California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Legislation and Regulation Committee
Chair Report

Seung Oh, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice Chair
Cheryl Butler, Licensee Member
Jose De La Paz, Public Member
Shirley Kim, Public Member
Nicole Thibeau, Licensee Member

I. Call to Order, Establishment of Quorum, and General Announcements

II. Public Comment for Items Not on the Agenda, Matters for Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

III. Approval of July 15, 2021, Committee Meeting Minutes

No meeting minutes are available for July 15, 2021 as the meeting was canceled.

IV. Discussion and Consideration of Draft Frequently Asked Questions Relating to Senate Bill 212 (Chapter 1004, Statutes of 2018) Solid Waste: Pharmaceutical and Sharp Waste Stewardship

Attachment 1

Relevant Law
Chapter 2 of Pharm 3 of Division 30 of the Public Resources Code (PRC) in general terms establishes the requirements for pharmaceutical and sharps waste stewardship programs. As included in the provisions, the primary regulator of the program is the California Department of Resources Recycling and Recovery (Cal Recycle)

PRC section 42031 provides reporting requirements to the California Board of Pharmacy, including a list and description of drugs or sharps that are covered or not covered as provided by the manufacturer or other specified covered entity.

Background
As the Board has undertaken implementation of the provisions with the Cal Recycle, staff have identified several common questions related to the Board's purview for the stewardship programs. To assist covered entities and others with an understanding of the requirements, frequently asked questions have been developed as staff believe they have broad applicability. The FAQs have been reviewed by staff at the California Department of Public Health and Cal Recycle.

For Committee Discussion and Consideration
During the meeting members will have the opportunity to review the FAQs and determine if they are appropriate to recommend approval by the Board or to provide other direction to staff.

Attachment 1 includes a copy of the draft FAQs.

V. Discussion and Consideration of California Code of Regulation Sections 1717 and 1717.4 Related to Electronic Prescriptions Including Possible Changes

Attachment 2

Relevant Law
Business and Professions Code section 688 establish the requirements for electronic prescribing including the capabilities for prescribers and dispensers.

CCR section 1717, in general establishes some provisions of pharmacy practice, including a provision for a pharmacist to transfer a prescription.

CCR section 1717.4 establishes provisions for electronic transmission of prescriptions.

Background
Given the recent enactment of the provisions of BPC 688, conforming changes are necessary to the Board's regulation to avoid conflict within various provisions of Pharmacy Law.

For Committee Consideration and Discussion
During the meeting members will have the opportunity to review proposed regulation language. This draft language is undergoing legal review. Updates to the language will be provided during the meeting should changes be necessary based on this review.

Attachment 2 includes a copy of the language.

Should the committee believe the language as presented is appropriate, the following motion could be used to recommend initiation of the rulemaking process to the Board.

> Recommend initiation of a rulemaking to amend CCR sections 1717 and 1717.4 based on the policy discussions. Authorize the chair and executive officer to further refine the language consistent with the policy discussions as may be required by control agencies (DCA or Agency). Additionally, authorize the executive officer to make any non-substantive changes prior to initiation of the rulemaking. Further, if no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulation at sections 1717 and 1717.4 as noticed for public comment.

VI. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

Provided below are several measures for the Committee's consideration. A brief summary of each measure is provided along with staff comments and recommendations. A link to each measure and committee bill analysis is also provided. During the meeting members will have the opportunity to discuss each measure and the Board's current position, if applicable, to determine what changes, if any, are appropriate.

1. Assembly Bill 458 (Kamlager) Importation of Prescription Drugs
   Version: As Amended March 23, 2021
   Status: Referred to Committee on Health
   Committee Analysis: None on File
   Summary: Would create the Affordable Prescription Drug Importation Program in CHHSA, under which the state would be a licensed wholesaler that imports prescription drugs, as specified, for the exclusive purpose of dispensing those drugs to program participants. Further, would authorize a contracted importer to import a prescription drug from a Canadian supplier if specified requirements are met and would authorize CHHSA to expand the importation program to authorize a manufacturer, wholesale distributor, or pharmacy in a foreign country other than Canada to export prescription drugs to California if specified requirements are met, including a change in federal law.
   Board Position: None
   Comments: The author's office has indicated that a decision to move the bill is under consideration.
   Fiscal Impact: Undetermined

2. Assembly Bill 646 (Low) Department of Consumer Affairs: Boards: Convictions
   Version: As Amended April 14, 2021
   Status: Held in Committee
   Committee Analysis: Assembly Business and Professions Committee Analysis
   Summary: Would require professional licensing boards under the Department of Consumer Affairs that post information on their internet website about a revoked license due to a criminal conviction to update or remove information about the revoked license should the board receive an expungement order related to the conviction, as specified.
   Board Position: None
   Comments: The author's office indicates their intention to move the bill.

3. Assembly Bill 1328 (Irwin) Clinical Laboratory Technology and Pharmacists
   Version: As Amended July 14, 2021
   Status: Held in Committee
   Committee Analysis: Assembly Business and Professions Committee Analysis
   Summary: Would amend several provisions of the Business and Professions Code to expand the authority for pharmacists to perform CLIA-waived tests either approved or authorized by the FDA upon patient request or hospital authorization provided that there is a valid and respective CLIA certificate of waiver and laboratory license, with some exceptions. Exceptions include CLIA waived tests that are used for surgery, diagnosis or treatment of heart failure, female fertility, or ovulation prediction. Further, would require a pharmacist to notify the patient's primary care provider, or other appropriate physician and surgeon, of any abnormal test results. In the event the patient refuses consent or does not have a primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care service providers to contact for ongoing patient care. Further, would amend Pharmacy Law to declare that pharmacy practice is a patient and public health-oriented health service that is continually evolving to include more sophisticated and comprehensive patient care and public health activities.
   Board Position: Support
   Comments: The author's office indicates that a decision to move the bill will be made later this year.
   Fiscal Impact: Undetermined

4. Senate Bill 731 (Durazo) Criminal Records: Relief
   Version: As Amended September 02, 2021
   Status: Motion to Reconsider Filed
   Committee Analysis: Assembly Public Safety Committee Analysis
   Summary: Under existing law, effective July 1, 2022, the Department of Justice is required to review arrest records on a monthly basis to identify arrest and conviction records that are eligible for record relief under specified conditions. This measure would make the current provisions effective for arrests that occurred on or after January 1, 2021 and would expand many of the provisions to include any felony arrest or conviction under specified conditions. Further, the measure would prohibit state or federal summary criminal history information from including records of arrest or convictions that were granted relief, unless the records require the record-holder to register as a sex offender or other conditions. Recent amendments provide that relief granted pursuant to this section does not release the defendant from an unexpired criminal protective order.
   Board Position: Oppose Unless Amended
   Comments: As a consumer protection agency, the Board must have access to full information to evaluate an individual's background prior to making a licensing decision. The Board's authority to take action on various types of past criminal or arrest has been limited over the past several years. This measure appears to place additional limits on the information the Board receives as part of its investigation and evaluation of an applicant prior to licensure, and could encompass more serious felonies that should have a bearing on a licensure.

