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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
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# Legislation and Regulation Committee Report

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## a. 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 determine if the Board should establish a position on any of the measures.

1. Assembly Bill 82 (Weber) Dietary Supplements for Weight Loss and Over-the-Counter Diet Pills
   **Version**: As Revised January 9, 2024
   **Status:** In Senate, referred to Rules for Assignment
   **Committee Analysis**: Assembly Floor Analysis
   **Summary**: Would prohibit a retail establishment from selling dietary supplements for weight loss or over-the-counter diet pills to any person under 18 years of age without a prescription. Would require the State Department of Public Health to develop a notice for distribution and posting describing some of the possible side effects of taking such products and will require CDPH to consult with the FDA and other stakeholders to determine which dietary supplements for weight loss and OTC diet pills will be subject to the section. Establishes a July 1, 2024, effective date.
   **Committee Recommendation:** No position.
   **Staff Comments:** The author's office reports that children are abusing OTC weight loss products without the knowledge of parents or guardians and without physician oversight. A 2019 study published in the American Journal of Public Health found that use of diet pills and laxatives for weight control was associated with higher odds of a first eating disorder diagnosis within one to three years than for those that did not report using these products.

The Board could experience an increase in pharmacy applications if retailers determine it appropriate to continue to sell products that become prescription only under the provisions of the measure. Staff also believe implementation of the measure will require education of licensees as well as monitoring the activities undertaken by CDPH regarding identification of the dietary supplements and OTC products that will be subject to the requirements.

**Support:** Academy for Eating Disorders
- Alaska Eating Disorders Alliance
- Alliance for Eating Disorders Awareness
- Be Real USA
- Center for Science in the Public Interest
- Children's Advocacy Institute
- Eating Disorders Coalition
- EREVNA, Policy for the People
- FINIXERUNT Policy Institute
- For You
- International Socioeconomic Society & Finxerunt Policy Institute
- Multi-service Eating Disorders Association
- National Association of Anorexia Nervosa and Associated Disorders
- National Eating Disorders Association
- NCARTH
- Project Heal
- Realize Your Beauty, INC.
- Renfrew Center for Eating Disorders
- Strategic Training Initiative for the Prevention of Eating Disorders
- The Eating Disorder Foundation

**Opposition:** California Chamber of Commerce
National Products Association

**Fiscal Impact:** Anticipated to be minor and absorbable.

**Public comment**: None.

2. Assembly Bill 1842 (Reyes, 2024) Health Care Coverage: Medication-Assisted Treatment

**Version**: As Introduced January 16, 2024

**Status:** Ordered to Third Reading

**Committee Analysis**: Assembly Health Committee

**Summary**: Would prohibit a health care service plan or health insurer from requiring prior authorization or step therapy for a naloxone or other opioid antagonist approved by the FDA or a buprenorphine or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder.

**Committee Recommendation:** Establish a support position.
**Staff Comments:** The Board has a long history of supporting measure that facilitate better access to naloxone and other medication assisted treatments.
**Support:** (3/15/2024)

- California Academy of Child and Adolescent Psychiatry
- California Black Health Network
- California Hospital Association
- California State Association of Psychiatrists
- County Behavioral Health Directors Association of California
- Ella Baker Center for Human Rights
- Health Access California
- Steinberg Institute

**Opposition**: (3/15/2024)

- America's health Insurance Plan
- Association of California Life and health Insurance Companies
- California Association of Health Plans

**Fiscal Impact:** The Board anticipates any fiscal impact would be minor and absorbable and associated with educational activities.
**Public comment:** None.

**3.** Assembly Bill 1902 (Alanis, 2024) Prescription Drug Labels: Accessibility
**Version:** As Amended March 12, 2024
**Status:** Referred to Assembly Appropriations Committee
**Committee Analysis:** Assembly Business and Professions Committee
**Summary:** Would require a pharmacy to provide translated directions for use on prescription labels, in the language made available to the Board. Further, would require a pharmacy to provide to a person, at no additional cost, an accessible prescription label affixed to container that meets all of the following:

- Is available to the person in a timely manner comparable to other patient wait times and lasting for at least the duration of the prescription.
- Is appropriate to the disability and language of the person making the require thought use of audible, large print, Braile, or translated labels.
- Conforms to the format-specific best practices established by the United State Access Board and the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care.

Would require the dispenser to ensure that a prescription label is compatible with a prescription reader if a reader is provided. Would exempt prescription drugs dispensed and administered by an institutional

pharmacy or correctional institution unless the person with a disability is provided a prescription upon their release from the health care facility. Would require the Board to promulgate regulations.
**Committee Recommendation:** No position, continue to monitor.
**Comments:** The policy goals of the measure are extremely laudable, but staff is unclear if the legislation, as written, can be implemented.
**Fiscal Impact:** Staff anticipate a fiscal impact of about $10,000 primarily related to regulation language development and promulgation. Implementation activities will also encompass education of licensees through a variety of means.
**Support:** California Council of the Blind (sponsor)

- AARP
- California Academy of Child and Adolescent Psychiatry
- California Alliance for Retired Americans
- Californians for SSI
- Disability Rights California
- Educate. Advocate.
- LeadingAge California
- Western Center on Law & Poverty

**Opposition**: None.
**Committee Discussion:** Members support the policy goal of the measure but noted some concerns. Members noted that additional information was necessary to under the technology capabilities to implement as well as the costs. Members expressed some concerns about potential liability issues that could arise if the label provided in braille is not correct. Members noted concerns with translated labels with a member sharing a personal experience where the label was translated incorrectly. Members suggested that staff engage with the author's office to explore potential alternative means to meet the policy goal.
**Public comment**: Public comment stated the law requires a pharmacy to make a reasonable accommodation and suggested that providing braille is a reasonable accommodation and suggested an option. Public comment also suggested that the costs of providing the services could be passed on to the health care plan.

4. Assembly Bill 2115 (Haney, 2024) Controlled Substances
   **Version:** As Amended April 1, 2024
   **Status:** Assembly Business and Professions Committee hearing, April 16, 2024
   **Committee Analysis:** None.
   **Summary:** As amended would authorize a nonprofit or fee clinic to dispense a schedule II controlled substance for the purpose of relieving

acute withdrawal symptoms while arrangements are being made for referral for treatment.
Further, would establish provisions related to treatment for patients of a narcotic treatment program including:

- Would allow for a medical evaluation of a patient prior to admittance to a detoxification or maintenance treatment, if verified by the treatment program.
- Would also provide the following items related to narcotic treatment program (NTP) operations:
    - Authorize a patient to decline laboratory testing under specified conditions within two weeks of the date of admittance.
    - Prohibit an NTP from denying a patient maintenance treatment due to the length of time a person has been addicted to opiates.
    - A patient receiving maintenance treatment is not precluded from receiving medications for opioid use disorder by refusing to participate in counseling services.
    - An NTP shall update a patient's treatment plan annually.
    - The initial dose of methadone provided to a patient in an NTP shall not exceed 50 milligrams unless there is sufficient medical rationale for a higher dose.
    - The decision to dispense take-home doses of narcotic replacement therapy medications shall be determined by a medical practitioner who must consider specified criteria.

**Board Position:** Support, established by President Oh through his delegated authority.
**Comments**: According to the author's office, thousands of people die from overdose each year because of the unnecessary laws preventing access to methadone. The intense requirements dissuade patients from pursuing treatment, and it often becomes easier from them to self-medicate their symptoms by buying drugs off the street. The measure will expand methadone access and align with recent changes in federal guidelines. This measure is sponsored by City and County of San Francisco and supported by Smart Justice California.
**Fiscal Impact**: The Board anticipates any fiscal impact would be minor and absorbable and associated with educational activities.
**Committee Discussion:** Members noted agreement with the support position established by President Oh.
**Public comments:** Public comment suggested that the language of the bill is unclear and suggested that the measure needs to be amended to clarify who is allowed to dispense the medication as well as if such dispensing would be required to be reported to CURES.

5. Assembly Bill 2169 (Bauer-Kahan, 2024) Prescription Drug Coverage: Dose Adjustments
   **Version:** As amended March 21, 2023
   **Status:** Referred to Assembly Appropriations Committee
   **Committee Analysis:** Assembly Health
   **Summary:** Would allow a health care professional to request authority to adjust the dose or frequency of a drug to meet specific medical needs of the enrollee without prior authorization under specified conditions, including that the dose has not been adjusted more than two times without prior authorization.
   **Committee Recommendation:** Establish a support position.
   **Comments**: According to the author's office, the nature of chronic conditions means that dose changes are standard practice for effective care and a change in dosage is not a different treatment, but insurance policies treat them equivalently. The Chron's and Colitis Foundation is the sponsor of the measure.
   **Fiscal Impact**: Any impact would be minor and absorbable.
   **Support:** (4/5/2024)
   - Chron's & Colitis Foundation (sponsor)
   - California Chapter American College of Cardiology
   - California Chronic Care Coalition
   - California Life Sciences
   - California Medical Association
   - California Retired Teachers Association
   - Children's Specialty Care Coalition
   - National Multiple Sclerosis Society, MS-CAN
   - Oncology Nursing Society

   **Opposition:** (4/5/2024)
   - America's Health Insurance Plans
   - Association of California Life & Health Insurance Companies
   - California Association of Health Plans

   **Public comment**: Public comment suggested that the measure is unclear about whom is authorized to adjust the dose or frequency.

6. Assembly Bill 2269 (Flora, 2024) Board Membership Qualifications: Public Member
   **Version:** As introduced February 8, 2024
   **Status:** Assembly Appropriations Committee hearing, April 17, 2024
   **Committee Analysis:** Assembly Business and Professions Committee
   **Summary:** Would reduce the prohibition of a public member of any board from having a specified relationship (employer, contractual relationship,

etc.) with a licensee of that board within to 3 years (currently five years) of the public member's appointment.
**Committee Recommendation:** No position.
**Comments**: According to the author's office, "public members serve a vital role on professional licensing boards, providing an important check and balance to the professional members in assuring that boards achieve their consumer protection goral. To that end, current law appropriately prohibits a public member from having had a significant recent employment or contractual relationship with a licensee. AB 2269 would update and simplify that statute by repealing an arbitrary exception to that prohibition for relationships not exceeding 2 percent of a licensee's employment or business."
**Fiscal Impact**: Any impact would be minor and absorbable.
**Committee Discussion**: Members determined the Board should not establish a position on the measure.
**Public comment**: None.

7. Assembly Bill 2271 (Ortega, 2024) Coverage for Naloxone Hydrochloride
**Version:** As introduced February 8, 2024
**Status:** Referred to Assembly Health Committee
**Committee Analysis:** None.
**Summary:** Would designate prescription and OTC opioid reversal products as a covered benefit under Medi-Cal. Would require the same for health plans. Further, would prohibit plans from imposing any cost-sharing that exceeds $10/package and would prohibit high deductible health plans from imposing cost sharing. Provisions are predicated on funding from the Naloxone Distribution Project. Measure includes a sunset provision, with the provision becoming inoperative when the state records 500 or fewer opioid deaths in a calendar year.
**Committee Recommendation:** Establish a support position.
**Comments**: The author's office notes that "while making naloxone available OTC is an important step in combatting the opioid, and specifically, fentanyl crisis, this action will not make much of a difference if the drug is not affordable."
**Fiscal Impact**: Any impact would be minor and absorbable.
**Committee Discussion:** Members noted support for the measure highlighting that OTC products are only helpful if someone can afford it. Members indicated that if the measure is enacted the Board will need to develop educational materials to assist pharmacies with operationalizing the provisions.
**Public comments**: Members were advised that the California Society of Health Systems Pharmacists supports the measure.

8. Assembly Bill 2445 (Wallis, 2024) Prescriptions: Personal use

Pharmaceutical Disposal System
**Version:** As introduced February 13, 2024
**Status:** Assembly Business and Professions Committee hearing, April 16, 2024
**Committee Analysis:** None
**Summary:** Would prohibit a dispenser from dispensing an opioid unless it also provides a personal use pharmaceutical disposal system to the patient. Specifies that the provisions become operational only upon the Legislature enacting a framework for the governing of personal pharmaceutical disposal system program.
**Committee Recommendation:** No position.
**Comments**: Staff have recently been advised that this measure is not moving forward this year.
**Fiscal Impact**: Unknown
**Committee Discussion:** Members expressed concerns with the costs and logistics associated with the measure. Members suggested that the Chair monitor the provision with staff.
**Public comment**: Public comment suggested more information about the measure is necessary.

9. Assembly Bill 3063 (McKinnor, 2024) Pharmacies: Compounding
**Version:** As introduced February 16, 2024
**Status:** Referred to Assembly Appropriations Committee
**Committee Analysis:** Assembly Business and Professions Committee
**Summary:** Would exempt from the definition of compounding, the adding of a flavoring agent to enhance palatability. Would require a pharmacy to retain documentation that a flavoring agent was added to the prescription and that the documentation shall be made available to the Board. Would establish a January 1, 2030 sunset date.
**Board Position:** Oppose Unless Amended, established by President Oh consistent with his delegated authority.
**Comments**: This measure is similar to AB 782 (McKinnor, 2023) which was vetoed by the Governor. Board staff note concerns with this measure. As previously discussed during public meetings including as part of the regulation development process for compounding regulations, the addition of flavoring agents has been determined by USP to be compounding as adding of flavoring agents can destabilize a product. The USP, while not a government entity, works closely with governmental agencies to provide standards of identify, strength, quality and purity to help safeguard the global supply of medicine, dietary supplements and food ingredients. The standards may be enforced by states and the FDA. The FDA has separately confirmed that "the adding of a flavoring agent would generally be considered compounding under section 503A for the FD&C Act."

The Federal Food, Drug and Cosmetic Act establishes, in provisions of 503A, the conditions under which a pharmacist (or others) may compound. The provisions explicitly state that the compounding much comply with the United States Pharmacopoeia chapter on pharmacy compounding.

Generally speaking, when there is a conflict between state and federal law, the more restrictive law must be followed, meaning that even if AB 782 passes, the provisions in 503A will remain in place and enforceable and or applicable to the Board in its regulation as well the FDA and potentially accreditors that assess for compliance with USP as a condition of accreditation.

This measure recently passed through the Assembly Business and Professions Committee.

**Fiscal Impact**: The Board anticipates a fiscal impact of approximately $20,000, which is considered absorbable.
**Support**: Association of California Healthcare Districts

- Association of Regional Center Agencies
- California Coalition for Children's Safety and Health
- California Community Pharmacy Coalition
- Children's Specialty Care Coalition
- Jordan's Guardian Angels
- Maxim Healthcare Services
- The Arc & United Cerebral Palsy California Collaboration

**Opposition**: California State Board of Pharmacy
**Committee Discussion:** Members noted agreement with the position established by President Oh because the measure is contrary to federal law and national standards.
**Public comment**: None.

10. Assembly Bill 3146 (Essayli, 2024) Healing Arts: Sex-Reassignment
**Version:** As introduced February 16, 2024
**Status:** Awaiting Referral
**Committee Analysis:** None.
**Summary:** Would state the intent of the Legislature to enact subsequent legislation prohibiting a health care provider from providing sex-reassignment prescriptions or procedures to a patient under 18 years of age unless certain conditions are met.
**Committee Recommendation:** Establish an oppose position.
**Staff Comments**: Staff have been advised that amendments will be crossed. It is staff's understanding that the general framework is taking some of the provisions from the "Protect Kids" ballot initiative and prohibiting medical transition of minors among other provisions.

**Fiscal Impact**: Unknown
**Committee Discussion:** Members discussed the measure and concern with the legislative intent. Members noted that the legislation is based on a ballot initiative that is very transphobic. Members agreed that the measure should be opposed; however, some members indicated that it may be premature to take a position, given the legislation in its current form only establishes legislative intent without details.
**Public comment**: None.

11. Senate Bill 966 (Wiener, 2024) Pharmacy Benefits
**Version:** As Introduced January 24, 2024
**Status:** Senate Business, Professions and Economic Development Committee hearing, April 15, 2024
**Committee Analysis:** None on File
**Summary:** Would establish the regulation of Pharmacy Benefit Managers (PBMs) within the Board's jurisdiction as specified, including the following:
    - Establish licensure requirements for PBMs and require renewal every two years. (Fees for the measure have not yet been established.)
    - Further, the measure would require a PBM to provide to the Board, on or before April 1, 2027, and each subsequent year, a report that contains specified information required by BPC 4441 and would further require the Board to provide to the legislature, by August 1, 2027 and each subsequent year, a report on the investigation received. As specified the report would contain aggregate data and shall exclude any information that the Board determine would cause financial, competitive or proprietary harm to a PBM.
    - Would prohibit a PBM from doing any of the following:
        - Require an enrolled or insured to use only an affiliated pharmacy that is a retail pharmacy
        - Financially induce an enrollee to transfer a prescription only to a retail affiliated pharmacy
        - Require a nonaffiliated pharmacy to transfer a prescription to a retail affiliated pharmacy except under specified circumstances.
        - Unreasonably restrict an enrolled or insured from using a participate pharmacy, as specified.
        - Communication to an enrolled verbally, electronically, or in writing that the enrolled is required to have a prescription dispensed at a particulate affiliated pharmacy if there are other pharmacies that have the ability to dispense the medication or provide the services.
    - Would provide the Board with enforcement authority over a PBM that violates applicable regulations as well as cease and desist authority if a PBM is not licensed appropriately.
    - Would provide the Board with authority to examine or audit information to determine compliance with the provisions of the Chapter.

- Would provide authority for the Attorney General to retain the ability to prosecute state and federal antitrust and unfair competition violations.

**Board Position:** Support Position established by President Oh, via delegated authority.
**Staff Comments**: Staff notes that the Board has received public comments and complaints from consumers and health care providers stemming from actions by PBMs. Such complaints range in the types of medications involved from maintenance medications (such as the treatment of high blood pressure) to specialty medications (generally high-cost medications used to treat complex, chronic conditions). Investigations have revealed that the root cause of some delays in access, for example, stems from mandates established by PBM. Regrettably at this time the Board lacks jurisdiction and cannot take any meaningful action for the patient nor can the Board evaluate the system and regulate for systemic changes to address the root causes of such delays, thereby preventing future harm. Staff believes that enactment of the measure would provide the Board with the authority to address these issues.

California has a long history of fighting for its residents, removing barriers that impede access to care and providing regulators with tools to protect California patients. As an example, Business and Professions Code section 733 provides a clear example of policy makers embracing a patient's right to timely access to prescription medications, yet many times delays in therapy are caused by PBM business practices. PBMs are not subject to the requirements of this section.

Further, staff notes that the measure is intended to be cost neutral with the Board recovering the license and enforcement costs through its fees. Staff suggested that an appropriate application and renewal fee model may be:

$25,000 plus $6,000 per contract/application or renewal.

Board staff recommend that the Board consider offering technical amendments in the following areas:

1. Establish an annual renewal requirement consistent with all other entities licensed by the Board and consistent with the annual reporting requirements.
2. Extend the August 1, annual legislative report deadline to November 30. Such an extension will allow sufficient time for staff to prepare the Board for consideration at the Board's annual fall meeting.

**Fiscal Impact**: Board staff anticipate a fiscal impact of about $618,000 annually, primarily related to licensure, investigations, review of annual reports, data analysis, and preparation of the annual legislative report.
**Committee Discussion:** Members agreed with the support position established by President Oh and discussed some of the generally provisions including the potential for the Board to look into financial reports. Members also questioned if a designated person, similar to a designated representative, should be included as part of the licensure requirements.
**Public comment**: Public comment also spoke in support of the measure.

