antineoplastics. Please explain your reasoning for two layers of gloves when they are not needed

1751.4(h)	<b>Jeffrey Nehira</b> Dignity Health	This statement says when using a compounding aseptic containment isolator full garbing must occur, which includes two layers of gloves... Two layers of gloves are not consistent with most PEC operational guidelines and deviate from manufacturer recommendations. Clarification needs to be made since manufacturers recommend an intermediary cloth glove that allows for easy removal of the hand from the containment glove. Donning of sterile gloves with aseptic isolators also does not make sense since the outside portion of the glove and the barrier isolator can be maintained in a non-sterile environment.
1751.4(h)	<b>Ernest Pieper</b> Glenn Medical Center	For compounding in cleanroom environments, sterile gloves may be donned in the ante area or the cleanroom which have ISO 8 or ISO 7 air standards respectively. 1715.5 (5) states: "...followed by the donning of sterile gloves may occur within the ante or buffer area or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with nonsterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected." Sterile gloves used in cleanrooms are exposed to relatively dirty air versus ISO 5. The gloves may come in contact with a variety of supplies and objects, even the attire of the preparer. There seems to be no time limit to the use of these gloves, as long as the preparer remains in the ante area or cleanroom. Inspection of holes or tears is subjective to the diligence of the preparer.  In great contrast, the attached gloves in a containment aseptic isolator are continually exposed to ISO 5 air quality in the interior of the isolator. They cannot touch the variety of dirty objects that are accessible to gloves worn on the hand. The integrity of isolator gloves can also be assured by monitoring the pressure differential of the CAI. There is no logic or evidence that donning sterile gloves over intact, sanitized isolator gloves provides any additional protection to the public. The paper package for sterile gloves might even introduce potentially harmful particulate matter into the compounding area with a loss if ISO 5 air quality.
1751.4(h)	<b>Douglas Barcon</b> Barcon & Associates	In order to include a CACI, after "compounding aseptic isolator" consider adding "or a compounding aseptic containment isolator"
1751.4(k)	<b>Brian Warren</b> California Pharmacist Association	<del>(j)</del> (k) The sterile compounding area <b>is of</b> the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-22 <b>24</b> degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.  Technical fix to change "is" to "of."  Also, fix Celsius to Fahrenheit conversion error. 75 degrees Fahrenheit is 23.9 degrees Celsius (which could be rounded to 24 degrees Celsius).
1751.4(k)	<b>Douglas Barcon</b> Barcon & Associates	Change "is" to "in"
1751.4(k)	<b>Jeffrey Nehira</b> Dignity Health	The requirement of 20-22 degree C room temperature for compounding sterile preparations puts undo burden on pharmacies with a narrow temperature range smaller than the definition of controlled room temperature defined above. ("Controlled room temperature" means 20 degrees to 25 degrees C (68-77 degrees F.) Request leaving room temperature as defined in previous sections.
1751.4(k)	<b>BJ Bartleson</b> California Hospital Association	The degree conversion between Celsius and Fahrenheit needs to be changed from Celsius 20-22, to, 20-24. CHA would like to offer that since this range closely mirrors the controlled room temperature already required for the drugs, perhaps eliminating the specific temperature range would be reasonable.
1751.4(k)	<b>Candace Fong</b> <b>Clara Evans</b> Dignity Health	The conversion factor from Fahrenheit to Centigrade is inaccurate and should be updated from 20-22C to 20-24C. In addition, since this range closely mirrors the controlled room temperature already required for drug storage Dignity Health recommends eliminating the specific temperature range all together.

1751.4(k)	<b>University Compounding Pharmacy</b> Joe Grasela	Please correct the Celsius to Fahrenheit conversion error 22 degrees Celsius = 71.6 degrees Fahrenheit
1751.5(a)(1)	<b>Jeffrey Nehira</b> Dignity Health	"...unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing are not required." Recommend removal of this statement since the use of any PEC should be according to manufacturer specification. PECs go through a certification process and manufactured accordingly. Products are sampled using these PECs and environmental testing is done by the pharmacy every 6 months according to the manufacturer recommendations. Manufacturers would not take on the liability of the product since it is dependent on the environment they are used. The environmental sampling done every 6 months should validate the necessity for PPE beyond manufacturer recommendation.
1751.5(a)(4)	<b>Jeffrey Nehira</b> Dignity Health	Request addition of statement, "If jewelry cannot be removed, then it must be thoroughly cleaned and covered."
1751.5(a)(5)	<b>Jeffrey Nehira</b> Dignity Health	Recommend removing the first word, "sterile". If gloves have been tested for compatibility with disinfection with isopropul alcohol, the gloves should not need to be "sterile" before disinfection. Once sterile gloves are donned, they will immediately become contaminated when products are picked up for sterile preparation. This would require disinfection regardless of the original sterility of the glove.
1751.5(a)(6)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: Prohibiting the use of nail polish in an ISO Class 5 or 7 area supersedes the nationally enforceable USP 797 regulation that only makes the stipulation that artificial nails or extenders are prohibited. In fact, there are studies that have reviewed nail polish used in these areas and have found no direct correlation that nail polish increases the number of particles shed from compounding personnel which lead to an increased risk of microbial contamination of critical sites of CSP's. Solution: Remove "nail polish" from this section.
1751.5(b)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	Please verify the correct code is being cited here. There are not any apparent exceptions listed in 1751.4(g). Perhaps referring to the exceptions listed in 1751.5(a)(1)?
1751.6(e)	<b>Douglas Barcon</b> Barcon & Associates	Paragraph (e) is embedded in (d). Add a line feed to shift (e) to next line.
1751.6(e)(1)(E)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for concern: The statement "which contain the same amount or greater of volume transferred during the selected manipulations" implies that the media-fill test performed by personnel must involve a volume transfer the same size or greater than the largest volume transfer performed by the pharmacy when compounding sterile products. It would be difficult to establish this threshold; furthermore, media-fill test kits are commercially manufactured and designed with specific volume transfers and procedures to mimic the most complex manipulation performed by the pharmacy.  Solution: Remove the portion of the sentence stating "and which contain the same amount or greater of volume transferred during the selected manipulations".
1751.6(e)(1)	<b>Douglas Barcon</b> Barcon & Associates	Suggest adding "Hazardous and non-hazardous spills and knowledge of MSDS information" as a lettered paragraph; perhaps as (K)

1751.7(b)	<b>P. Kim Peterson</b> University of California, Davis Medical Center	Recommendation/ Comments: Materials could imply the drugs and diluents. We use non drug products and media in order to test staff. Please consider exploring language that would separate those preparing (technicians) from those checking (pharmacists) in completing this hands on testing. Didactic instruction and knowledge validation could be used for pharmacists that would allow alignment with new electronic systems for validating the preparation by technicians of the product prior to release of the preparation to the patient. This meets the intent and allows the pharmacist with physical limitations or working outside of the area to not have to perform the media fill tests. Of note, schools of pharmacy do not necessarily routinely train pharmacists in sterile compounding in a working or lab environment to perform these manipulations.
1751.7(e)	<b>Douglas Barcon</b> Barcon & Associates	On first line of text change "preparation" to "preparations"  Delete (1) immediately following (e) on first line because (1) is used again in second paragraph.
1751.7(e)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	<p>1751.7 (e) Sterile Compounding Quality Assurance and Process Validation</p> <p>In a circumstance where a 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,</p> <p>(1) Prior to dispensing:</p> <p>(A) Notifying the prescriber of the inability to conduct testing;</p> <p>(B) Suggesting an available alternative product to the prescriber; and</p> <p>(C) Securing the prescriber's <b>and patient's</b> written consent to dispense.</p> <p>(2) And subsequent to dispensing:</p> <p><b>(A) Send random sample for sterility and pyrogen testing as part of process validation</b></p> <p><b>(B) Notify physician if results demonstrate microbial growth or pyrogens</b></p> <p><b>(C) Have protocol approved by the Pharmacy &amp; Therapeutics Committee</b></p> <p>Would recommend including this section back into the regulation revision to avoid patient loss of life or intense suffering due to the inability to provide emergency medications to patients. In rare circumstances medications such as Alum and Formalin are needed to treat hemorrhagic cystitis that can be life- threatening. Evidence supports that these drugs are needed when other measures fail. The patient could bleed to death without this provision.</p>

1751.7(e)	Brian Warren California Pharmacist Association	<p><del>(e)</del>(e)(1) Batch-produced sterile injectable drug preparation compounded from one or more non-sterile ingredients except as provided in paragraph (2), non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, 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. Exempt from pyrogen testing are non-injectable ophthalmic and inhalation preparation.</p> <p><del>(1)</del>(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:</p> <p>(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less.</p> <p>(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 14 5 days or less.</p> <p>(C) Preparations compounded for administration to a single patient that meet all of the following criteria:</p> <p>(i) Are needed for emergency administration to prevent the loss of life or intense suffering, as determined by the prescriber or institution, and only in a quantity sufficient for an emergency course of therapy.</p> <p>(ii) Have a chemical stability of 14 days or less according to a nationally recognized reference, such as Trissel's Stability of Compounded Formulations, the Merck Manual, or the American Society of Health-System Pharmacists' Compounding Sterile Preparations.</p> <p>(iii) Are intended to fill a need for a drug classified as currently in shortage on the list of Current and Resolved Drug Shortages and Discontinuations maintained by the federal Food and Drug Administration, listed on the Current Drug Shortage Bulletins maintained by the American Society of Health-System Pharmacists, or on backorder with the institution.</p> <p><b>Continued on Next Row</b></p>
1751.7(e)	Brian Warren California Pharmacist Association	<p><b>Continued from Previous Row</b></p> <p>First, we recommend a technical fix to renumber what should be paragraph (2) of subsection (e), which is currently numbered as a second paragraph (1).</p> <p>Second, we recommend modifying subparagraph (B) of paragraph (2) to allow for no more than a 14-day course of therapy. Testing for sterility and pyrogens takes up to 14 days to complete. Allowing an exemption from end-product testing for a course of therapy sufficient for administration to a single patient for 14 days ensures that the patient has access to the medication while a longer course of therapy awaits release from quarantine following receipt of end-product testing results.</p> <p>Third, we recommend exempting a narrow class of preparations from end-product testing to ensure patient access. We propose exempting emergency use preparations that are for drugs experiencing shortage or on back-order and where chemical stability is 14 days or less. Our proposed exemption is for preparations that meet all three of these criteria.</p> <p>A number of sterile preparations have chemical stability of 14 days or less. Some of these are needed in emergency situations, so they cannot be compounded in advance for patient-specific use, and compounding in advance for office use can be difficult to accurately predict. Additionally, some of these preparations are compounded due to need for drugs experiencing a shortage or are on backorder. Key examples include epinephrine, sodium bicarbonate, and IV calcium (gluconate and chloride). For further examples of CSPs with abbreviated chemical stability, see Trissel's Stability of Compounded Formulations, the Merck Manual, or the American Society of Health-System Pharmacists' Compounding Sterile Preparations.</p>

1751.7(e)(1)	<b>Michael Tou</b> Providence Health	<p>Proposed Text: (e)(1) Batch-produced sterile injectable drug preparation compounded from one or more non-sterile ingredients except as provided in paragraph (2), non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, before dispensing...</p> <p>(1) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens</p> <p>Providence requires that it be renumbered to (e)(2): <del>(1)</del>(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens</p>
1751.7(f)	<b>Judith Brosz</b>	<p>On January 27, 2015, a sterile compounding inspection took place at El Camino Hospital in Mountain View, CA. Certain informal statements made by the inspectors in an e-mail exchange implied that all pharmacists in the department, regardless of whether or not they actually worked in the sterile processing environment, had to pass the rigorous practical test involving long standing times and repeated manipulation of needles.</p> <p>This universal requirement will make it difficult or impossible for those with disabilities to work in any capacity in a hospital pharmacy.</p> <p>Specifically, the testing requirement was broadened to include not only pharmacists producing the sterile product, and pharmacists directly supervising technicians inside the sterile environment, but those pharmacists whose duties only include checking final sterile products remotely using computerized systems such as DoseEdge. These are quite different tasks. The latter is also a duty more accommodating to a disabled pharmacist.</p> <p>To correct this situation, for myself and other disabled pharmacists, I have recommended adding 1751.7 (f) or an equivalent statement to clarify that that remote computer checking should not have identical training requirements to the actual production or direct supervision of sterile drug preparations in the controlled sterile processing environment.</p> <p>DoseEdge and similar systems have no mechanism for supervision of pharmacy technicians to ensure the proper sterile processing procedures are followed. It is not a direct supervision method.</p> <p>Written competency tests are appropriate, but practical tests of cleaning and needle handling should not be necessary if a pharmacist has no actual duties inside the controlled environment.</p>
1751.8	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: "Multiple dose vials of allergen extracts, when compounded in accordance with the section of USP Chapter 797 entitled "Allergen Extracts as CSPs", shall be assigned the beyond use dates recommended by the manufacturer."</p> <p>Rationale: Allergen extracts are specialized CSPs and are frequently not subject to the standard BUD rules delineated in USP Chapter 797.</p>
1751.8	<b>Jeffrey Nehira</b> Dignity Health	<p>This section of Title 16 seems to try and copy the definitions of low, medium, and high risk compounding. Recommend using verbiage straight from USP797 to eliminate confusion.</p>
1751.8(a)(1)	<b>Douglas Barcon</b> Barcon & Associates	<p>An ISO Class 5 PEC is also a CAI or CACI.</p> <p>With that said, after "1751.4(f)(1)-(3)" insert "and manufacturer documentation shows compliance with USP 797 when located in an area where air quality is worse than ISO Class 7 or is non-ISO classified" ..., using only...</p>

1751.8(a)(3)	<b>Douglas Barcon</b> Barcon & Associates	After “penetrating disinfected stoppers on vials with sterile needles and syringes” add “or spiked transfer devices” to not exclude use of such devices
1751.8(e)	<b>Douglas Barcon</b> Barcon & Associates	Add at end after “ante-area”: “or within a segregated compounding area”  If I interpreted this correctly, without this change to exclude a segregated compounding area, a compounded product may be given either a 12-hour BUD or an immediate use BUD depending on compounding staff choice. There will be no continuity.
1751.8(e)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: Many large health care facilities already employ the use of an “immediate use only” label for reasons other than a 1 hour BUD (e.g. criticality of the drug, cost of the drug, etc.) In addition, other regulatory agencies (i.e. The Joint Commission) have stipulations in existence for labeling “immediate use” sterile products (i.e. medication name, strength, quantity, diluent and volume, expiration date when not used within 24 hours, and expiration time when expiration occurs in less than 24 hours). To avoid confusion, it would be beneficial to specifically remove the requirement of labeling the product for “immediate use only” and impose the existing regulation of the expiration time when expiration occurs in less than 24 hours.  Solution: Replace the requirement of labeling for “immediate use only” with the exact one hour beyond use date and time.
1751.8(e)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: This section does not stipulate as to whether this applies to all healthcare professionals who are qualified to engage in immediate use sterile compounding drug preparation outside the profession of pharmacy.  Solution: Please clarify and insert verbiage to make clear of whether or not this stipulation applies to all professions outside of pharmacy who are qualified to engage in immediate use sterile compounding (e.g. RN).
1751.8(e)(1)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: Other regulatory agencies (i.e. The Joint Commission) have stipulations in existence for one to compound immediate use sterile products which include: “...a delay could harm the patient ...or the products stability is short. To mitigate risk of confusion we recommend adopting similar language that would accomplish the intent of this section.  Solution: Reword section to use “a delay could harm the patient” or “the products stability is short”.
1751.9(a)	<b>Jeffrey Nehira</b> Dignity Health	Exemptions should be made for use during a procedure. Most ampules are used in the operating room and are used on the sterile field.