   The author's office has indicated their intention to move the bill this year.

   Fiscal Impact: Minor and absorbable.

VII. Board Adopted Regulations Under Final Review by the Office of Administrative Law

Attachment 3

1. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

   Summary of Regulation: This proposal amends the drug loss reporting requirements to further define when drug losses must be reported and to increase clarity for the regulated public.

   Status: OAL decision due by February 23, 2022.

2. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Summary of Regulation: This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

   Status: Approved by OAL on January 11, 2022 with an April 1, 2022 effective date.

3. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification

   Summary of Regulation: This proposal amends the board's regulations regarding the requirements for a licensee to maintain a current electronic mail address with the board, should the licensee have one.

   Status: Filed with OAL on December 6, 2021. OAL decision due by January 18, 2022.

4. Proposed Regulation to Amend Title 16 CCR Section 1746.4, Related to Administering Vaccines

   Summary of Regulation: This proposal amends the vaccination reporting requirements to the primary care physician to upon patient request.

   Status: Filed with OAL on December 13, 2021. OAL decision due by January 25, 2022.

VIII. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or Business, Consumer Services and Housing Agency

Attachment 4

Provided below is a summary of each of the regulations currently undergoing pre-notice review. As there are many steps included in the pre-review process, the status is detailed below. Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**. The full timelines for each of the regulation are included in **Attachment 4**.

1. Proposed Regulation to Amend Title 16 CCR Section 1735.2 to Update the Compounding Self-Assessment Form 17M-39

   Summary of Regulation: This proposal updates the Self-Assessment form 17M-39 (rev. 02/12) as incorporated by reference in Title 16 CCR section 1735.2.

   Status: Submitted to DCA on **July 14, 2021**.

IX. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Attachment 5

1. Proposed Regulation to Amend Title 16 CCR Section 1707.6 Related to the Notice to Consumers

   Summary of Regulation: This proposal amends the board's regulations regarding the notice to consumers to update the wording on the poster.

   Status: Approved by Board in October 2021. Staff drafting rulemaking documents to be submitted in February 2022.

X. Future Committee Meeting Dates

The committee will meet on the following dates:

- April 26, 2022
- July 18, 2022

Attachment 1

Draft – Frequently Asked Questions: Pharmaceutical and Sharps Waste Stewardship Programs

1. How does a covered entity submit a list of products?
   You can email the list of covered and non-covered products to BOPStwardship@dca.ca.gov. The Board provides a template (add the link) to facilitate the submission and its review. Pursuant to Public Resources Code section 42031(a)(1), a covered entity must submit both a list of covered products, and a "a list and description of any drugs or sharps that are not covered products" to the Board. A covered entity is responsible for the accuracy and completeness of the list.
   Reference: PRC 42031(a)(1)

2. How often shall a covered entity submit the list of products?
   Public Resources Code section 42031(a)(2) specifies that a covered entity or a stewardship organization on behalf of a group of covered entities shall submit an updated list with highlighted changes to the Board on or before January 15 of each year or upon request.
   Reference: PRC 42031(a)(2)

3. Are auto-injectors and pre-filled syringes "covered products"?
   Yes. Pursuant to Public Resource Code (PRC) section 42030 (g), "covered product" means a covered drug or home-generated sharps waste.
   Reference: PRC 42030(g);

4. Are intramuscular injection needles used by ultimate users at home "covered products"?
   Yes. Intramuscular injection needles, such as the ones for testosterone injection, are used to penetrate skin for the delivery of medication. They are "home-generated sharps waste" pursuant to Health & Safety Code Section 117671, and thus "covered products" pursuant to Public Resource Code section 42030 (g).
   Reference: PRC 42030(g); HSC 117671

5. Can an ultimate user bring sharps waste to a pharmacy or deposit sharps waste into a drug take-back kiosk?

   Pursuant to CCR 1776.1(e), medical sharps and needles shall not be deposited into a drug take-back kiosk. Under BPC 4146, a pharmacy is permitted but not required to accept sharps containers. Please check https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/ for more information about sharps waste stewardship.
   Reference: CCR 1776.1(e); BPC 4146

6. Some drugs are only being used in clinical settings. Are they "covered drugs"?

Pursuant to Public Resource Code section 42030(e)(1), a "covered drug" means a drug sold, offered for sale, or dispensed in or into the State of California. Additionally, Business and Professions Code section 4024 defines "dispense" and BPC 4016 defines "administer".
Based on the relevant sections of the law, a drug that is SOLELY administered in clinical settings within the definition of BPC section 4016, and not offered, sold or dispensed to a patient in California, would not be considered a "covered drug". The Board prefers that potential covered entities submit to the Board a statement why its drugs should not be considered "covered drugs" based on any such statutory interpretation. The potential covered entity is responsible for the truthfulness of such statement.
Reference: PRC 42030(e)(1); BPC 4016, 4024

7. Are APIs (Active Pharmaceutical Ingredients) "covered drugs"?
   APIs are not finished drugs, thus not "covered drugs" pursuant to Public Resource Code section 42030(e).
   Reference: PRC 42030(e)

8. How do I know if I am a "covered entity"?
   Please refer to Public Resource Code section 42030(f) for the definition of "covered entity". Please contact CalRecycle at pharmasharpsenforcement@calrecycle.ca.gov for interpretive questions regarding a "covered entity".
   Reference: PRC 42030(f)

9. Where can I find the list of "covered products" and "covered entities"?
   Pursuant to California Public Resource Code 42035(a)(1), on or before June 30, 2022, CalRecycle will post on its Internet Web site (https://www.calrecycle.ca.gov/epr/pharmasharps) a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter. The law does not require posting of a list of "covered products".
   Reference: PRC 42035(a)(1)

10. Where can I find information regarding stewardship organizations and stewardship plans?
    You can find information about potential stewardship organizations at https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities
    You can find information about Pharmaceutical Stewardship Plans at https://www.calrecycle.ca.gov/epr/pharmasharps/pharma/plan, and Home-Generated Sharps Waste Plans at https://www.calrecycle.ca.gov/epr/pharmasharps/sharps/plan.