12. Senate Bill 1067 (Smallwood-Cuevas, 2024) Healing Arts: Expedited Licensure Process: Medically Underserved Area or Population
**Version:** As Introduced February 12, 2024
**Status:** Senate Appropriations Committee, hearing April 22, 2024
**Committee Analysis:** Senate Business, Professions and Economic Development Committee
**Summary:** Would require the Board (and other DCA healing arts Boards) to develop a process to expedite the licensure process by giving priority review to applications for which the applicant demonstrates that they intend to practice in a medically underserved area or serve a medically underserved population.
**Committee Recommendation:** No position.
**Staff Comments**: Board staff currently expedite Military, Veteran, Military Spouse, and Refugee applications. Board staff are concerned that as additional applications are expediated, it will result in delays for all applicants.

Medically underserved population is defined in Section 128552 of the Health and Safety Code, as the Medi-Cal program and uninsured populations.

**Fiscal Impact**: Board staff anticipate a fiscal impact, primarily related to updating applications and forms, development of policies and procedures, and processing applications. Given the broad nature of the expansion, it is possible the Board's could receive a significant increase in application requesting an expedite.
**Support: (April 5, 2024)**
- Alameda Health Consortium
- Altamed Health Services Corporation
- Apla Health
- Arroyo Vista Family Health Center
- Asian Health Services
- California Consortium for Urban Indian Health

- CAPA
- Chapa-de Indian Health
- Communicare+ole
- Community Clinic Association of Los Angeles County (CCALAC)
- Comprehensive Community Health Centers
- CPCA Advocates, Subsidiary of The California Primary Care Association
- DAP Health
- Dientes Community Dental
- Eisner Health
- El Proyecto Del Barrio, INC.
- Family Health Centers of San Diego
- Friends of Family Health Center
- Golden Valley Health Centers
- Health Alliance of Northern California
- Health and Life Organization, Inc./ Dba Sacramento Community Clinics
- Health Center Partners of Southern California
- Hill Country Community Clinic
- Inland Family Community Health Center
- LA Clinica De LA Raza, INC.
- LA Maestra Community Health Centers
- Lifelong Medical Care
- Neighborhood Healthcare
- North Coast Clinics Network
- North East Medical Services
- North East Medical Services
- Northeast Valley Health Corporation
- Petaluma Health Center
- San Ysidro Health
- Share Our Selves
- Shasta Cascade Health Centers
- Shasta Community Health Center
- The Children's Clinic, "serving Children and Their Families"/TCC Family Health Truecare
- Unicare Community Health Center
- Venice Family Clinic
- Wellspace Health
- West County Health Centers, INC.

**Oppose: (April 5, 2024)**

- None of file

**Committee Discussion:** Member sought clarification on medically underserved areas and the broad nature of the measures. Members noted the potential negative impact to other licensees that may result from the reprioritization of such applications.

**Public comment:** Public comment noted that state and federal law defines a medically underserved area of underserved populations. Action item: update chair report to include definition of the of "medically underserved."

13. Senate Bill 1365 (Glazer, 2024) Pharmacy Technicians: Supervision
**Version:** As Introduced February 16, 2024
**Status:** Senate Business, Professions and Economic Development Committee, hearing April 15, 2024
**Committee Analysis:** Senate Business, Professions and Economic Development
**Summary:** Would allow a pharmacy with only one pharmacist to have up to six pharmacy technicians performing those tasks.
**Committee Recommendation:** Establish an oppose position.
**Comments**: Staff anticipates a significant increase in investigations involving the following types of violations: Medication errors, Failure to provide patient consultation, Delay in therapy, Failure to comply with quality assurance regulations, and HIPAA violations.

The Board recently conducted a survey of California licensed pharmacist. Results of the survey will be discussed at the April 10 Licensing Committee meeting. After the Committee and Board have an opportunity to evaluate the results of the survey and discuss the issue it may be appropriate to consider offering amendments if the measure moves.
**Fiscal Impact**: Board staff anticipate a fiscal impact of about $1.1 million, annually, primarily related to staffing needs for an increase is the number of investigations.
**Support: (April 12, 2024)**

- California Community Pharmacy Association

**Oppose: (April 12, 2024)**

- California Medical Association
- SEIU California
- United Food and Commercial Workers, Western States Council
- United Nurses Association of California/Union of Health Care Professionals
- Number individuals

**Committee Discussion:** Members were advised that the Licensing Committee is asking for more specific information related to the recent survey. Members note that the survey results that have been released indicated that a 1:6 ratio is not supported. Members agreed that the measure was not appropriate with some members suggesting an oppose position with others in favor of establishing an oppose unless amended position. Members noted the need for staff to engage with the author's

office and express concerns with the current measure. Member comments appeared to suggest consensus among members that there should be an update to the ratio, but needed additional information from the survey. Members also considered if different ratios are appropriate in different settings and noted concerns with pharmacist accountability and liability concerns.
**Public comment**: Public comment also referenced the survey results in suggested that the results seem to indicate a transition to 1:2 or 1:3 followed by allowing the PIC to decide. Suggested this is a great opportunity to work with the author's office. Members received comments in support of the bill including a suggestion that the measure will increase access to medication and that the increase ratio is not a mandate or requirement. Members received comments that the ratio should be determined by the type of pharmacy including that phone infusion pharmacies should be considered the same a closed-door pharmacies. Members also received comments in opposition to the measure and suggestion that changes to the ratio should be pharmacist driven. Public comment also noted that the Board has the authority to change the ratio for hospitals and other institutions via regulation.

14. Senate Bill 1468 (Ochoa Bogh and Roth, 2024) Department of Consumer Affairs
**Version:** As Amended March 20, 2024
**Status:** Senate Business, Professions and Economic Development Committee hearing, April 8, 2024.
**Committee Analysis:** Senate Business, Professions and Economic Development
**Summary:** Would require the Board (and other DCA healing arts Boards) that licenses a prescriber to develop and biannually disseminate to each licensee informational and educational material regarding the federal "Three Day Rule."
**Committee Position:** Establish a support position.
**Comments**: The federal "Three Day Rule" authorizes a practitioner who is not specifically registered to conduct a narcotic treatment program to dispense not more than a 3-day supply of narcotic drugs to one person or for one person's use at one time for the purpose of initiating maintenance treatment or detoxification treatment while arrangements are being made for referral for treatment.
**Fiscal Impact**: Staff anticipate a fiscal impact of about $10,000 primarily related to the development of informational and educational material.
**Support: (April 12, 2024)**
Smart Justice California
**Opposition:**
None of file

**Committee Discussion:** Members spoke in support of the measure and noted that education was appropriate.
**Public comment**: Public comment noted support for the concept of the legislation but suggested the author needs help in crafting language to establish a 3-day supply.

**b. Proposed Regulation Related to the Use of Digital Signatures**

Relevant Law
Government Code section 16.5 establishes the authority for government agencies to accept digital signatures that meet specified conditions.

Title 2, California Code of Regulations Section 22003 establish regulations specifying acceptable technologies for acceptance of digital signatures and designate Public Key Cryptography as an acceptable technology.

Background
As part of the April 2023, the Board approved a policy statement related to the acceptance of digital signatures. To fully implement the requirements establishing the authority and parameters for digital signatures, the Board must promulgate regulations.

Summary of Committee Discussion and Action
During the meeting members considered proposed regulation language and noted agreement with the draft text.

Public comment: Members heard comments suggesting that the Board read the regulation. Counsel reminded members that the language is consistent with the attributes included in the Board's policy statement.

**Committee Recommendation**: Recommend initiation of a rulemaking to adopt California Code of Regulations, Title 16, section 1700 as proposed. Authorize the executive officer to further refine the language consistent with the committee's discussion and to make any nonsubstantive changes prior to presenting the proposed rulemaking to the Board.

**Attachment 1** includes a copy of the proposed language.

**c. Draft Frequently Asked Questions related to Cultural Competency Continuing Education**

Relevant Law

Business and Professions Code section 4202 establishes the licensure requirements for pharmacy technicians. Effective January 1, 2024 the section was amended to prohibit the Board from renewing a pharmacy technician license unless the pharmacy technician submits proof satisfactory to the Board that they have successfully completed at least one hour of participation in a "cultural competency course as defined.

Pending CCR 1732.8 implements and clarifies the continuing education requirements for pharmacy technicians.

Background
For the past several months staff have received a significant increase in calls from pharmacy technicians seeking information on the continuing education requirements. To assist with broader dissemination of information, Board staff have developed frequently asked questions.

Summary of Committee Discussion and Action
During the meeting members discussed the draft FAQs. Members noted agreement with the FAQs.

Public comment: Public comment suggested that the Board is not required to provide the CE training, but that the Board set the parameters for the training.

**Committee Motion**: Recommend approval of the draft FAQs related to continuing education for pharmacy technicians.

**Attachment 2** includes a copy of the draft FAQs.

## Board Regulations

The full timelines for each regulation are included within the respective attachments.

### d. Board-Adopted Regulations Approved by the Office of Administrative Law

**Attachment 3**

1. Proposed Regulation to Amend Title 16 CCR section 1706.6 Related to the Military Spouse Temporary License

   **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 OAL on March 21, 2024, with an immediate effective date.

2. Proposed Regulation to Amend Title 16 CCR section 1707.6 Related to the Notice to Consumer

   **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 OAL on March 27, 2024. Effective July 1, 2024.

**e. Board-Adopted Regulations Undergoing Final Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency**

**Attachment 4**

1. Proposed Regulation to Amend Title 16 CCR Section 1732.5 and Add Section 1732.8 Related to Continuing Education

   **Summary of Regulation:** This proposal amends the board's regulations regarding continuing education requirements.

   **Status:** Submitted for DCA Final Review on April 4, 2024.

**f. Board-Adopted Regulations Staff Drafting Final Rulemaking Documents**

**Attachment 5**

1. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to Opioid Antagonist

   **Summary of Regulation:** This proposal amends the board's regulations regarding the furnishing of opioid antagonists by pharmacists.

   **Status:** Adopted by the Executive Officer via Delegated Authority. Board staff preparing Final Rulemaking Documents.

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

**Attachment 6**

1. Proposed Regulation to Add Title 16 CCR sections 1750 and 1750.1

Related to Outsourcing Facilities

**Summary of Regulation:** This proposal adds to the board's regulations regarding the licensure requirements for Outsourcing facilities.

**Status:** Submitted for pre-review on February 6, 2023.

2. Proposed Regulation to Add Title 16 CCR section 1746.6 Related to Medication Assisted Treatment Protocol

**Summary of Regulation:** This proposal adds to the board's regulations regarding medication assisted treatment.

**Status:** Submitted for pre-review on June 23, 2023. Board staff revising rulemaking documents.

3. Proposed Regulation to Amend Title 16 CCR sections 1735 *et seq*, Add sections 1736 *et seq*, 1737 *et seq*, and 1738 *et seq*, and Repeal sections 1751 *et seq* Related to Compounded Drug Preparations

**Summary of Regulation:** This proposal amends the board's regulations regarding compounding.

**Status:** Approved by Agency April 2, 2024. Pending with Board staff for filing with the Office of Administrative Law to initiate the rulemaking process.

4. Proposed Regulation to Amend Title 16 CCR section 1708.2 Related to Discontinuance of Business

**Summary of Regulation:** This proposal amends the board's regulations regarding facility discontinuance of business.

**Status:** Returned to DCA for pre-review on April 5, 2024.

5. Proposed Regulation to Amend Title 16 CCR section 1749 Related to the Fee Schedule

**Summary of Regulation:** This proposal amends the board's regulations regarding the fee schedule.

**Status:** Refer to Board Agenda Item VIII.

6. Proposed Regulation to Amend Title 16 CCR section 1711 Related to Quality Assurance

   **Summary of Regulation:** This proposal amends the board's regulations regarding quality assurance programs.

   **Status:** Returned to DCA for pre-review on April 6, 2024.

7. Proposed Regulation to Amend Title 16 CCR section 1793.65 Related to Pharmacy Technicians

   **Summary of Regulation:** This proposal amends the board's regulations to extend the sunset date of the pharmacy technician certification programs approved by the Board.

   **Status:** Submitted for pre-review on April 6, 2024.

**h. Discussion and Consideration of Board Approved Regulations – Board Staff Drafting Initial Rulemaking Documents**

**Attachment 7**

1. Proposed Regulation to Amend Title 16 CCR Sections 1715 and 1784 Related to the Community Pharmacy, Hospital Pharmacy, and Dangerous Drug Distributor Self-Assessment Forms

   **Summary of Regulation:** This proposal amends the board's regulations regarding the self-assessment forms for a community pharmacy, hospital pharmacy, and dangerous drug distributors.

   **Status:** Approved by the Board on February 8, 2024. Board staff drafting initial rulemaking documents.

# Attachment 1

DEPARTMENT OF CONSUMER AFFAIRS
**TITLE 16. PHARMACY**

## PROPOSED REGULATORY LANGUAGE

### Digital Signatures

| **Legend:** | Added text is indicated with an underline. |
|---|---|

**Adopt section 1700 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

§ 1700. Digital Signatures.

Consistent with the authority established in Government Code section 16.5, in any written communication, application, or other document in which a signature is required or used, the Board shall accept digital signatures that meet the requirements set forth in the California Code of Regulations, Title 2, section 22003(a).

Note: Authority cited: Section 16.5, Government Code. Reference cited: Section 16.5, Government Code.

# Attachment 2

1. **What are the CE requirements to renew my pharmacy technician (TCH) license?**

   Effective January 1, 2024, TCH licensees must successfully complete at least one hour of participation in a cultural competency course each renewal period (*i.e.*, every two years) (see Business and Professions Code section 4202(d)). Please note, all CE must be completed prior to signing and submitting your renewal application.

   The term "cultural competency course" means a cultural competency and humility course that meets the following criteria, as outlined in Business and Professions Code section 4231(a):

   1. The course focuses on patients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, or queer, or who question their sexual orientation or gender identity and expression.
   2. The course is approved from an accreditation agency approved by the Board.
   3. The course covers recognized health disparities faced by Black, Indigenous, and people of color.
   4. The course contains elements demonstrating how sexual identity is directly impacted through intersectionality.

2. **Does the California State Board of Pharmacy (Board) have a list of recommended CE providers and/or courses?**

   No. The Board does not maintain a list of CE providers/courses and does not endorse or recommend any specific provider or course. The Board recommends that, prior to registering for any cultural competency course, licensees confirm compliance with the course provider to ensure the course meets the requirements set forth in Business and Professions Code section 4231(a).

3. **Do I need to submit proof of completion of CE with my license renewal application?**

   You **do not** need to submit proof of completion of CE with your renewal application. If you are randomly selected for an audit of your CE compliance, the Board will send a letter to your address of record requesting proof of successful completion of CE.

4. **Why has my license status been changed to "CE Inadequate – License Held" even though I completed my CE?**

   Your license status has been changed to "CE Inadequate – License Held" because you failed to answer the continuing education question on your renewal application.

   In order to change your license status back to "active", you will need to download a new renewal application and complete it in its entirety: https://pharmacy.ca.gov/licensees/personal/tch.shtml.

   Please email your completed renewal application to renewalstatus@dca.ca.gov so we may resolve this for you. Once Board staff has reviewed your amended renewal application, your updated license status will be reflected on the Board's website.

5. **Can the Board issue an extension if I cannot finish my CE on time?**

   No. Currently, there is no provision in pharmacy law for the Board to grant any TCH licensee an extension to complete the required CE for renewal of their license.

6. **Can the Board issue an exemption from completion of the cultural competency CE renewal requirement for a TCH license?**

   No. Currently, there is no provision in pharmacy law for the Board to grant a TCH licensee an exemption from completion of the required CE for renewal of their license.

7. **Aside from the cultural competency CE requirement, are there any other CE requirements for pharmacy technicians to renew their Board-issued license?**

   No. However, if you hold a CPhT certificate, you may wish to contact the issuing organization (PTCB or NHA) directly regarding their CE requirements. The Board is not associated with PTCB or NHA.

**Should you have any further questions, please contact the CE desk via email at Pharmacy.CE@dca.ca.gov.**

# Attachment 3

**Legislation and Regulation Committee**
**Regulation Timeline**

## XIV.d. Board-Adopted Regulations Approved by the Office of Administrative Law

1. Proposed Regulation to Add Title 16 CCR Section 1706.6, Related to Military Temporary Licensure

   **Timeline:**
   Approved by Board: October 27, 2022
   Submitted to DCA for Pre-Notice Review: November 18, 2022
   Comment Period: (45-Day) April 14, 2023 to May 30, 2023
   Comment Period: (15-day) June 28, 2023 to July 12, 2023
   Adopted via EO Delegation: July 13, 2023
   Submitted to DCA for Final Review: August 31, 2023
   Submitted to OAL for Final Review: October 18, 2023
   Withdrawn from OAL Final Review: December 4, 2023
   Comment Period: (15-Day) December 13, 2023 to December 28, 2023
   Adopted via EO Delegation: January 18, 2024
   Submitted to DCA for Final Review: January 19, 2024
   Submitted to OAL for Final Review: February 8, 2024
   **Approved by OAL: March 21, 2024**
   **Effective Date: March 21, 2024**

2. Proposed Regulation to Amend Title 16 CCR Section 1707.6, Related to the Notice to Consumer

   **Timeline:**
   Approved by Board: October 28, 2021
   Submitted to DCA for Pre-Notice Review: April 11, 2022
   Comment Period: February 24, 2023 – April 10, 2023
   Adopted by the Board: April 19, 2023
   Submitted to DCA for Final Review: July 11, 2023
   Submitted to OAL for Final Review: September 26, 2023
   Withdrawn from OAL Final Review: November 2, 2023
   Comment Period: (15-Day) December 13, 2023 to December 28, 2023
   Adopted by the Board: February 8, 2024
   Submitted to DCA for Final Review: February 8, 2024
   Submitted to OAL for Final Review: February 13, 2024
   **Approved by OAL: March 27, 2024**
   **Effective Date: July 1, 2024**

# Military Spouse Temporary Licensure
# 16 CCR § 1706.6

**Title 16. Board of Pharmacy**
**Order of Adoption**

**Add section 1706.6 to Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1706.6. Temporary Licenses for Military Spouses/Domestic Partners**

(a) Definitions: For the purposes of this section, the following definitions shall apply:

(1) "Disciplined" means that the applicant's license was placed on probation, revoked, suspended, reproved, censured, reprimanded, restricted, limited, or conditioned.

(2) "Jurisdiction" shall mean a California or another state's licensing board or agency, any agency of the federal government, or another territory of the United States.

(3) "Disciplinary proceeding" shall mean any proceeding or investigation under the authority of the licensing jurisdiction pursuant to which a licensee may be disciplined.

(4) "Good standing" shall mean that the applicant has not been disciplined, is not the subject of an unresolved complaint or review procedure and is not the subject of any unresolved disciplinary proceeding.

(5) "Original licensing jurisdiction" shall mean the entity that issued a license to the applicant authorizing the applicant to practice within the same scope for which the applicant seeks a temporary license from the Board.

(6) "License" shall mean a license of the same type that the applicant is applying for, or comparable authority to practice in another state, district, or territory of the United States.