1751.9(b)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	<p>(e) <b>(3)</b> 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 storage circumstance.</p> <p><b><u>(4) The use of technologies, techniques, materials, and procedures other than those described in this sterile compounding section is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein" (USP 797 page 1).</u></b></p> <p>Additionally, as a result, counterfeit chemotherapy is an area of national concern, until such time as E-Pedigree is available.</p> <p>Closed system transfer devices (CTSD) protect the vial from entry of external bacteria after initial puncture beyond the USP 797 approved 6 hour time limit. It has been shown that one of these systems maintains sterility of the vials to which it is attached for up to 168 hours (7 days).</p> <p>Recommendation: Allowance to use CTSDs with supporting literature to extend the beyond use date of single dose vials of chemotherapy to 24 hours or use through the end of the shift, whichever is shorter. This recommendation is more conservative than the timeframe of 7 days listed in the CTSD study and would assist institutions in conserving scarce chemotherapy medications.</p> <p>Metzger ML, Billett A, Link MP. The Impact of Drug Shortages on Children with Cancer- The Example of Mechlorethamine. New Eng/ 1 Med, 2012; 367:2461-3.</p> <p>Giorgi D, Sadeghipour F, Favet J, et al. Sterility validity period of vials after multiple sampling under vertical laminar airflow hood. 1 Oneal Pharm Practice, 2005; 11:57-62.</p> <p>Edwards M, Solimando D, Grollman F, et al. Cost savings realized by use of the PhaSeai™ closed-system transfer device for preparation of antineoplastic agents. 1 Oneal Pharm Practice. 2013; 19:338-47.</p>
1751.9(a)(b)(c)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Include above language from USP 797 allowing the use of proven technologies with quality assurance procedures (for example, Closed System Transfer Devices) allowing for extension of BUD for single-dose vials.</p> <p>Rationale: One of the hallmarks of USP and Current Good Manufacturing Practices (cGMP) is the ability of entities under the guidelines to be innovative and advance practice with validated processes that differ from the current standards. The advancement of knowledge, technology, and validation processes in a very fluid environment must be allowed to flourish; thus the ability to design programs that meet or exceed current outcomes is essential. The key statement allowing this within the USP 797 is as follows:</p> <p>"The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."</p>
Overall Comment	<b>Michael Tou</b> Providence Health	<p>Allow exemptions from compliance: The modified text intends to align state regulations with proposed USP 800 national guidance for the preparation of hazardous drugs. We request the board issue exemptions to hospital pharmacies unable to immediately comply with the new requirements, including external ventilation. Our pharmacies wish to continue providing life-saving therapies to our most vulnerable patients as they implement a corrective action plan. The board should consider the lengthy regulatory approval required by OSHPD for any modifications to our hospital pharmacies when granting exemptions. Additionally, hospitals must go through a lengthy internal governance process to obtain financing for these types of projects. The board's guidance in allowing temporary exemptions from compliance should be developed with hospital pharmacy input prior to enforcement of the final rule</p>

Overall Comment	<b>Judith Brosz</b>	<p>Indiscriminate use of “employees,” “personnel” “staff,” “compounding personnel, and “sterile compounding personnel.”</p> <p>The broad range of terms leaves too much room for interpretation, as some of these terms could be used to generate a “universal” requirement for specific training that is not actually necessary for all staff in a pharmacy.</p> <p>This was addressed in greater detail in comments presented at the last comment cycle.</p>
Overall Comment	<b>BJ Bartleson</b> California Hospital Association	<p>At the June 25, 2015, Board meeting, during discussion of the sterile compounding modified regulations, the Board clearly stated hospitals that do not presently meet the proposed regulations for physical plant and venting issues, and/or who will not meet by the regulatory mandated date, could be granted a program waiver. The program waiver would be considered based on the development of a detailed plan of correction and corresponding timeline of planned implementation, and full completion of updated requirements as determined in the plan of correction.</p> <p>CHA agrees the containment of hazardous drug residue during hazardous sterile compounding is necessary, reasonable and in full alignment with forthcoming USP 800 guidance. With that being said, the proposed requirement for a separate negative pressure room for all hazardous sterile drug compounding, and the requirement for external venting, will require many hospitals to make significant physical plant changes, ventilation reconfigurations, along with potential purchase and or procurement of new or modified equipment, to perform successfully under the newly revised guidelines. Specifically, section 1735.1 (c) requiring BSC or CACI to be vented externally, 1735.6(e) requiring a physically separate room with negative pressure, and, 1751.4(i) requiring unidirectional airflow in CAI/CACI. These changes could range widely across our diverse hospital pharmacies relative to cost and time required for changes</p> <p><b>Continued on Next Row</b></p>
Overall Comment	<b>BJ Bartleson</b> California Hospital Association	<p><b>Continued from Previous Row</b></p> <p>CHA and its members would appreciate involvement in any Board activity that may occur defining the program waiver process and its components, especially as specific details are determined such as plan of correction requirements, forms, permits, approvals, timelines, etc. CHA is putting an ad hoc team of pharmacists, facilities experts, OSPHD and others, to assist in member support as we move through the final phases of the regulatory process. We are updating the sterile compounding matrixes developed by the CHA/CSHP work group, covering such items as physical plant requirements, policies, procedures and frequency of documentation, lab testing and temperature monitoring requirements. We plan to implement a member webinar that will discuss the USP transition from 797 to 800, the proposed and finalized regulations, along with tools and solutions, including a gap analysis, and best practice examples from the field.</p> <p>We appreciate the Board’s flexibility and accommodating approach to afford all stakeholders a voice in creation and design of sterile compounding regulations that both meet the ultimate goal of patient safety, as well as recognizing the flexibility necessary to address the varied complexities of health care systems, hospitals and organizations across the state</p>

Overall Comment	<b>Candace Fong</b> <b>Clara Evans</b> Dignity Health	<p>While Dignity Health agrees containment of hazardous drug residue during hazardous sterile compounding is necessary, reasonable and in full alignment with USP 800 guidance, the proposed requirement for a separate negative pressure room for all hazardous sterile drug compounding, and the requirement for venting to the outside, will require significant physical plant changes, ventilation reconfigurations, and investment in new or modified equipment. For Dignity Health, at least 15 of our hospitals in California will require a build out of separate negative pressure rooms, with ventilation outside, to compound hazardous drugs. The remaining facilities with existing negative pressure rooms will require assessment of their ability to comply with new regulations. Total cost estimated to build and/or retrofit negative pressure rooms is estimated conservatively at \$3 million for construction costs alone, in addition to the additional time it will take to plan and seek approval from OSHPD, which often takes at least six months.</p> <p>Dignity Health respectfully requests the Board to provide program flexibility to allow hospitals to assess, plan and implement venting requirements and room construction, and time to move those changes through the complicated Office of Statewide Health Planning and Development (OSHPD) approval process. Thus, Dignity Health respectfully requests the Board solicit stakeholder input when establishing program flexibility, particularly in the development of specific plan of correction requests, templates, and timelines</p>
Overall Comment	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	Ability to provide emergency therapy to patients to avoid patient loss of life or intense suffering when other hemorrhagic cystitis treatments have failed
Overall Comment	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	Ability to provide chemotherapy to patients in the setting of continued drug shortages of cancer medications by using equivalent or superior technologies for preserving medication vials
Overall Comment	<b>University Compounding Pharmacy</b> Joe Grasela	Sections that address Hazardous compounding seem to have been derived from the proposed language in USP 800 which has yet to pass and become a standard. They are still in the early stages of their submission/revisions. It is in CaBOP's best interest to wait until the language in USP 800 is finalized prior to making it law. Adding the language prematurely and then having to potentially change it again once USP 800 is final may certainly cause unnecessary distress, construction, and financial burden for many hospitals, compounding pharmacies, and other facilities/institutions that compound preparations.

# **Compounding**

## **First Modified Text**

## Title 16. Board of Pharmacy

### Modified Text

Changes made to the originally proposed language are shown by ~~double strike through~~ for deleted language and double underline for added 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 that is commercially available in the marketplace~~

~~(d)~~(c) 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” means an ISO Class 8 or better air quality 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 or~~ cleanroom, and maintains air flows from clean to dirty areas.

(b) “Beyond use date” means the date, or date and time, after which administration of a compounded drug preparation shall not ~~be begun~~ begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) “Biological Safety Cabinet (BSC)” means a ventilated cabinet for compounded sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet should be appropriately removed by properly designed external building ventilation.

~~(d) “Buffer area” means an area which maintains segregation from the adjacent ante area by means of specific pressure differentials. The principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante area. The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.~~

~~(e)~~(d) “Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, ~~becomes~~ is an active

ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

~~(f)~~(e) “Cleanroom or clean area or buffer area” means a ~~physically separate~~ room or area with walls and doors with HEPA-filtered air that provides ~~at least an~~ ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a ~~A~~ minimum ~~differential~~ positive pressure ~~differential~~ of 0.02- to 0.05-inch water column ~~relative to all adjacent spaces~~ is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of at least 0.01 inches of water column relative to all adjacent spaces is required.

~~(h)~~(f) “Compounding Aseptic Containment Isolator (CACI)” means a unidirectional compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where ~~volatile~~ hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed external building ventilation.

(g) “Compounding Aseptic Isolator (CAI)” means a form of isolator specifically designed for non-hazardous compounding pharmaceutical ingredients or preparations while bathed with unidirectional air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded.

(i) “Controlled cold temperature” means 2 degrees to 8 degrees C (35.6 degrees to 46.4 degrees F).

(j) “Controlled freezer temperature” means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

(k) “Controlled room temperature” means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

(l) “Copy or essentially a copy” of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(m) “Daily” means occurring every day that a pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

(n) Displacement airflow method: a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more from the clean area across the line of demarcation into the ante area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.

~~(n)(o) “Dosage unit” means a quantity sufficient for one administration to one patient, except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered one dosage unit.~~

~~(a)(e)(p)~~ “Equipment” means items that must be calibrated, maintained or periodically certified.

~~(e)(q)~~ “First air” means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

~~(e)(r)~~ “Gloved fingertip sampling” means a process whereby compounding personnel lightly

press each fingertip and thumb onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

~~(s)~~ “(Hazardous)” means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

~~(s)(t)~~ “(Integrity)” means retention of potency until the expiration beyond use date noted provided on the label, so long as the preparation is stored and handled according to the label directions after it is dispensed.

~~(u)~~ “(Lot)” means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

~~(v)~~ “(Media-fill test)” means a test that mimics compounding procedures using a growth-based media to demonstrate the competency of compounding personnel in aseptic techniques. The media fill test must mimic the most complex compounding procedures performed by the pharmacy that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. To be valid, media fill tests must be conducted on both the most routine and the most challenging compounding procedures performed.

~~(w)~~ “(Non-sterile-to-sterile batch)” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

~~(x)~~ “(Parenteral)” means a preparation of drugs administered in a manner other than through the digestive tract. This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation. It does not include topical, sublingual, rectal or buccal routes of administration.

~~(y)~~ “(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.

~~(z)~~ “(Potency)” means active ingredient strength within +/- 10% (or the range specified in

USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range may be calculated and defined in the master formula.

~~(e)~~(aa) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

~~(aa)~~(ab) "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. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

~~(ab)~~(ac) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of unidirectional HEPA-filtered first air for the exposure of critical sites when compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

~~(ae)~~(ad) "Process validation" means demonstrating that when a process is repeated 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.

~~(ad)~~(ae) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

~~(d)~~~~(ae)~~(af) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, ~~and~~ the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula ~~record~~ document.

~~(af)~~(ag) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot

perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile 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. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing non-hazardous sterile-to-sterile compounded preparations.

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meeting the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a)-(b).

(e)(ag) "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 preparation 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” ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~is~~ ordered by the prescriber or the prescriber’s agent and paid for by the prescriber ~~at a price that fairly reflects the fair market value of each drug preparation,~~ 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’s office and signed for by the prescriber or the prescriber’s agent; 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 for human medical practices, or~~ a 120-hour supply for veterinary medical practices, solely to the prescriber's own ~~veterinary~~ veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding ~~the quantity provided for office use~~ is reasonable considering the intended use of the compounded medication and the nature of the prescriber’s practice; and

~~(3)~~ (5) for ~~With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to~~ for ~~all prescribers to whom the pharmacy furnishes, 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 an 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 commercially available 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, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

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

(1) Active ingredients to be used.

(2) Equipment to be used.

~~(3) Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

~~(5) Process and/or procedure~~ Specific and essential compounding steps 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.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(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~~ the beyond use date indicated on the label, so long as label instructions for storage and handling

are followed after the preparation 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 compendial 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 the compounded drug preparation should not be used, stored, transported or administered; and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~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~~ ingredient in the compounded drug ~~product~~ preparation, nor shall it exceed 180 days for non-aqueous formulations, 14 days for water-containing oral formulations, and 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations, from preparation unless a ~~longer~~ later date is supported by stability studies of finished drugs or compounded drug ~~products~~ preparations using ~~the same~~ identical ~~components~~ ingredient, specific and essential compounding steps, quality reviews, 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)~~ 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 (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. 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.~~

(k) Packages of ingredients, both active and inactive, 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 and 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 and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions.~~

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~~ document.

(2) The compounding document shall include the following:

~~(2)(A)~~ (A) The date the drug ~~product~~ preparation was compounded.

~~(2)(B)~~ (B) The identity of ~~the any~~ pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation.

~~(4)(C)~~ (C) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

~~(5)(D)~~ (D) The quantity of each ~~component~~ ingredient used in compounding the drug ~~product~~ preparation.

~~(6)(E)~~ (E) 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. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (k) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(E)) are sterile ~~products~~ preparations compounded on a one-time basis in a single lot for administration within seventy-two (72) hours to a ~~in~~patient 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) Through 2nd Supplement (35 37<sup>th</sup> Revision, Effective ~~May~~ December 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)(F)~~ (F) A pharmacy-assigned reference or lot number for the compounded drug ~~product~~ preparation.

~~(8)(G)~~ (G) The ~~expiration~~ beyond use date or beyond use date and time of the final compounded

drug ~~product~~ preparation, expressed in the compounding ~~record~~ document in a standard date and time format.

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

(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 ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). 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, either written in English or translated into English, for chemicals, bulk drug substances, and drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding 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 and under California Code of Regulations section 1707.5, the label of a compounded drug ~~product~~ preparation shall contain the generic or brand name(s) of ~~the principal~~ all 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. Exempt from the requirements of this paragraph are those sterile drug preparations compounded within a health care facility solely for administration, by a licensed health care professional, to a patient of the facility. To be treated as such, the "health care facility" must be licensed under Health and Safety Code section 1250.

(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 of the preparation, pharmacy reference or lot number, and expiration beyond use date and shall not be subject to minimum font size requirements.

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 policyies and procedures 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. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.

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

(c) The policyies and procedures manual shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes~~ or to the policyies or procedures manual.

(2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent ~~verification~~ information demonstrates the potential for adverse effects with continued use ~~of a compounded drug product.~~ The plan shall ensure that all affected doses can be accounted for during the recall.

(3) 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.

(4) 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.

(45) Documentation of the methodology used to test validate integrity, potency, quality, and labeled strength of compounded drug products preparations. The methodology must be

appropriate to compounded drug preparations.

(5) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures manual by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures manual approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) 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 within the pharmacy.

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 compound~~ing of ed~~ compounded drug ~~products~~ preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned 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, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded ~~in writing in a form~~ which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in a physically separate room with the following requirements:

(1) Minimum of 12 air changes per hour; and

(2) Maintained at a negative pressure of at least 0.01 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) All surfaces with the room shall be smooth, seamless, impervious, and non-shedding.

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) A pharmacy engaged in compounding shall maintain documentation that demonstrates personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation that personnel involved in compounding was trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the sterile compounding process. ~~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. Additionally, documentation demonstrating that staff have been trained on all policies and procedures shall be maintained.~~

(b) The pharmacy shall develop and maintain an ongoing 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 analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing, ~~analysis of compounded drug products~~ preparations. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collected~~ maintained along with the

compounding ~~record~~ document and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(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 within the pharmacy ~~or~~ and within patient care areas of a hospital where furnished drug is returned for redispensing.

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 or~~ cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 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 505.5 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, 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. Certification records must be retained for at least 3 years in the pharmacy.~~

~~(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 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better buffer area or cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.~~

(A) When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) they are exempt from the room requirement listed in 1751(b)(3)

~~(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, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.~~

~~(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, and 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), any pharmacy engaged in any compounding of for sterile drug products preparations compounded from one or more non-sterile ingredients, shall make and keep maintain the following records must be made and kept by readily retrievable within the pharmacy:~~

~~(1) The Documents evidencing training and competency evaluations of employees in sterile product drug preparation policies and procedures.~~

~~(2) Results of hand hygiene and garbing assessments 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 tests.~~

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

~~(2)-(5) Documents indicating daily recordation documentation of room, R refrigerator, and freezer temperatures appropriate for sterile compounded 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(s).

(7) Documents indicating daily ~~documentation recordation~~ of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

~~(4)-(8)~~ Other facility quality control logs-records 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~~ chemicals, bulk drug substances, drug products, or other ingredients.