11. What are the responsibilities of a wholesaler in compliance with SB212?
    A wholesaler may be considered a "covered entity" per the tiered definition under Public Resource Code 42030(f). Wholesalers should coordinate with appropriate entities

in their supply chains to determine how statutory and regulatory requirements will be met.
In addition, a wholesaler has the reporting responsibility pursuant to Public Resource Code 42035(c). A wholesaler shall determine if covered products are in compliance with the law, by verifying that the covered entities providing the covered products are in compliance with the law and shall notify CalRecycle if it determines that the covered entity is not listed on CalRecycle's Internet Web site.
Reference: PRC 42030(f), Reference: PRC 42035(c)

12. How can a pharmacy participate in a stewardship plan for pharmaceutical or home-generated sharps waste?

    A pharmacy can contact approved stewardship plan operators for participating in the program. Please check https://www.calrecycle.ca.gov/epr/pharmasharps/coveredentities/for approved stewardship plans and their contact information.

13. Are compounded medications "covered drugs"?
    Compounded medications are exempted from section 505 of the Federal Food, Drug and Cosmetics Act (21 U. S.C. 355). Therefore, compounded medications are not "covered drugs" under the stewardship program.
    Reference: PRC 42030(e)(1)

14. Can a covered entity include non-covered drugs to the covered drug list?
    The intent of the SB212 is to ensure the safe disposal of pharmaceutical and home-generated sharps wastes. In the spirit of the law, the Board does not view it as a violation of law if a covered entity voluntarily elects non-covered drugs to be covered under a stewardship plan.

15. Where can I get more information if needed?
    You can find more information at CalRecycle's web site: https://www.calrecycle.ca.gov/epr/pharmasharps. Questions regarding "covered drugs" or "covered products" should be directed to bopstewardship@dca.ca.gov. Questions regarding "covered entity" and other provision of SB212 should be directed to pharmasharpsenforcement@calrecycle.ca.gov

16. How do I know if an over-the-counter drug is a "covered drug"?
    Public Resource Code 42030(e)(1)(B) states a drug marketed under an over-the-counter drug monograph is a "covered drug". Pursuant to Public Resource Code 42030(e)(1)(A), non-prescription drugs (over-the-counter drugs) marketed under NDA or ANDA pursuant to Section 505 of the Federal Food, Drug and Cosmetic Act or Section 351 of the Federal Public Health Service Act are also "covered drugs". There are some exclusions pursuant to Public Resource Code 42030(e)(2)(C). Please note whether a product is a cosmetic or/and a drug under the law is determined by a product's intended use. Different laws and regulations apply to each type of product. The Board

recommends potential covered entities examine their over-the-counter drugs for their intended uses and contact appropriate agents, including potentially a lawyer, for guidance of whether their particular product is a covered drug.
Reference: PRC 42030(e)(1)(A); 42030(e)(1)(B); 42030(e)(2)(C); FDA Is It a Cosmetic, or a Drug, or Both?

Rev 1/11/2022

Attachment 2

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to current regulation text are indicated with ~~single strikethrough~~ for deletions and single underline for additions.

Amend Section 1717 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1717. Pharmacy Practice.

a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided:
(1) a patient med pak is reused only for the same patient;
(2) no more than a one-month supply is dispensed at one time; and
(3) each patient med pak bears an auxiliary label which reads, “store in a cool, dry place.”
(b) In addition to the requirements of Business and Professions Code section 4040, the following information shall be maintained for each prescription on file and shall be readily retrievable:
(1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising pharmacist before they are dispensed.
(2) The brand name of the drug or device; or if a generic drug or device is dispensed, the distributor's name which appears on the commercial package label; and
(3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
(4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
(c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself. All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing, or furnishing. Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of this subsection.
(d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in a State other than California in accordance with Business and Professions Code section 4005.
(e) A pharmacist ~~may~~ shall transfer a prescription for Schedule III, IV or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, section 1306.25.
Prescriptions for other dangerous drugs which are not controlled substances ~~may~~ shall also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription; identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the

receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of section 1716 of this Division. Information maintained by each pharmacy shall at least include:
(1) Identification of pharmacist(s) transferring information;
(2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
(3) Original date and last dispensing date;
(4) Number of refills and date originally authorized;
(5) Number of refills remaining but not dispensed;
(6) Number of refills transferred.
(f) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initializing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

Note: Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 688, 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116, 4117 and 4342, Business and Professions Code.

Amend Section 1717.4 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1717.4. Electronic Transmission of Prescriptions

(a) Except as otherwise ~~prohibited~~ allowed by law, prescriptions ~~may~~ shall be transmitted by electronic means from the prescriber to the pharmacy.
(b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.
(c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.
(d) An “interim storage device” means as electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.
(e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the

prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.
(f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.
(g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.
(h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 688, 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.