(b) An applicant for a pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL, or a designated paramedic temporary license pursuant to section 115.6 of the Business and Professions Code ("Code") shall submit a completed application to the Board and meet all of the requirements of this section and section 115.6 of the Code to be eligible for a temporary license. A completed application shall provide the following information:

(1) The applicant's identifying and contact information:

(A) Applicant's full legal name ((Last Name) (First Name) (Middle Name) and, if applicable, (Suffix)),

(B) Other name(s) applicant has used or has been known by,

(C) Applicant's address of record (The address of record may be a post office box number or other alternate address.),

(D) Applicant's physical address, if different than the applicant's address of record,

(E) Applicant's email address,

(F) Applicant's telephone number,

(G) Applicant's Social Security Number or Individual Taxpayer Identification Number, and,

(H) Applicant's birthdate (month, day, and year).

(2) The applicant shall indicate that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders and shall provide the following documentation with the application:

(A) Certificate of marriage or certified declaration/registration of domestic partnership filed with the California Secretary of State or other documentary evidence of legal union with an active duty member of the Armed Forces, and,

(B) A copy of the military orders establishing their spouse or partner's duty station in California.

(3) The applicant shall disclose whether the applicant holds a current, active, and unrestricted license and provide written verification from the applicant's original licensing jurisdiction that the applicant's license or other comparable authority is in good standing under that jurisdiction. The verification shall include all of the following:

(A) the full legal name of the applicant and any other name(s) the applicant has used or has been known by,

(B) the license type and number issued to the applicant by the original licensing jurisdiction, and relevant law(s) and regulation(s) under which the license was issued,

(C) the name and location of the licensing agency,

(D) the issuance and expiration date of the license, and,

(E) information showing that the applicant's license is currently in good standing.

(4) The applicant shall attest that the applicant meets all of the requirements for temporary licensure as set forth in Business and Professions Code Section 115.6 (c)(1) through (5), including that the applicant has not committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the Business and Professions Code or this division at the time the act was committed and that the applicant is aware that a

violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the Board of Pharmacy.

(5) The applicant shall also attest that the applicant has not been disciplined by a licensing entity in another jurisdiction and is not the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.

(6) The applicant shall submit fingerprints for use by and accessible to the Board in conducting criminal history information record checks through the California Department of Justice.

(7) For applicants for a temporary pharmacist license, the applicant has successfully completed the California Practice Standards and Jurisprudence Examination (CPJE).

(8) The applicant shall sign a statement attesting to the fact that the applicant meets all the requirements for the temporary license, and that the information submitted in the application is accurate, to the best of the applicant's knowledge.

(c) In addition to the above requirements, and prior to submission of the application specified in subsection (b), applicants for a temporary pharmacist license must successfully complete the Board's law and ethics examination designated as the California Practice Standards and Jurisprudence Examination (CPJE) for Pharmacists set forth in Section 4200 of the Code, which tests the applicant's knowledge and proficiency in state and federal laws and provisions of safe patient care~~,~~ and the items set forth in Section 4200.2 and 4200.3 (d) of the Code.

(d) Upon issuance of a temporary license in accordance with Section 115.6(a) of the Code, the Board shall provide written notice to the applicant of the following:

(1) That the temporary license is nonrenewable;

(2) That the license expires 12 months after issuance, upon issuance or denial of a standard license, upon issuance or denial of a license by endorsement, or upon issuance or denial of an expedited license pursuant to Section 115.5 of the Code, whichever occurs first; and,

(3) Any holder of a temporary license desiring to continue their licensure or to practice in California after expiration of their temporary license shall apply for and obtain a standard pharmacist, advanced practice pharmacist, pharmacy technician, designated representative, designated representative-reverse distributor, designated representative-3PL, or a designated paramedic license, as applicable, in accordance with Sections 4200, 4202, 4210, 4053, 4053.1, 4053.2, and 4202.5 of the Code.

Authority: Sections 115.6 and 4005, Business and Professions Code.
Reference: Sections 30, 115.6, 480, 4200, Business and Professions Code.

# Notice to Consumers
# 16 CCR § 1707.6

**Title 16. Board of Pharmacy**
**Order of Adoption**

***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 must also include a QR code that assists limited-English-proficient individuals and informs 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 Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese. It shall contain the following text:

~~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 dose; 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 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 the drug or device ~~a copayment;~~ or the pharmacist determines doing so would be against the law or potentially harmful to the patient's 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 use 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 Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese.

~~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~~ they request 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) As an alternative to posting the notice from subdivision (b) in a conspicuous place, pharmacies may instead provide the notice on a patients' written receipt.

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

# Attachment 4

**Legislation and Regulation Committee**
**Regulation Timeline**

## XIV.e. Board-Adopted Regulations Undergoing Final Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16 CCR Section 1732.5 and add Section 1732.8, Related to Continuing Education

**Timeline:**
Approved by Board: February 7, 2023
Submitted to DCA for Pre-Notice Review: June 30, 2023
Comment Period: December 15, 2023 – January 29, 2024
Adopted Via EO Delegation: January 31, 2024
**Submitted to DCA for Final Review: April 4, 2024**

# Continuing Education 16 CCR §§ 1732.5 and 1732.8

**Title 16. Board of Pharmacy**
**Proposed Regulation Text**

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

**Amend Section 1732.5 to Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1732.5. Renewal Requirements for Pharmacists.**

(a) Except as provided in ~~S~~section 4234 of the Business and Professions Code and ~~S~~section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the ~~b~~Board, that the applicant has completed 30 hours of continuing education (CE) in the prior 24 months.

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal ("required CE hours") shall be completed by participation in a Board provided CE course in Law and Ethics. Further, beginning January 1, 2024, at least one (1) hour of the required CE hours shall be completed by participating in a cultural competency course from an accreditation agency approved by the Board pursuant to section 1732.05, covering the specified content areas as required by section 4231 of the Business and Professions Code. ~~Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision~~.

(c) Pharmacists providing specialized patient-care services, as identified in subsections (c)(1)-(4) below, shall complete specialized CE (as part of the required CE hours) as follows:

(1) At least one (1) hour of approved CE specific to smoking cessation therapy, as required by section 4052.9 of the Business and Professions Code, if applicable.

(2) At least two (2) hours of approved CE specific to travel medicine, as set forth in section 1746.5 of this Article, if applicable.

(3) At least one (1) hour of approved CE specific to emergency contraception drug therapy, as required by Business and Professions section 4052.3, if applicable.

(4) At least one (1) hour of approved CE specific to immunizations and vaccinations, as set forth in section 1746.4 of this Article, if applicable.

(d) Pharmacists who prescribe any Schedule II controlled substances (as defined in Health and Safety Code section 11055) shall complete at least one (1) hour of the required CE hours by participating in a Board approved CE course once every four (4) years on the risks of addiction associated with the use of Schedule II drugs, as required by section 4232.5 of the Business and Professions Code.

(~~c~~e) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course demonstrating compliance with the provisions of this section.

(f) "Board approved CE course" shall mean coursework from a provider meeting the requirements of section 1732.1.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052.3, 4052.8, 4052.9, 4231, ~~and~~ 4232, and 4232.5, Business and Professions Code.

***Add Section 1732.8 of Title 16 of the California Code of Regulations, to read as follows:***

§ 1732.8. Renewal Requirements for Pharmacy Technicians.

(a) Beginning January 1, 2024, as a condition of renewal, a pharmacy technician licensee shall submit proof satisfactory to the Board that the applicant has completed at least one (1) hour of continuing education (CE) in a cultural competency course covering the specified content areas, from an accreditation agency approved by the Board pursuant to section 1732.05, during the two years preceding the application for renewal, as required by section 4202 of the Business and Professions Code. All pharmacy technicians shall retain their certificate of completion for four (4) years from the date of completion of the cultural competency course demonstrating compliance with the provisions of this section.

(b) If an applicant for renewal of a pharmacy technician license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the Board that the licensee has completed the cultural competency course as required, the Board shall not renew the license and shall issue the applicant an inactive pharmacy technician license.

(c) If, as part of an investigation or audit conducted by the Board, a pharmacy technician fails to provide documentation substantiating the completion of CE as required in subsection (a), the Board shall cancel the active pharmacy technician license and issue an inactive pharmacy technician license in its place. A licensee with an inactive pharmacy technician license issued pursuant to this section may obtain an active pharmacy technician license by submitting renewal fees due and submitting proof to the Board that the pharmacy technician has completed the required CE.

NOTE: Authority cited: Sections 462 and 4005, Business and Professions Code. Reference: Sections 462 and 4202, Business and Professions Code.

# Attachment 5

**Legislation and Regulation Committee**
**Regulation Timeline**

## XIV.f. Board-Adopted Regulations Staff Drafting Final Rulemaking Documents

1. Proposed Regulation to Amend Title 16 CCR Section 1746.3 Related to Opioid Antagonist

   **Timeline:**
   Approved by Board: February 7, 2023
   Submitted to DCA for Pre-Notice Review: March 1, 2023
   Comment Period: December 15, 2023 – January 29, 2024
   Comment Period: (15-day) March 1, 2024 to March 16, 2024
   Adopted Via EO Delegation: March 21, 2024
   **Pending with Staff for Final Rulemaking Documents**

# Opioid Antagonist 16 CCR § 1746.3

**DEPARTMENT OF CONSUMER AFFAIRS**
**Title 16. Board of Pharmacy**

## Modified Regulatory Language
## Opioid Antagonist Protocol

**Legend:** Added text is indicated with an underline.
Deleted text is indicated by ~~strikeout~~.
**Modified Text Legend**: Added text is indicated with a double underline.
Deleted text is indicated by ~~double strikeout~~.

**Amend section 1746.3 to Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1746.3. Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~.**

A pharmacist furnishing an opioid antagonist for overdose reversal ~~naloxone hydrochloride~~ pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:
(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.
(2) "Recipient" means the person to whom ~~naloxone hydrochloride~~ an opioid antagonist is furnished.

(b) Training. Prior to furnishing ~~naloxone hydrochloride~~ an opioid antagonist, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program or equivalent curriculum-based training program, completed in a Board recognized school of pharmacy, specific to the use of opioid antagonists for overdose reversal. ~~naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.~~

(c) Protocol for Pharmacists Furnishing Opioid Antagonists ~~Naloxone Hydrochloride~~. Before providing an opioid antagonist ~~naloxone hydrochloride~~, the pharmacist shall:
~~(1) Screen the potential recipient by asking the following questions:~~
~~(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);~~
~~(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);~~
~~(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient~~

~~answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)~~

~~The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.~~

(~~2~~1) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the opioid antagonist furnished ~~antidote naloxone~~.

(~~3~~2) When an opioid antagonist ~~naloxone hydrochloride~~ is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding ~~naloxone hydrochloride~~ the opioid antagonist furnished.

(~~4~~3) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. ~~A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form.~~ A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(~~5~~4) Labeling: A pharmacist shall label the ~~naloxone hydrochloride~~ opioid antagonist consistent with law and regulations. ~~The person to whom the drug is furnished shall also receive the FDA-approved medication guide.~~ ~~Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.~~

~~(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet. The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.~~

(~~7~~5) Notifications: ~~If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.~~

~~If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared~~

~~with the primary care provider, as permitted by the patient and that primary care provider.~~

At the request of the patient, a pharmacist shall notify the identified primary care provider, if any, of the product furnished or enter appropriate information in a shared patient record system as permitted by the primary care provider. If the patient does not have or does not identify a primary care provider, ~~or chooses not to give notification consent, then~~ the pharmacist shall provide the patient a written record of the drug~~(s) and/or device(s)~~ furnished ~~and advise the patient~~ along with a recommendation for the patient to consult with an appropriate health care provider of the patient's choice.

~~(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.~~

~~(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.~~

NOTE: Authority cited: Section 4052.01, Business and Professions Code. Reference: Section 4052.01, Business and Professions Code.

# Attachment 6

**Legislation and Regulation Committee**
**Regulation Timeline**

## XIV.g. 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 1750 and 1750.1, Related to the Outsourcing Facilities

   **Timeline:**
   Approved by Board: October 26, 2022
   Submitted to DCA for Pre-Notice Review: February 6, 2023

2. Proposed Regulation to Add Title 16 CCR section 1746.6 Related to the Medication Assisted Treatment Protocol

   **Timeline:**
   Approved by Board: February 7, 2023
   Submitted to DCA for Pre-Notice Review: June 23, 2023
   Returned to Board staff for Review: January 30, 2024

3. Proposed Regulation to Amend Title 16 CCR sections 1735 et seq, Add sections 1736 et seq, 1737 et seq, and 1738 et seq, and Repeal sections 1751 et seq Related to Compounded Drug Preparations

   **Timeline:**
   Approved by Board: April 20, 2023
   Submitted to DCA for Pre-Notice Review: June 30, 2023
   Approved by Agency: April 2, 2024
   Comment Period: (45-Day) April 19, 2024 to June 3, 2024

4. Proposed Regulation to Amend Title 16 CCR section 1708.2, Related to the Discontinuance of Business

   **Timeline:**
   Approved by Board: February 7, 2023
   Submitted to DCA for Pre-Notice Review: September 4, 2023
   Returned to Board staff for Review: February 8, 2024
   Returned to DCA for Review: April 5, 2024

5. Proposed Regulation to Amend Title 16 CCR section 1749 Related to the Fee Schedule

   **Timeline:**
   Approved by Board: April 20, 2023
   Submitted to DCA for Pre-Notice Review: June 30, 2023
   Returned to Board staff for Review: March 21, 2024

6. Proposed Regulation to Amend Title 16 CCR section 1711 Related to Quality Assurance

   **Timeline:**
   Approved by Board: February 7, 2023
   Submitted to DCA for Pre-Notice Review: September 4, 2023
   Returned to Board staff for Review: February 29, 2024
   Returned to DCA for Review: April 6, 2024

7. Proposed Regulation to Amend Title 16 CCR Section 1793.65 Related to Pharmacy Technicians

   **Timeline:**
   Approved by Board: February 8, 2024
   Submitted to DCA for Pre-Notice Review: April 6, 2024

# Outsourcing Facilities
# 16 CCR § 1750

## Title 16. Board of Pharmacy

**Proposal To Add Article 6.5 and Sections 1750 and 1750.1 in Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**Article 6.5 Outsourcing Facilities**

**1750 Outsourcing Facility Requirements**

(a) Each outsourcing facility defined under section 4034 of the Business and Professions Code shall compound all sterile products and nonsterile products in compliance with federal current good manufacturing practices (cGMP) applicable to outsourcing facilities under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)) and shall meet the requirements of this Article.

(b) In addition to subsections (a) and (c), an outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall comply with all applicable federal and state laws and regulations, including all of the following:

(1) Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 (commencing with section 1700.1) – Poison Prevention Packaging,

(2) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 (commencing with section 210.1) – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General,

(3) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 (commencing with section 211.1) – Current Good Manufacturing Practice for Finished Pharmaceuticals,

(4) Code of Federal Regulations, Title 21, Chapter II, Parts 1301 (commencing with section 1301.01) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances,

(5) Code of Federal Regulations, Title 21, Chapter II, Part 1304 (commencing with section 1304.01) – Records and Reports of Registrants with the Drug Enforcement Administration,

(6) Code of Federal Regulations, Title 21, Chapter II, Part 1305 (commencing with section 1305.01) -- Orders for Schedule I and II Controlled Substances,

(7) Code of Federal Regulations, Title 21, Chapter II, Part 1306 (commencing with section 1306.01) -- Prescriptions,

(8) Code of Federal Regulations, Title 21, Chapter II, Part 1311 (commencing with section 1311.01 -- Requirements for Electronic Orders and Prescriptions,

(9) The Uniform Controlled Substances Act (Health and Safety Code, Division 10 (commencing with section 11000),
(10) Chapters 1, 4, 6 and 8 of the Sherman Food, Drug, and Cosmetics Law (Health and Safety Code, Division 104, Part 5 (commencing with Section 109875) -,
(11) United States Code, Title 21, Chapter 9, Subchapter V, Part A (commencing with section 351) – Drugs and Devices, and,
(12) United States Code, Title 21, Chapter 13, Part C (commencing with section 821) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, except for sections 821, 822a, and 826a of that Part.

(c) An outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall dispense patient-specific compounded preparations pursuant to a prescription for an individual patient in compliance with all applicable provisions of state and federal laws and regulations relating to a pharmacy as follows:
(1) Orally transmitted prescriptions are received and reduced to writing by a pharmacist consistent with the provisions of Business and Professions Code section 4070 and section 1717(c) of this Division and are issued by an appropriately licensed prescriber.
(2) Internet prescriptions are only dispensed pursuant to a prior good faith examination as required in Business and Professions Code section 4067(a) and are issued only by an appropriately licensed prescriber.
(3) Electronic prescriptions meeting the requirements of Business and Professions Code section 688 are issued only by an appropriately licensed prescriber.
(4) Controlled substances prescriptions meet the requirements of Health and Safety Code sections 11164(a), 11164.5, 11167.5, and 11162.1 and Business and Professions Code section 688.
(5) Each prescription contains all information required by Business and Professions Code sections 4040 and 4070.
(6) Each prescription label complies with the provisions of Business and Professions Code sections 4076, 4076.5, and 4076.6 and section 1707.5 of this Division.
(7) Drug warnings are provided orally or in writing consistent with the provisions of Business and Professions Code sections 4074 and 4076.7, section 1744 of this Division, and section 290.5 of Title 21 of the Code of Federal Regulations.

(8) Prescriptions are dispensed in containers meeting the requirements of section 1473(b) of Title 15 of the United States Code, section 1700.15 of Title 16 of the Code of Federal Regulations, and section 1717(a) of this Division.
(9) Patient consultation is provided consistent with the provisions of section 1707.2 of this Division.
(10) Prior to consultation as required in section 1707.2, a pharmacist shall review drug therapy and patient medication records consistent with the provisions of section 1707.3 of this Division.
(11) The facility shall maintain medication profiles consistent with the provisions of section 1707.1 of this Division.
(12) All Schedule II through V controlled substance dispensing data are reported to the CURES Prescription Drug Monitoring Program as required in Health and Safety Code section 11165.
(13) A pharmacist communicates with the patient or patient's agent if a medication error occurs consistent with the provisions of section 1711.
(14) Medication errors must be documented as part of the facility's quality assurance program consistent with the provisions of Business and Professions Code section 4125 and section 1711 of this Division.
(15) Patient information and prescriptions are kept confidential consistent with the provisions of the Confidentiality of Medical Information Act (Civil Code sections 56 and following), and section 1764 of this Division.
(16) Prescription refills must comply with Business and Professions Code section 4063, Health and Safety Code section 11200, and sections 1717 and 1717.5 of this Division.
(17) All records of disposition are maintained for at least three years consistent with Business and Professions Code sections 4081 and 4105.

(d) For the purposes of this section, "appropriately licensed prescriber" shall mean any health care professional listed in Section 4040(a)(2) of the Business and Professions Code.

**Proposal to Add Section 1750.1 to Article 6.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1750.1 Self-Assessment of an Outsourcing Facility (Resident and Nonresident)**

(a) Each outsourcing facility as defined under section 4034 of the Business and Professions Code shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the outsourcing facility's designated quality control personnel, before July 1 of

every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, for compliance with federal current good manufacturing practices as referenced in section 1750 (cGMP) and provisions of state law related to pharmacies, Pharmacy law and this Division related to patient specific prescriptions. For the purposes of this section, "designated quality control personnel" shall mean an individual or individuals from the quality control unit as defined in section 211.22 of Title 21 of the Code of Federal Regulations ("quality control unit") identified by the outsourcing facility as the person or persons responsible for the facility's operations as detailed in the FDA Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, Guidance for Industry.