~~(6)-(10)~~ Preparation records including the master ~~formula document work sheet~~, the preparation ~~compounding document work sheet~~, and records of end-product evaluation ~~testing and~~ 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, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, and license number of the 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 California Code of Regulations section s 1707.5 and 1735.4, a pharmacy ~~which~~ that compounds sterile ~~injectable drug products~~ preparations shall include the following information on the labels for each such ~~those products~~ preparation:

- (a) ~~The~~ The telephone number of the pharmacy. ~~except~~ The telephone number is not required on the label for sterile ~~injectable drug products~~ preparations dispensed ~~for~~ to inpatients ~~of a~~ within the hospital pharmacy.
- (b) Name (brand or generic) and ~~concentration~~ strength, volume, or weight of each active 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.”

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 drug preparations shall maintain a written policies and procedures manual for compounding. Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove

fingertip, and viable air sampling.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Facility management including certification and maintenance of controlled environments and related equipment.

(9) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

(10) Hand hygiene and garbing.

(11) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

(12) Media-fill testing procedure.

(13) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.

(14) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

(15) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(16) Procedures for handling, compounding and disposal of infectious materials. The written

policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

(17) Proper use of equipment and supplies.

(18) Quality assurance program.

(19) Record keeping requirements.

(20) Temperature monitoring in compounding and controlled storage areas.

(21) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

(22) Use of automated compounding devices (if applicable).

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

~~(a) Any pharmacy engaged in compounding sterile injectable drug products preparations shall maintain a written policies and procedures manual for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action, 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 product compounded drug preparations based on the intended route of administration and recommended rate of administration.~~

~~(3) Proper use of E equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable drug products Hand hygiene and garbing.~~

~~(5) Procedures for handling cytotoxic agents Media fill testing procedure.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(8) Compounded sterile drug preparation stability and beyond use dating.~~

~~(9) Visual inspection and other final quality checks of sterile drug preparations.~~

~~(10) Use of automated compounding devices (if applicable).~~

~~(11) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula.~~

~~document.~~

~~(12) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.~~

~~(13) Airflow considerations and pressure differential monitoring.~~

~~(14) Cleaning and maintenance of ISO environments and segregated compounding areas.~~

~~(15) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.~~

~~(16) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.~~

~~(17) Temperature monitoring in compounding and controlled storage areas.~~

~~(18) Facility management including certification and maintenance of controlled environments and related equipment.~~

~~(19) Action levels for colony forming units (CFUs) detected during viable surface testing, sampling, glove fingertip, and volumetric viable air sampling.~~

~~(b)(20) The determination and approval by a pharmacist of 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)(21) 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. Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(22) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(23) Daily and monthly cleaning and disinfection schedule for the controlled areas and any~~

~~equipment in the controlled area as specified in section 1751.4.~~

(b) For lot compounding, the pharmacy shall maintain a written policies and procedures manual that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formulas ~~documents~~ and compounding ~~documents~~ ~~work sheets~~.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain a written policies and procedures manual for compounding that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Sterilization methods ~~and shall include sterilization method suitability testing for each master formula document~~.

(2) End-product evaluation, ~~quantitative,~~ and ~~qualitative~~ testing.

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

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding sterile ~~injectable products~~ drug preparations, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding. This review must be documented by a signature and date.

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

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator~~

workstations).

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. 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.~~

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.**

(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:~~

~~Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.~~

~~(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur.~~

on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently (at least every 30 minutes), including:

(1) At the beginning of each shift;

(2) Before ~~and after~~ each lot;

(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 daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent 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 air quality. 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. Unidirectional ~~Compounding~~ aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 ~~buffer area or~~ cleanroom 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 or are not located within an ISO Class 7 ~~buffer area or~~ cleanroom 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 cytotoxic sterile hazardous agents shall do so in accordance with Section 505.125.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. ~~The hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). ~~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. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug

ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, ~~complete with. Garbing shall include~~ hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two layers of gloves with the outermost glove tested to meet ASTM D6978-05 standard. ~~Where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply.~~

(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) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use unidirectional air flow patterns.~~

~~(j) Viable surface sampling shall be done at least quarterly every six months for all sterile-to-sterile compounding and monthly quarterly for all non-sterile-to-sterile compounding. Volumetric Viable air sampling shall be done by impaction volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and volumetric viable air sampling shall be performed 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)(k)~~ The sterile compounding area is the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-22 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

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, unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing is not required.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or 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 any wrist, hand, finger, and or wrist other visible jewelry or piercing 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 or~~ cleanroom. 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 exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 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 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). Exceptions are as listed in 1751.4(g).

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 ~~drug 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 or greater 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 ~~Quality Assurance 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 aseptic 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 or greater 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 promote 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. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, 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.

(c) All sterile 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 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.

~~(c)~~ (e)(1) Batch-produced sterile injectable drug preparation compounded from one or more non-sterile ingredients except as provided in paragraph (2), non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, 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. Exempt from pyrogen testing are non-injectable ophthalmic and inhalation preparation.

(1) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less.

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients. Non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, 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.~~

~~(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 conformity with and 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 does not exceed the expiration date or beyond use date provided by the manufacturer for any component in the preparation, and that, 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 (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a ~~more an~~ extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area ~~or compounded entirely within a CAI or CACI which meets the requirements in 1751.4(f)(1)-(3)~~, 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.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI or CACI which meets the requirements in 1751.4(f)(1)-(3), 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.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: ~~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.~~

~~For the purposes of this subdivision, “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.~~

~~(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI or CACI which meets the requirements in 1751.4(f)(1)-(3).~~

~~(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:~~

~~(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile 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.~~

~~(e) 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. A PEC used solely to compound ‘immediate use’ preparations need not be placed within an ISO Class 7 ~~buffer area or~~ cleanroom, with an ante-area.

(1) 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 ~~shall be labeled with a BUD and~~ 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 shall be labeled with a BUD and 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 storage circumstance.

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 ~~injectable 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.

**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 policies 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.

# **Compounding**

## **45-Day Comments**

Code Section	Commenter	Comment
1735(b)	<b>John Cronin</b> Institute for Community Pharmacy	<p>(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.</p> <p>In a general sense, this definition is consistent with the definition of "compounding" found in 21 USC 353a, which is the section of the federal law that deals with compounding in pharmacies. However, the language dealing with activities that are excluded from compounding is slightly different. 21 USC 353a(e) reads:            "As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling."</p> <p>This federal definition is somewhat broader than the language at the beginning of the proposed §1735(b), which appears to be limited to "reconstitution," which is not further defined in the proposed regulation. Without further clarification, this could cause confusion regarding the preparation of certain commercially available products, such as Benzamycin® or Phospholine Iodide® (two products from my earlier days as a practicing pharmacist) which involve preparation prior to dispensing that may not meet all definitions of "reconstitution." To illustrate the possible confusion that can occur, I've included excerpts from the labeling for Benzamycin® and Phospholine Iodide® which show the manufacturer's directions for preparation for these products, as well as two common, but inconsistent, definitions of "reconstitution."</p> <p><b>Continued on next Row.</b></p>
1735(b)	<b>John Cronin</b> Institute for Community Pharmacy	<p><b>Continued from previous Row.</b></p> <p>The first question then, is whether preparation of commercially available products consistent with manufacturer directions is, or should, be excluded from the definition of "compounding" even if those directions call for more than simple "reconstitution." A further question is whether the exemption should be limited to "oral, rectal, topical or injectable administration" as included in the proposed §1735(b) or whether it should extend to products intended for use in the eye or ear, which is consistent with the federal law.</p> <p>Should the Board feel that preparation of any product that is consistent with manufacturer labeling should be excluded from the definition of compounding, we suggest the following amendment of §1735(b) to make it consistent with the federal language found at 21 USC 353a(e):            "(b) 'Compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling 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."</p> <p>Should the Board decide to leave the language as proposed, some clarification of the intent of the language and the intended definition of "reconstitution" should be provided as a reference for pharmacists and the board's inspectors.</p> <p>If the Board believes these products should be included within the definition of "compounding," the Board should provide a clear indication of whether the manufacturer's directions and labeling are adequate to comply with the compounding documentation included elsewhere in these proposed regulations.</p>

Code Section	Commenter	Comment
1735(b)	<b>Doug O'Brien</b> Kaiser Permanente	<p>The proposed language is missing some very common and important categories of products that the standards of practice do not call for extra specified conditions, such as Phospholine Iodide eye drops. Relying on the term “topical” to include such categories is unrealistic and adding some specific terms will reduce confusion.</p> <p>Recommendation: Add wording to indicate that the examples are not all inclusive and specifically the categories of “ophthalmic” and “otic” to the list of products where “Compounding” does not include “reconstitution”.</p> <p>Use the following language :“(b) “Compounding” does not include reconstitution of a drug pursuant to a manufacturer’s direction(s), such as for ophthalmic otic, 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.</p> <p>Rationale: Several of the most popular products are ophthalmic products that only have to be reconstituted following manufacturer’s instructions</p>
1735.1	<b>Judith Brosz and Robert Stein</b>	<p>Adding the new definitions would make references in other regulations more specific and clear.</p> <p>The proposed additional definitions (indicated by dashes here) would be plugged into the appropriate subsection of 1735.1, and the lettering would be rearranged accordingly.</p> <p>(-) “Controlled area” or “designated area” for sterile processing means any area where the environment is specifically controlled to prevent contamination of sterile compounds. Areas such as the cleanroom, CAI, or CACI would be included in this definition, as would an ante room requiring special preparation to enter.</p> <p>(-) “Sterile compounding personnel” refers to personnel who are actively preparing sterile compounds in the controlled area, or directly supervising such a person in the controlled area.</p> <p>On January 27, 2015, a sterile compounding inspection took place at El Camino Hospital in Mountain View, CA. Certain statements in the inspection report implied that all pharmacists in the department, regardless of whether or not they actually worked in the sterile processing environment, had to pass the rigorous practical test involving long standing times and repeated manipulation of needles.</p> <p>The interpretation that this is a universal requirement makes it difficult or impossible for those with disabilities to work in any capacity in a hospital pharmacy. We do not believe the intent of the regulation is to preclude employers from providing reasonable accommodations to disabled personnel.</p> <p>To correct this situation, for Dr. Brosz and other disabled pharmacists similarly situated, we are recommending some changes in Title 16 that would make clear that the hands-on aseptic testing requirements are limited to those actually working or supervising inside the controlled sterile processing environment, rather than a universal requirement that would exclude disabled people from working in a hospital pharmacy at all.</p>
1735.1	<b>BJ Bartleson</b> California Hospital Association	<p>Insert new section after (p), titled “Fully automated IV Robotics”- means a system where the actual compounding is done in an enclosed ISO 5 area by a machine with programming that allows the product to be compounded without human touch in the compounding space”</p> <p>IV robotics requires a definition in order to have instructions for issues such as cleaning.</p>

Code Section	Commenter	Comment
1735.1	<b>Lynn Paulsen</b>	<p>CACI/CAI refers to ventilation building requirements. Requesting a delay until USP 800 to finalized.</p> <p>It is unclear why the ventilation requirements apply to the CACI/CAI and not the biological safety cabinets.</p> <p>Additionally, a definition needs to be added for "Automation or Robotics." Language provided by CHA</p>
1735.1(a)	<b>Judith Brosz and Robert Stein</b>	<p>(a) "Ante-area" means an ISO Class 8 or better air quality where <del>personnel</del> <u>Sterile Compounding Personnel</u> hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed ...</p> <p>To more clearly differentiate the duties and requirements for those involved in sterile compounding, we have added definitions of "sterile compounding personnel" and "controlled area," and refer to these terms throughout the regulations that apply exclusively to sterile compounding.</p>
1735.1(c)	<b>Judith Brosz and Robert Stein</b>	<p>(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounded sterile drug preparations, having an open front with inward airflow for <del>personnel</del> <u>Sterile Compounding Personnel</u> protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.</p>
1735.1(d)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Adopt the USP Chapter 797 definition for buffer area, "An area where the primary engineering control is located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs."</p> <p>Rationale: The proposed definition is not in alignment with USP Chapter 797, which allows for the compounding of hazardous drugs in a buffer area that utilizes the airflow displacement method.</p> <p>The result of this definition (taken in context with the definitions of cleanroom and segregated compounding area) is that neither a CACI nor a BSC can be used to prepare chemotherapy in a cleanroom configuration that utilizes the airflow displacement method.</p> <p>This definition imposes significant and very expensive new requirements as cleanrooms utilizing the airflow displacement method will need to be remodeled to separate the buffer area from the ante-area with walls/doors.</p> <p>This change in definition would necessitate remodeling and construction costs exceeding \$60 million for our organization.</p>
1735.1(d)	<b>Douglas Barcon</b> Barcon & Associates	<p>Change "The principle of displacement airflow shall be employed" to "Instead of physical separation from the ante-area, the principle of displacement airflow shall be employed." Without such a change, the regulation states that a buffer area could only use displacement airflow, which is incorrect.</p> <p>Alternate change to above: After "The principle of displacement airflow shall be employed" add to the sentence "where there is no physical separation from the ante-areas by walls or doors."</p> <p>To improve the definition of a "buffer area", change the first sentence to: " "Buffer area" means an area where the primary engineering control (PEC) is located which provides at least an ISO Class 7 or better air quality and maintains segregation from the adjacent ante-area by means of specific pressure differentials."</p> <p>Inclusion of the ISO Class 7 or better air quality is a necessary requirement of a buffer area for sterile compounding in USP 797 and is the location of the PEC, even though it is duplicated in the definition of a cleanroom. Also, remove "physically" because "located" alone confers the same meaning.</p>

Code Section	Commenter	Comment
1735.1(d)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	<p>Concerned about the language “for hazardous compounds, or for chemotherapy compounds”. To not permit the displacement concept to maintain clean room area requirements will have significant impact for some facilities in terms of remodeling and construction costs. Outside of the costs and time necessary to complete facility modifications to meet this requirement, there could be negative impacts if a pharmacy could not continue to provide the potentially life-saving “hazardous” medications needed as a facility works towards gaining compliance with the requirement. Some geographic areas of the State may not have a nearby health facility to provide this type of service or the ability to handle the order volume currently managed by the Pharmacy.</p> <p>Understanding a key element of proposed USP &lt;800&gt; is to require that hazardous drugs be stored in a negative or normal/pressure, and compounding must be completed in certified biological safety cabinets or compounding aseptic containment isolators in a separate room with negative pressure, attempts to harmonize State with Federal Standards may be indicated. However, if the BOP adopts the modified text as proposed and there are not reasonable timelines and expectations for compliance established, it could severely limit patient access to needed care or place tremendous burdens on patients and those supporting their care to travel to a facility that is compliant with the regulation.</p> <p>Please consider the following clarifying information:            the verbiage in USP 797 specific to “displacement concept” reads, “The displacement concept shall not be used for high-risk compounding.” The reference cited “ISO 14644-4:2001 Cleanrooms and associated controlled environments-Design, construction, and start-up” includes section A.5.2 which describes the displacement concept. The displacement concept is described in this reference as a means to effectively separate clean and less clean adjacent zones without any mention of hazardous compounds or chemotherapy. As such, the term “high-risk” should be taken to mean high risk of microbial contamination as described in USP &lt;797&gt;.</p> <p>Our facility currently meets the “low volume” exemption described in USP &lt;797&gt;, hazardous CSP prepared in an ISO 5 CACI using closed-system transfer devices. The PEC (CACI) is located in the ISO 7 buffer area (located in a non-negative pressure clean room). The buffer area is not physically separated from the ante-area, the principle of displacement airflow is employed.</p> <p>Please delete the language “for hazardous compounds, or for chemotherapy compounds” and consider reintroducing at a later time after fully assessing impacts to Pharmacies holding Sterile Compounding Licenses in this state and establishing reasonable timelines for gaining compliance.</p>
1735.1(d)	<b>Katherine Palmer            Rita Shane</b> Cedars-Sinai Medical Center	<p>"Buffer area" means an area which maintains segregation from the adjacent ante-area by means of specific pressure differentials (<b><u>A minimum differential positive pressure of 0.02- to 0.05- inch water column is required.</u></b> <b><u>If physical separation (walls/doors) does not exist between the buffer and ante area,</u></b> the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40ft per minute or more from the buffer area across the line of demarcation into the ante-a rea. The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, <del>for hazardous compounds, or for chemotherapy compounds.</del></p> <p>In the absence of a physically separated buffer and ante area for medication preparation, USP 797 allows the use of displacement airflow. Application of this to hazardous drug areas is essential for organizations that don't have a separate room to allow for hazardous medication preparation for cancer patients. In the board response to comments, the terms high-risk and hazardous are used interchangeably (Attachment 2- third response to comment on 1735.1(f).</p> <p><b><i>(FYI: Attachment 2 was not provided.)</i></b></p>