Attachment 3

Regulation Timeline

VII. Board Adopted Regulations Under Final Review by the Office of Administrative Law

1. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Reporting Drug Losses

   Timeline:
   Approved by Board: January 29, 2020
   Submitted to DCA for Pre-Notice Review: June 3, 2020
   Submitted to DCA Budgets for Review: October 27, 2020
   Returned to the Board: March 1, 2021
   Noticed by OAL for 45-Day Comment Period: June 4, 2021
   Adopted by the Board: July 29, 2021
   Submitted to DCA for Final Review: July 29, 2021
   Submitted to OAL for Final Review: September 14, 2021
   OAL decision due by February 23, 2022

2. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Timeline:
   Approved by Board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: January 26, 2017
   Returned to the board on: March 28, 2017
   Re-submitted to DCA for Pre-Notice Review: May 24, 2018
   Returned to the board: August 6, 2018
   Re-submitted to DCA for Pre-Notice Review: August 16, 2018
   Returned to the board: November 2, 2018
   Re-submitted to DCA for Pre-Notice Review: December 20, 2018
   Returned to the board: January 3, 2020
   Re-submitted to DCA for Pre-Notice Review: January 14, 2020
   Returned to the Board: April 22, 2020
   Re-submitted to DCA for Pre-Notice Review: October 21, 2020
   Returned to the Board: November 16, 2020
   Re-submitted to DCA for Pre-Notice Review: December 3, 2020
   Returned to the Board: March 2, 2021
   Re-submitted to DCA for Pre-Notice Review: April 16, 2021
   Noticed by OAL for 45-Day Comment Period: July 23, 2021
   Adopted by the Board: September 23, 2021
   Submitted to DCA for Final Review: September 23, 2021
   Submitted to OAL for Final Review: November 30, 2021
   OAL decision due by January 11, 2022
   Approved by OAL on January 11, 2022 and effective April 1, 2022

3. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification

   Timeline:
   Approved by Board: July 29, 2020
   Submitted to DCA for Pre-Notice Review: February 11, 2021
   Returned to the board on: March 23, 2021
   Re-submitted to DCA for Pre-Notice Review: June 10, 2021
   Noticed by OAL for 45-Day Comment Period: September 3, 2021
   Adopted by the Board: October 27, 2021
   Submitted to DCA for Final Review: October 27, 2021
   Submitted to OAL for Final Review: December 6, 2021
   OAL decision due by January 18, 2022

4. Proposed Regulation to Amend Title 16 CCR Section 1746.4, Related to Administering Vaccines

   Timeline:
   Approved by Board: July 28, 2021
   Submitted to DCA for Pre-Notice Review: August 5, 2021
   Returned to the board: August 9, 2021
   Re-submitted to DCA for Pre-Notice Review: August 10, 2021
   Noticed by OAL for 45-Day Comment Period: October 8, 2021
   Adopted by the Board: December 2, 2021
   Submitted to DCA for Final Review: December 2, 2021
   Submitted to OAL for Final Review: December 13, 2021
   OAL decision due by January 25, 2022

Reporting Drug Losses
16 CCR § 1715.6

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.

(3) Any other ~~substantial~~ significant loss as determined by the pharmacist-in-charge.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

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

Pharmacy Ownership, Management, and Control, Including Through Trusts
16 CCR § 1709

Title 16. Board of Pharmacy
Proposed Text

To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1709. ~~Names of Owners and Pharmacist In Charge~~ Disclosure and Notification Requirements

(a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership ~~(individual, partnership or corporation)~~ and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership ~~transfer of permit~~ and shall require a new application for ~~a change of ownership~~ licensure:

(1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.

(d) If any beneficial interest of the pharmacy is held in trust, the applicant, licensee, or any person with management or control of the pharmacy, shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and annual renewal, report the name of any other person in any position with management or control of the pharmacy.

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the annual renewal, the name, address and contact information for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and annual renewal shall also include the name, address, and contact information for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the pharmacy.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4110, 4111, 4112, 4113, 4120, ~~4124~~, ~~4130~~, ~~4133~~, ~~4141~~, ~~4149~~, ~~4160~~, ~~4161~~, ~~4196~~, 4201, 4302, ~~4304,~~ 4305, 4307, 4308, and 4330, Business and Professions Code.

Address Change Notification
16 CCR § 1704

Title 16. Board of Pharmacy
Proposed Text

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Amend Section 1704 to Title 16 of the California Code of Regulations, to read as follows:

§ 1704. ~~Change of~~ Providing Addresses.

(a) Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

(b) Each applicant and person holding a certificate, license, permit, or registration who has an electronic mail address shall provide to the Board that electronic mail address and shall maintain a current electronic mail address, if any, with the Board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4100, Business and Professions Code.

Administering Vaccines
16 CCR § 1746.4

Title 16. Board of Pharmacy
Proposed Text

Amend Section 1746.4 to Title 16 of the California Code of Regulations, to read as follows:

§ 1746.4. Pharmacists Initiating and Administering Vaccines.

(a) A pharmacist initiating and/or administering any vaccine pursuant to section 4052 or 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: A pharmacist must complete one hour of ~~ongoing~~ continuing education focused on immunizations and vaccines from an approved provider once every two years.
(d) Notifications: At the request of a patient, ~~A~~ a pharmacist shall notify, each patient's primary care provider of any vaccine 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 a 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. A pharmacist shall notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days of the administration of any vaccine.
(e) Immunization Registry: A pharmacist shall report, in accordance with section 4052.8, subdivision (b)(3), of the Business and Professions Code, the information described in section 120440, subdivision (c), of the Health and Safety Code within 14 days of the administration of any vaccine. A pharmacist shall inform each patient or the patient's guardian of immunization record sharing preferences, detailed in section 120440, subdivision (e), of the Health and Safety Code.
(f) Documentation: For each vaccine administered by a pharmacist, a patient vaccine administration record shall be maintained in an automated data processing or manual record mode such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy or facility's normal operating hours. A pharmacist shall provide each patient with a vaccine administration record, which fully documents the 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, 4052.8 and 4081, Business and Professions Code; Section 120440, Health and Safety Code; and Section 300aa-25, Title 42, United States Code.

Attachment 4

Regulation Timeline

VIII. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16 CCR Section 1735.2 to Update the Compounding Self-Assessment Form 17M-39

   Timeline:
   Approved by Board: January 28, 2021
   Submitted to DCA for Pre-Notice Review: **July 14, 2021**

Self-Assessment Form
16 CCR § 1735.2
17M – 39

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations 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; 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, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

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

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

Ownership: ☐Sole Owner ☐Partnership ☐Corporation ☐LLC
☐Non-Licensed Owner ☐Other (please specify) _____

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties): (Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

Community Pharmacy & Hospital Outpatient Pharmacy Compounding 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 question. 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.

ALL COMPOUNDING Complete Sections 1 through 10.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐ ☐ ☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐ ☐ ☐ 1.2 Each pharmacist involved with compounding understands the definitions in CCR 1735.1.