(b) Each outsourcing facility shall designate a member of the quality control unit to be responsible for compliance with this section. The name and job title of the designated member must be maintained as part of the records of the outsourcing facility in accordance with Business and Professions Code section 4081.

(c) In addition to the self-assessment required in subdivision (a) of this section, the designated quality control personnel shall complete a self-assessment within 30 days whenever:
   (1) A new outsourcing facility license is issued.
   (2) There is a change in the designated quality control personnel.
   (3) There is a change in the licensed physical location of an outsourcing facility to a new address.

(d) Each outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall complete the "Outsourcing Facility Self-Assessment," Form 17M-117 (New. 9/2022), which is hereby incorporated by reference and contains the following components:
   (1) The designated quality control personnel shall provide identifying information about the outsourcing facility including:
      (A) Name, license number of the premises, and the license expiration date;
      (B) Address, phone number, website address, if applicable, and type of ownership;
      (C) U.S. Food and Drug Administration (FDA) Federal Establishment Identification number, expiration date and date of most recent

inspection completed by the FDA pursuant to Section 360 of Title 21 of the United States Code;

(D) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory pursuant to Title 21, Code of Federal Regulations section 1304.11; and,

(E) Hours of operation of the licensee.

(2) The designated quality control personnel shall list the name of each staff person involved in the dispensing of patient specific prescriptions at the facility at the time the self-assessment is completed, and each person's role within the facility's operations.

(3) The designated quality control personnel shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated quality control personnel shall provide a written corrective action or action plan describing the actions to be taken to come into compliance with the applicable law or regulation cited on the self-assessment form for which a "no" response was provided.

(5) The designated quality control personnel shall initial each page of the self-assessment form with original handwritten initials in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(6) The designated quality control personnel shall certify, under penalty of perjury of the laws of the State of California, on the final page of the self-assessment that:

(A) They have completed the self-assessment of the licensed premises for which they are responsible;

(B) Any deficiency identified within the self-assessment will be corrected and list the timeframe for correction;

(C) They acknowledge receiving the following notice: "All responses on this form are subject to verification by the Board of Pharmacy"; and,

(D) The information provided in the self-assessment form is true and correct.

(E) The certification, made under penalty of perjury of the laws of the State of California that the information provided in the self-

assessment form is true and correct, may be an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and have received notice that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. The certification shall be made, under penalty of perjury of the laws of the State of California, that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(e) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection in accordance with Business and Professions Code section 4081.

(f) The outsourcing facility is responsible for compliance with this article.

(g) Any identified areas of deficiency identified in the self-assessment shall be corrected as specified in the timeframe listed in the certification as provided in subsection (d)(6).

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4034, 4129- 4129.9, Business and Professions Code.

**California State Board of Pharmacy**
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Sacramento, CA 95833
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www.pharmacy.ca.gov

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

## Outsourcing Facility Self-Assessment

Sections 4129.1(b) and 4129.2(b) of the Business and Professions Code (BPC) and section 1750 of Title 16 of the California Code of Regulations (CCR) require any Outsourcing Facility licensed in the state of California to be compliant with federal current Good Manufacturing Practices (cGMP) and other federal laws as specified in Section 1750.**The assessment shall be performed before July 1 of every odd-numbered year by the facility's designated quality control person (as defined in CCR section 1750.1).** The designated quality control personnel must also complete a self-assessment within 30 days whenever: (1) a new outsourcing license has been issued; (2) there is a change in the designated quality control personnel; or (3) there is a change in the licensed physical location of the outsourcing facility. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

This self-assessment should be completed in its entirety, may be completed online, printed, initialed, signed and readily retrievable and available for Board inspection in the pharmacy as required by BPC section 4081. Do not copy a previous assessment. This is meant as a guide for Board requirements for filling a patient specific prescription to be furnished within and into the state of California by a licensed Outsourcing Facility.

**Note**: The licensed Outsourcing Facility can only dispense compounded drug preparations from its licensed location pursuant to a prescription within or into the state of California. Further, Outsourcing Facilities are not licensed pharmacies and may not provide or accept transferred prescriptions from pharmacies or other outsourcing facilities.

All references to the Business and Professions Code (BPC) are to Division 2, Chapter 9. All references to the California Code of Regulations (CCR) are to Title 16.

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

Facility Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐

Other ☐ (please specify) _____

License #: _____ Exp. Date:_____ Date of Last FDA Inspection: _____

FDA EIN #: _____ Registration Date: _____ _____ DEA Number: _____

Name(s) of Designated Quality Control Personnel Responsible for Compliance (attach additional sheets if necessary): _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

Website address (optional): _____

_____
Initials

**Facility Staff (Please include license type and license number where appropriate):** (Please use additional sheets if necessary)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____
17. _____
18. _____
19. _____
20. _____

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Initials

**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.**

# Section I
## Prescription Specific Regulations

### Duties of a pharmacist in an Outsourcing Facility filling patient specific prescriptions
### 1. A pharmacist:

**Yes No N/A**

☐ ☐ ☐ 1.1 Transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
☐ ☐ ☐ 1.2 Provides consultation, training, and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
☐ ☐ ☐ 1.3 Receives a new prescription order from the prescriber; (BPC 4070[a]), (CCR 1793.1[a])
☐ ☐ ☐ 1.4 Consults with the patient; (BPC 4052[a][8], CCR 1707.2, CCR 1793.1[b])
☐ ☐ ☐ 1.5 Identifies, evaluates, and interprets a prescription; (CCR 1793.1[c])
☐ ☐ ☐ 1.6 Interprets the clinical data in a patient medication record; (CCR 1793.1[d])
☐ ☐ ☐ 1.7 Consults with any prescriber, nurse, health professional or agent thereof; (1793.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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### 2. Patient Consultation

**Yes No N/A**

☐ ☐ ☐ 2.1 Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707.2)
- ☐ 2.1.1 Whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 2.1.2 Whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 2.1.3 Upon request;
- ☐ 2.1.4 Whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment; and
- ☐ 2.1.5 All the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

☐ ☐ ☐ 2.2 The facility maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)
☐ ☐ ☐ 2.3 The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)
☐ ☐ ☐ 2.4 Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation and provided in accordance with nondisclosure obligations of Civil Code 56.10. (Civil Code 56.10, CCR 1714[a], 1764)

**Yes No N/A**

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Initials

☐ ☐ ☐ 2.5 Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)
☐ ☐ ☐ 2.6 If prescription medication is mailed or delivered, the facility ensures that: (CCR 1707.2[b][1])
- ☐ 2.6.1 The patient receives written notice of his or her right to request consultation (CCR 1707.2 [b][1][A]);
- ☐ 2.6.2 The patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation (CCR 1707.2 [b][1][B]);
- ☐ 2.6.3 A pharmacist is available to speak with the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is schedule to occur within one business hour, for no fewer than six days per week, and for a minimum of 40 hours per week (CCR 1707.2 [b][1][C]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 3. Prescription Requirements

**Yes No N/A**

☐ ☐ ☐ 3.1 Prescriptions or electronic data transmission prescriptions are complete with all the required information and, if electronic, reduced to the required writing by a pharmacist. (BPC 4040, 4070)
☐ ☐ ☐ 3.2 Orally transmitted prescriptions are received and reduced to writing only by a Pharmacist. (BPC 4070[a], CCR 1717[c])
☐ ☐ ☐ 3.3 If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (BPC 4071)
☐ ☐ ☐ 3.4 If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717[c], 1712)
☐ ☐ ☐ 3.5 The security, accuracy and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])
☐ ☐ ☐ 3.6 Facsimile prescriptions are received from a prescriber's office. (BPC 4040[c])
☐ ☐ ☐ 3.7 Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (BPC 4067[a])
☐ ☐ ☐ 3.8 Except for those prescriptions written under Health and Safety Code (HSC) sections 11159.2, 11159.3 and 11167.5, all written controlled substances prescriptions (Schedules II - V) are on California Security Prescription forms meeting the requirements of HSC 11162.1. (HSC 11162.1, 11164[a], 11167.5)
☐ ☐ ☐ 3.9 All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 11164[a][1], 11166)
☐ ☐ ☐ 3.10 All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100)
☐ ☐ ☐ 3.11 The facility confirms compliance with the following: “No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank. A person may dispense a dangerous drug that is not a controlled substance pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance,

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Initials

pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs they have prescribed. 'Preprinted multiple checkoff prescription blank,' as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug, i.e., a 'checkoff,' indicates a prescription order for that drug." (CCR 1717.3)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 4. Refill Authorization

**Yes No N/A**

☐ ☐ ☐ 4.1 Refill authorization from the prescriber for dangerous drugs or dangerous devices is obtained before refilling a prescription. (BPC 4063, 4064[a])

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

☐ ☐ ☐ 4.3 Refills are documented. (CCR 1717)

☐ ☐ ☐ 4.4 Refills for Schedule II controlled substances are prohibited. (HSC 11200[c])

☐ ☐ ☐ 4.5 Refills for Schedule Ill and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (HSC 11200[a]-[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 5. Medication Errors related to a patient specific prescription

**Yes No N/A**

☐ ☐ ☐ 5.1 The facility has an established quality assurance program that documents medication errors attributable, in whole or in part, to the facility or its personnel. (BPC 4125, CCR 1711)

☐ ☐ ☐ 5.2 Quality assurance policies and procedures are maintained in the facility and are immediately retrievable. (CCR 1711[c])

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

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

☐ ☐ ☐ 5.5 Investigation of the medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

**Yes No N/A**

☐ ☐ ☐ 5.6 In addition to all complaint and adverse drug reaction tracking compliant with the

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Initials

CFR, the record for quality assurance review for a medication error contains: (CCR 1711[e])

☐ 5.6.1 Date, location, and participants in the quality assurance review;
☐ 5.6.2 Pertinent data and other information related to the medication error(s) reviewed;
☐ 5.6.3 Findings and determinations; and
☐ 5.6.4 Recommended changes to policy, procedure, systems, or processes, if any.

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 6. Erroneous or Uncertain prescriptions

**Yes No N/A**

☐ ☐ ☐ 6.1 If a prescription contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐ ☐ ☐ 6.2 Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (HSC 11153)

☐ ☐ ☐ 6.3 Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if they know or have objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 7. Labeling for a patient specific prescription

**Yes No N/A**

☐ ☐ ☐ 7.1 In addition to the requirements for labeling listed in the CFR, the prescription label contains all the required information specified in BPC 4076. (BPC 4076)

☐ ☐ ☐ 7.2 The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707.5)

☐ ☐ ☐ 7.3 The beyond use date of a drug's effectiveness is accurately identified on the label. (BPC 4076[a][9])

☐ ☐ ☐ 7.4 The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record and includes the statement "generic for __ " where the brand name is inserted, and the name of the

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Initials

manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (BPC 4076[a][1], CCR 1707.5[a][1][B], CCR 1717[b][2])

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

☐ ☐ ☐ 7.6 The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (BPC 4076[a][11])

☐ ☐ ☐ 7.7 Whenever an opioid prescription drug is dispensed to patient for outpatient use, the facility prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7)

☐ ☐ ☐ 7.8 When requested by a patient or patient representative, the facility provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appear on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a])

☐ ☐ ☐ 7.9 The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[b], BPC 4076.7, CCR 1744[a])

☐ ☐ ☐ 7.10 The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (CCR 1744[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 8. Furnishing and Dispensing

**Yes No N/A**

☐ ☐ ☐ 8.1 If the prescription is filled by a pharmacy technician, before dispensing, the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or records by their identity as the reviewing pharmacist in a computer system by a secure means. (BPC 4115, 4115.5[b][3], CCR 1712, 1793.7[a])

**Yes No N/A**

☐ ☐ ☐ 8.2 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717[a])

☐ ☐ ☐ 8.3 Patient package inserts are dispensed with all estrogen medications.

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Initials

(21 CFR 310.515)

☐ ☐ ☐ 8.4 The facility provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c]. (21 CFR 201.57[c])

☐ ☐ ☐ 8.5 Medication guides are provided on required medications. (21 CFR, Part 208)

☐ ☐ ☐ 8.6 The facility furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription. (BPC 4126.5[a][5])

☐ ☐ ☐ 8.7 Controlled substance prescriptions are not filled or refilled more than six months from the date written. (HSC 11200[a])

☐ ☐ ☐ 8.8 Refills for Schedule Ill and IV controlled substance prescriptions are limited to a maximum of 5 times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply. (HSC 11200[b])

☐ ☐ ☐ 8.9 The facility dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, under the following provisions: (BPC 4064.5).

- ☐ 8.9.1 The prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; (BPC 4064.5[a])
- ☐ 8.9.2 The prescriber has not indicated "no change to quantity" or words of similar meaning; (BPC 4064.5[d])
- ☐ 8.9.3 The patient has completed an initial 30-day supply (this is not required where the prescription continues the same medication as previously dispensed in a 90-day supply); (BPC 4064.5[a][1], 4064.5[b])
- ☐ 8.9.4 The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
- ☐ 8.9.5 The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; (BPC 4064.5[a][3])
- ☐ 8.9.6 The pharmacist is exercising their professional judgment; and (BPC 4064.5[a][4])
- ☐ 8.9.7 The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 9. Confidentiality of Prescriptions

**Yes No N/A**

☐ ☐ ☐ 9.1 Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐ ☐ ☐ 9.2 All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐ ☐ ☐ 9.3 The facility ensures electronically transmitted prescriptions are received maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

**Yes No N/A**

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

☐ ☐ ☐ 9.5 If the facility has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure

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Initials

of confidential medical information except as authorized by law. (CCR 1717.1)

☐ ☐ ☐ 9.6 Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 10. Record Keeping Requirements in addition to compliance with cGMP

**Yes No N/A**

☐ ☐ ☐ 10.1 Completed self-assessments are kept on file in the facility and maintained for three years after completion. (CCR 1750.1[e])

☐ ☐ ☐ 10.2 All drug acquisition and disposition records (complete accountability) are maintained for at least three years. For any record maintained electronically, a hardcopy is able to be produced upon inspection and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records, including: (BPC 4081, 4105, 4169, 4333, CCR 1718)

- ☐ 10.2.1 Prescription records (BPC 4081[a])
- ☐ 10.2.2 Purchase Invoices for all prescription drugs (BPC 4081[b])
- ☐ 10.2.3 Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 10.2.4 Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 10.2.5 U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 10.2.6 Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05)
- ☐ 10.2.7 Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 11. Patient specific prescriptions may not be returned and reused by the facility.

**Yes No N/A**

☐ ☐ ☐ 11.1 Patient specific prescriptions are not returned and reused by the facility**.**

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

# Section II

## Code of Federal Regulation Part 211 for all Outsourcing Facilities

**Quality Systems, validation control, facility control and training**

### 12. CFR Part 211, Subpart B, Organization and Personnel

**Yes No N/A**

☐ ☐ ☐ 12.1 Compliance with sections 211.22 through 211.34 in their entirety

**Facility**

### 13. CFR Part 211, Subpart C Buildings and Facilities

**Yes No N/A**

☐ ☐ ☐ 13.1 Compliance with Sections 211.42 through 211.58 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Equipment**

### 14. CFR Part 211, Subpart D Equipment

**Yes No N/A**

☐ ☐ ☐ 14.1 Compliance with sections 211.63 through 211.72 in their entirely.

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Compounding and manufacture of the product**

### 15. CFR Part 211, Subpart E Control of Components and Drug Product Containers and Closures

**Yes No N/A**

☐ ☐ ☐ 15.1 Compliance with sections 211.80 through 211.94 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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### 16. CFR Part 211, Subpart F—Production and Process Controls

**Yes No N/A**

☐ ☐ ☐ 11.1 Compliance with sections 211.100 through 211.115 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

### 17. CFR Part 211, Subpart G—Packaging and Labeling Control

**Yes No N/A**

☐ ☐ ☐ 17.1 Compliance with sections 211.122 through 211.137 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Distribution, storage,**

### 18. CFR Section 211, Subpart H—Holding and Distribution

**Yes No N/A**

☐ ☐ ☐ 19.1 Compliance with sections 211.142 through 211.150

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Release of product for sale**

### 19. CFR Section 211, Subpart I—Laboratory Controls

**Yes No N/A**

☐ ☐ ☐ 18.1 Compliance with sections 211.160 through 211.176 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Record keeping**

### 20. CFR Part 211, Subpart J—Records and Reports

**Yes No N/A**

☐ ☐ ☐ 20.1 Compliance with sections 211.180 through 211.198 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Returns**

### 21. CFR part 211, Subpart K—Returned and Salvaged Drug Products

**Yes No N/A**

☐ ☐ ☐ 21.1 Compliance with sections 211.204 through 211.208 in their entirety for products not sold pursuant to a patient specific prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

# Section III

## DEA Controlled Substances Inventory, as applicable to your facility

### 22. Inventory:

**Yes No N/A**

☐ ☐ ☐ 22.1 Is completed biennially (every two years). (21 CFR 1304.11[c])
☐ ☐ ☐ 22.2 Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1])
☐ ☐ ☐ 22.3 All completed inventories are available for inspection for three years. (CCR 1718)
☐ ☐ ☐ 22.4 Indicates on the inventory record whether the inventory was taken at the open of business or at the close of business. (21 CFR 1304.11 [a])
☐ ☐ ☐ 22.5 Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])
☐ ☐ ☐ 22.6 Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the facility uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][4])
☐ ☐ ☐ 22.6 Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)
☐ ☐ ☐ 22.7 A U.S. Official Order Form (DEA Form 222) or electronic equivalent (CSOS) is utilized when ordering all Schedule II-controlled substances. When Schedule II Controlled substance orders are received by the facility, for each item received, the date and quantity received is indicated on the DEA Form 222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])
☐ ☐ ☐ 22.8 When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the facility reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide the prescription. (HSC 11167[c]-[d])
☐ ☐ ☐ 22.9 The facility generates a controlled substances printout for refills of Schedule II-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the facility maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.
☐ ☐ ☐ 22.10 Any controlled substances drug theft or significant loss is reported within one business day of discovery to the DEA (21 CFR 1301.74[c].)
☐ ☐ ☐ 22.11 A report is submitted to the Board within 30 days of the date of discovery of any loss of a controlled substance or any other significant drug losses as specified in Section 1715.6. (CCR 1715.6)
☐ ☐ ☐ 22.12 Pharmacists are creating initial prescription records and prescription labels by hand, or a pharmacist initials or signs prescription records and prescription labels by recording the identity of the pharmacist in a computer system by a secure means. This computer system does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the facility. (CCR 1712, 1717[b][1], 1717[f])

**Yes No N/A**

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Initials

☐ ☐ ☐ 22.13 All Schedule II through V controlled substances dispensing data is successfully transmitted within one working day from the date the controlled substance is released to the patient through the CURES System Administrator. [HSC 11165(d)])

☐ ☐ ☐ 22.14 The facility has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon discovering a suspicious order or series of orders, notify the DEA administration and the Special Agent in charge of DEA in their area. (21 USC 832[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

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**DESIGNATED QUALITY CONTROL PERSONNEL CERTIFICATION:**

I, (please print) _____, Title _____ hereby certify that I have completed the self-assessment of this outsourcing facility of which I am the designated quality control person. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Designated Quality Control Personnel)

**ACKNOWLEDGEMENT BY FACILITY OWNER OR OFFICER:**

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment in the timeframe identified in the Designated Quality Control Personnel Certification above could result in the revocation of the outsourcing facility's license issued by the California State Board of Pharmacy.