Code Section	Commenter	Comment
1735.1(d)	<b>University Compounding Pharmacy</b> Joe Grasela	<p>Definition for "Buffer area" and "Clean room" In USP 797 are used interchangeably (pg 12 of USP 797). It would be best to clarify that a "Buffer area" is a designated area with no separated doors or walls with a line of demarcation from the Ante room while a "Clean room" is a physical room with walls and/or door separation from the Ante room that allows for compounding of Hazardous and High risk preparations.</p> <p>We associate our "clean room/buffer room" with walls and the door as our line of demarcation that allows us to compound "Hazardous" or "High risk" compounds. With this clarification, we would then term our sterile compounding room as a "clean room" as opposed to a "buffer area".</p> <p>When USP 800 is released, your current definition of "clean room" doesn't address the negative pressure room requirements (ie: 0.01-0.03 inches of water column, externally vented, 30 ACPH).</p> <p>(d) "Buffer area" means an area which maintains segregation from the adjacent ante area by means of specific pressure differentials. The principle displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle...The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.</p>
1735.1(e)	<b>Brian Warren</b> California Pharmacist Association	<p>(e) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, <del>becomes</del> <u>is</u> an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.</p> <p>An inactive ingredient does not become active.</p>
1735.1(f)	<b>Doug O'Brien</b> Kaiser Permanente	<p>This definition is misleading and inaccurate, because it states that a cleanroom must provide ISO Class 7 or better air quality. There are other acceptable configurations of cleanrooms. For example, a cleanroom could also be a physically separate room that contains a buffer area, in which the air quality is ISO Class 7 or better; and an ante area, in which the air quality is ISO Class 8 or better. Displacement airflow concept described in 1735.1 (d) could be used.</p> <p>Recommendation: Adopt the USP Chapter 797 definition for cleanroom: "A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class."</p> <p>This definition accommodates all acceptable cleanroom configurations</p> <p>Remodeling and construction costs exceeding \$10 million to convert existing cleanrooms to provide ISO Class 7 air quality.</p>

Code Section	Commenter	Comment
1735.1(f)	<b>University Compounding Pharmacy</b> Joe Grasela	<p>Definition for "Buffer area" and "Clean room" In USP 797 are used interchangeably (pg 12 of USP 797). It would be best to clarify that a "Buffer area" is a designated area with no separated doors or walls with a line of demarcation from the Ante room while a "Clean room" is a physical room with walls and/or door separation from the Ante room that allows for compounding of Hazardous and High risk preparations.</p> <p>We associate our "clean room/buffer room" with walls and the door as our line of demarcation that allows us to compound "Hazardous" or "High risk" compounds. With this clarification, we would then term our sterile compounding room as a "clean room" as opposed to a "buffer area".</p> <p>When USP 800 is released, your current definition of "clean room" doesn't address the negative pressure room requirements (ie: 0.01-0.03 inches of water column, externally vented, 30 ACPH).</p> <p>(f) "Clean room" means a physically separate room with walls and doors that provides at least an ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located. Minimum differential positive pressure of 0.02-0.05 inch water column is required.</p>
1735.1(f)	<b>Douglas Barcon</b> Barcon & Associates	Change to "A minimum differential positive pressure of 0.02-to 0.05-inch water column is required" to "A minimum differential positive pressure of 0.02-to 0.05-inch water column is required to segregate the room from the surrounding unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment."
1735.1(g)	<b>Douglas Barcon</b> Barcon & Associates	<p>Change to "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for compounding non-hazardous pharmaceutical ingredients or preparations."</p> <p>A negative pressure CACI should be used to compound hazardous pharmaceutical ingredients or preparations. A CAI should not be used to compound antineoplastic hazardous drugs per draft USP 800 revision Fall 2014 (C151881).</p>
1735.1(h)	<b>Douglas Barcon</b> Barcon & Associates	<p>After volatile, add ", particle-generating, aerosol-producing, or sterile"</p> <p>This is a composite of board of pharmacy text and USP 800 revision Fall 2014 (C151881) sections 5.3.1 and 5.3.2.</p>
1735.1(j)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: In the May 2015 Compilation version, what was omitted was "or a range otherwise specified by the pharmaceutical manufacturer." We believe that this is verbiage that should be kept to encapsulate all of the scenarios where it is warranted to store certain medications outside of the "-25 C to -10 C" range.</p> <p>Solution: Reinsert the verbiage "or a range otherwise specified by the pharmaceutical manufacturer" to better encapsulate all possible scenarios.</p>

Code Section	Commenter	Comment
1735.1(j)	<b>Douglas Barcon</b> Barcon & Associates	<p>Cannot have two definitions for “controlled freezer temperature.” Use of “or” creates two definitions. Note that there is no definition of “controlled freezer temperature” in USP General Chapter 659 Packaging and Storage Requirements, USP 797, or the general notices in USP-37 NF-32.</p> <p>Should delete the word “controlled” from definition and leave remainder of text intact to be consistent with USP 797. Delete “manufacturer” and replace with “manufacturer(s) of the respective products.”</p> <p>There is some concern that products which specify a temperature range colder than -25 degrees C on the lower end of the range, such as a vaccine at -40 degrees C, could be comingled at the colder temperature in the same freezer with products that specify -20 degrees C at the low end of the range, and this could jeopardize stability of the product or container with the storage limitation of -20 degrees C if stored colder than -20 degrees C. A separate freezer may be necessary to accommodate products with -40 degree C storage conditions to avoid comingling.</p>
1735.1(l)	<b>Douglas Barcon</b> Barcon & Associates	<p>This definition precludes a pharmacy from compounding a sterile preparation, such as premixed large volume intravenous solutions and for example, a 1 gram cefazolin or ceftriaxone antibiotic IVPB, if a manufacturer provides these as frozen IVPB products or inactivated IVPB form. Proprietary bag-vial systems such as ADD-Vantage, Mini-Bag Plus, and others require physical attachment to the infusion bag and should not be considered a commercially available compounded product in the regulation, or many compounded antibiotic IVPBs would be considered a copy. Also need to comply with the Drug Quality and Security Act regarding sterile preparations demonstrably difficult to compound.</p> <p>Suggest changing to: “Copy or essentially a copy” of a commercially available drug product includes all preparations that are comparable in active ingredients <u>and dosage form</u> to commercially available drug products, <u>except premixed large volume intravenous solutions that are not demonstrably difficult to compound: premixed, inactivated, or frozen small volume parenteral products; or proprietary bag-vial systems such as ADD-Vantage, AddEASE, Mini-Bag Plus, and others; and does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.</u></p>
1735.1(m)	<b>Lynn Paulsen</b>	Should occur "every" day and not just when the pharmacy is open.
1735.1(m)	<b>BJ Bartleson</b> California Hospital Association	<p>“Daily “means occurring every day.</p> <p>Pharmacies must be responsible to check refrigerated temperatures every day- the term operating may be interpreted as either open that day or operating as a licensed pharmacy and therefore should be removed.</p>
1735.1(n)	<b>Brian Warren</b> California Pharmacist Association	<p>(n) “Dosage unit” means a quantity sufficient for one administration to one patient, <del>except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered one dosage unit.</del></p> <p>Suggested modification to conform with modifications suggested to Section 1751.7(e) (see below). Further, substantive provisions (i.e., requirements and exceptions) should be placed in the substantive provisions of the regulations, not the definitions (see Martineau R. and Salerno M., Legal, Legislative, and Rule Drafting in Plain English, Thomson West, 2005). By placing the exception for self-administered ophthalmic drops in the definitions section, pharmacists may not understand its impact.</p>
1735.1(q)	<b>Judith Brosz and Robert Stein</b>	(q) “Gloved fingertip sampling” means a process whereby compounding <del>personnel</del> <u>Sterile Compounding Personnel</u> lightly press each fingertip and thumb onto appropriate growth media ...

Code Section	Commenter	Comment
1735.1(r)	<b>Douglas Barcon</b> Barcon & Associates	<p>In order to bring in line with the NIOSH List of Anti-Neoplastic and Other Hazardous Drugs document and reinforce and clarify the regulation, suggest changing definition to include hazardous drugs portion too:  "Hazardous" means all anti-neoplastic agents and other hazardous drugs as identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.</p> <p>This change also provides guidance to the PIC in regard to hazardous drugs that are not anti-neoplastic agents.</p>
1735.1(s)	<b>Lynn Paulsen</b>	It is unclear why both integrity and potency (y) are defined separately.
1735.1(t)	<b>Doug O'Brien</b> Kaiser Permanente	<p>The wording of this definition is confusing and requires clarification. We believe "lot" could be interpreted two different ways.</p> <p>1. It could be interpreted to include different types of preparations that are prepared during one uninterrupted continuous cycle of compounding. A typical example of this interpretation in a hospital pharmacy: compounding four doses of azithromycin 500 mg/250mL dextrose 5% for four different patients, and two doses of famotidine 40 mg in 250mL dextrose 5% 250mL for one patient, and five doses of furosemide 100mg/100mL dextrose 5% for five different patients. All of these would be prepared in an uninterrupted continuous cycle of compounding.</p> <p>Recommendation: If the above example is the intended interpretation, then we recommend this language:  "Lot" means one or more different compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s)."</p> <p>2. It could be interpreted to mean a single type of drug preparation compounded during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s). Using the example above, four doses of azithromycin 500 mg/250mL dextrose 5% for four different patients would be considered one lot.</p> <p>Recommendation: If interpretation #2 is correct, then we recommend this language:  "Lot" means a single type of drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s)."</p>
1735.1(t)	<b>BJ Bartleson</b> California Hospital Association	"Lot" designation should be limited to the products made in anticipation of an order and cannot be tracked any other way. For example, a lot should be differentiated from six 1.5 gram Vancomycin doses made for six specific patients in a hospital pharmacy or six doses made for a patient at home.
1735.1(t)	<b>William Stuart</b> Hartley Medical	<p>Recommend:  "Lot" means <del>one</del> two or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).</p> <p>Rationale:  Lot being "one or more" would encompass every patient-specific prescription or unit of one. This would require each prescription to undergo testing. This clause seems to be directed towards covering all batches but is unknowingly infringing onto patient-specific prescriptions. Testing patient-specific prescriptions would increase the volume needed to prepare, which would increase the amount of drug needed. The testing and the increase in the amount of drug would needlessly raise the price and delay of the therapy.  The above recommendation will also align with the use of "two or more" in the definition of "Non-sterile-to-sterile batch" in 1735.1(v).</p>

Code Section	Commenter	Comment
1735.1(t)	<b>Katherine Palmer Rita Shane</b> Cedars-Sinai Medical Center	<p>"Lot" means <del>one or more</del> <b>"non-sterile to sterile batch" which means any compounded drug preparation containing two or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.</b> compounded drug preparation(s) during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).</p> <p>OR</p> <p>Alternatively, recommend changing definition of "lot" to "greater than one dose" in order to ensure timely preparation of compounded drugs to treat emergency patients' conditions where immediate administration of medications is essential. When medications are prepared as single doses, time is of the essence and documentation requirements for a lot would delay patient treatment.</p> <p>"Lot" means <del>one or more</del> <b>"greater than one dose of compounded drug preparation prepared in anticipation of immediate patients needs.</b> compounded drug preparation(s) during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).</p>
1735.1(u)	<b>Judith Brosz and Robert Stein</b>	(u) "Media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic techniques of compounding <del>personnel</del> <b>Sterile Compounding Personnel</b> or processes routinely employed do not result in microbial contamination. ...
1735.1(u)	<b>William Stuart</b> Hartley Medical	<p>Recommend: "Media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. To be valid, media-fill tests must be conducted on <del>both the most routine and</del> the most challenging compounding procedures performed.</p> <p>Rationale: The "most routine procedure" is not referenced beyond this definition nor in USP &lt;797&gt;. We recommend removing the most routine procedure to remain consistent with the following uses of media-fill tests in the proposed text and USP:</p> <p>1751.6(e)(1)(E) "Aseptic preparation procedures using media-fill tests which are <b>as complicated as the most complex manipulations</b> performed by staff and which contain the same amount or greater volume transferred during the selected manipulations."</p> <p>1751.7(b) "Each individual involved in the preparation of sterile drug preparations must first successfully demonstrate competency by successfully performing aseptic media-fill tests before being allowed to prepare sterile drug preparations. The media fill testing process shall be <b>as complicated as the most complex manipulations</b> performed by staff and contain the same amount or greater of volume transferred during the compounding process..."</p> <p><b>Media-Fill Test Procedure</b>—This test or an equivalent test is performed at least annually under conditions that closely simulate <b>the most challenging or stressful conditions encountered during compounding.</b></p>
1735.1(w)	<b>Lynn Paulsen</b>	Does it include topical. Defintion needs to be further defined. Okay with Irrigation, Ophthalmic, Inhalation, Through the skin.
1735.1(y)	<b>Lynn Paulsen</b>	Potency USP 797 requirements of +/- 10% is not addressing the dilution of commercial product. They are addressing making a product from chemical ingredients. Need to define dilutions separately because of titrations. Commerical products are already +/-10% and then are diluted the resulting diluted product will exceed +/-10%. USP standard is for USP products and is different than diluting products.
1735.1(y)	<b>Jeannette Hanni</b>	Exempt when final product is the result of dilutions. Example: 1gram in 250cc bag. The bag is already is +/- 10% (USP Standard). Adding the 1gram will change the potency further.

Code Section	Commenter	Comment
1735.1(y)	<b>Doug O'Brien</b> Kaiser Permanente	Recommendation: ""Potency" means active ingredient strength within +/- 10% of the labeled amount for sterile commercial products.  Rationale: Sterile commercial products are already at +/- 10% so unable to meet this requirement for sterile compounded preparations in which multiple commercial products are utilized to compound the final preparation.
1735.1(y)	<b>BJ Bartleson</b> California Hospital Association	With the definition as stated, the potency definition will be impossible to meet. For example: a typically compounded product is Vancomycin 1 gram injected into a 250 ml bag of normal saline. The 250 ml bag is a commercially available product purchased from manufacturers who may add as much as 25 ml's of overfill to their bags, which would result in a volume of 275 ml's. The 1 gram Vancomycin vial from the manufacturer is reconstituted with 20 ml's of sterile water and added to the 275 bag of saline, equaling a final volume of 295 ml's resulting in a final concentration of 3.39 mg/ml (1000mg/295ml), the labeled potency of the 1g/250ml piggyback would result in a discrepancy of 15%- well above the +/-10% allowance. These are simple compounds from standard manufacturer ingredients and will result in a continuous state of non-compliance with the potency range as defined in the proposed regulations.
1735.1(y)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: USP 797 only describes potency in terms of ensuring potency by monitoring controlled storage areas. In addition, considering the many drugs that could be compounded (biosimilars, immune mediators, blood derivatives, etc) it may be too arbitrary to put such a hard limit on this definition.  Solution: Remove section that defines "potency" altogether.
1735.1(ab)	<b>Amy Gutierrez</b>	At today's sterile compounding training, we discussed the use of sterile compounding robots, which have become popular in California. As we don't have reference to robots in our regs, I am proposing a modification to 1735.1 (ab) to the following (changes in bold):  (ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of unidirectional HEPA-filtered first air for the exposure of critical sites when compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, <b>sterile compounding automated robots</b> , compounding aseptic isolators, and compounding aseptic containment isolators.
1735.1(ae)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	Comments: "...the absence of inactive ingredients other than those listed on the master formula record." There are times when the compounding record inactive ingredients will slightly deviate from the master formula record. For instance, if the sweetener stevia is outdated, we may use (one time only) acesulfame as the sweetener. Or we may use Ora Plus sugar free in place of Ora Plus, if there is a backorder from our wholesaler for the Ora Plus listed in the master formula record. When these rare changes take place, compounders SHOULD MAKE NOTE ON THE COMPOUNDING RECORD, but should not be required to modify the master formula record. Please note: these are rare exceptions.  Recommendation: Change "master formula record" to "compounding record."