2. Compounding Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐ ☐ ☐ 2.1. The pharmacy does not compound drug preparations prior to receipt of a valid prescription unless under the following conditions as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

☐ ☐ ☐ 2.2. The pharmacy prepares and stores a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐ ☐ ☐ 2.3. The pharmacy compounds a reasonable quantity of drug preparation which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- ☐ 2.3.1. Is ordered by the prescriber or the prescribers' agent on 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 sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- ☐ 2.3.2. Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- ☐ 2.3.3. Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- ☐ 2.3.4. The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**

☐ 2.3.5. 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 preparation; (CCR 1735.2[c][5]) **AND**

☐ 2.3.6. Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

Yes No N/A

☐ ☐ ☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

☐ 2.4.1. Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

☐ 2.4.2. Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

☐ 2.4.3. Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

☐ ☐ ☐ 2.5. The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

☐ 2.5.1. Active ingredients used.

☐ 2.5.2. Equipment to be used.

☐ 2.5.3. Beyond use date (BUD).

☐ 2.5.4. Inactive ingredients used.

☐ 2.5.5. Specific and essential compounding steps.

☐ 2.5.6. Quality reviews required at each step.

☐ 2.5.7. Post-compounding process or procedures, if required.

☐ 2.5.8. Instructions for storage and handling.

☐ ☐ ☐ 2.6. The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐ ☐ ☐ 2.7. The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐ ☐ ☐ 2.8. All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐ ☐ ☐ 2.9. Every compounded drug preparation is given a 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 is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

☐ 2.9.1. For non-sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][1][A-F])

- ☐ 2.9.1.1. The shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
- ☐ 2.9.1.2. The chemical stability of any one ingredient in the compounded drug preparation;
- ☐ 2.9.1.3. The chemical stability of the combination of all ingredients in the compounded drug preparation,
- ☐ 2.9.1.4. For non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
- ☐ 2.9.1.5. For water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
- ☐ 2.9.1.6. For water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
- ☐ 2.9.1.7. The pharmacist, using his or her professional judgment establishes an extended date as provided in (D), (E), and (F), if the pharmacist researched(s) by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors pharmacist analyzed included: i) the nature of the drug and its degradation mechanism, (ii) the dosage form and its components, (iii) the potential for microbial proliferation in the preparation, (iv)the container in which it is packaged, (v) the expected storage conditions, and (vi) the intended duration of therapy. Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

☐ 2.9.2. For sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][2][A-D])

- ☐ 2.9.2.1. The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation,
- ☐ 2.9.2.2. The chemical stability of any one ingredient in the sterile compounded drug preparation,
- ☐ 2.9.2.3. The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and
- ☐ 2.9.2.4. The beyond use date assigned for sterility in CCR 1751.8.

☐ 2.9.3. For sterile compounded drug preparations, extension of a beyond use date is supported by the following: (CCR 1735.2[i][3][A-C])

- ☐ 2.9.3.1. Method Suitability Test,
- ☐ 2.9.3.2. Container Closure Integrity Test, and
- ☐ 2.9.3.3. Stability Studies.

☐ 2.9.4. The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients,

specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

☐ 2.9.5. Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

Yes No N/A

☐ ☐ ☐ 2.10. The pharmacist performing, or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation. (CCR 1735.2[j])

☐ ☐ ☐ 2.11. Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐ ☐ ☐ 2.12. Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

- ☐ 2.12.1. Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.
- ☐ 2.12.2. Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐ ☐ ☐ 3.1. The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

- ☐ 3.1.1. The master formula document.
- ☐ 3.1.2. A compounding log consisting of a single document containing all of the following:
- ☐ 3.1.2.1. The name and strength of the compounded drug preparation.
- ☐ 3.1.2.2. The date the drug preparation was compounded.
- ☐ 3.1.2.3. The identity of the pharmacy personnel who compounded the drug preparation.
- ☐ 3.1.2.4. The identity of the pharmacist reviewing the final drug preparation.
- ☐ 3.1.2.5. The quantity of each component used in compounding the drug preparation.
- ☐ 3.1.2.6. The manufacturer or supplier, expiration date and lot number of each component.
- ☐ 3.1.2.7. The pharmacy assigned reference or lot number for the compounded drug preparation.
- ☐ 3.1.2.8. The beyond use date or beyond use date and time of the final compounded drug preparation.
- ☐ 3.1.2.9. The final quantity or amount of drug preparation compounded.

☐ 3.1.2.10. Documentation of quality reviews and required post-compounding process and procedures.

Yes No N/A

☐ ☐ ☐ 3.2. The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

☐ ☐ ☐ 3.3. Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐ ☐ ☐ 3.4. The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3[d]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐ ☐ ☐ 4.1. Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])

- ☐ 4.1.1. Name of the compounding pharmacy and dispensing pharmacy (if different);
- ☐ 4.1.2. Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- ☐ 4.1.3. Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- ☐ 4.1.4. The beyond use date for the drug preparation;
- ☐ 4.1.5. The date compounded; and
- ☐ 4.1.6. The lot number or pharmacy reference number.

☐ ☐ ☐ 4.2. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐ ☐ ☐ 4.3. Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

Yes No N/A

☐ ☐ ☐ 4.4. Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and beyond use date. (CCR 1735.4[d])

☐ ☐ ☐ 4.5. All hazardous agents bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐ ☐ ☐ 5.1. The pharmacy maintains written policies and procedure for compounding which establish procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])

☐ ☐ ☐ 5.2. The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])

☐ ☐ ☐ 5.3. The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- ☐ 5.3.1. Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- ☐ 5.3.2. A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures 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).
- ☐ 5.3.3. Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- ☐ 5.3.4. 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.
- ☐ 5.3.5. Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.

☐ 5.3.6. Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
☐ 5.3.7. Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
☐ 5.3.8. Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
☐ 5.3.9. 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.
☐ 5.3.10. Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
☐ 5.3.11. Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐ ☐ ☐ 6.1. The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐ ☐ ☐ 6.2. All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐ ☐ ☐ 6.3. All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])
☐ 6.3.1. Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐ ☐ ☐ 6.4. When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐ ☐ ☐ 6.5. Hazardous drug compounding is completed in an externally exhausted physically separate room with the following requirements: (CCR 1735.6[e])
☐ 6.5.1. 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 preparations are assigned a BUD of 12 hours or less or when nonsterile products are compounded; and

☐ 6.5.2. 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
☐ 6.5.3. For sterile compounding, each BSC or CACI shall be externally exhausted.
☐ 6.5.3. For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted,
☐ 6.5.4. All surfaces within the room are smooth, seamless, impervious, and non-shedding.