Signature _____ Date _____
(Outsourcing Facility Owner or Officer)

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Initials

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

- Business and Professions Code, Division 1, Chapter 1 – General Provisions
- Business and Professions Code, Division 2, Chapter 1 – General Provisions
- Business and Professions Code, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation, Title 16, Division 17 – California State Board of Pharmacy
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- Code of Federal Regulations, Title 21, Chapter II, Parts 1301, 1304, 1305, 1306, 1311
- Health and Safety Code, Division 10 – Uniform Controlled Substances Act
- Health and Safety Code, Division 104, Part 5 - Sherman Food, Drug, and Cosmetics Law
- United States Code, Title 21, Chapter 9, Subchapter V, Part A – Federal Food, Drug, and Cosmetic Act
- United States Code, Title 21, Chapter 13 – Drug Abuse Prevention and Control

Initials

# Medication Assisted Treatment Protocol 16 CCR § 1746.6

Proposal to Add CCR Section 1746.6 Pharmacist Provided Medication-Assisted Treatment

(a) A pharmacist may initiate, modify, administer, or discontinue medication-assisted treatment pursuant to Section 4052(a)(14) consistent with all relevant provisions of federal law and shall satisfy the requirements of this section.
    1. The pharmacist possesses appropriate education and training to provide such treatment consistent with the established standard of care used by other health care practitioners providing medication-assisted treatment including nationally accepted guidelines.
    2. The pharmacist must ensure a confidential patient care area is used to provide the services. The patient may not waive consultation.
    3. Assessment of the substance use disorder is performed including physical and laboratory examinations for signs and symptoms of substance use disorder. Initial assessment may be waived if the patient is referred to the pharmacist for treatment following diagnosis by another health care provider.
    4. Development of a treatment plan for substance use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment is provided as indicated.
    5. Documentation of the pharmacist's assessment, clinical findings, plan of care, and medications dispended and administered will be documented in a patient record system and shared with a patient's primary care provider or other prescriber, if one if identified.
    6. A pharmacist performing the functions authorized in this section shall do so in collaboration with other health care providers.

(b) For purposes of this section medication assisted treatment includes any medication used to treat a substance use disorder.

# Compounding
# 16 CCR §§
# 1735 and 1751
# *et. seq*

**Title 16. Board of Pharmacy**
**Proposed Regulation**

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

**Amend title of Article 4.5 and Repeal sections 1735, 1735.1, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, and 1735.8 of Article 4.5, adopt a new title for and amend section 1735.2, adopt new titles and sections 1735, 1735.1, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8, 1735.9, 1735.10, 1735.11, 1735.12, 1735.13, and 1735.14 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**Article 4.5 <u>Nonsterile</u> Compounding ~~in Pharmacies~~**

~~**1735. Compounding in Licensed Pharmacies**~~

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

(1) ~~Altering the dosage form or delivery system of a drug~~

~~(2) Altering the strength of a drug~~

~~(3) Combining components or active ingredients~~

~~(4) Preparing a compounded drug preparation from chemicals or bulk drug substances~~

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

~~(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052,and 4127, Business and Professions Code.~~

**<u>1735. Compounding Definitions.</u>**

<u>In addition to the definitions contained in United States Pharmacopeia (USP) General Chapter 795 titled *Pharmaceutical Compounding – Nonsterile Preparations* "USP Chapter 795" for the purposes of this article, the following definitions apply to this article and supplement the definitions provided in USP Chapter 795.</u>

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations that contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

(b) "Essentially a copy" of a commercially available drug product means all preparations that include the same API(s) as the commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(c) Designated person(s) means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded nonsterile preparations ("CNSP") for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

(d) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as purified water or sterile water for injection.

(e) "Integrity" means retention of strength until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.

(f) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, or the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formulation record as specified in USP Chapter 795.

(g) "Repackaging" means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation, when the act is not done pursuant to a prescription.

(i) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

**~~1735.1. Compounding Definitions~~**

(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.

(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building exhausting. This external exhaust should be dedicated to one BSC or CACI.

d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

e) "Cleanroom or clean area or buffer area" means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

1) For nonhazardous compounding a positive pressure differential of 0.02-to 0.05-inch water column relative to all adjacent spaces is required.
2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

(f) "Compounding Aseptic Containment Isolator (CACI)" means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the

exhaust air from the isolator shall be appropriately removed by properly designed external building exhaust. This external exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.

(g) "Compounding Aseptic Isolator (CAI)" means a form of isolator specifically designed for nonhazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.

h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

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

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

m) "Displacement airflow method" means a concept which utilizes a low pressure differential high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-

~~sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.~~

~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient.~~

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

~~p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.~~

~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.~~

~~r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.~~

~~(s) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.~~

~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).~~

~~(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.~~

~~(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.~~

~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not (x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded~~

preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.

y) "Potency" means active ingredient strength within +/-10% (or the range specified in USP37NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.

(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

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

(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding.

~~The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations. include topical, sublingual, rectal or buccal routes of administration.~~

~~(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).~~
~~(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).~~
~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug preparation~~
~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

**1735.1. Introduction and Scope**

In addition to the standards in the USP Chapter 795, the preparation of CNSP shall meet the following requirements of this article.

(a) For the purposes of this article, nonsterile compounding occurs, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.

(b) Repackaging of a conventionally manufactured drug product shall be not considered compounding but must be compliant with USP Chapter 1178, *Good Repackaging Practices*.

(c) Reconstitution of a conventionally manufactured drug product in accordance with directions that have not been Food and Drug Administration (FDA) approved in accordance with 21 U.S.C.A Section 355 is considered compounding and this article applies.

(d) Notwithstanding subdivision (a), a limited quantity of CNSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care individual patients based on a documented history of prescriptions for those patient populations.

(e) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office
(2) for furnishing of not more than 7-day supply, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;

(f) In addition to prohibitions and requirements for compounding established in federal law, no CNSP shall be prepared that:

(1) Is essentially a copy of one or more commercially available drug products, unless:

(A) the drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispense, or

(B) the compounding produces a clinically significant difference of the medical need of an identified individual patient, as determined:

(1) by the prescribing practitioner,

(2) the compounding pharmacist, and

(3) the dispensing pharmacist(s).

(C)) Documentation describing the conditions in (1)(A) & (1) (B) is maintained in a readily retrievable format

(2) Is made with any component not suitable for use in a CNSP for the intended patient population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).

(g) Prior to allowing any CNSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CNSP and related supplies furnished.

(h) CNSPs with human whole blood or human whole blood derivatives shall be prepared in compliance with Health and Safety Code section 1602.5.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4105, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

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

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

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

~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and~~
~~(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, 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; and~~
~~(6) Does not exceed an amount the pharmacy can reasonably and safely compound.~~

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

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

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

(1) Active ingredients to be used.
(2) Equipment to be used.
(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.
(4) Inactive ingredients to be used.
(5) Specific and essential compounding steps used to prepare the drug.
(6) Quality reviews required at each step in preparation of the drug.
(7) Post-compounding process or procedures required, if any.
(8) Instructions for storage and handling of the compounded drug preparation.

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

(g) The pharmacist performing or supervising compounding is 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.

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

(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.

(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:
(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
(B) the chemical stability of any one ingredient in the compounded drug preparation;
(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,
(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,

(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and

(F) 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.

(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches 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 the pharmacist must analyze include:

(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) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

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

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

~~(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:~~

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

~~(2) such ingredients cannot be used for any sterile compounded drug preparation more than~~

~~(1) year after the date of receipt by the pharmacy.~~

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

## 1735.2. Personnel Training and Evaluation

In addition to the standards in the USP Chapter 795, the preparation of CNSP shall meet the following requirements of this article.

(a) In addition to the training required by USP Chapter 795 training and competencies procedures for all personnel who compound or have direct oversight of personnel performing compounding, verifying, and/or handling a CNSP shall also address the following topics:

(1) Quality assurance and quality control procedures,

(2) Container closure and equipment selection, and

(3) Component selection and handling.

(b) A pharmacist responsible for, or directly supervising, the compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, strength, quality, and labeled strength of a CNSP as described in the facilities SOPs as referenced in section 1735.11.

(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:

(1) Is sufficient for administration or application to patients solely in the prescriber's office,-or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted prior to furnishing.

(d) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of ongoing training and evaluation shall not be involved in compounding or oversight of the preparation of a CNSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1735.11. Documentation must be maintained demonstrating compliance.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

**~~1735.3. Recordkeeping of Compounded Drug Preparations~~**

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

~~(1) The master formula document.~~

~~(2) A compounding log consisting of a single document containing all of the following:~~

~~(A) Name and Strength of the compounded drug preparation.~~

~~(B) The date the drug preparation was compounded.~~

~~(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.~~

~~(D) The identity of the pharmacist reviewing the final drug preparation.~~

(E) The quantity of each ingredient used in compounding the drug preparation.

F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (l) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile — in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.

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

H) The beyond use date or beyond use date and time of the final compounded drug, expressed in the compounding document in a standard date and time format.

I) The final quantity or amount of drug preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

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

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA-registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic

~~media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).~~

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

**1735.3. Personnel Hygiene and Garbing**

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other medical conditions to determine if such condition could contaminate a CNSP or the environment ("contaminating conditions"). After such evaluation and determination the supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) A gown and face mask shall be used whenever a closed system processing device is required.

(c) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

(d) Gloves shall be wiped or replaced before beginning a CNSP that has different components.

(e) Non-disposable garb shall be cleaned with a germicidal cleaning agent and sanitized with 70% isopropyl alcohol before re-use.

(f) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

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

~~(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:~~

~~(1) Name of the compounding pharmacy and dispensing pharmacy (if different);~~

~~2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;~~

~~(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;~~

~~(4) The beyond use date for the drug preparation;~~

~~(5) The date compounded; and~~

~~6) The lot number or pharmacy reference number.~~

~~(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.~~

~~(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.~~

~~(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).~~

~~(e) All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."~~

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

## 1735.4. Building and Facilities

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.

(c) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the law or the facilities SOPs

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301, 4306.5 and 4332 of the Business and Profession Code.

**~~1735.5. Compounding Policies and Procedures~~**

~~(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.~~

~~(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.~~

~~(c) The policies and procedures shall include at least the following:~~

~~1) Procedures for notifying staff assigned to compounding duties of any changes in policies .~~

~~2) A written plan for recall of a dispensed compounded drug preparation where subsequent demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).~~

~~3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in , and for training on these procedures as part of the staff training and competency evaluation process.~~

~~(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) 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.~~

~~(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.~~

~~(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.~~

~~8) Dates and signatures accompanying any revisions to the policies and procedures approved by pharmacist-in-charge.~~

~~9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.~~

~~10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.~~

~~(11) Policies and procedures for proper garbing when compounding with hazardous products. shall include when to utilize double shoe covers.~~

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

## 1735.5. Cleaning And Sanitizing

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) In addition to the documentation requirements in USP Chapter 795, the facility's documentation of each occurrence of the cleaning and sanitizing of the compounding area shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents used.

(b) Any cleaning or sanitizing agents used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

## ~~1735.6. Compounding Facilities and Equipment~~

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

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

~~c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.~~

~~(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.~~

~~(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:~~

~~(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non sterile products are compounded; and~~

~~2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and~~

~~(3) A) For sterile compounding, each BSC or CACI shall also be externally exhausted. y~~

~~(B) 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.; For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.~~

~~Each PEC in the room shall also be externally vented; and~~

~~4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.~~

~~(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.~~

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

## 1735.6. Equipment And Components

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Any equipment used to compound a CNSP shall be used in accordance with the manufacturer's specifications.

(b) Any component used to compound a CNSP shall be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers' specifications and requirements.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

~~**1735.7. Training of Compounding Staff**~~

~~(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.~~

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

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

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

**1735.7. Master Formulation and Compounding Records**

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) A CNSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 795 and identified in that document the following additional elements:

(1) When a source is referenced to support the assigned beyond-use date (BUD); each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.

(2) Instructions for storage and handling of the CNSP.

(b) Where a facility does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 795 standards and this section.

(c) A compounding record (CR) shall be a single document. The document shall satisfy the compounding record requirements in USP Chapter 795, as well as the following:

(1) The date and time of preparation. The time of preparation is the time when compounding the CNSP started, which also determines when the assigned BUD starts.(2) The manufacturer, lot number, and expiration date for each component.

(3) The assigned internal identification number shall be unique for each CR.

(4) The total quantity compounded shall include the number of units made and the volume or weight of each unit.

(5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

**~~1735.8. Compounding Quality Assurance~~**

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

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

~~(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.~~

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

~~(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.~~

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

## 1735.8. Release Inspections and Testing

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

A pharmacist performing or supervising the nonsterile compounding is responsible for the integrity, quality, and labeled strength of a CNSP until the beyond-use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4036.5, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

## 1735.9. Labeling

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) A CNSPs label shall also include the following:

(1) Route of intended administration, and

(2) Name of compounding facility and dispensing facility (if different).

(b) A CNSPs Labeling shall also include:

(1) Any special handling instructions,

(2) Any applicable warning statements, and

(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

**1735.10. Establishing Beyond-Use Dates**

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Beyond-use dates (BUDs) assigned with only a date shall expire at 11:59 p.m. on that date.

(b) A CNSP's BUDs shall not exceed:

(1) The chemical and physical stability data of the active pharmaceutical ingredient (API) and any added component in the preparation,

(2) The compatibility and degradation of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components, or,

(4) The potential for microbial proliferation in the CNSP.

(c) If a licensee chooses to use antimicrobial effectiveness testing results provided by an current FDA-registered drug establishment or outsourcing facility or published in current peer-reviewed literature sources, the reference (including the raw data and testing method suitability), shall be readily retrievable in accordance with Business and Professions Code section 4081 in its entirety for three years from the last date the CNSP was dispensed.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

**1735.11. Standard Operating Procedures (SOPs)**

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) The facility's standard operating procedures (SOPs) for nonsterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding, and disposal of infectious materials. The written SOPS shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPS as described in this article.

(b) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the facility's SOPs. The SOPs shall be updated any time changes are made to compounding processes, facility changes or other changes occur that impact the CNSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(c) Failure to follow written SOPs shall constitute a basis for enforcement action.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

## 1735.12. Quality Assurance And Quality Control

The requirements of this section apply to nonsterile compounding in addition to the standards established in USP Chapter 795.

(a) The quality assurance program shall also comply with section 1711 and the standards contained in USP Chapter 1163, entitled *Quality Assurance in Pharmaceutical Compounding*. In addition, the program shall include in its SOPs the following:

(1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) The Board shall be notified in writing within 72 hours of the facility's receipt of a complaint of a potential quality problem or the occurrence of an adverse drug event involving a CNSP.

(c) All complaints related to a potential quality problem with a CNSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence of the adverse event. Such review shall be documented and dated as defined in the SOPs.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

## 1735.13. CNSP Packaging and Transporting

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

There shall be written procedures recorded in the facility's SOPs (as described in Section 1735.11) describing validated processes for storage, shipping containers and transportation of temperature sensitive CNPSs to preserve quality standards for integrity, quality and labeled strength.

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

## 1735.14. Documentation

The requirements of this section apply to nonsterile compounding in addition to the standards established by USP Chapter 795.

(a) Records shall be maintain as required by USP Chapter 795 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon to meet the requirements of this article. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change

Note: Authority cited: Sections 4001.1, 4005, 4057, 4126.8 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4105, 4126.8 and 4169, 4301 and 4332 of the Business and Profession Code.

**Title 16. Board of Pharmacy**

**Proposed Regulation**

**Repeal Article 7 and sections 1751-1751.12 of Article 7 and add new titles and sections 1736- 1736.21, to Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1736 Sterile Compounding Definitions**

The definitions in in this section shall be applicable to this Article and supplement the definitions provided in USP Chapter 797.

(a) "Compounding personnel" means any person involved with any procedure, activity or oversight of the compounding process.

(b) "Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations ("CSP" for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(d) "Designated compounding area or compounding area" means a restricted location with limited access designated for the preparation of CSP, where only activities and items related to compounding are present.

(e) "Essentially a copy" of a commercially available drug product means all preparations that include the same API(s) , as the commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(f) "Integrity" means retention of potency until the beyond use date provided on the label, when the preparation is stored and handled according to the label directions.

(g) "Quality" means the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formula record as specified in USP 797.

(h) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4127, 4301 and 4332 of the Business and Profession Code.

**1736.1 Introduction and Scope.**

This article applies to compounded sterile preparations (CSP)s as defined in United States Pharmacopeia (USP) General Chapter 797 (Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article.

(a) For the purposes of this article, sterile compounding occurs, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.

(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available

(c) Notwithstanding subdivision (a) a limited quantity of CSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for individual patients based on a documented history of prescriptions for those patient populations.

(d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office

(2) for furnishing of not more than a 120-hour supply, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;

(a)With the exception of a topical ophthalmics where up to a 28 days supply may be furnished to veterinarian's office for individual patient. Such topical ophthalmics shall be complaint with USP 797 section 14.5, Multiple-Dose CSPs .

(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that:

(1) Is essentially a copy of one or more commercially available drug products, unless:

(A) that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispense, or

(B) the compounding produces a clinically significant difference of the medical need of an identified individual patient, as determined:

(1) by the prescribing practitioner,

(2) the compounding pharmacist, and

(3) the dispensing pharmacist(s).

(C)) Documentation describing the conditions in (1)(A) & (1) (B) is maintained in a readily retrievable format

(2) Is made with any component not suitable for use in a CSP for the intended patient population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).

(3) Is made with a non-sterile component for which a conventionally manufactured sterile product is available and appropriate for the intended CSP.

(4) Where sterilization is required, it cannot be sterilized within the licensed location.

(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.

(h) CSPs with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and

4127, Business and Professions Code.

## 1736.2 PERSONNEL TRAINING AND EVALUATION

The requirements of this section apply to sterile compounding in addition to the standards in USP Chapter 797.

(a) In addition to the training required by USP 797, training and competencies procedures for all personnel who compound or have direct oversight of compounding personnel training shall also address the following topics:

(1) Quality assurance and quality control procedures,
(2) Container closure and equipment selection,
(3) Component selection and handling, and
(4) Sterilization techniques, when applicable.

(b) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

1. The SOPs related to compounding are identical
2. The SEC facility designs are sufficiently similar to accommodate the use of the same SOPs.
3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(c) Aseptic manipulation ongoing training and competency shall occur each time and for each staff member involved in an event where the quality assurance program yields an unacceptable result as defined in the SOPs referenced in section 1736.17 that may indicate microbial contamination of CSPs due to poor practices. Aseptic manipulation ongoing training and competency procedures shall be defined in the facilities SOPs.

(d) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation, may continue to provide only direct oversight for no more than 14 days while applicable aseptic manipulation ongoing training and competency evaluation results are pending.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1736.17. Documentation must be maintained demonstrating compliance.

Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4114, 4115, 4127, 4301 and 4332 of the Business and Profession Code.

## 1736.3 PERSONNEL HYGIENE AND GARBING

The requirements of this section apply sterile compounding in addition to the requirements in USP Chapter 797.

(a) The pharmacist overseeing compounding shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) The pharmacist overseeing compounding shall not allow personnel to enter the compounding area with visible non-removable piercings that increase the risk of contamination of CSP.

(c) Garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP define specific processes that must be followed to prevent contamination.

(d) Restricted access barrier system (RABS) and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOP.