Code Section	Commenter	Comment
1735.1(a)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Allow compounding of hazardous drugs in a segregated compounding area within a CACI by removing the language "non-hazardous". The applicable sentence would read, "The segregated sterile compounding area shall be restricted to preparing non-hazardous sterile to sterile compounded preparations."</p> <p>Rationale: The USP 797 definition of a Segregated compounding area is "a designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12 hour or less BUD". USP 797 section Placement of Primary Engineering Controls allows placement of a CACI (used for hazardous drug compounding) in less clean than ISO Class 7 areas if the following conditions are met:</p> <ul style="list-style-type: none"> <li>-The isolator shall provide isolation from the room and maintain ISO Class 5 during the dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs</li> <li>-Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations</li> <li>-Not more than 3520 particles per m3 shall be counted during material transfer, with the particle count probe located as near to the transfer door as possible without obstructing the transfer.</li> </ul>
1735.1(a)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units). The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. If one were to believe that this is an unverified study then one would have to question most of the conclusions derived from USP 797 as many of the conclusions taken from there are not based on "randomized controlled trials". We believe that we can remove the 3 foot no sink/drain requirement when CACIs are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model.</p> <p>Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.</p>
1735.1(a)	<b>Anonymous</b>	<p>Recommendation/ Comments:</p> <p>While some PEG may gain benefit by having the 3 foot perimeter, other PEG's such as barrier isolators does not have such requirement, yet for other poorly designed PEGs, the 3 foot may still not be enough. Therefore, the size of the demarcated area should be according to PEG's mfg recommendation/specification, rather than a fixed 3 foot for all. I checked with my barrier isolator mfg, and there is a list of location requirements and specifications, but mfg does not require a 3 foot clearance. Having such clearance provides no additional safety margin. Barrier isolator is already a self-contained "clean room" and "ante room". To require another 3 foot clearance around it is like saying there needs to be 3 foot clearance outside the clean room.</p> <p>The fiscal impact of this regulation is much more than anticipated, and in some cases, there is no safety margin gained. Many smaller hospitals and satellite pharmacies have recently undergone renovations to be in compliance with the current regulation. Most isolators are 4 to 5 foot wide. Requiring another 3 foot perimeter means the room has to be at least 10 foot. Smaller hospital pharmacies and satellite pharmacies simply do not have the space. Passing this regulation would mean more renovations and construction, which may interrupt patient care and reduce safety margin.</p>
1735.2	<b>Lynn Paulsen</b>	Some Hospitals have not changed from expiration date to BUDs and the change cannot be done overnight due to the training of thousands of nurses and staff. An implementation schedule over the next year or two would be necessary.

Code Section	Commenter	Comment
1735.2(c)(1)	<b>Doug O'Brien</b> Kaiser Permanente	<p>This proposed regulatory language is vague and does not reflect either California statutory authority nor federal case law. The term “fair market value” cannot practically apply to pharmacy-compounded items because there are no published prices that compounding pharmacies can use to determine that fair market value, unlike resources that are available for products approved for distribution in interstate commerce by the FDA. Compounding pharmacies are prohibited by anti-trust law from contacting other compounding pharmacies to discuss established prices. Further, there is no reference material available to even determine which competing pharmacies are compounding and distributing the exact same compounded products. Each compounding pharmacy has to determine its own pricing based on its costs, risk calculations, and marketing strategy. Generally speaking the costs per unit compounded by a pharmacy will be substantially higher than the market value of FDA approved similar products because of a lack of “economy of scale” vs manufacturing facilities.</p> <p>Further, Calif. Business and Professions Code Section 4380 establishes in California statutory law recognition of two federal court cases that allow non-profit institutions to acquire products at prices generally unavailable to for-profit organizations and use of those products for the treatment of specified patients related to the not-for-profit institutions, e.g. certain hospitals and health plans. Such products are often supplied to physicians in medical office environments at no charge for treatment of such patients. This includes pharmacy-compounded products supplied to prescribers for prescriber office use under Business and Professions Code Section 4052(a)(1).</p>
1735.2(c)(1)	<b>Brian Warren</b> California Pharmacist Association  (Also commented on at hearing by Tony Park)	<p><del>(1) Is ordered by the prescriber or the prescriber’s agent and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation, 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</del></p> <p>The proposed requirement that physician office use compounded preparations be sold “at a price that fairly reflects the fair market value of each drug preparation” is arbitrary, difficult to enforce, and beyond the scope of the Board’s mandate of protection of the public health and safety. In no other statute or regulation does the Board attempt to regulate the prices or pricing of prescription drugs dispensed by pharmacists.</p> <p>The Board’s Initial Statement of Reasons states that the changes to Section 1735.2 are intended to ensure that compounding regulations reflect current statutory provisions and are in alignment with USP 37 &lt;797&gt;. does not specify the purpose for this change.</p>
1735.2(d)(3)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many medications that are in short supply in “real time” may not be on the ASHP or FDA drug shortage list in a timely manner (e.g. most recent example IV Protonix January 2015). ASHP and FDA recognize that this may happen as they have to rely on clear communications to them for their source of information.</p> <p>Solution: Add “Manufacturer, Wholesaler, and/or Distributor acknowledge and provide documentation that the drug is in short supply.”</p>

Code Section	Commenter	Comment
1735.2(d)(3)	<b>Michael Tou</b> Providence Health	<p>(d) No pharmacy or pharmacist shall compound a <u>sterile</u> drug preparation that:  (3) is a copy or essentially a copy of one or more commercially available <u>compendial</u> drug products...</p> <p>The current wording of 1735.2(d)(3) prohibits pharmacies from diluting their own vancomycin 1 gram as in the example above because it is “essentially a copy” of a commercially-available drug product.</p> <p>The implications of this restriction would be far-reaching:</p> <ul style="list-style-type: none"> <li>- Costs to pharmacies and costs to treat patients would be exponentially more expensive if pharmacies cannot compound their own sterile IVPBs even when a commercial premix product is available.</li> <li>- Manufacturers who produce premixed products would corner the market and profit from this regulation. Generic drug manufacturers that produce FDA approved drug vials and solutions to be used for sterile compounding will suffer.</li> <li>- Drug shortages will worsen since premix sterile dilution products are the only ones that could be used in the state. It will drive the demand for these premix IVPB products and the lone manufacturers would not be able to meet the needs of pharmacies.</li> <li>- In the event of a drug recall of a premix commercially-available product, pharmacies may not be able to perform compounding unless the drug appears on the ASHP or FDA drug shortage list. If the rest of the country is not restricting pharmacies from compounding copies or essential copies of commercially-available drug products, no shortage will be listed.</li> </ul> <p>Even TPN (total parenteral nutrition) is available commercially as premixed bags. TPN contents are usually customized to meet the nutrition, caloric, and electrolyte needs for the patient. Some of the TPN formulas are available as premixed bags from the manufacturers. The language in this section would prohibit the pharmacy from preparing a TPN formula that matches those available as TPN products. It would not be feasible for pharmacies to stock every commercially available TPN bag in order to provide the TPN needs for every patient. Being able to compound the TPN using sterile products is a necessity.</p> <p><b>Continued on Next Row:</b></p>
1735.2(d)(3)	<b>Michael Tou</b> Providence Health	<p><b>Continued from Previous Row:</b></p> <p>We agree that preparation of sterile drug products that are copies or essentially copies of commercially-available drug products should be prohibited when those processes involve utilizing non-sterile ingredients to prepare sterile drug products unless there is a documented current drug shortage and appropriate safety measures and procedures are followed. For example, preparation of calcium chloride sterile solution for injection utilizing non-sterile calcium powder.</p> <p>Non-sterile compounding of commercially-available drugs should be permitted for non-parenteral administration. For example, caffeine citrate oral solution is commercially available in a ready-to-administer solution but is also safely compounded utilizing caffeine powder, citric acid powder, and water to prepare essentially the same drug product with the strength/concentration and formulation. Stability studies have been done on the extemporaneous compounded formulation from these powders and have been shown to be safe and effective for treating patients.</p>
1735.2(e)(5)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: The language may be too broad. We understand it would be hard to place exactly what is required considering all of the entities that will be using these regulations, but perhaps we can narrow the language by inserting phrases such as “essential compounding steps”. This will help facilitate pharmacies to receive approval during the policy approving process who are based in institutions with multidisciplinary committees by leaving out unwanted minutia of the compounding process in policies and procedures.</p> <p>Solution: Reword section to state “Specific and essential compounding steps used to prepare the drug”</p>

Code Section	Commenter	Comment
1735.3(a)(1)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comment: The description of this section warrants naming the document that will contain all of this information (a)(1) through (a)(9). In practice it is referred to as a compounding log or formula log.</p> <p>Recommendation: Clarify the reference term for the document that is described in section 1735.3(a)1 as a “compounding formula record” or “compounding record” or “compounding work sheets” as referenced in 1751.3 (b)(1).</p> <p>Question: Can the master formula record be contained in electronic format? Though the master formula record is critical to consistency from batch to batch (or lot to lot) of the same compounded preparation, it does not contain any information that would not be included on the compounding record (which is much more specific to what and how a preparation was made).</p> <p>Recommendation: Clarify that the master formula record must be available but does not have to be maintained WITH the compounding record.</p>
1735.3(a)(5)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comments: The term “component” is inconsistent with language in section 1735.2 e1 and 1735.2 e4 which reference active ingredients and inactive ingredients respectively.</p> <p>Recommendation: Change the term “component” to “ingredient.”</p>
1735.3(a)(6)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comments: The term “component” is inconsistent with language in section 1735.2 e1 and 1735.2 e4 which reference active ingredients and inactive ingredients respectively.</p> <p>Recommendation: Change the term “component” to “ingredient.”</p>
1735.3(a)(6)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Include ambulatory oncology clinic pharmacies in the seventy-two (72) hour exception language, in a manner similar to inpatient pharmacies.</p> <p>Rationale: Ambulatory oncology clinic pharmacies compound preparations in a similar manner to inpatient pharmacies</p>
1735.4(c)	<b>Brian Warren</b> California Pharmacist Association	<p>(c) Drug <del>products</del> 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), <del>concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration beyond use date</del> and shall not be subject to minimum font size requirements.</p> <p>The Board is proposing to add the name of the compounding pharmacy and dispensing pharmacy to the text of what must be included on unit-dose containers that are too small or otherwise impractical for full compliance with all labelling requirements. Adding this additional text to unit-dose labels may place space limitations on those labels, thereby necessitating that labels be printed in a smaller font size. This modification is within the scope of these proposed regulations because the Board is adding additional text to be included on the label.</p>
1735.5(a)	<b>Brian Warren</b> California Pharmacist Association  (Also commented on at hearing by Tony Park)	<p>(a) Any pharmacy engaged in compounding shall maintain a written <del>policy</del>ies and procedures 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. <u>Any <b>material</b> failure to follow the pharmacy’s written policies and procedures <b>may shall</b> constitute a basis for disciplinary action.</u></p> <p>Regulations should give the Board the authority to take disciplinary action, they should not require that the board take disciplinary action. Additionally, disciplinary action should be taken for material failure to follow policies and procedures, not for any deviations irrelevant to the compounding of drugs.</p>

Code Section	Commenter	Comment
1735.6(d)	<p><b>Brian Warren</b> California Pharmacist Association</p> <p>(Also commented on at hearing by Tony Park)</p>	<p>(d) <b>(1)</b> Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.</p> <p><b>(2) Any pharmacy engaged in any hazardous drug compounding shall perform such compounding with the use of a powder containment hood.</b></p> <p>All pharmacies compounding hazardous drugs should use powder containments hoods to ensure pharmacist and pharmacy technician safety.</p>
1735.8(c)	<p><b>Doug O'Brien</b> Kaiser Permanente</p>	<p>Recommendation: "The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, of compounded drug preparations. The criteria by which preparations would be tested for potency, quantitative analysis, and labeled strength analysis shall be described in the quality assurance plan. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding record and master formula.</p> <p>Rationale: This language could be interpreted to require that quantitative and qualitative analysis be performed on all compounded products regardless of cost, availability of the actual assay, or scientific validity. It has been our experience that some Board of Pharmacy inspectors have interpreted this language to require end product potency testing of all pharmacy-compounded products. KP. Many pharmacy professionals disagree with those requirements as they are inconsistent with the intent and provisions of the regulation 1735, et. seq. Pharmacies are compliant with 1735.8(c) if they have a PLAN that includes the elements mentioned above. Quantitative and qualitative laboratory type testing is not required unless specified for each product in our policies and procedures generally or by category - or in the Master Formula for a particular product. Test records of tests only have to be retained if such test was done either as a matter of policy or pursuant to an investigation after the raising of a quality concern for particular compounded preparation or a batch of a compounded preparation.</p> <p>Please see the detailed testimony from KP regarding this issue which was presented to the BOP Enforcement and Compounding Committee on September 16, 2014.</p> <p>The Board's proposed regulation language perpetuates substantial confusion and inhibits compliance and enforcement. As proposed the regulation would add major costs to hospital and other pharmacy-compounding thus adversely affecting the cost and affordability for therapeutic availability, the effectiveness and safety of patient care with scientific justification.</p>
1735.8(e)	<p><b>Douglas Barcon</b> Barcon &amp; Associates</p>	<p>Change "or" to "and", so the QA plan includes responding to out-of-range temperatures in the pharmacy and patient care areas versus one or the other.</p>
1751(b)(3)	<p><b>Brian Warren</b> California Pharmacist Association</p>	<p><del>(6)</del> (3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better buffer area or cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, <u>with the exception of emergency eye rinsing stations</u>. A sink may be located in an ante-area.</p> <p>This comment was submitted during the last rulemaking and had been accepted, though was not incorporated into this rulemaking. Additionally, the definition of a segregated sterile compounding area in Section 1735.1(af) includes the exception for emergency eye-rinsing stations. The emergency eye-rinsing station should be included here for consistency.</p>

Code Section	Commenter	Comment
1751(b)(3)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many hospitals have established pharmacy satellites nearby patient care areas to serve our most vulnerable patients (e.g. Intensive Care Units). The central pharmacy is too far from these patient care areas and the pharmacy satellites provide a venue to provide patient care that is closer to the patients. These pharmacy satellites are one room that provides a place for the pharmacy to perform order verification, drug storage, and drug preparation. Many of the pharmacy satellites have very limited room, thus the pharmacy will place compounding aseptic containment isolators (CACIs) which are enclosed to the surrounding environment and should have evidence from the manufacturer that they meet USP chapter 797 and Controlled Environment Testing Association (CETA) requirements. If one were to believe that this is an unverified study then one would have to question most of the conclusions derived from USP 797 as many of the conclusions taken from there are not based on “randomized controlled trials”. We believe that we can remove the 3 foot no sink/drain requirement when CACIs are used to support pharmacy satellites. The alternative would be to close these pharmacy satellites that do not have the room to abide by the 3 foot no sink/drain rule which is not consistent with a patient centered care model.</p> <p>Solution: Make an exception that if the ISO Class 5 PEC is a CACI, that the three foot sink/drain rule does not apply while maintaining that sinks and drains should not be placed in a buffer area or in ISO class 7 or better.</p>
1751(b)(3)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: In the March 2015 BOP Draft (5th Draft) there was verbiage that stated “with the exception of emergency eye-rinsing stations”. We believe that this exception is the safest for the employees preparing sterile products and complies with NIOSH Guidelines.</p> <p>Solution: Reinsert the exception to include emergency eye-rinsing stations in these areas in addition to the above solution (Number 2) to allow CACI’s be an exception also.</p>
1751.1	<b>Judith Brosz and Robert Stein</b>	<p>(a) In addition to the records required by section 1735.3 , any pharmacy engaged in any compounding of sterile drug preparations, shall make and keep the following records within the pharmacy:</p> <p>(1) Documents evidencing training and competency evaluations of <del>employees</del> <u>Sterile Compounding Personnel</u> in sterile drug preparation policies and procedures.</p> <p>(2) Results of hand hygiene and garbing assessments of <u>Sterile Compounding Personnel</u> with integrated gloved fingertip testing.</p> <p>(3) Results of assessments of <del>personnel</del> <u>Sterile Compounding Personnel</u> for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.</p> <p>References to personnel made more specific to indicate those actually engaged in sterile compounding in the controlled environment.</p>