CORRECTIVE ACTION OR ACTION PLAN:

_____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐ ☐ ☐ 7.1. The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

☐ ☐ ☐ 7.2. The pharmacy has developed and maintains 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. (CCR 1735.7[b])

☐ ☐ ☐ 7.3. Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐ ☐ ☐ 8.1. The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

Yes No N/A

☐ ☐ ☐ 8.2. The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

- ☐ 8.2.1. Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])
- ☐ 8.2.2. Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])
- ☐ 8.2.3. Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])
- ☐ 8.2.4. Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])
- ☐ 8.2.5. Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Compounding Consistent with United States Pharmacopeia – National Formulary (BPC 4126.8)

Yes No N/A

☐ ☐ ☐ 9.1. The compounding of drug preparation is consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

10. Duties of a Pharmacy Issuing a Compounded Drug Recall (BPC 4126.9)

Yes No N/A

☐ ☐ ☐ 10.1. When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (BPC 4126.9[a][1-2])

- ☐ 10.1.1. Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- ☐ 10.1.2. The recalled drug was dispensed, or is intended for use, in this state.

Yes No N/A

☐ ☐ ☐ 10.2. A recall notice issued pursuant to subdivision (a) is made as follows: (BPC 4126.9[b][1-3])

- ☐ 10.2.1. If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.
- ☐ 10.2.2. If the recalled drug was dispensed directly to the prescriber, the notice is be made to the prescriber, who shall ensure the patient is notified.
- ☐ 10.2.3. If the recalled drug was dispensed directly to a pharmacy, the notice is be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.

☐ ☐ ☐ 10.3. If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (BPC 4126.9[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparation? (BPC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 11 through 27.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparation:

11. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐ ☐ ☐ 11.1. Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (BPC 4123)

- ☐ 11.1.1. The contractual arrangement is reported to the board within 30 days of commencing that compounding.

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐ ☐ ☐ 12.1. The pharmacy conforms 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 compounding. (CCR 1751[a])

☐ ☐ ☐ 12.2. The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

- ☐ 12.2.1. The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.
- ☐ 12.2.2. The pharmacy is ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.
- ☐ 12.2.3. The environments within the pharmacy meet at least the following standards: (CCR 1751[b])
- ☐ 12.2.3.1. Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.
  - ☐ 12.2.3.1.1. Certification records must be retained in the pharmacy.
- ☐ 12.2.3.2. Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.
- ☐ 12.2.3.3. A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better 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.
- ☐ 12.3.3.4. There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.5 and 505.5.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

☐ ☐ ☐ 13.1. The pharmacy has designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

- ☐ 13.1.1. In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration

meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])

- ☐ 13.1.2. Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])
- ☐ 13.1.3. The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. (24 CCR 1250.4[3])
- ☐ 13.1.4. A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])
- ☐ 13.1.5. The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])
  - ☐ 13.1.5.1. An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
  - ☐ 13.1.5.2. An ISO Class 5 cleanroom.
  - ☐ 13.1.5.3. A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐ ☐ ☐ 13.2. The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.5)

- ☐ 13.2.1. Be ventilated in a manner not interfering with laminar air flow.

☐ ☐ ☐ 13.3. Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.5.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐ ☐ ☐ 14.1. In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])

- ☐ 14.1.1. Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.
- ☐ 14.1.2. Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

- ☐ 14.1.3. 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.
- ☐ 14.1.4. Results of viable air and surface sampling.
- ☐ 14.1.5. Biannual video of smoke studies in all ISO Class 5 certified spaces.
- ☐ 14.1.6. Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
  - ☐ 14.1.6.1. Controlled room temperature.
  - ☐ 14.1.6.2. Controlled cold temperature.
  - ☐ 14.1.6.3. Controlled freezer temperature.
- ☐ 14.1.7. Certification(s) of the sterile compounding environment(s).
- ☐ 14.1.8. Documents indicating daily documentation 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.
- ☐ 14.1.9. Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).
- ☐ 14.1.10. Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.
- ☐ 14.1.11. Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

Yes No N/A

☐ ☐ ☐ 14.2. The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps 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, license type and number of the prescriber. (CCR 1751.1[b])

☐ ☐ ☐ 14.3. The pharmacy maintains and retains 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 are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐ ☐ ☐ 15.1 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, the pharmacy label each compounded sterile drug preparation with at least the following information: (CCR 1751.2[a-c])

- ☐ 15.1.1. The telephone number of the pharmacy.
- ☐ 15.1.2. Instructions for storage, handling, and administration.
- ☐ 15.1.3. All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly.":

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

☐ ☐ ☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. (CCR 1751.3[a])

☐ ☐ ☐ 16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- ☐ 16.2.1. 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.
- ☐ 16.2.2. Airflow considerations and pressure differential monitoring.
- ☐ 16.2.3. An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- ☐ 16.2.4. Cleaning and maintenance of ISO environments and segregated compounding areas.
- ☐ 16.2.5. Compounded sterile drug preparation stability and beyond use dating.
- ☐ 16.2.6. Compounding, filling, and labeling of sterile drug preparations.
- ☐ 16.2.7. Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- ☐ 16.2.8. Depyrogenation of glassware (if applicable)
- ☐ 16.2.9. Facility management including certification and maintenance of controlled environments and related equipment.
- ☐ 16.2.10. For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

- ☐ 16.2.11. Hand hygiene and garbing.
- ☐ 16.2.12. Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- ☐ 16.2.13. Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- ☐ 16.2.14. Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which 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.
- ☐ 16.2.15. Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- ☐ 16.2.16. 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.
- ☐ 16.2.17. 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.
- ☐ 16.2.18. Proper use of equipment and supplies.
- ☐ 16.2.19. Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- ☐ 16.2.20. Record keeping requirements.
- ☐ 16.2.21. Temperature monitoring in compounding and controlled storage areas.
- ☐ 16.2.22. The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- ☐ 16.2.23. Use of automated compounding devices (if applicable).
- ☐ 16.2.24. Visual inspection and other final quality checks of sterile drug preparations.

Yes No N/A

☐ ☐ ☐ 16.3. For lot compounding, the pharmacy maintains ~~a~~ written policies and procedures which include~~s~~ at least the following: (CCR 1751.3[b][1-3])

- ☐ 16.3.1. Use of master formula documents and compounding logs.
- ☐ 16.3.2. Appropriate documentation.
- ☐ 16.3.3. Appropriate sterility and potency testing.