(e) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.4 FACILITIES AND ENGINEERING CONTROLS

The requirements of this section apply to sterile compounding in addition to the requirements in USP Chapter 797.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) If an SCA is used:

(1) Except for walls, the SCA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SCA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(c) (1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler and also provide comfortable conditions for compounding personnel attired in the required garb.

(2) The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.

(d) Where a pass-through is installed in a secondary engineering control after [OAL insert effective date], the doors must be interlocking. An existing secondary engineering control that has a pass-through that is not an interlocking device, may continue to be used if the SOPs document that two doors may not be opened at the same time.

(e) Except as provided in (d) dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system. No passive ceiling or wall penetrations are allowed.

(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in the law or the facilities SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.5 CERTIFICATION AND RECERTIFICATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Testing and certification of all classified areas shall be completed by a

qualified technician knowledgeable with certification methods and procedures outlined within the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003, Revised 2022), which is hereby incorporated by reference.

(b) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on report issued by the certifying technician.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.6 MICROBIOLOGICAL AIR AND SURFACE MONITORING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) SOPs shall specify steps to be taken when the microbiological air and surface monitoring action levels are exceeded including the investigative and corrective actions, allowable activities, and resampling procedures.

(b) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Professional judgement and SOPs shall be used to determine the appropriate action necessary to remedy identified trends. Investigation must be consistent with the deviation and must include evaluation of trends.

(c) Environmental sampling shall be done in compliance with the most recent edition of the Controlled Environment Testing Association (CETA)'s Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.7 CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTANTS AND STERILE 70% IPA

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

(c) In addition to the documentation requirements in USP Chapter 797, the facility's documentation of each occurrence of the cleaning, disinfecting, and applying of sporicidal disinfectants in the compounding area shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents used.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.8 INTRODUCING ITEMS INTO THE SEC AND PEC

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA. These SOPs will define at a minimum, what product is to be used, the dwell time required, and how dwell time will be monitored and documented.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.9 EQUIPMENT, SUPPLIES, AND COMPONENTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) All equipment and supplies used to compound CSP shall be used, in accordance with manufacturers' specifications and shall be surface

compatible.

(b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. SOPs shall specify the frequency and process of cleaning, maintenance, and calibration, including when incubation of samples is taking place such that samples are not compromised. All cleaning, maintenance, and calibration shall be documented and dated as defined in the SOPs.

(c) Any component used to compound a CSP shall be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers' specifications and requirements.

(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA) and suitable for use in sterile pharmaceuticals. A COA which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. API and excipient components provided without this data shall not be used in a CSP

(1) When the COA is received from a supplier, it must provide the name and address of the manufacturer .

(e) When a bulk drug substance, or API, is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed 21 CFR 216, unless authorized by a public health official in an emergency use situation for a patient specific compounded sterile preparation.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.10 STERILIZATION AND DEPYROGENATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Dry heat depyrogenation shall be done in compliance with USP Chapter 1228.1, Dry Heat Depyrogenation.

(b) Sterilization by filtration shall be done in compliance with USP Chapter 1229.4, Sterilizing Filtration of Liquids.

(1) Filter dimensions and the CSP to be sterilized by filtration shall permit the sterilization process to be completed without the need for replacement of the filter during the process.

(c) Steam sterilization shall be done in compliance with USP Chapter 1229.1, Steam Sterilization by Direct Contact.

(d) Dry heat sterilization shall be done in compliance with USP Chapter 1229.8, Dry Heat Sterilization.

(e) No compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in this section.

(f) Sterilization of supplies and/or container–closure systems shall be done in compliance with USP Chapter 1229, Sterilization of Compendial Articles.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.11 MASTER FORMULATION AND COMPOUNDING RECORDS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 797 and identified in that document the following additional elements:

(1) When a source is referenced to support the assigned beyond-use date (BUD); each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CSP is dispensed.

(2) Instructions for storage and handling the compounded drug preparation.

(b) Where a facility does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 797 and this section.

(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, as well as the following:

(1) The date and time of preparation. The time of preparation is the time when compounding the CSP started, which also determines when the assigned BUD starts.

(2) The assigned internal identification number shall be unique for each CR.

(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs.

(4) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.

(5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation

(6) When applicable, endotoxin level calculations and results.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4114, 4115, 4126.8, 4169 and 4127, Business and Professions Code.

## 1736.12 RELEASE INSPECTIONS AND TESTING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A pharmacist performing, or supervising sterile compounding is responsible for the integrity, quality, and labeled strength of a CSP until the beyond use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CSP for storage and handling after receiving the CSP.

(b) Validation of an alternative method for sterility testing shall be done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods and shall document the method-suitability for each CSP formulation for which the alternate method is used.

(c) Injectable CSP's made from nonsterile components regardless of Category, must be tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results must

be reviewed and documented in the compounding record prior to release.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**1736.13 LABELING**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP label shall also include the following:
(1) Route of intended administration, and
(2) the solution utilized, if applicable and
(3) Instructions for administration.
(A)For admixed CSPs, the rate of infusion, or range of rates of infusion as prescribed, or the duration, when the entire CSP shall be administered
(4) Name of compounding facility and dispensing facility (if different).

(b) Any CSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076, 4114, 4115, 4123, 4126.8, and 4127, Business and Professions Code.

**1736.14 ESTABLISHING BEYOND-USE DATES**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP's beyond-use date (BUD) shall not exceed:
(1) The chemical and physical stability data of the active pharmaceutical ingredient and any added substances in the preparation,

(2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components.

(b) A CSP labeled with a BUD with only a date shall expire at 11:59 p.m. on that date.

(c) Prior to dispensing a CSP that requires sterility and endotoxin testing for BUD determination, test results shall be received. Results must be within acceptable limits. Test results must be retained as part of the compounding record.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**1736.15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A single-dose container entered or punctured outside of an ISO Class 5 area, must be discarded immediately.

(b) A single-dose container entered or punctured inside of an ISO class 5 area must be discarded within 12 hours.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**1736.16. USE OF CSPS AS COMPONENTS**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article including Category 1, Category 2, or Category 3.
(b) Nothing in this section shall prohibit the use of a CSP obtained from a California licensed outsourcing facility.

**1736.17 Standard Operating Procedures (SOPS)**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) The facility's standard operating procedures (SOPs) for sterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding, and disposal of infectious materials. The written SOPsS shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPS as described in this article.

(b) The SOPs shall specify the steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(c) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to compounding processes, facility changes or other changes that impact the CSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.18 QUALITY ASSURANCE AND QUALITY CONTROL

The requirements of this section apply to sterile compounding in addition to the standards established in USP Chapter 797.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following:

(1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) Recalls and adverse reporting must be completed in compliance with relevant provisions of law.

(c) In addition to subsection (b), all complaints related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8, 4127, 4127.2, and 4127.11, Business and Professions Code.

## 1736.19 CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) There shall be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality and labeled strength.

(b) Packaging materials shall protect CSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transportation personnel.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.20 DOCUMENTATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Records shall be maintained as required by USP Chapter 797 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the

changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4105, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.21 COMPOUNDING ALLERGENIC EXTRACTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.

(b) Compounding of allergenic extracts are limited to patient-specific prescriptions and the conditions limited to Category I and Category 2 CSPs as specified in USP 797.

(c) Any stock solution made shall comply with the requirements established in USP 51, Antimicrobial effectiveness testing and container closure integrity tests consistent with USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation. Compounding records are required for stock solutions.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**Title 16. Board of Pharmacy**

**Proposed Regulation**

**Repeal Article 7 and sections 1751-1751.12 of Article 7 and add new titles and sections 1736- 1736.21, to Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1736 Sterile Compounding Definitions**

The definitions in in this section shall be applicable to this Article and supplement the definitions provided in USP Chapter 797.

(a) "Compounding personnel" means any person involved with any procedure, activity or oversight of the compounding process.

(b) "Designated person(s)" means one or more individuals assigned by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of the compounded sterile preparations ("CSP" for the purposes of this article). Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(d) "Designated compounding area or compounding area" means a restricted location with limited access designated for the preparation of CSP, where only activities and items related to compounding are present.

(e) "Essentially a copy" of a commercially available drug product means all preparations that include the same API(s) , as the commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(f) "Integrity" means retention of potency until the beyond use date provided on the label, when the preparation is stored and handled according to the label directions.

(g) "Quality" means the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means the absence of harmful levels of contaminants, including but not limited to filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, or the absence of inactive ingredients other than those listed on the master formula record as specified in USP 797.

(h) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4127, 4301 and 4332 of the Business and Profession Code.

**1736.1 Introduction and Scope.**

This article applies to compounded sterile preparations (CSP)s as defined in United States Pharmacopeia (USP) General Chapter 797 (Chapter 797), titled *Pharmaceutical Compounding – Sterile Preparations*. In addition to the standards in the USP Chapter 797, the preparation of a CSP shall meet the following requirements of this article.

(a) For the purposes of this article, sterile compounding occurs, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription, unless otherwise specified in this article.

(b) CSPs for direct and immediate administration as provided in the Chapter shall only be done in those limited situations where the failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need. Documentation for each such CSP shall include identification of the CSP, compounded date and time, number of units, the patient's name and patient's unique identifier and the circumstance causing the immediate need. Such documentation may be available in the patient's medical record and need not be redocumented by the compounding staff if already available

(c) Notwithstanding subdivision (a) a limited quantity of CSP may be prepared and stored in advance of receipt of a patient specific prescription document where, and solely in such quantity, as is necessary to ensure continuity of care for individual patients based on a documented history of prescriptions for those patient populations.

(d) A reasonable quantity of a compounded drug preparation may be furnished to a veterinary office for use by the veterinarian that is sufficient:

(1) for administration or application to veterinary patients solely in the veterinarian's office

(2) for furnishing of not more than a 120-hour supply, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing;

(a)With the exception of a topical ophthalmics where up to a 28 days supply may be furnished to veterinarian's office for individual patient. Such topical ophthalmics shall be complaint with USP 797 section 14.5, Multiple-Dose CSPs .

(e) In addition to prohibitions and requirements for compounding established in federal law, no CSP shall be prepared that:

(1) Is essentially a copy of one or more commercially available drug products, unless:

(A) that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA Drug Shortages Database that are in short supply at the time of compounding and at the time of dispense, or

(B) the compounding produces a clinically significant difference of the medical need of an identified individual patient, as determined:

(1) by the prescribing practitioner,

(2) the compounding pharmacist, and

(3) the dispensing pharmacist(s).

(C)) Documentation describing the conditions in (1)(A) & (1) (B) is maintained in a readily retrievable format

(2) Is made with any component not suitable for use in a CSP for the intended patient population, unless allowable under Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA).

(3) Is made with a non-sterile component for which a conventionally manufactured sterile product is available and appropriate for the intended CSP.

(4) Where sterilization is required, it cannot be sterilized within the licensed location.

(f) Prior to allowing any CSP to be compounded within a pharmacy, the pharmacist-in-charge shall complete a self-assessment consistent with the requirements established in section 1715.

(g) In addition to the provisions provided in Section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning proper use, storage, handling and disposal of the CSP and related supplies furnished.

(h) CSPs with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and

4127, Business and Professions Code.

## 1736.2 PERSONNEL TRAINING AND EVALUATION

The requirements of this section apply to sterile compounding in addition to the standards in USP Chapter 797.

(a) In addition to the training required by USP 797, training and competencies procedures for all personnel who compound or have direct oversight of compounding personnel training shall also address the following topics:

(1) Quality assurance and quality control procedures,
(2) Container closure and equipment selection,
(3) Component selection and handling, and
(4) Sterilization techniques, when applicable.

(b) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

1. The SOPs related to compounding are identical
2. The SEC facility designs are sufficiently similar to accommodate the use of the same SOPs.
3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(c) Aseptic manipulation ongoing training and competency shall occur each time and for each staff member involved in an event where the quality assurance program yields an unacceptable result as defined in the SOPs referenced in section 1736.17 that may indicate microbial contamination of CSPs due to poor practices. Aseptic manipulation ongoing training and competency procedures shall be defined in the facilities SOPs.

(d) Compounding personnel or persons with direct oversight over personnel performing compounding, who fail any aspect of the aseptic manipulation ongoing training and competency evaluation shall not be involved in compounding or oversight of the preparation of a CSP until after successfully passing training and competency in the deficient area(s) as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of the aseptic manipulation ongoing training and competency evaluation, may continue to provide only direct oversight for no more than 14 days while applicable aseptic manipulation ongoing training and competency evaluation results are pending.

(e) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1736.17. Documentation must be maintained demonstrating compliance.

Note: Authority cited: Sections 4001.1, 4005, 4126.8, 4127 of Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4114, 4115, 4127, 4301 and 4332 of the Business and Profession Code.

## 1736.3 PERSONNEL HYGIENE AND GARBING

The requirements of this section apply sterile compounding in addition to the requirements in USP Chapter 797.

(a) The pharmacist overseeing compounding shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) The pharmacist overseeing compounding shall not allow personnel to enter the compounding area with visible non-removable piercings that increase the risk of contamination of CSP.

(c) Garb shall be donned in an anteroom or immediately outside the segregated compounding area (SCA). Donning and doffing garb shall not occur in the anteroom at the same time unless the facility's SOP define specific processes that must be followed to prevent contamination.

(d) Restricted access barrier system (RABS) and pharmaceutical isolator sleeves and gloves shall be changed according to both the manufacturer's recommendations and the facility's SOP.

(e) Any garbing accommodations provided by the designated person shall be documented and the record shall include the name of the individual granted the accommodation, date granted and description of the reasons for granting the accommodation. The record shall be retained in accordance with Business and Professions Code section 4081.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.4 FACILITIES AND ENGINEERING CONTROLS

The requirements of this section apply to sterile compounding in addition to the requirements in USP Chapter 797.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) If an SCA is used:

(1) Except for walls, the SCA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SCA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(c) (1) Designated compounding area(s) shall typically be maintained at a temperature of 20° Celsius or cooler and also provide comfortable conditions for compounding personnel attired in the required garb.

(2) The temperature shall be monitored in each room of the designated compounding area each day that compounding is performed, either manually or by a continuous recording device.

(d) Where a pass-through is installed in a secondary engineering control after [OAL insert effective date], the doors must be interlocking. An existing secondary engineering control that has a pass-through that is not an interlocking device, may continue to be used if the SOPs document that two doors may not be opened at the same time.

(e) Except as provided in (d) dynamic interactions between areas and rooms with classified air shall be controlled through a heating, ventilation, and air condition (HVAC) system. No passive ceiling or wall penetrations are allowed.

(f) No CSP shall be compounded if the compounding environment fails to meet criteria specified in the law or the facilities SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.5 CERTIFICATION AND RECERTIFICATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Testing and certification of all classified areas shall be completed by a

qualified technician knowledgeable with certification methods and procedures outlined within the Controlled Environment Testing Association (CETA)'s Certification Guide for Sterile Compounding Facilities as specified in this section. Testing shall be performed in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003, Revised 2022), which is hereby incorporated by reference.

(b) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on report issued by the certifying technician.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.6 MICROBIOLOGICAL AIR AND SURFACE MONITORING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) SOPs shall specify steps to be taken when the microbiological air and surface monitoring action levels are exceeded including the investigative and corrective actions, allowable activities, and resampling procedures.

(b) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Professional judgement and SOPs shall be used to determine the appropriate action necessary to remedy identified trends. Investigation must be consistent with the deviation and must include evaluation of trends.

(c) Environmental sampling shall be done in compliance with the most recent edition of the Controlled Environment Testing Association (CETA)'s Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.7 CLEANING, DISINFECTING, AND APPLYING SPORICIDAL DISINFECTANTS AND STERILE 70% IPA

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Any cleaning, disinfecting, and sporicidal disinfectants used by the facility to meet the requirements in this article shall be used in accordance with manufacturers' specifications

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

(c) In addition to the documentation requirements in USP Chapter 797, the facility's documentation of each occurrence of the cleaning, disinfecting, and applying of sporicidal disinfectants in the compounding area shall include a record of the identity of the person completing the cleaning and sanitizing as well as the product name of the cleaning and sanitizing agents used.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.8 INTRODUCING ITEMS INTO THE SEC AND PEC

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

SOPs shall specify the process and products to be used on any equipment and other items entering from an unclassified area into the clean side of the anteroom, entering a PEC, and entering the SCA. These SOPs will define at a minimum, what product is to be used, the dwell time required, and how dwell time will be monitored and documented.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.9 EQUIPMENT, SUPPLIES, AND COMPONENTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) All equipment and supplies used to compound CSP shall be used, in accordance with manufacturers' specifications and shall be surface

compatible.

(b) Incubators used by the facility shall be cleaned, maintained, calibrated, and operated in accordance with manufacturers' specifications. For incubators without specific manufacturers' specifications, cleaning shall take place at least every 30 days and calibration shall take place at least every 12 months. SOPs shall specify the frequency and process of cleaning, maintenance, and calibration, including when incubation of samples is taking place such that samples are not compromised. All cleaning, maintenance, and calibration shall be documented and dated as defined in the SOPs.

(c) Any component used to compound a CSP shall be used and stored in accordance with all federal laws and regulations and industry standards including the manufacturers' specifications and requirements.

(d) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA) and suitable for use in sterile pharmaceuticals. A COA which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. API and excipient components provided without this data shall not be used in a CSP

(1) When the COA is received from a supplier, it must provide the name and address of the manufacturer .

(e) When a bulk drug substance, or API, is used to compound a CSP, it shall comply with a USP drug monograph, be the active substance of an FDA approved drug, or be listed 21 CFR 216, unless authorized by a public health official in an emergency use situation for a patient specific compounded sterile preparation.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.10 STERILIZATION AND DEPYROGENATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Dry heat depyrogenation shall be done in compliance with USP Chapter 1228.1, Dry Heat Depyrogenation.

(b) Sterilization by filtration shall be done in compliance with USP Chapter 1229.4, Sterilizing Filtration of Liquids.

(1) Filter dimensions and the CSP to be sterilized by filtration shall permit the sterilization process to be completed without the need for replacement of the filter during the process.

(c) Steam sterilization shall be done in compliance with USP Chapter 1229.1, Steam Sterilization by Direct Contact.

(d) Dry heat sterilization shall be done in compliance with USP Chapter 1229.8, Dry Heat Sterilization.

(e) No compound of a CSP from nonsterile components shall be prepared when the licensed location cannot also sterilize the CSP as described in this section.

(f) Sterilization of supplies and/or container–closure systems shall be done in compliance with USP Chapter 1229, Sterilization of Compendial Articles.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.11 MASTER FORMULATION AND COMPOUNDING RECORDS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP shall not be compounded until the facility has first prepared a written master formulation record in compliance with USP Chapter 797 and identified in that document the following additional elements:

(1) When a source is referenced to support the assigned beyond-use date (BUD); each source referenced shall be readily retrievable at the time of compounding and shall be maintained for three years from the date each CSP is dispensed.

(2) Instructions for storage and handling the compounded drug preparation.

(b) Where a facility does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 797 and this section.

(c) A compounding record (CR) shall be a single document. The document shall satisfy the requirements of USP Chapter 797, as well as the following:

(1) The date and time of preparation. The time of preparation is the time when compounding the CSP started, which also determines when the assigned BUD starts.

(2) The assigned internal identification number shall be unique for each CR.

(3) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs.

(4) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.

(5) The identity of each person performing the compounding, that has direct oversight of compounding, and pharmacist verifying the final drug preparation

(6) When applicable, endotoxin level calculations and results.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4114, 4115, 4126.8, 4169 and 4127, Business and Professions Code.