Code Section	Commenter	Comment
1751.1	<b>Michael Tou</b> Providence Health	<p>Add to Section 1751.1 definition:            Compensial drugs are drug products or preparations for which there is a monograph provided in an official compendia (e.g. United States Pharmacopeia, National Formulary, or Homeopathic Pharmacopeia) recognized by the Food, Drug, and Cosmetic Act. The compendium sets forth standards for the strength, quality and purity of the drug product.            -OR-            Add: (4) Compounding (reconstitution and/or dilution) of FDA approved drug products is excluded from this restriction.</p> <p>If the intent of the board was to prevent what would essentially be the manufacturing of copies of compendial drug products by pharmacies, the language needs to be modified to clearly indicate this.            Dilution/reconstitution and compounding of drug products using FDA-approved drug products should be exempted.</p> <p>Providence recommends changing the language to allow compounding (reconstitution and/or dilution) using FDA-approved drug products. The proposed language seen in the center column can be interpreted to prohibit dilution of FDA-approved drug products per FDA instructions, if there is a pre-diluted (premix) drug product commercially available.</p> <p>As defined in 1735.1(l) "copy or essentially a copy" of a commercially-available drug product would include all diluted intravenous infusion bags, including IV piggy backs or IVPBs that are available as premix bags from the manufacturer.            Some brand name manufacturers have FDA-approved "premixed" IV bags that are ready-to-administer and are virtually the same preparation as other FDA-approved drug vials that are diluted prior to administration per the FDA-approved package insert instructions. Premix IV bags would fall into the definition since they are commercially-available drug products.</p> <p><b>Continued in Next Row:</b></p>
1751.1	<b>Michael Tou</b> Providence Health	<p><b>Continued from Previous Row:</b></p> <p>For example: Vancomycin is available as a frozen premix IVPB bag in different strengths that are the most commonly prescribed (e.g., 1 gram). The frozen premix bag is thawed and administered to the patient without further dilution.            Vancomycin is more commonly available as a sterile powder vial that requires further dilution (per FDA-approved package insert instructions and labeling) into an IV solution bag prior to administration.            Vancomycin premix IVPB is 1 gram of vancomycin in D5W 200ml. Pharmacies can typically prepare that same IVPB bag of 1 gram of vancomycin in D5W 200ml using a vancomycin sterile powder vial, reconstituting it as directed with sterile water and further diluting the 1 gram amount into an IVPB bag of D5W solution.            The resulting preparations are the same: same active and inactive drug and diluent, same dose, same volume. The cost of utilizing the sterile powder vial of vancomycin and the plain D5W IV solution bag is less expensive than purchasing the vancomycin bag that is already diluted and ready-to-administer.</p>
1751.1(a)(5)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: In the March 2015 BOP Draft (5th Draft) there was verbiage that stated the recordation was for "sterile compounded drug preparations". The new verbiage removed the word "sterile" implying that all compounded drug preparations required this documentation which in not the focus of the intended section.</p> <p>Solution: Reinsert the verbiage "sterile" in the compounded drug preparation requirement to maintain consistent with the section.</p>
1751.1(a)(5)(c)	<b>Douglas Barcon</b> Barcon & Associates	<p>There is no definition of "controlled freezer temperature" in USP general chapter 659 Packaging and Storage Requirements, USP 797, or the general notices in USP-37 NF-32. Suggest deletion of the word "controlled" as in 1735.1 (j) comment.</p>

Code Section	Commenter	Comment
1751.1(a)(7)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: USP 797 allows for at least daily documentation or by using a continuous recording device. We would like to continue to allow the use of a continuous recording device as an alternative which would also give the facility better “real time” data.  Solution: Reword the section to state “Documents indicating daily recordation or by continuous recording device of air pressure differentials...”
1751.1(a)(10)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	Comments: The terms “preparation work sheet” and “master work sheet” are inconsistent with compounding record and master formula record.  Recommendation: Be consistent in the terms for a master formula record (well prescribed in section 1735.3) and the compounding record (see comments regarding 1735.3 (a)(1).
1751.2(b)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	Comments: This can become a very long list depending on the formulation. Why do we need to include the inactive ingredients as well as the active ingredients when this is not done for non-sterile compounding? Do you want us to list on the label how much hydrochloric acid or sodium hydroxide we added to get to the right pH? How would this be indicated correctly? For instance, we start with a 1% HCl solution and add 3 drops to a final volume of 15 ml.... the math to determine the final strength is doable (0.01%), but may vary from batch to batch and will have no relevance to the end user.  Recommendation: Please provide clarification on implementation specific to inactive ingredients.
1751.2(b)	<b>Michael Tou</b> Providence Health	Name and strength, volume or weight of each <u>active</u> ingredient contained in the sterile drug preparation.  Request clarification or guidance on this requirement for “each ingredient:” <ul style="list-style-type: none"> <li>- Are inactive ingredients required on the label?</li> <li>- If inactive ingredients are required on the label, please exclude inactive agents used to reconstitute a powder vial (e.g., sterile water) that will be further diluted in solution for the sterile compounded drug preparation. If sterile water appears on the label of the compounded sterile drug preparation, it would be confusing for those reading the label since the sterile water for reconstitution is not part of the prescription or drug order and of no clinical significance to the patient.</li> <li>- Providence recommends that each active ingredient be required on the label and the only inactive ingredient(s) required should be the final diluent solution used to dilute the sterile compounded preparation’s active ingredient. This would be consistent with the modified language proposed in 1735.1(ae). 1735.1(ae) implies that only active ingredients are listed on the label and inactive ingredients do not have to be listed on the label because they are in the compounding log: (d)(w)(ae) “Quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed noted on the compounding log label.</li> <li>- 1735.4(c) requires the name(s) of the active ingredient(s) only. It does not require the inactive ingredients as well.</li> <li>- Sterile compounded drug preparations are prepared in single-dose containers or unit-dose containers and each ingredient would not fit on the label if inactive ingredients were also required.</li> </ul> <p><b>Continued on next Row:</b></p>

Code Section	Commenter	Comment
1751.2(b)	<b>Michael Tou</b> Providence Health	<p><b>Continue from Previous Row:</b></p> <p>Providence also recommends changing the requirement of the concentration on the label to include the strength, volume or weight of the ingredient(s).</p> <ul style="list-style-type: none"> <li>- This would be consistent with labeling requirements from 1735.4(c) that require the name of the active ingredient(s), strength, volume or weight of the preparation.</li> <li>- B&amp;PC 4076 requires only the strength of the drug.</li> <li>- If the active ingredient dose or strength is on the label and the final volume of the diluent is also on the label, then the concentration should not be required. Most drugs that are sterile compounded preparations are prescribed, ordered and prepared as the drug dose only (not the concentration). For example, prescribers order Vancomycin 1 gram IV once. The current labels typically will state the drug name, dose, and volume and name of the appropriate diluent: "Vancomycin 1 gram in 200ml of Normal Saline." This is much more clear and accurate than if the label were to state vancomycin 5mg/ml which is the concentration.</li> </ul>
1751.3	<b>Judith Brosz and Robert Stein</b>	<p>(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain a written policies and procedures manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:</p> <p>...</p> <p>(12) Orientation, training, and competency evaluation of <del>staff</del> <u>Sterile Compounding Personnel</u> in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.</p> <p>The original word "staff" may be subject to misinterpretation and lead to a universal practical testing requirement in a pharmacy.</p> <p>Additionally, in various sections of the proposed regulations, staff are referred to as "personnel," "staff," and "employees." We believe these terms are intended to refer to the same individuals and recommend using consistent terminology.</p>
1751.3	<b>Lynn Paulsen</b>	USP 797 requires indentifying CFUs to genesis level to trigger action. This is because individual bacteria of a specific type may trigger action; while others may not require immediate action until 10 or more CFUs are identified.
1751.3(a)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comments: The items in this list are fine, but the order of this list is awkward and feels like someone just threw a bunch of ideas down during a brainstorming session.</p> <p>Recommendation: Sort this list by importance, sequence of events (Garbing and Gloving procedure should occur before fingertip testing), or alphabetically as done for definitions.</p>
1751.3(b)(1)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comments: The term "compounding work sheets" is inconsistent with language in several other sections.</p> <p>Recommendation: Change "compounding work sheets" to "compounding formula record."</p>

Code Section	Commenter	Comment
1751.4(d)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Consider a typical scenario in a clean room in a hospital pharmacy. During a 15-minute period of compounding operations, pharmacy personnel could compound four doses of azithromycin 500 mg/250mL dextrose 5% for four different patients, two doses of famotidine 40 mg in 250mL dextrose 5% 250mL for one patient, and five doses of furosemide 100mg/100mL dextrose 5% for five different patients. Under the definition of "lot", pharmacy personnel would be required to clean and disinfect the ISO Class 5 PEC before and after each lot – four times in 15 minutes. If one considers the number of lots that would be compounded in four hours, the PECs would need to be cleaned and disinfected 50 to 60 times.</p> <p>We therefore recommend that 1751.4(d)(2) be deleted.</p> <p>Subsections 1751.4(d)(1) , 1751.4(d)(3) , and 1751.4(d)(4) are sufficient.</p> <p>Proposed language adds confusion and inhibits compliance and enforcement Unnecessary cleaning delays product provision and increases costs that will adversely affect patient access to care.</p>
1751.4(d)	<b>William Stuart</b> Hartley Medical	<p>Recommend:</p> <p>(d) Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:</p> <ol style="list-style-type: none"> <li>(1) At the beginning of each shift;</li> <li>(2) Before <del>and after</del> each <u>lot batch</u>;</li> <li>(3) <u>Not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring;</u></li> <li><del>(3)</del>(4) After <del>each</del> spills; and</li> <li>(5) When surface contamination is known or suspected.</li> </ol> <p>Rationale: We recommend remaining consistent with USP &lt;797&gt; guidelines.</p> <p>Site: ISO Class 5 Primary Engineering Control Minimum Frequency: "At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected" (Source: Chapter &lt;797&gt;, Table 3. Minimum Frequency of Cleaning and Disinfecting Compounding Areas, USP 38-NF 33, February 2015)</p>
1751.4(d)	<b>BJ Bartleson</b> California Hospital Association	No change in wording proposed- Simple recommendation to changing the numbering from 1751.4 (d) to 1754.4 (d)(1) for entire section so the below can be added.
1751.4(d)(2)	<b>BJ Bartleson</b> California Hospital Association	<p>Insert new language, "alternate cleaning schedules may be submitted to the Board, as in the case of fully automated IV robots"</p> <p>A contained robotic compounder is possible contaminated by the cleaning process. An alternative schedule such as mini clean daily, full clean weekly, etc., should be appended to the self-assessment form with documentation for the first submission.</p>
1751.4(d) & (e)	<b>Lynn Paulsen</b>	<p>Add language for self cleaning robot. A self-contained robot is not cleaned after every prep. Contamination comes from hands and arms. Mini-clean once a day, full clean once a week. Manufacturer instructions. Board can review alternative methods for approval. The cleaning requirements as is would eliminate the ability to use robotics in California.</p>

Code Section	Commenter	Comment
1751.4(d)(2)	<b>Rheta Sandoval</b> Kaweah Delta Health Care	<p>Cleaning AND disinfecting surfaces of the ISO Class 5 PEC before and after each lot (per the proposed definition in 1735(t)) may not be feasible depending on the scale of operations. There could be interference with timely medication preparation and dispensing in the hospital setting and significant operational impacts. For hospital pharmacies that are preparing upwards of 60,000 dosage units annually, 5 minutes or more spent cleaning surfaces followed by disinfecting surfaces in the ISO 5 PEC before and after compounding each "lot" would have a definite impact on operations and costs. USP and ASHP Guidelines on Compounding Sterile Preparations requires cleaning and disinfecting before each batch, with a "batch" defined differently than the BOPs proposed definition of "lot". Adopting USP 797s minimum frequency of cleaning and disinfecting the PEC with the term "batch" interchanged with "lot" could result in a regulation that would be difficult if not impossible for some facilities to comply with depending on compounding volume.</p> <p>The USP intent of the cleaning the PEC with a germicidal detergent is that it only needs to be done once a day (end of the compounding day or the beginning) (Personal Communication. Eric S. Kastango, MBA, RPh, FASHP. 3/25/15). The work areas need to be disinfected with sterile IPA or another suitable agent before each batch (Personal Communication. Eric S. Kastango, MBA, RPh, FASHP. 3/25/15). In the "Cleaning and Disinfecting the Compounding Area" section of USP &lt;797&gt;, it states "When the surface to be disinfected has heavy soiling, a cleaning step is recommended prior to the application of the disinfectant".</p> <p>In light of these points and keeping the general principle of cleaning in mind, that "all surfaces need to be visibly wetted, but not dripping, and the agent must be allowed to air dry" (K. Douglas, ES. Kastango. Requirements and Best Practices for Sanitizing Engineering Controls, pppmag, September 2013), the proposed regulation 1751.4(d)(2) is not feasible across all pharmacy sterile compounding settings.</p> <p>Please consider the following modification:            1. Revise 1751.4(d)(2) to read: before and after each lot (at minimum, disinfection);</p>
1751.4(d)(2)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: The most recent USP 797 regulations state that cleaning of the ISO 5 PEC should occur at the beginning of each work shift, before each batch (USP 797 only uses the word batch in referencing high-risk compounding) preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches. With the new proposed definition of "lot," interruption of workflow of hospital compounding in order to clean before and after each lot may impact the timeliness of medication delivery to patient and could introduce potential for medication errors.</p> <p>Solution: Remove "before and after each lot" and replace with "every 30 minutes during continuous compounding."</p>
1751.4(d)(4)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comments: We do not access our cleanroom on a daily basis, but use it approximately one or two times per week. As "daily" is defined in section 1735.1(m) as every day a pharmacy is operating, this regulation would require that my staff enter and clean the counters, work surfaces and floors even on days that the facility is not used! This, in my opinion, would increase the risk of contamination by excessive entry that is not necessary.</p> <p>Recommendation: Clarify the regulation by changing "daily" to "on each day of use."</p>
1751.4(e)	<b>BJ Bartleson</b> California Hospital Association	<p>"Outside the PEC, counters, cleanable work and table surfaces and floors shall be cleaned with germicidal detergent and rinsed with water daily. Walls, ceilings, storage shelving, and stools shall be cleaned with a germicidal detergent and rinsed with water monthly "</p> <p>CHA has concerns that the definitions of disinfectants and germicidal detergent overlap significantly. Disinfection of walls, ceilings, stools and floors as separate and distinct from the germicidal detergent is not supported by evidence.</p>

Code Section	Commenter	Comment
1751.4(e)	<b>Michael Tou</b> Providence Health	Counters, <u>and</u> cleanable work surfaces <del>and floors</del> shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent daily. <u>Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress.</u>  Providence recommends adding USP 797 wording for floor cleaning requirements. The current proposed wording of this section requires a three-step cleaning for floors which USP 797 does not require (a germicidal detergent and water and a disinfecting agent). If a single cleaning agent both cleans and disinfects it can be used alone according to USP 797. Water is not required separately for floor cleaning and a separate disinfecting agent is not required.
1751.4(e)	<b>Lynn Paulsen</b>	Stated 1754.4 @ hearing; however, that section does not exist.  Germicidal cleaner – Need to identify the difference between germicidal cleaner and disinfectant. Germicidal cleaner is a disinfectant with detergent. USP 797 germicidal cleaner followed by water. Hood would be cleaned with germicidal cleaner and alcohol. Change language for floors, ceiling, walls, shelves – clean with germicidal cleaner and water and nothing after that.
1751.4(f)	<b>Douglas Barcon</b> Barcon & Associates	Within the same section of USP 797 that includes numbers (1), (2), and (3) criteria, it also states: “It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 (see Table 1) for 0.5-um and larger particles.”  While criteria (1), (2), (3) include “shall” as in the source text of USP 797 in the section on placement of primary engineering controls, the intent in USP 797 is to also include manufacturer documentation that the CAI or CACI will meet criteria (1), (2), (3) in conditions worse than an ISO Class 8 ante-area, i.e., uncontrolled air quality or non-ISO classified room.  Note that USP 797 makes no reference to placement of a CAI or CACI in an ISO Class 8 compliant area. It must be inferred that CAI or CACI placement in such area would fall under the same category as air quality worse than ISO Class 8 because it exceeds ISO Class 7.  Suggest add (4): (4) manufacturer documentation/certification states that the CAI or CACI is compliant with (1), (2), and (3) of this section when located in located in environments where the background particle counts exceed ISO Class 8 for 0.5-um and larger particles or is a non-ISO classified area.  The addition of “or is a non-ISO classified area” was made because CAI/CACI manufacturers also test their units for compliance in regular room air, which is not tested for ISO compliance but generally is worse than ISO Class 8.  Section 1751.4 (h) addresses placement of a CAI in a non-ISO classified room but seems out of sync with the criteria in section 1751.4 (f) and conflicts with it if not changed.
1751.4(g)	<b>Brian Warren</b> California Pharmacist Association	<u>During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene <del>and garbing</del> must occur, complete with <del>hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two layers of gloves with the outermost glove tested to meet ASTM 6978-05. Where the documentation provided by CACI manufacturer does not require</del> <u>garbing, only the two glove requirement shall apply.</u>  The proposed regulations require use of a hair cover, beard cover, full gown, and shoe covers. Given the complete isolating nature of compounding within aseptic containment isolators, it is unclear why these garbing requirements are necessary.</u>