☐ ☐ ☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains a written policies and procedures for compounding which included at least the following. (CCR 1751.2[c][1-2])

- ☐ 16.4.1. Process validation for chosen sterilization methods.
- ☐ 16.4.2. End-product evaluation, quantitative, and qualitative testing.

Yes No N/A

☐ ☐ ☐ 16.5. All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

☐ ☐ ☐ 17.1. No sterile drug preparation is 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 drug preparations (CCR 1751.4[a])

☐ ☐ ☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired (CCR 1751.4[b])

☐ ☐ ☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐ ☐ ☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])

- ☐ 17.4.1. All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- ☐ 17.4.2. Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.
- ☐ 17.4.3. Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- ☐ 17.4.4. 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.

☐ ☐ ☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])

- ☐ 17.5.1. At the beginning of each shift;
- ☐ 17.5.2. At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- ☐ 17.5.3. After each spill; and
- ☐ 17.5.4. When surface contamination is known or suspected.

Yes No N/A

☐ ☐ ☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality (CCR 1751.4[f])

- ☐ 17.6.1. Certification and testing of primary and secondary engineering controls are 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 which would impact the device or area.
- ☐ 17.6.2. Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).
  - ☐ 17.6.2.1. Certification records are retained for at least 3 years.
- ☐ 17.6.3. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])
  - ☐ 17.6.3.1. Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
  - ☐ 17.6.3.2. 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.
  - ☐ 17.6.3.3. 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.
- ☐ 17.6.4. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are 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.

☐ ☐ ☐ 17.7. 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.

- ☐ 17.7.1. Additionally, each PEC used to compound hazardous agents shall be externally vented.
- ☐ 17.7.2. The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).
- ☐ 17.7.3. Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])
- ☐ 17.7.4. During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers,

and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

Yes No N/A

☐ ☐ ☐ 17.8. 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 who 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. (CCR 1751.4[h])

☐ ☐ ☐ 17.9. Compounding aseptic isolators and compounding aseptic containment isolators 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. (CCR 1751.4[i])

☐ ☐ ☐ 17.10. Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. (CCR 1751.4[j])

- ☐ 17.10.1. Viable air sampling is be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and is done at least once every six months.
- ☐ 17.10.2. Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling.
- ☐ 17.10.3. Viable air sampling is performed under dynamic conditions which simulate actual production.
- ☐ 17.10.4. Viable surface sampling is performed under dynamic conditions of actual compounding.
- ☐ 17.10.5. When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation includes, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

☐ ☐ ☐ 17.11. The sterile compounding area in the pharmacy has a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐ ☐ ☐ 18.1. When compounding sterile drug preparations, the following standards are met: (CCR 1751.5[a][1-6])

- ☐ 18.1.1. Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.
- ☐ 18.1.2. Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.
- ☐ 18.1.3. Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.
- ☐ 18.1.4. Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic devices.
- ☐ 18.1.5. Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn.
- ☐ 18.1.6. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom.
- ☐ 18.1.7. Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects.
- ☐ 18.1.8. Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.
- ☐ 18.1.9. Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

☐ ☐ ☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐ ☐ ☐ 19.1. Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐ ☐ ☐ 19.2. The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations 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. (CCR 1751.6[b])

☐ ☐ ☐ 19.3. Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment (CCR 1751.6[c])

☐ ☐ ☐ 19.4. The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations (CCR 1751.6[d])

☐ ☐ ☐ 19.5. The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

- ☐ 19.5.1. The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure 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: (CCR 1751.6[e][1][A-J])
  - ☐ 19.5.1.1. Aseptic technique.
  - ☐ 19.5.1.2. Pharmaceutical calculations and terminology.
  - ☐ 19.5.1.3. Sterile preparation compounding documentation.
  - ☐ 19.5.1.4. Quality assurance procedures.
  - ☐ 19.5.1.5. Aseptic preparation procedures.
  - ☐ 19.5.1.6. Proper hand hygiene, gowning and gloving technique.
  - ☐ 19.5.1.7. General conduct in the controlled area (aseptic area practices).
  - ☐ 19.5.1.8. Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
  - ☐ 19.5.1.9. Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
  - ☐ 19.5.1.10. Container, equipment, and closure system selection.
- ☐ 19.5.2. Each person engaged in sterile compounding has successfully completed 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. (CCR 1751.6[e][2])

☐ 19.5.2.1. 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.
☐ 19.5.2.2. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.
☐ 19.5.2.3. Each person's proficiency and continuing training needs must be reassessed at least every 12 months.
☐ 19.5.2.3. Results of these assessments must be documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐ ☐ ☐ 20.1. There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])
- ☐ 20.1.1. The quality assurance program shall include at least the following: (CCR 1751.7[a][1-3])
  - ☐ 20.1.1.1. Procedures for cleaning and sanitization of the sterile preparation area.
  - ☐ 20.1.1.2. Actions to be taken in the event of a drug recall.
  - ☐ 20.1.1.3. Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

☐ ☐ ☐ 20.2. The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])
- ☐ 20.2.1. Each individual's competency is 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. (CCR 1751.7[b][2])
- ☐ 20.2.2. The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])
  - ☐ 20.2.2.1. The quality assurance program yields an unacceptable result.
  - ☐ 20.2.2.2. 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 affecting airflow or traffic patterns, or when improper aseptic techniques are observed.

☐ 20.2.3. The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

Yes No N/A

☐ ☐ ☐ 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed 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. (CCR 1751.7[c])

☐ ☐ ☐ 20.4 Re-evaluation of garbing and gloving competency occurs 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. (CCR 1751.7[d])

☐ ☐ ☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms 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 applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

- ☐ 20.5.1. The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B)
  - ☐ 20.5.1.1. 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.
  - ☐ 20.5.1.2. Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐ ☐ ☐ 21.1. Every sterile compounded drug preparation is given and labeled with a beyond use date incompliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in sterile the 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, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended beyond use date, conforms to the following limitations:

Yes No N/A

☐ ☐ ☐ 21.2. The beyond use date states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])

- ☐ 21.2.1. 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 which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and
- ☐ 21.2.2. 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
- ☐ 21.2.3. 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.