## 1736.12 RELEASE INSPECTIONS AND TESTING

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A pharmacist performing, or supervising sterile compounding is responsible for the integrity, quality, and labeled strength of a CSP until the beyond use date indicated on the label provided the patient or the patient's agent follows the label instructions provided on the CSP for storage and handling after receiving the CSP.

(b) Validation of an alternative method for sterility testing shall be done in compliance with USP Chapter 1223, Validation of Alternative Microbiological Methods and shall document the method-suitability for each CSP formulation for which the alternate method is used.

(c) Injectable CSP's made from nonsterile components regardless of Category, must be tested to ensure that they do not contain excessive bacterial endotoxins, as established in USP Chapter 85, Bacterial Endotoxins. Results must

be reviewed and documented in the compounding record prior to release.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**1736.13 LABELING**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP label shall also include the following:
(1) Route of intended administration, and
(2) the solution utilized, if applicable and
(3) Instructions for administration.
(A)For admixed CSPs, the rate of infusion, or range of rates of infusion as prescribed, or the duration, when the entire CSP shall be administered
(4) Name of compounding facility and dispensing facility (if different).

(b) Any CSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076, 4114, 4115, 4123, 4126.8, and 4127, Business and Professions Code.

**1736.14 ESTABLISHING BEYOND-USE DATES**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A CSP's beyond-use date (BUD) shall not exceed:
(1) The chemical and physical stability data of the active pharmaceutical ingredient and any added substances in the preparation,

(2) The compatibility of the container–closure system with the finished preparation (e.g., possible leaching, interactions, and storage conditions),

(3) The shortest remaining expiration date or BUD of any of the starting components.

(b) A CSP labeled with a BUD with only a date shall expire at 11:59 p.m. on that date.

(c) Prior to dispensing a CSP that requires sterility and endotoxin testing for BUD determination, test results shall be received. Results must be within acceptable limits. Test results must be retained as part of the compounding record.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**1736.15. USE OF CONVENTIONALLY MANUFACTURED PRODUCTS AS COMPONENTS**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A single-dose container entered or punctured outside of an ISO Class 5 area, must be discarded immediately.

(b) A single-dose container entered or punctured inside of an ISO class 5 area must be discarded within 12 hours.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**1736.16. USE OF CSPS AS COMPONENTS**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) A compounded stock solution intended for use in a CSP must comply with all provisions of this article including Category 1, Category 2, or Category 3.
(b) Nothing in this section shall prohibit the use of a CSP obtained from a California licensed outsourcing facility.

**1736.17 Standard Operating Procedures (SOPS)**

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) The facility's standard operating procedures (SOPs) for sterile compounding shall be followed and shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding.

(2) In addition to the SOPs required in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, SOPs must also be developed to describe the following:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding, and disposal of infectious materials. The written SOPsS shall describe the facility protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins.

(D) The method for complying with any other requirements specifically required to be addressed in the facility's SOPS as described in this article.

(b) The SOPs shall specify the steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(c) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to compounding processes, facility changes or other changes that impact the CSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(d) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.18 QUALITY ASSURANCE AND QUALITY CONTROL

The requirements of this section apply to sterile compounding in addition to the standards established in USP Chapter 797.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following:

(1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) Recalls and adverse reporting must be completed in compliance with relevant provisions of law.

(c) In addition to subsection (b), all complaints related to a potential quality problem with a CSP and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8, 4127, 4127.2, and 4127.11, Business and Professions Code.

## 1736.19 CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) There shall be written procedures for qualification of storage, shipping containers and transportation of temperature sensitive CSPs to preserve quality standards for integrity, quality and labeled strength.

(b) Packaging materials shall protect CSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transportation personnel.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.20 DOCUMENTATION

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Records shall be maintained as required by USP Chapter 797 or this article, in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the

changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4081, 4105, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

## 1736.21 COMPOUNDING ALLERGENIC EXTRACTS

The requirements of this section apply to performing sterile compounding in addition to the requirements in USP Chapter 797.

(a) Any allergenic extract compounding shall take place in a dedicated PEC. No other CSP may be made in this PEC.

(b) Compounding of allergenic extracts are limited to patient-specific prescriptions and the conditions limited to Category I and Category 2 CSPs as specified in USP 797.

(c) Any stock solution made shall comply with the requirements established in USP 51, Antimicrobial effectiveness testing and container closure integrity tests consistent with USP Chapter 1207, Sterile Product Packaging – Integrity Evaluation. Compounding records are required for stock solutions.

Authority cited: Sections 4001.1, 4005, 4126.8, and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4114, 4115, 4126.8 and 4127, Business and Professions Code.

**Title 16. Board of Pharmacy**
**Proposed Regulation**

**Proposal to Add Article 4.7 and add new titles and section 1737 – 1737.18 to Division 17 or Title 16 of the California Code of Regulations to read as follows:**
**Article 4.7 Hazardous Drugs**

**1737 Handling of Hazardous Drugs**
In addition to the standards established by United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), titled *Hazardous Drugs – Handling in Healthcare Setting* shall meet the requirements of this Article.

A licensee performing non-sterile and sterile HD compounding shall comply with this article in addition to Article 4.5 and Article 4.6.

**1737.1 Introduction and Scope**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

In addition to providing consultation in compliance with section 1707.2, consultation shall be provided to the patient and/or patient's agent concerning on handling and disposal of an HD or related supplies furnished.

**1737.2 List of Hazardous Drugs**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Designated person" is a single individual approved by the pharmacist-in-charge to be responsible and accountable for the performance and operation of the facility and personnel as related to the handling of hazardous drugs. Nothing in this definition allows for the designated person to exceed the scope of their issued license. When the designated person is not a pharmacist, the Pharmacist-in-Charge (PIC) must review all practices related to the operations of the facility that require professional judgement.
(b) If an assessment of risk is performed as allowed in USP Chapter 800, it shall be performed or approved and documented at least every 12 months by the designated person and the pharmacist-in-charge, professional director of a clinic, or designated representative-in-charge, as applicable.

(c) The facility's list of HDs must be reviewed and approved by the designated person and the pharmacist-in-charge, professional director of a clinic, or

designated representative-in-charge, as applicable. Approval shall be documented at least every 12 months.

**1737.3 Types of Exposure**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Each entity shall ensure that all employees are aware of the types of risks of HD exposures that may occur as documented in the Chapter. This shall be documented in SOPs and training documents.

**1737.4 Responsibilities of Personnel Handling Hazardous Drugs**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The Pharmacist-in-charge, designated representative-in-charge, or professional director, as applicable shall be responsible for all activities and decisions made or approved by the designated person.

**1737.5 Facilities and Engineering Controls**
The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) When a containment primary engineering control (C-PECs), used for nonsterile and sterile HDs is placed in the same room, biannual certification must document that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. Specific standard operating procedures (SOPs) shall be written to address the maintenance of the ISO 7 classification.

(c) Compounding volatile HDs:
(1) HEPA filters shall not be the only means of containment used.
(2) for sterile compounding, a biological-safety cabinet (BSC) as defined in USP Chapter 800 Class II Type A1 shall not be used
(b) Where a pass-through is installed in a C-SEC the doors must be gasketed and interlocking. A pass-through is not allowed between the C-SEC into an unclassified space.

(c) Effective January 1, 2026, all pass-through doors shall be a HEPA purge type.

(d) Facility room pressure monitoring equipment shall be placed consistent with CETA Guidelines CAG-003:2022. SOPs shall address corrective and remedial actions in the event of pressure differentials and air changes per hour excursions.

(e) Containment Supplemental Engineering Controls (CSTDs) shall not be used to extend the in-use time, BUD, or expiration of any manufactured product or HD CSP.

**1737.6 Environmental Quality and Control**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) An entity's SOPs shall address environmental wipe sampling for HD surface residue, its frequency, areas of testing, levels of measurable contamination, and actions when those levels are exceeded.

(b)When actionable levels of contamination is found, at minimum the following shall occur:

(1) Reevaluate work practices
(2) Reevaluate the appropriateness of deactivation, decontamination and cleaning agents
(3) Re-train personnel on deactivation, decontamination and cleaning
(4) Re-train personnel on donning and doffing appropriate PPEs

**1737.7 Personal Protective Equipment (PPE)**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Two pairs of gloves that meet the ASTM D-6978 standard shall be worn for handling HD waste, cleaning HD spills, and performing routine cleaning in HD areas.

(b) The outer pair of gloves that meets the ASTM D-6978 standard chemotherapy gloves shall be changed every 30 minutes during compounding unless otherwise recommended by the manufacturer's documentation. Documentation from the manufacturer shall be readily retrievable. For sterile compounding both pairs of gloves labeled to meet the ASTM D-6978 standard chemotherapy gloves shall be sterile.

(c) Outer gloves used for compounding must be changed between each different HD drug and the standards established in Chapter 800 if continuously compounding a single HD preparation. The facilities SOPs shall define the

circumstances under which the gowning and gloves must be changed between HD handling/preparations.

(d) PPE shall be removed to avoid transferring contamination to skin, the environment, and other surfaces. PPE worn during compounding shall be disposed of in the proper waste container before leaving the C-SEC. SOPS must be in place which describe in detail the donning and doffing of PPE and where it takes place in the C-SEC.

(e) An appropriate full-facepiece, chemical cartridge-type respirator, or powered air-purifying respirator (PAPR) shall be worn when there is a risk of respiratory exposure to HDs, including when:

(1) Attending to HD spills larger than what can be contained with a spill kit
(2) Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC
(3) There is a known or suspected airborne exposure to powders or vapors.

**1737.8 Hazard Communication Program**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

The designated person is responsible for participating in the development of the entity's hazardous communication program. The program shall be documented in SOPs and training documents.

**1737.9 Personnel Training**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any person assigned to provide the training specified in this section shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facilities SOPs as referenced in section 1737.17. Documentation must be maintained demonstrating compliance.

(b) Personnel of any facility responsible for handling HD who fail any aspect of training in handling HDs, shall not be involved in handling HDs until after successfully passing reevaluations in the deficient area(s), as detailed in the facility's SOPs. A person with only direct oversight over personnel who fails any aspect of handling HD and ongoing training and competency evaluation, may

continue to provide only direct oversight for no more than 14 days while applicable handling HD ongoing training and competency evaluation results are pending.

**1737.10 Receiving**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

All HD API and antineoplastic HDs shall be shipped and received from the supplier in segregated impervious plastic and labeled as HD on the outside of the delivery container.

**1737.11 Labeling, Packaging, Transport and Disposal**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any compounded HD preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

(b) All HD API and antineoplastic HDs shall be transported in an impervious plastic container and labeled as HD on the outside of the container.

**1737.12 Dispensing Final Dosage Form**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Equipment used in nonsterile compounding shall be dedicated for use with HDs and shall be decontaminated after each use.

**1737.13 Compounding**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations. Where the compounding is a sterile preparation, the preparation mat shall be sterile. The preparation mat shall be changed immediately if a spill occurs, after each HD drug, and at the end of daily compounding activity.

(b) Only one HD drug may be handled in a C-PEC at one time if making multiple preparations.

**1737.14 Administering**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) When dispensing an HD to a patient or caregiver for administration, the pharmacy shall

1. Place the HD in a decontaminated impervious plastic container with an HD label on the outside of the container and
2. For an antineoplastic HDs, attach and prime all tubing and attach a CSTD when appropriate.

(b) There shall be a sufficient supply of gloves that meet the ASTM D-6978 standard, to allow for appropriate administration, handling, and disposal of HD drugs by the patient or the patient's agent when dispensing an antineoplastic HD.

**1737.15 Deactivation, Decontamination, Cleaning, and Disinfecting**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Deactivating, decontaminating, cleaning, disinfecting and sporicidal agents shall be used in accordance with manufacturers' specifications and shall be surface compatible.

(b) Agents used for deactivation, decontamination, cleaning and disinfecting all areas and equipment involved in HD handling shall be applied through the use of wipes wetted with appropriate solution and shall not delivered by a spray bottle to avoid spreading HD residue.

(c) SOPs for decontamination and deactivation procedures for the final HD preparation shall be created by the entity in accordance with the entity's SOPs and approved by the pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable.

**1737.16 Spill Control**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) The entity shall have an SOP addressing the use of appropriate full-facepiece, chemical cartridge-type respirator, or powered air-purifying respirator (PAPR) if the capacity of the spill kit is exceeded or if there is known or suspected airborne exposure to vapors or gases.

(b) The entity shall maintain a list of properly trained and qualified personnel able to clean up an HD spill. An SOP shall outline how a qualified personal will be available at all times while HDs are handled.

**1737.17 Documentation and Standard Operating Procedures**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

(a) Any entity engaged in the compounding or handling of HDs shall maintain and follow written SOPs.

(b) The SOPs for compounding or handling HDs shall include at least the following:

(1) Hazard communication program
(2) Occupational safety program
(3) Designation of HD areas
(4) Receipt
(5) Storage
(6) Compounding, if applicable
(7) Use and maintenance of proper engineering controls (e.g., C-PECs, C-SECs, and CSTDs), if applicable
(8) Hand hygiene and use of PPE based on activity (e.g., receipt, transport, compounding, administration, spill, and disposal), if applicable
(9) Deactivation, decontamination, cleaning, and disinfection
(10) Dispensing, if applicable
(11) Transport
(12) Administering, if applicable
(13) Environmental monitoring (e.g., wipe sampling)
(14) Disposal
(15) Spill control
(16) Medical surveillance

(c) The pharmacist-in-charge, professional director of a clinic, designated representative-in-charge, as applicable, shall work with the entity's designated person to ensure HD handling SOPs are reviewed at least every 12 months and this review is documented.

(d) SOPs shall be updated whenever changes are implemented. Such changes shall be disseminated in a written format to the staff responsible for handling HDs prior to implementation. All notifications of such changes and the changes shall be documented in SOPs and training documents.

(e) Failure to follow written SOPs shall constitute a basis for enforcement action.

**1737.18 Medical Surveillance**

The requirements of this section apply to the handling of HDs in addition to the standards in USP Chapter 800.

Elements of a medical surveillance program shall be consistent with the entity's Human Resource policies and employees handling HDs must be aware of the program.

Repeal:

~~**1708.3. Radioactive Drugs.**~~

~~A radioactive drug is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act or a radioactive biological product as defined in 21 CFR 600.3(ee) which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug or biological product which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds, potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Section 4025, Business and Professions Code.~~

~~**1708.4. Pharmacist Handling Radioactive Drugs.**~~

~~A pharmacist handling radioactive drugs must be competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. He must have completed a nuclear pharmacy course and/or acquired experience in programs approved by the Board. Education and experience in non-approved programs may be granted partial or equivalent credit, if, in the opinion of the Board, such programs provide the level of competence as approved programs or the Nuclear Pharmacy Competency Statement adopted by the Board.~~

~~Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4021, 4022, 4025, 4036 and 4037, Business and Professions Code.~~

~~**1708.5. Pharmacy Furnishing Radioactive Drugs.**~~

~~A pharmacy furnishing radioactive drugs is any area, place or premises described in a permit issued by the board where radioactive drugs are stored, processed, compounded, repackaged, or dispensed. A pharmacy exclusively furnishing radioactive drugs shall be exempt from the patient consultation area requirements of Title 16 Cal. Code of Regulations Section 1714(a) unless the Board finds that the public health and safety require their application.~~

~~A pharmacist qualified under Section 1708.4 to furnish radioactive drugs shall be in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs shall be under the immediate and direct supervision of such a qualified pharmacist.~~

~~Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4008 and 4008.2, Business and Professions Code.~~

## Proposal to Add Article 4.8 as proposed with the following:

## Article 4.8 Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

## 1738. Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

This article applies to radiopharmaceuticals as defined in USP Chapter 825. In addition to the requirements provided in this Article, the processing of radiopharmaceuticals shall comply with the standards established by United States Pharmacopeia General Chapter 825, titled *Radiopharmaceuticals –*

*Preparation, Compounding, Dispensing, and Repackaging* ("USP Chapter 825" for the purposes of this Article).

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.1 INTRODUCTION**

In addition to the definitions contained in USP Chapter 825, the following definitions apply to this Article and supplement the standards established in USP Chapter 825 when not otherwise provided in USP Chapter 825.

(a) "Added substances" means ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms inactive ingredients, excipients, and pharmaceutical ingredients.

(b) "Designated person" means a pharmacist identified as assigned, responsible, and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.

(c) "Component" means any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.

(d) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as sterile water for injection.

(e) "Processing," "processed" or "processing activity" means the preparation, compounding, repackaging, or dispensing of a radiopharmaceutical.

(f) The use of technologies, techniques, material, and procedures not described in USP 825 shall be based upon published peer-reviewed literature or documents meeting FDA approved labeling requirements in accordance with sections 201.56 and 201.57 of title 21, Code of Federal Regulations, showing the technologies, techniques, material, and procedures to be equivalent or superior to those described in USP Chapter 825.

(g) Processing with human whole blood or human whole blood derivatives shall be done in compliance with Health and Safety Code section 1602.5.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.2 RADIATION SAFETY CONSIDERATIONS**

In addition to the standards in the USP Chapter 825, the processing of radiopharmaceuticals shall meet the following radiation safety requirements of this section.

(a) Radiation detectors and measuring devices, and other necessary equipment may be placed inside an ISO Class 5 PEC but must be placed in a manner that minimizes disruptions of airflow.

(b) Disposable absorbent pads shall be changed after each type of radiopharmaceutical processing.

(c) Any deviation made to lower radiation exposure to workers shall be evaluated and documented in an SOP by the designated person prior to the deviation occurring. Exceptions to the environmental controls requirements must be documented in the specific radioactive materials license conditions issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, or a specific radioactive materials license issued by another state or the United States Nuclear Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.3. IMMEDIATE USE OF STERILE RADIOPHARMACEUTICALS**

The processing of radiopharmaceuticals for immediate use may only be done in a patient care setting meeting the applicable requirements in this Article. The patient care facility shall maintain all records required in Section 9 of USP Chapter 825 in accordance with Business and Professions Code section 4081.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.4 PERSONNEL QUALIFICATIONS, TRAINING, AND HYGIENE**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions which could contaminate a sterile radiopharmaceutical, or the environment shall not be allowed to enter the compounding area unless approved by the designated person. Any approvals provided by the designated person shall be documented and the record shall include the name of the individual granted approval, the approval date and time, the reason for granting approval, and the identification of the designated person making the decision.

(b) The pharmacist with direct oversight over personnel performing radiopharmaceutical processing shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of radiopharmaceuticals as defined in the facilities SOPs.

(c) Aseptic manipulation competency initial training and competency and ongoing training and competency documentation shall include the Primary Engineering Control (PEC's) type and PEC unique identifier used during the evaluation. Aseptic manipulation competency evaluation and requalification shall be performed using the same procedures, type of equipment, and materials used in aseptic compounding. Aseptic qualifications from one premises may be used for another premises if all of the following conditions are met:

1. TheSOPs related to compounding are identical.
2. The SEC facility designs are sufficiently similar to accommodate the use of the same SOPs.
3. The PECs are of the same type and sufficiently similar to accommodate the use of the same SOPs describing use and cleaning.

(d) SOPs must clearly define the acceptable use and cleaning for reusable gowns that prevent possible contamination of the CSP and designated compounding area. However, laundered garb must not be reused beyond one day unless garb is laundered with a validated cycle. The facility's SOPs must describe the process that must be followed should the facility allow for the reuse of garb.

(e) Eyeglasses shall be cleaned as part of hand hygiene and garbing, consistent with the standards specified in the SOPs.