Code Section	Commenter	Comment
1751.4(g)	<b>BJ Bartleson</b> California Hospital Association	Remove the last sentence that states, "where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply"  CHA believes that a CACI manufacturer should not eliminate the requirement for protective garb and feels this has been confused with CAI requirements.
1751.4(g)	<b>University Compounding Pharmacy</b> Joe Grasela	Gloves tested to meet ASTM 6978-05 are standard practice for assessment of resistance of medical gloves to permeation by chemotherapy drugs. Why is it necessary to double glove? USP 800 doesn't require or propose a double glove when working with hazardous compounds.  During the hazardous drug compounding that is performed in a compounding aseptic containing aseptic containment isolator, full hand hygiene and garbing must occur, complete with hair cover,...and two layers of gloves with the outermost glove tested to meet ASTM 6978-05.
1751.4(i)	<b>Bruce Lepley</b> Community Regional Pharmacy	Reason for Concern: The most recent USP 797 regulations state that viable surface sampling be done periodically. Many hospitals conduct surface sampling every six months to coincide with the requirements for PEC and cleanroom certification. Pharmacies may also not have access to qualified individuals every quarter for surface sampling, but would have access to these qualified individuals every six months for the PEC and cleanroom certifications.  Solution: Reduce the viable surface sampling requirement to every six months to coincide with other sampling that will be performed by qualified outside vendors.
1751.4(j)	<b>Brian Warren</b> California Pharmacist Association	<u>(j) The pharmacy shall have a comfortable and well-lighted working environment, which includes an <b>appropriate</b> room temperature <del>of 20 degrees Celsius (68 degrees Fahrenheit) or cooler</del> to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.</u>  The structure of the working environment standards in Section 1751.4(j) do not contemplate compounding pharmacies using exclusively compounding aseptic isolators and/or compounding aseptic containment isolators. Some of these PECs do not require full garbing. If a compounding pharmacist is not wearing full garbing, the proposed temperature of 20 degrees Celsius may be uncomfortably cold for that pharmacist. We recommend requiring that comfortable conditions be maintained without mandating a specific temperature.
1751.4(j)	<b>Judith Brosz and Robert Stein</b>	(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 <del>personnel</del> <u>Sterile Compounding Personnel</u> when attired in the required compounding garb.
1751.4(j)	<b>Anonymous</b>	Since this proposed regulation is intended to address comfort, then it should be a range to accommodate everyone. What is a comfortable temperature is very subjective. Some Californians will find 68 degrees too cold, especially during winter. There is already a regulation defining controlled room temperature. Do we really need another state law to tell us what is comfortable for us? Please let me decide what is comfortable for me.
1751.4(j)	<b>Lynn Paulsen</b>	Some Hospitals do not have air conditioners or may keep an area cool, but not at or below 68 degrees. Recommendation is to eliminate temperature or change the wording. The cost to add air conditioning to hospitals would be substantial and would not be offset by patient safety.
1751.4(j)	<b>BJ Bartleson</b> California Hospital Association	Remove temperature requirement so section will read: "The pharmacy shall have a comfortable and well lighted working environment that maintains comfortable conditions for compounding personnel when attired in the required compounding garb."  Some hospital pharmacies are challenged with precision temperature control, however can continue to maintain a comfortable temperature for employees. The exact temperature stated in this section cannot be supported by evidence and is not required by Cal/OSHA. Therefore, CHA recommends removal of the exact temperature of 68 degrees.

Code Section	Commenter	Comment																					
1751.4(j)	<b>Douglas Barcon</b> Barcon & Associates	The temperature in this section should pertain to the sterile compounding area only per USP. It should not pertain to the whole pharmacy. Cooling the entire pharmacy to 68 degrees Fahrenheit will generally cause staff not garbed for compounding to feel cold and will cause excessive HVAC energy consumption. This may be good to increase profits for PG&E, Southern California Edison, and Sempra Energy, but is not an efficient use of energy.																					
1751.5(a)(4)	<b>Judith Brosz and Robert Stein</b>	(a)(4) <del>Compounding personnel</del> <u>Sterile Compounding Personnel</u> shall not wear hand, finger, or wrist jewelry. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.																					
1751.5(a)(6)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Change the wording to indicate that only persons with “exposed” rashes, sunburn, weeping sores, etc. and “exposed” cosmetics” be excluded from the designated areas.  “Individuals experiencing with exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing exposed cosmetics shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.”</p> <p>Rationale: The is no risk to patients unless the specified conditions are exposed.</p> <p>Proposed language adds confusion and inhibits compliance and enforcement. The is only a safety risk if the conditions specified are exposed. The rest of section 1751.5 specifies that 100% or nearly 100% of a person’s body is covered with “Personal protective equipment”, from head to toe.  The proposed unnecessary provision would cause patient care delays and increase costs that will adversely affect patient access to care. If a NON-exposed condition is discovered after compounding, this proposed regulation provision would cause confusion about what subsequent procedure should be followed. Should the product be recalled despite no risk from a NON-exposed condition? Further, there are serious employee privacy concerns. Should management require a “strip search inspection” before each compounding session to assure that products will not have to be recalled?</p>																					
1751.5(a)(6)	<b>Dennis Lau</b>	<p>Many hospital pharmacy departments are staffed with very few staff members thereby necessitating all staff members, including administrators to be called into action for compounding sterile products.</p> <p>1. Could the Board specify the cosmetic types or formulations not allowed (shedding of flakes and particles) in ISO Class 5 and ISO Class 7 compounding areas similar to the FDA cosmetic product categories outlined below?  FDA Product category code = 03 [Eye Makeup Preparations]</p> <table border="0"> <tr> <td>a. Eyebrow Pencil</td> <td>b. Eyeliner</td> <td>c. Eye Shadow</td> </tr> <tr> <td>d. Eye Lotion</td> <td>e. Eye Makeup Remover</td> <td></td> </tr> <tr> <td>f. Mascara</td> <td>g. Other Eye Makeup Preparations</td> <td></td> </tr> </table> <p>FDA Product category code = 07 [Makeup Preparations (not eye)]</p> <table border="0"> <tr> <td>a. Blushers (all types)</td> <td>b. Face Powders</td> <td>c. Foundations</td> </tr> <tr> <td>d. Leg and Body Paints</td> <td>e. Lipstick</td> <td>f. Makeup Bases</td> </tr> <tr> <td>g. Rouges</td> <td>h. Makeup Fixatives</td> <td></td> </tr> <tr> <td>i. Other Makeup Preparations</td> <td></td> <td></td> </tr> </table> <p>2. Would the Board allow use of face shields as is used in surgery by operating room nurses for persons wearing cosmetics?</p> <p>3. Would the Board allow use of cosmetic “sealers” used by professional makeup artists?</p>	a. Eyebrow Pencil	b. Eyeliner	c. Eye Shadow	d. Eye Lotion	e. Eye Makeup Remover		f. Mascara	g. Other Eye Makeup Preparations		a. Blushers (all types)	b. Face Powders	c. Foundations	d. Leg and Body Paints	e. Lipstick	f. Makeup Bases	g. Rouges	h. Makeup Fixatives		i. Other Makeup Preparations		
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Code Section	Commenter	Comment
1751.5(a)(6)	<b>BJ Bartleson</b> California Hospital Association	<p>"Individuals experiencing active infections, visible rashes or other breaks in exposed skin integrity shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas. Cosmetics, gel nails or nail polish are not allowed. Eyelash extensions are not prohibited."</p> <p>CHA suggests new wording in this section to improve specificity and compliance with the regulation.</p>
1751.6	<b>Judith Brosz and Robert Stein</b>	<p>1751.6. Sterile Compounding Consultation; Training of Sterile Compounding <del>Staff</del> Personnel</p> <p>(b) The pharmacist-in-charge shall ensure that all <del>pharmacy personnel engaging in compounding sterile drug preparations</del> <u>Sterile Compounding Personnel</u> have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents.</p> <p>(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of <del>pharmacy personnel engaged</del> <u>Sterile Compounding Personnel</u> in compounding sterile drug preparations.</p> <p>(e) Pharmacies that compound sterile drug preparations must comply with the following training requirements:</p> <p>(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that <del>each person working in the designated area</del> <u>Sterile Compounding Personnel</u> <del>has</del> <u>have</u> the knowledge and skills necessary to perform their assigned tasks properly. ...</p> <p>(E) Aseptic preparation procedures using media-fill tests which are as complicated as the most complex manipulations performed by <del>staff</del> <u>Sterile Compounding Personnel</u> and which contain the same amount or greater of volume transferred during the selected manipulations.</p> <p>(2) <del>Each person engaged in sterile compounding</del> <u>Sterile Compounding Personnel</u> must <u>each</u> successfully complete practical skills training in aseptic technique and aseptic area practices.</p>
1751.7(b)	<b>Judith Brosz and Robert Stein</b>	<p>(b) <del>Each individual involved in the preparation of sterile drug preparations</del> <u>Sterile Compounding Personnel</u> must <u>each</u> first successfully demonstrate competency by successfully performing aseptic media-fill tests before being allowed to prepare sterile drug preparations. The media fill testing process shall be as complicated as the most complex manipulations performed by <del>staff</del> <u>Sterile Compounding Personnel</u> and contain the same amount or greater of volume transferred during the compounding process. ...</p> <p>If microbial growth is detected, then the <del>employee's</del> <u>Sterile Compounding Personnel's</u> sterile preparation process must be evaluated, corrective action taken and documented, and the media-fill testing repeated. <del>Personnel</del> <u>Sterile Compounding Personnel</u> 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. Aseptic work practice assessments via media fill tests must be revalidated, as appropriate to the circumstance or <del>personnel</del> <u>Sterile Compounding Personnel</u> found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile drug preparations is 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.</p>
1751.7(b)	<b>Judith Brosz and Robert Stein</b>	<p>(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, all <del>compounding personnel</del> <u>Sterile Compounding Personnel</u> 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 preparations.</p>

Code Section	Commenter	Comment
1751.7(e)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	<p>1751.7 (e) Sterile Compounding Quality Assurance and Process Validation            In a circumstance where a 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,</p> <p>(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 <b>and patient's</b> written consent to dispense.</p> <p>(2) And subsequent to dispensing:  <b>(A) Send random sample for sterility and pyrogen testing as part of process validation</b>  <b>(B) Notify physician if results demonstrate microbial growth or pyrogens</b>  <b>(C) Have protocol approved by the Pharmacy &amp; Therapeutics Committee</b></p> <p>Would recommend including this section back into the regulation revision to avoid patient loss of life or intense suffering due to the inability to provide emergency medications to patients. In rare circumstances medications such as Alum and Formalin are needed to treat hemorrhagic cystitis that can be life-threatening. Evidence supports that these drugs are needed when other measures fail. The patient could bleed to death without this provision.</p>
1751.7(e)	<b>Marie Cottman</b> Pacific Compounding Pharmacy	<p>Comments: With regards to pyrogen testing, this regulation is in conflict with USP &lt;797&gt;, &lt;85&gt; and &lt;771&gt; recommendations for testing ALL sterile products. USP &lt;797&gt; specifically exempts ophthalmic drops and inhalations from testing for pyrogens. Additionally, USP &lt;85&gt; only provides guidance and limits for pyrogens found in injectable products. <b>There is no defined limit</b> of a pyrogen for a sterile ophthalmic drop or for an inhalation. Without a defined industry standard, it is inappropriate to expect that compounders can comply with this regulation as proposed.</p> <p>Recommendation: Clarify that pyrogen testing is for sterile INJECTABLE drugs only.</p> <p>Consider rewording 1751.7 (e):  <u>All Non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility. Additionally, non-sterile-to-sterile batch injectable drug preparations shall be subject to documented end product testing for pyrogens and shall be quarantined until the end product testing confirms both sterility and acceptable levels of pyrogens, per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and/or 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.</u></p> <p>References:            USP &lt;797&gt; High Risk Sterile Compounds Sterility Testing and Bacterial Endotoxin (Pyrogen) Testing.            USP &lt;85&gt; Bacterial Endotoxins Testing            USP &lt;771&gt; Ophthalmic Preparations- Quality Tests. This document is consistent with &lt;797&gt; and &lt;85&gt; in that on page 8, <u>Sterility</u> is a quality test required for ALL ophthalmic dosage forms, but <u>Bacterial Endotoxins</u> is required <b>only</b> for injected ophthalmic drug products.</p>

Code Section	Commenter	Comment
1751.7(e)	<p><b>Brian Warren</b> California Pharmacist Association</p> <p>(Also commented on at hearing by Tony Park)</p>	<p><del>(c) (e) (1)</del> <del>Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients.</del> <b><u>Except as provided in paragraph (2), <del>n</del> n</u></b> on-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, 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.</p> <p><b><u>(2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:</u></b></p> <p><b><u>(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less.</u></b></p> <p><b><u>(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 30 days or less.</u></b></p> <p><b><u>(C) Preparations compounded in a batch of 25 or fewer doses for a single patient that are terminally sterilized by autoclave or dry heat sterilization.</u></b></p> <p><b><u>(D) Preparations needed for emergency administration to prevent the loss of life or intense suffering, when compounded for administration to a single patient and only in a quantity sufficient for the emergency course of therapy.</u></b></p> <p><b><u>(E) Preparations compounded for a single patient with a chemical stability of 14 days or less.</u></b></p> <p>As stated in the Board’s Initial Statement of Reasons, the justification for changes to this section is to address “the problem of ensuring that board regulations are aligned with compounding standards in USP 37 &lt;797&gt; and reducing such discrepancy for the compounding profession who are compounding drug products in California and shipping into California so as to ensure the safety of all consumers receiving compounded drugs in California.” As currently drafted, the Board’s proposed regulation is not in alignment with USP &lt;797&gt;, and could negatively impact patients due to delays in availability of non-sterile-to-sterile preparations and increases in the cost of non-sterile-to-sterile preparations.</p> <p><b>Continued on the next ROW</b></p>
1751.7(e)	<p><b>Brian Warren</b> California Pharmacist Association</p>	<p><b>Continued from previous ROW</b></p> <p>We also acknowledge the Board’s mandate to protect patient safety above all other considerations and understand the intent of adopting standards that are more strict than USP &lt;797&gt;. As such, we recommend establishing a limited number of narrow exceptions to the Board’s end-product testing requirements. The recommended exceptions are consistent with USP &lt;797&gt;.</p> <p>These narrow exceptions include non-sterile-to-sterile compounds for single-patient, short term ophthalmic products (which is already included by the Board) and inhalation products. Additionally, we propose an exception for small batches compounded for a single patient that are terminally sterilized. Always requiring end-product testing for these preparations will unnecessarily increase costs and harm patient access to these important medications (by about \$150 per batch tested).</p> <p>We also recommend an exception for emergency use. This is particularly important when hospitals experience drug shortages. Absent this exception, it is likely that these preparations will be compounded by non-pharmacists in the hospital setting who have no sterile compounding qualifications. For example, consider the use of LETS (lidocaine, epinephrine, tetracaine, and sodium metabisulfite) solution, commonly used for sterile irrigation and topical anesthesia for lacerations in children. LETS solution should be treated as a non-sterile-to-sterile preparation with terminal sterilization using microfiltration. However, LETS “kits” are also sold in convenient packaging containing all pre-weighed ingredients in their raw, nonsterile forms, which are then compounded in a non-sterile environment using sterile water with or without terminal sterilization. Practices such as this will likely become more common if facilities and providers experience delays in accessing non-sterile-to-sterile preparations from sterile compounding pharmacies. Use of these kits by healthcare personnel other than pharmacists trained in sterile compounding presents a threat to the public health and safety.</p> <p>Lastly, we recommend an exception for preparations with short-term chemical stability. These preparations will experience chemical degradation prior to completion of end-product testing, which takes 14 days.</p>

Code Section	Commenter	Comment
1751.7(f) - Add	<b>Judith Brosz and Robert Stein</b>	<p><u>(f) Personnel that are not directly engaged in sterile compounding, but are involved in other compounding activities such as remote checking of compounded products outside the controlled area, do not need to perform practical aseptic preparation tests, but shall otherwise complete all written competency examinations on the process.</u></p> <p>Added (f) to clarify that remote checking should not have identical training requirements to actual production of sterile drug preparations in the controlled environment. While written competency tests are appropriate, demonstrations of cleaning and needle handling are not necessary for those personnel not entering the controlled area.</p>
1751.8	<b>Lauren Berton</b> CVS Health	<p>It is recommended that the members of the Board review the possibility of removing all language in the 1751.8 a-e and only refer to USP chapter 797 as suggested below. This recommendation is based on reviews and changes to USP chapters on Beyond Use Dating, which would require rewriting of the current rules with every change.</p> <p>1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations. In conformity with and 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 does not exceed the expiration date or beyond use date provided by the manufacturer for any component in the preparation, and that, 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 (USP37-NF32) <del>Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference,</del> that would justify a more extended beyond use date, <u>be labeled with a beyond use date that conforms to the following limitations the storage and beyond use dating guidelines in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32).</u></p>
1751.8	<b>Douglas Barcon</b> Barcon & Associates	Delete “a more” and replace with “an”
1751.8	<b>Doug O'Brien</b> Kaiser Permanente	Recommendation: Add specific language stating that the BUDs defined in sections (a) through (d) may be utilized for preparations compounded in CAIs or CACIs that meet the requirements delineated in 1751.4(f)
1751.8(a)	<b>Douglas Barcon</b> Barcon & Associates	There is no definition for “controlled freezer temperature” in USP 659, USP 797, or general notices in USP-37 NF-32. USP 797 states: “and for 45 days in solid frozen state between -25 degrees and -10 degrees C.” Inconsistent freezer temperatures throughout the freezer can result in some sterile compounded drug preparations or products (premixed piggybacks) being in semi-solid state even though the reported temperature is within range. The key is solid frozen state to qualify for 45-days BUD. Suggest incorporate USP 797 definition including solid frozen state.