☐ ☐ ☐ 21.3. The beyond use date states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])

- ☐ 21.3.1. 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 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
- ☐ 21.3.2. The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
- ☐ 21.3.3. The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐ ☐ ☐ 21.4. The beyond use date states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days 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: (CCR 1751.8[c])

☐ 21.4.1. 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 which meets the requirements in 1751.4(f)(1)-(3).

Yes No N/A

☐ ☐ ☐ 21.5. The beyond use date states 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: (CCR 1751.8[d])

☐ 21.5.1. 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

☐ 21.5.2. 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

☐ 21.5.3. 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.

☐ ☐ ☐ 21.6. Any sterile compounded drug preparation which 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 is be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

☐ 21.6.1. 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.

☐ 21.6.2. 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.

☐ 21.6.3. "Immediate use" preparations are only compounded 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.

☐ 21.6.4. 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. (CCR 1751.8[e])

Yes No N/A

☐ ☐ ☐ 21.7. The beyond use date for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐ ☐ ☐ 22.1. Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐ ☐ ☐ 22.2. 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, is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

- ☐ 22.2.1. When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.
- ☐ 22.2.2. When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.
- ☐ 22.2.3. If the puncture time is not noted on the container, the container is immediately discarded.

☐ ☐ ☐ 22.3. Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within twenty-eight (28) days from initial opening or puncture. (CCR 1751.9[c])

- ☐ 22.3.1. Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance.
- ☐ 22.3.2. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container is immediately be discarded.

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Sterile Compounding Reference Materials (CCR 1751.10)

Yes No N/A

☐ ☐ ☐ 23.1. The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Sterile Compounding License Renewal (BPC 4127.1, 4127.15, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (BPC 4127.1, 4127.15 4127.2)

Yes No N/A

☐ ☐ ☐ 24.1. The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐ ☐ ☐ 24.2. The board reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

☐ ☐ ☐ 24.3. The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.

☐ ☐ ☐ 24.4. The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.

☐ ☐ ☐ 24.5. The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

☐ ☐ ☐ 24.6. A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (BPC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Hospital Satellite Compounding Pharmacy (BPC 4127.15)

Yes No N/A

☐ ☐ ☐ 25.1. A hospital satellite compounding pharmacy compounds sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

☐ ☐ ☐ 25.2. The services provided shall be directly related to the services or treatment plan administered in the physical plant.

CORRECTIVE ACTION OR ACTION PLAN: _____

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26. Nonresident Pharmacy (BPC 4127.2)

Yes No N/A

☐ ☐ ☐ 26.1. Pharmacy notifying the board within 10 days of the suspension of any accreditation held by the pharmacy.

☐ ☐ ☐ 26.2. Pharmacy provides to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

☐ ☐ ☐ 26.3. Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

CORRECTIVE ACTION OR ACTION PLAN: _____

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27. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (BPC 4127.9)

Yes No N/A

☐ ☐ ☐ 27.1. The pharmacy contacts the recipient pharmacy, prescriber or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (BPC 4127.9[a] BPC 4127.1 and 4127.2)

☐ ☐ ☐ 27.2. A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (BPC 4127.9[b][1])

☐ ☐ ☐ 27.3. A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (BPC 4127.9[b][2])

Yes No N/A

☐ ☐ ☐ 27.4. A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (BPC 4127.9[b][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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 by _____. 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 _____ _____
(Pharmacist-in-Charge) Date

ACKNOWLEDGEMENT BY 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 in the timeframe identified in the Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____
Date

Attachment 5

Regulation Timeline

IX. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16 CCR Section 1707.6 Related to the Notice to Consumers

   Timeline:
   Approved by Board: October 28, 2021
   Staff drafting rulemaking documents to be submitted in February 2022

Notice to Consumers
16 CCR § 1707.6

Title 16. Board of Pharmacy
Proposed Text

Underline is text that will be added. ~~Strikethrough~~ is text that will be deleted.

Amend Section 1707.6 to Title 16 of the California Code of Regulations, to read as follows:

§ 1707.6. Notice to Consumers.

(a) ~~In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b).~~ Every pharmacy shall post a notice containing the text in subsection (b) and shall place the notice in a conspicuous place, physically accessible to a prescription drug consumer (consumer) so that the consumer can easily read the notice, and use the QR code displayed on the notice to obtain language translation of the notice. Such notice shall be posted at all locations where a consumer receives medication. Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by ~~prescription drug~~ consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; ~~and~~ (4) The video screen utilizes QR code technology for the consumer to access translation of the notice, with sufficient display time for consumers to access the QR code; and (5) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b) The notice shall contain the following text~~:~~. It must also include a QR code that assists limited-English-proficient individuals and alerts consumers that the QR code may be used to obtain a translation of the notice. Consumers must be able to use the QR code to obtain translation of the notice in the top 16 languages spoken by limited-English-proficient individuals in California, as determined by the U.S. Department of Health and Human Services, Office of Civil Rights and the California Department of Health Care Services.

~~NOTICE TO CONSUMERS~~

KNOW YOUR RIGHTS

California law requires a pharmacist to speak with you upon your request, every time you get a new prescription, and every time you get a new prescription dosage form, strength, or written directions.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

TALK TO THE EXPERT – SPEAK WITH YOUR PHARMACIST

Before you leave the pharmacy, CHECK ~~taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a does; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.~~

- the patient name on the label is correct;
- the medication matches the description on the label;
- the name of the medicine and what it does;
- how and when to take the medication, for how long, and what to do if you miss a dose;
- possible side effects and what you should to do if they occur;
- whether the medication will work safely with other medicines or supplements; and
- what foods, drinks, or activities should be avoided while taking the medicine.

The address and contact information for consumers to send any complaints about the pharmacy:

California State Board of Pharmacy

2720 Gateway Oaks Drive, Suite 100

Sacramento, CA 95833

(916) 518-3100

www.pharmacy.ca.gov.

~~*This* pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.~~

~~*You* may ask this pharmacy for information on drug pricing and of generic drugs.~~

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in the top 16 languages spoken by limited-English-proficient individuals in California, as determined by the U.S. Department of Health and Human Services, Office of Civil Rights, and the California Department of Health Care Services.

~~This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.~~

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

(d) Every pharmacy shall either post or provide on the patient's written receipt a statement describing patients' rights per Business and Professions Code sections 733 and 4122.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.