Code Section	Commenter	Comment
1751.8(a)	<b>University Compounding Pharmacy</b> Joe Grasela	<p>...in the absence of passing a sterility test ...</p> <p>(a) The beyond use date shall specify that the storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days at controlled freezer temperature...(1) The preparation is compounded entirely within an ISP Class 5 PEC located in an ISO Class 7 buffer area or cleanroom...using only sterile ingredients, products, components, and devices,...(2) ...using not more than 3 commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container...</p> <p>(b) The beyond use date shall specify that storage and exposure periods <b>cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days at controlled freezer temperature</b>, there the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area or cleanroom....a compounded sterile preparation that will be administered <b>either to multiple patients or to one patient on multiple occasions...</b>(2) <b>The compounding process involves complex manipulations other than the single-volume transfer...</b></p> <p>Section (b) is clearly defines the end user and applicable to multiple patients or to one patient using a multi-use container however section (a) does not define it's end user. Is section (a) also applicable to multiple patients or multi-use container as well?</p> <p>Section (b) is only applicable if using more than 3 commercially manufactured packages. Is that the only difference? Therefore why wouldn't section (a) be applicable for multiple users or multi-use container?</p>
1751.8(a)(1)	<b>Michael Tou</b> Providence Health	<p>(1) The preparation is compounded entirely within an ISO Class 5 PEC <del>in an ISO Class 7 buffer area or cleanroom with an ante-area</del>, or better air quality...</p> <p>The proposed language restricts sterile compounding with USP 797 defined beyond-use dating to only within an ISO 7 buffer area with an ante-area. USP 797 guidelines allow for sterile compounding within a CAI or CACI that meets all of the operational criteria as defined in Section 1751.4(f) and use of beyond-use dating specified. A buffer area and ante-area should not be required. Providence recommends adopting the wording used in USP 797.</p>
1751.8(b)	<b>Douglas Barcon</b> Barcon & Associates	<p>There is no definition for "controlled freezer temperature" in USP 659, USP 797, or general notices in USP-37 NF-32. USP 797 states: "and for 45 days in solid frozen state between -25 degrees and -10 degrees C." Inconsistent freezer temperatures throughout the freezer can result in some sterile compounded drug preparations or products (premixed piggybacks) being in semi-solid state even though the reported temperature is within range. The key is solid frozen state to qualify for 45-days BUD. Suggest incorporate USP 797 definition including solid frozen state.</p>
1751.8(b)(1)	<b>Michael Tou</b> Providence Health	<p>(1) The preparation is compounded entirely within an ISO Class 5 PEC <del>located in an ISO Class 7 buffer area or cleanroom with an ante-area</del>, or better air quality...</p> <p>The proposed language restricts sterile compounding with USP 797 defined beyond-use dating to only within an ISO 7 buffer area with an ante-area. USP 797 guidelines allow for sterile compounding within a CAI or CACI that meets all of the operational criteria as defined in Section 1751.4(f) and use of beyond-use dating specified. A buffer area and ante-area should not be required. Providence recommends adopting the wording used in USP 797.</p>
1751.8(c)	<b>Douglas Barcon</b> Barcon & Associates	<p>There is no definition for "controlled freezer temperature" in USP 659, USP 797, or general notices in USP-37 NF-32. USP 797 states: "and for 45 days in solid frozen state between -25 degrees and -10 degrees C." Inconsistent freezer temperatures throughout the freezer can result in some sterile compounded drug preparations or products (premixed piggybacks) being in semi-solid state even though the reported temperature is within range. The key is solid frozen state to qualify for 45-days BUD. Suggest incorporate USP 797 definition including solid frozen state.</p>

Code Section	Commenter	Comment
1751.8(c)	<b>William Stuart</b> Hartley Medical	<p>Recommend: The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days at controlled freezer temperature, where the sterile compounded drug preparation is compounded solely with aseptic manipulations 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.</p> <p>Rationale: <b>The clause, “or where the sterile compounded drug preparation lacks effective antimicrobial preservatives” is not referenced in USP &lt;797&gt;.</b></p> <p>Numerous CSP’s prepared do not contain antimicrobial preservatives, such as: Total Parenteral Nutrition, Large and Small Volume Parenterals, Antibiotics, and Morphine Infusions utilized in home care setting that are currently categorized as Low and Medium Risk preparations.</p> <p>Antimicrobial preservatives are contra-indicated in epidural / intrathecal infusions. Therefore, Morphine (Infumorph) and bupivacaine (Marcaine), which are currently categorized as Low Risk with a 14-day BUD, would change to 72 hours under proposed regulations.</p> <p>Certain compounded preparations have inherent antimicrobial properties. The active pharmaceutical ingredient, osmotic forces, base vehicle, and pH can contribute to decreased microbial survivability. (Source: Rosenberg H and Renkonen O: Antimicrobial Activity of Bupivacaine and Morphine. Anesthesiology 62: 178-179, 1985.)</p>
1751.8(e)(1)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Many large health care facilities already employ the use of an “immediate use only” label for reasons other than a 1 hour BUD (e.g. criticality of the drug, cost of the drug, etc.) In addition, other regulatory agencies (i.e. The Joint Commission) have stipulations in existence for labeling “immediate use” sterile products (i.e. medication name, strength, quantity, diluent and volume, expiration date when not used within 24 hours, and expiration time when expiration occurs in less than 24 hours). To avoid confusion, it would be beneficial to specifically remove the requirement of labeling the product for “immediate use only” and impose the existing regulation of the expiration time when expiration occurs in less than 24 hours.</p> <p>Solution: Replace the requirement of labeling for “immediate use only” with the exact one hour beyond use date and time.</p> <p>Reason for Concern: This section does not stipulate as to whether this applies to all healthcare professionals who are qualified to engage in immediate use sterile compounding drug preparation outside the profession of pharmacy.</p> <p>Solution: Please clarify and insert verbiage to make clear of whether or not this stipulation applies to all professions outside of pharmacy who are qualified to engage in immediate use sterile compounding (e.g. RN).</p>
1751.8(e)(2)	<b>Bruce Lepley</b> Community Regional Pharmacy	<p>Reason for Concern: Other regulatory agencies (i.e. The Joint Commission) have stipulations in existence for one to compound immediate use sterile products which include: “...a delay could harm the patient ...or the products stability is short. To mitigate risk of confusion we recommend adopting similar language that would accomplish the intent of this section.</p> <p>Solution: Reword section to use “a delay could harm the patient” or “the products stability is short”.</p>

Code Section	Commenter	Comment
1751.9(a), (b), (c)	<b>Doug O'Brien</b> Kaiser Permanente	<p>Recommendation: Include above language from USP 797 allowing the use of proven technologies with quality assurance procedures (for example, Closed System Transfer Devices) allowing for extension of BUD for single-dose vials.</p> <p>Rationale: One of the hallmarks of USP and Current Good Manufacturing Practices (cGMP) is the ability of entities under the guidelines to be innovative and advance practice with validated processes that differ from the current standards. The advancement of knowledge, technology, and validation processes in a very fluid environment must be allowed to flourish; thus the ability to design programs that meet or exceed current outcomes is essential. The key statement allowing this within the USP 797 is as follows:</p> <p>"The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein."</p> <p>The regulation as proposed is confusing to industry professionals and the Board of Pharmacy's intent.</p> <p>The recommendation aids in concordance with USP Chapter 797 National Standards and aids in reduction in drug wastage, increases opportunities to save drug during manufacturer shortages and may result in significant health care cost savings.</p>
1751.9(b)	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	<p><del>(e)</del> <b>(3)</b> 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 storage circumstance.</p> <p><b><u>(4) The use of technologies, techniques, materials, and procedures other than those described in this sterile compounding section is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein" (USP 797 page 1).</u></b></p> <p>Additionally, as a result, counterfeit chemotherapy is an area of national concern, until such time as E-Pedigree is available.</p> <p>Closed system transfer devices (CTSD) protect the vial from entry of external bacteria after initial puncture beyond the USP 797 approved 6 hour time limit. It has been shown that one of these systems maintains sterility of the vials to which it is attached for up to 168 hours (7 days).</p> <p>Recommendation: Allowance to use CTSDs with supporting literature to extend the beyond use date of single dose vials of chemotherapy to 24 hours or use through the end of the shift, whichever is shorter. This recommendation is more conservative than the timeframe of 7 days listed in the CTSD study and would assist institutions in conserving scarce chemotherapy medications.</p>
General Comment	<b>University Compounding Pharmacy</b> Joe Grasela	<p>Just a suggestion. If we go with USP 797 and 795 and 71 and 800 I think all the work is done for you. its reviewed by the usp and sent out to all states BOP'S and people involved for review. Also our inspection for a sterile license would satisfy other states that require 797 compliance.</p>
General Comment	<b>Michael Tou</b> Providence Health	<p>We urge the board to clarify the intent of the rule language in section 1735.2(d)(3) and 1751.2(b). The board committed to preparing guidance rather than amend the language for these two sections in response to our comments during previous rulemaking.</p>

Code Section	Commenter	Comment
General Comment	<b>Katherine Palmer</b> <b>Rita Shane</b> Cedars-Sinai Medical Center	1) Ability to provide emergency therapy to patients to avoid patient loss of life or intense suffering when other hemorrhagic cystitis treatments have failed.  2) Ability to provide chemotherapy to patients in the setting of continued drug shortages of cancer medications by using equivalent or superior technologies for preserving medication vials.

# **Attachment 7**

## **Medication Article 9.1**

### **Prescription Drug Take-Back Programs**

#### **Section 1776**

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and are also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

#### **Section 1776.1 Pharmacies**

- (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.
- (b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.6. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under California Health and Safety Code section 1250(c).
- (c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
- (d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.

- (e) The following dangerous drugs and devices are expressly prohibited from collection in a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.
- (f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.
  - (1) Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
  - (2) A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
  - (3) A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.
- (g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.
- (h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
  - (1) Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board. If the pharmacy later ceased to operate the collection receptacle, the pharmacy must notify the board within 30 days.
  - (2) Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
  - (3) Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.
  - (4) Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (i) If a pharmacy later ceases to operate a collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.

**1776.2 Mail Back Package and Envelope Services from Pharmacies**

- (a) Pharmacies that provide prescription drug take-back services may do so by

establishing mail back services, whereby the public may obtain from the pharmacy preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.

- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.
- (c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.
- (d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.
- (e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.6.
- (f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.
- (g) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

### **1776.3 Collection Receptacles in Pharmacies**

- (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
- (b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas.
- (c) In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.
- (d) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.
- (f) A liner as used in this article shall be made of material that is certified by the

manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.

- (1) The liner shall be waterproof, tamper evident and tear resistant.
  - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor.
- (g) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.
- (h) If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The containers shall be capable of being sealed and be kept clean and in good repair.
- (i) The liner may be removed from a locked receptacle only by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. If the liner is not already contained in a rigid container within the receptacle, the two employees shall immediately place the liner in a rigid container. Liners and their rigid containers shall not be opened, x-rayed, analyzed or penetrated.
- (l) Liners and their rigid containers that have been filled and removed from a collection receptacle, must be stored in a secured, locked location in the pharmacy no longer than three days.
- (m) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:
- (1) The unique identification numbers of all unused liners in possession of the pharmacy,
  - (2) The unique identification number and dates a liner is placed in the collection receptacle,
  - (3) The date the liner is removed from the collection receptacle,
  - (4) The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
  - (5) The date the liner was provided to a licensed DEA-registered reverse distributor for

destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor. If a common carrier is used to transport the liner to the reverse distributor, the company used, the signature of the driver, and any related paperwork (invoice, bill of lading) must be recorded.

- (n) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by licensed reverse distributor pick-up at the licensed pharmacy's premises.
- (o) The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (p) The board shall develop signage to appear on the collection receptacle to provide consumer information about the collection process.

#### **1776.4 Collection in Skilled Nursing Facilities**

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

- (a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.2. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.
  - (1) Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
  - (2) Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
  - (3) Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
  - (4) Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy

license.

- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.
- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
- (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
- (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed. The collection receptacle shall have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner.
- (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removable inner liner.
  - (1) The liner shall comply with provisions in this article. The receptacle shall allow deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be viewed, removed or counted.
  - (2) If the liner is not already itself rigid or already inside of a rigid container as it is removed from the collection receptacle, the liner must be immediately placed in a rigid container for storage, handling and transport. A rigid container may be disposable, reusable, or recyclable. Rigid containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Rigid containers may be of any color. All rigid containers must meet standards of the United States Department of Transportation for transport of medical waste. The rigid containers shall be capable of being sealed and be kept clean and in good repair.
- (i) A liner as used in this article shall be made of material that is certified by the manufacturer to meet American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes.
  - (1) The liner shall waterproof, tamper evident and tear resistant.
  - (2) The liner shall be opaque to prevent viewing or removal of any contents once the

liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer.

- (j) The collection receptacle shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
- (k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.
- (l) The installation, removal, transfer and storage of inner liners shall be performed only by:
  - (1) One employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
  - (2) By or under the supervision of two employees of the authorized collector pharmacy.
- (m) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (n) Liners still housed in a rigid container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners in the rigid containers and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (o) Records of the pickup, delivery and destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transported each liner.

#### **1776.5 Reverse Distributors**

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) registered DEA as a collector may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately licensed DEA distributor.

- (c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (d) A reverse distributor shall not employ as an agent or employee anyone who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.
- (f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
  - 1. Date of acquisition
  - 2. Number and the size (e.g., five 10-gallon liners, etc.)
  - 3. Inventory number of each liner or envelope/package
  - 4. The method of delivery to the reverse distributor, the signature of the individuals delivering the liners to the reverse distributor, and the reverse distributor's employees who received the sealed liner
  - 5. The date, place and method of destruction
  - 6. Number of packages and inner liners received
  - 7. Number of packages and inner liners destroyed
  - 8. The number and signature of the two employees of the registrant that witnessed the destruction.

#### **1776.6 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services**

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

- (a) When obtaining unused mail-back packages and envelopes for future distribution:
  - 1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
  - 2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.
- (b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.
- (c) For sealed mail-back packages received by the reverse distributor: the date of receipt

- and the unique identification of the individual package or envelope,
- (d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.
  - (e) For pharmacies using collection receptacles, for each liner:
    - 1. Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
    - 2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
    - 3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
    - 4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
    - 5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it and the signature of the driver.
  - (f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:
    - 1. The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).
    - 2. For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.