(f) Garb shall be donned and removed in an ante-area or immediately outside the SPRA. Donning and doffing garb shall not occur in the anteroom at the

same time unless the SOPs define specific processes which must be followed to prevent contamination.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.5. FACILITIES AND ENGINEERING CONTROLS**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) The temperature shall be monitored in SRPAs segregated radiopharmaceutical processing area and classified areas each day that processing is performed, either manually or by a continuous recording device.

(c) Storage and elution of non-direct infusion radionuclide generators shall take place in an ISO Class 8 or better area.

(d) If an SRPA is used:

(1) Except for walls, the SRPA's visible perimeter shall be at least 1 meter from all sides of the PEC or in a separate room.

(2) Surfaces within the SRPA shall be smooth, impervious, free from cracks and crevices, and non-shedding so they can be easily cleaned and disinfected and to minimize spaces in which microorganisms and other contaminants can accumulate.

(3) Compounding shall not take place in the SRPA.

(e)(1) Testing and certification of all classified areas shall be completed by a competent individual. A competent individual is a technician who possesses a current accreditation issued by The Controlled Environment Testing Association (CETA), or under the direct supervision of an individual who possesses a current accreditation issued by CETA Certification shall be completed consistent with the provisions established in the USP Chapter 797, titled "Pharmaceutical Compounding—Sterile Preparations" (USP Chapter 797). The facility shall review and maintain a copy of the accreditation documentation in accordance with requirements in section 1738.9.

(2) CETA standard(s) used to perform certification testing in all classified areas shall be recorded on the certification report as required and specified in USP Chapter 797.

(f) SOPs shall specify steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(g) All classified spaces and equipment must be recertified when there is any change in the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed. Further, SOPs must address the conditions under which recertification must also be completed when relocating a PEC.

(h) Activities and tasks carried out within the SRPA and classified areas shall be limited to only those necessary for processing a radiopharmaceutical.

(i) Food, drinks, and materials exposed in patient care and treatment areas must not enter SRPA or classified areas.

(j) A dynamic airflow smoke pattern test must be performed initially and at least every 6 months for all classified spaces and equipment. All dynamic airflow smoke pattern tests shall be immediately retrievable during inspection. A copy of the test shall be provided to the Board's inspector if requested in accordance with the timeframes set forth in Section 4105 of the Business and Professions Code.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.6. MICROBIOLOGICAL AIR AND SURFACE MONITORING**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) SOPs shall specify steps to be taken for processing radiopharmaceuticals when the microbiological air and surface monitoring action levels are exceeded, including the investigative and corrective actions, allowable activities, and resampling procedures.

(b) At a minimum every 6 months, air and surface sampling results shall be identified to at least the genus level, regardless of the CFU count to trend for growth of microorganisms. Professional judgement and SOPs shall be used to determine the appropriate action necessary to remedy identified trends. Investigation must be consistent with the deviation and must include evaluation of trends.

(c) Environmental sampling shall be done in compliance with the most recent edition of the Controlled Environment Testing Association (CETA)'s Certification Application Guide USP <797> Viable Environmental Sampling & Gowning Evaluation (CAG-009, Revised October 2022), which is hereby incorporated by reference.

(d) The designated person shall review the sampling results and identify data trends at least every time sample results are received. The designated person shall evaluate trends to determine if corrective action is needed. The results of the review shall be documented in the facility's SOPs and readily retrievable during inspection in accordance with the requirements in section 1738.9.

(e) Incubators must be calibrated and operated in accordance with the manufacturer's specifications and temperatures must be monitored during incubation, either manually or by a continuous recording device, and the results must be reviewed and documented as described in the facility's SOPs.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.7. CLEANING AND DISINFECTING**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Cleaning, disinfection, and sporicidal agents shall be used in accordance with manufacturers' specifications and shall occur at the minimum frequencies listed in Table 5 of USP Chapter 825. Incubators must be cleaned at least monthly.

(b) Reusable cleaning supplies, not for use in the PEC, shall not be stored within 1 meter of the PEC.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.8. ASSIGNING BUD**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A radiopharmaceutical CSP's beyond-use date (BUD) shall not exceed the shortest BUD of any of its components.

(b) No radiopharmaceutical CSP shall be administered after the labeled BUD. A dose shall not be sent for a scheduled administration that would occur after the labeled BUD.

(c) Extension of a conventionally manufactured kit with a suggested use-by time shall not exceed the BUDs in Table 7 of USP Chapter 825, for the sterility of the preparation or product.
Prior to the extension of a suggested use-by time for a conventionally manufactured kit, the SOPs must document at a minimum the following:

(1) Factors which necessitate its extension, which shall include a full assessment of patient needs for the extension.
(2) Evidence which supports that the extension maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each facility's location and kit.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.9. DOCUMENTATION**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) A record of a preparation must include a compounding record compliant with section 9.2 of USP Chapter 825.

(b) Records of preparation with minor deviations or compounding shall be a single document. The document shall satisfy the requirements of USP Chapter 825, as well as the following:

(1) The assigned internal identification number shall be unique for each preparation.

(2) The manufacturer, lot number, and expiration date shall be recorded for each component for CSPs. Documenting solely the National Drug Code (NDC) does not meet this requirement.

(3) The total quantity compounded shall include the number of units made and either the volume or the weight of each unit.

(4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation

(5) When applicable, endotoxin level calculations and readings.

(c) Records required by USP Chapter 825 or this Article, shall be maintained in a readily retrievable form, for at least three years from the date the record was created or relied upon. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(d) Records created shall be created and maintained in a manner to provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include the changes to the document, identification of individual who made the change, and the date of each change.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4081, 4105, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.10. PREPARATION**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) Processing nonsterile radiopharmaceutical shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).

(2) Only use an area which is suitably cleaned and is uncluttered.

(3) Have documented processes in its SOPs for activities (e.g., cleaning) between the preparation cycles of different nonsterile products.

(b) Processing sterile radiopharmaceutical (including intravascular devices) shall:

(1) Follow manufacturer preparation instructions, unless minor deviations are made pursuant to subsection (c).
(2) Use at least the minimum environmental standards from section 7 of USP Chapter 825.

(c) When preparing radiopharmaceuticals with minor deviations ("preparation with minor deviations" as defined in the USP Chapter 825) an SOP shall at least define the circumstances which necessitated the deviation and all quality control testing requirements and limits. Such circumstances shall, at a minimum, include patient need or facts that support the deviation that maintains the appropriate quality and purity (radiochemical purity and radionuclidic purity) as specified in individual monographs, and other applicable parameters as clinically appropriate in the professional judgment of the pharmacist.

For the purposes of this section, the facility shall have SOPs that cover and are specific to each location and manufacturer. Preparations with minor deviations shall maintain the same ingredients but may differ in their proportions. A deviation from the ingredients or proportions thereof exceeds the provisions allowed under a minor deviation and is not allowed under this Article.

(d) Equipment and supplies initially used for processing of blood components (included Red Blood Cells) shall be solely dedicated for processing of blood components. Equipment and supplies shall be thoroughly cleaned and disinfected, in accordance with section 1738.7, prior to initiation of the next patient's prescription.

(e) When processing blood components all garb must be removed and replaced for each patient.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.11. COMPOUNDING**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All compounding of radiopharmaceuticals shall comply with all radioactive materials licensing requirements for appropriate radiation safety considerations issued by the California Department of Public Health pursuant to section 30190 of Title 17 of the California Code of Regulations, another state licensing agency that issues specific radioactive materials licenses, or the United States Nuclear

Regulatory Commission pursuant to pursuant to section 32.72 of title 10 of the Code of Federal Regulations, and utilize applicable environmental controls.

b) All API and excipient components used to compound a CSP shall be manufactured by an FDA-registered facility, be accompanied by a Certificate of Analysis (COA) and suitable for use in sterile pharmaceuticals. A COA which includes the compendial name, the grade of the material, and the applicable compendial designations on the COA must be received and evaluated prior to use, unless components are commercially available drug products. API and excipient components provided without this data shall not be used in a CSP

(1) When the COA is received from a supplier, it must provide the name and address of the manufacturer .

(c) Except for sterile radiopharmaceuticals made for inhalation or ophthalmic administration, prior to releasing a sterile radiopharmaceutical made from one or more nonsterile component(s) results of bacterial endotoxin testing shall be reviewed and recorded. Results shall be documented in the compounding record specified in Section 9.2 of the USP Chapter 825.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.12. DISPENSING**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) All dispensed radiopharmaceutical doses shall be labeled with the information required by Business and Professions Code section 4076 and section 1707.5. Outer shielding labels shall contain the name and contact information of the dispensing pharmacy.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.13. REPACKAGING**

In addition to the requirements in the USP Chapter 825, the processing of radiopharmaceuticals shall comply with all of the requirements of this section.

(a) The inner container of a repackaged radiopharmaceutical shall be labeled with the following:

(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time

(b)The outer shielding of a repackaged radiopharmaceutical shall be labeled with the following:

(1) Standard radiation symbol
(2) The words "Caution—Radioactive Material"
(3) The radionuclide and chemical form (generic name)
(4) Radioactivity with units at time of calibration and the calibration time
(5) Volume, or number of units (e.g., capsules), as applicable
(6) Product expiration or BUD (consistent with Table 7 of USP Chapter 825), as applicable
(7) Special storage and handling instructions

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

**1738.14. QUALITY ASSURANCE AND QUALITY CONTROL**

The requirements of this section apply to the processing of radiopharmaceuticals in addition to the standards established in USP Chapter 825.

(a) The quality assurance program shall comply with section 1711 and the standards contained in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following:

(1) A written procedure for scheduled action, such as a recall, in the event any radiopharmaceutical processing is discovered to be outside the expected standards for integrity, quality, and purity.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(b) The Board shall be notified in writing within 72 hours of a complaint. Recalls and adverse reporting must be completed in compliance with relevant provisions of law.

(c) In addition to subsection (b), all complaints related to a potential quality problem with a radiopharmaceutical and all adverse events shall be reviewed by the pharmacist-in-charge within 72 hours of receipt of the complaint or occurrence. Such review shall be documented and dated as defined in the SOPs.

(d) The SOPs shall specify the steps to be taken if a classified area(s) fails to meet the specified ISO classification including the investigative and corrective actions, allowable activities, and retesting procedures.

(e) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge consistent with the SOPs. The SOPs shall be updated to reflect changes to compounding processes, facility changes or other changes that impact the CSP. Such SOP changes shall be disseminated to the affected staff prior to implementation.

(f) Failure to follow written SOPs shall constitute a basis for enforcement action.

Authority cited: Sections 4005, 4008 and 4008.2, Business and Professions Code. Reference: Sections 125.9, 4005, 4126.8, 4301, 4306.5, and 4342, Business and Professions Code.

# Discontinuance of Business
# 16 CCR § 1708.2

16 CCR § 1708.2

Proposal to Amend § 1708.2. Discontinuance of Business as follows:

(a) Any permit holder shall contact the board prior to transferring or selling any dangerous drugs, devices or hypodermics inventory as a result of termination of business or bankruptcy proceedings (collectively referred to as a "closure") and shall follow official instructions given by the board applicable to the transaction.
(b)In addition to the requirements in (a), a pharmacy that shall cease operations due to a closure shall complete the following:

(1) Provide written notice to its patients that have received a prescription within the last year, at least 30 days in advance of the closure. At a minimum this notice shall include:
(A) the name of the patient and/or legal representative of the patient, if known,
(B) the name and physical address of the pharmacy closure,
(C) the name of pharmacy where patient records will be transferred or maintained, and
(D) information on how to request a prescription transfer prior to closure of the pharmacy.
(2) Reverse all prescriptions for which reimbursement was sought that are not picked up by patients,
(3) Provide the board with a copy of the notice specified in subsection (b)(1),
(4) The pharmacist-in-charge shall certify compliance with the requirements in this section. In the event the pharmacist-in-charge is no longer available, the owner must certify the compliance along with a pharmacist retained to perform these functions.

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4080, 4081, 4113, 4332 and 4333, Business and Professions Code; and Section 11205, Health and Safety Code.

# Fee Schedule
# 16 CCR § 1749

Proposal to Amend 16 CCR § 1749 Fee Schedule as follows:

The application, renewal, penalties, and other fees, unless otherwise specified, are hereby fixed as follows:

(a) The fee for the issuance of any pharmacy license~~, including a remote dispensing site pharmacy license,~~ is seven hundred fifty dollars ($750) ~~five hundred seventy dollars ($570)~~. The fee for the annual renewal of any pharmacy license~~, including a remote dispensing site pharmacy license,~~ is one thousand twenty-five dollars ($1,025) ~~nine hundred and thirty dollars ($930)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(b) The fee for the issuance of any temporary pharmacy license is one thousand six hundred dollars ($1,600) ~~three hundred twenty-five dollars ($325)~~.

(c) The fee for the issuance of a pharmacy technician license is one hundred twenty dollars ($120) ~~one hundred ninety-five dollars ($195)~~. The fee for the biennial renewal of a pharmacy technician license is one hundred fifty dollars ($150) ~~one hundred ninety-five dollars ($195)~~. The penalty for failure to renew is seventy-five dollars ($75). ~~ninety-seven dollars and fifty cents ($97.50)~~.

(d) The application fee for examination as a pharmacist is two hundred sixty dollars ($260) ~~two hundred eighty-five dollars ($285)~~.

(e) The fee for regrading an examination is one hundred fifteen dollars ($115).

(f)(1) The fee for the issuance of an original pharmacist license is one hundred ninety-five dollars ($195) ~~two hundred and fifteen dollars ($215)~~.
(2) The application fee for an advanced practice pharmacist license is three hundred dollars ($300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist license expires.

(g)(1) The fee for the biennial renewal of a pharmacist license is four hundred fifty dollars ($450) ~~five hundred five dollars ($505)~~. The penalty fee for failure to renew is one hundred fifty dollars ($150).
(2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars ($300). The penalty fee for failure to renew is one hundred fifty dollars ($150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

(h) The fee for the issuance of a wholesaler or third-party logistics provider license is one thousand dollars ($1,000) ~~eight hundred twenty dollars ($820)~~. The fee for the annual renewal of a wholesaler or third-party logistics provider license is one thousand dollars ($1,000) ~~eight hundred twenty dollars ($820)~~. The penalty

for failure to renew is one hundred fifty dollars ($150). The fee for a temporary wholesaler or third-party logistics provider license is seven hundred fifteen dollars ($715).

(i) The fee for the issuance of a hypodermic license is five hundred fifty dollars ($550) ~~two hundred forty dollars ($240)~~. The fee for the annual renewal of a hypodermic needle license is four hundred dollars ($400) ~~two hundred eighty dollars ($280)~~. The penalty for failure to renew is one hundred fifty dollars ($150) ~~one hundred forty dollars ($140)~~.

(j) The fee for the issuance of a designated representative license pursuant to Section 4053 of the Business and Professions Code, a designated representative-3PL license pursuant to Section 4053.1 of the Business and Professions Code, or a designated representative-reverse distributor license pursuant to Section 4053.2 of the Business and Professions Code, is three hundred forty-five dollars ($345) ~~two hundred ten dollars ($210)~~. The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or a designated representative-reverse distributor is three hundred eighty-eight dollars ($388) ~~three hundred dollars ($300)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(k) The application fee for a license as a nonresident wholesaler or nonresident third-party logistics provider is one thousand dollars ($1,000) ~~eight hundred twenty dollars ($820)~~. The fee for the annual renewal of a nonresident wholesaler or nonresident third-party logistics provider is one thousand dollars ($1,000) ~~eight hundred twenty dollars ($820)~~. The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a nonresident wholesaler or nonresident third-party logistics provider temporary license is seven hundred fifteen dollars ($715).

(*l*) The fee for an intern pharmacist license is one hundred seventy-five dollars ($175) ~~two hundred thirty dollars ($230)~~. The fee for transfer of intern hours or verification of licensure to another state is one hundred twenty dollars ($120) ~~thirty dollars ($30)~~.

(m) The fee for the reissuance of any license, or renewal thereof, which must be reissued because of change in the information on a premises license, other than name change, is three hundred ninety-five dollars ($395) ~~one hundred thirty dollars ($130)~~.

(n) The fee for the reissuance of any license that has been lost or destroyed ~~or reissued due to a name change is~~ seventy-five dollars ($75) ~~forty-five dollars ($45)~~. The fee for processing an application to change a name or correct an address on a premises is two hundred six dollars ($206). The fee for the processing of an application to change a pharmacist-in-charge, designated

representative-in-charge, or responsible, manager on a premises license record is two hundred fifty dollars ($250).

(o) The fee for evaluation of continuing education courses for accreditation is forty dollars ($40) for each hour of accreditation requested.

(p) The fee for the issuance of a clinic license is six hundred twenty dollars ($620) ~~five hundred seventy dollars ($570)~~. The fee for the annual renewal of a clinic license is four hundred dollars ($400) ~~three hundred sixty dollars ($360~~). The penalty for failure to renew is one hundred fifty dollars ($150).

(q) The fee for the issuance of a ~~nongovernmental~~ license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is three thousand eight hundred seventy-five dollars ($3,875) ~~two thousand three hundred five dollars ($2,305)~~. The fee for the annual renewal of a ~~nongovernmental~~ license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is four thousand eighty-five dollars ($4,085) ~~one thousand eight hundred fifty-five dollars ($1,855)~~. The penalty for failure to renew a ~~nongovernmental~~ license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is one hundred fifty dollars ($150). The fee for a ~~nongovernmental~~ temporary license to compound sterile drug preparations or a hospital satellite compounding pharmacy temporary license is one thousand sixty-five dollars ($1,065) ~~seven hundred fifteen dollars ($715)~~.

(r) The fee for the issuance of a nonresident sterile compounding pharmacy license is eight thousand five hundred dollars ($8,500) ~~three thousand three hundred thirty-five dollars ($3,335)~~. The fee for the annual renewal of nonresident sterile compounding pharmacy license is eight thousand five hundred dollars ($8,500) ~~three thousand one hundred eighty dollars ($3,180)~~. The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a temporary nonresident sterile compounding pharmacy license is one thousand five hundred dollars ($1,500) ~~seven hundred fifteen dollars ($715)~~.

(s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer is three hundred forty-five dollars ($345) ~~two hundred ten dollars ($210)~~. The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer is three hundred eighty-eight dollars ($388) ~~three hundred dollars ($300)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(t) The fee for a veterinary food-animal drug retailer license is six hundred ten dollars ($610). The application fee for the annual renewal for a veterinary food-animal drug retailer is four hundred sixty dollars ($460). The fee for a veterinary

food-animal drug retailer temporary license is five hundred twenty dollars ($520) ~~two hundred and fifty dollars ($250)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(u) The fee for the issuance of a retired pharmacist license is fifty dollars ($50)~~shall be forty-five dollars ($45)~~.

(v) The fee for the issuance of a centralized hospital packaging pharmacy license is three thousand eight hundred fifteen dollars ($3,815) ~~one thousand one hundred fifty dollars ($1,150)~~. The fee for the annual renewal of a centralized hospital packaging pharmacy license is two thousand nine hundred twelve dollars ($2,912) ~~one thousand one hundred twenty five dollars ($1,125)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(w) The fee for the issuance of an outsourcing facility license is twenty-five thousand dollars ($25,000) ~~three thousand one hundred eighty dollars ($3,180)~~. The fee for the annual renewal of an outsourcing facility is twenty-five dollars ($25,000) ~~one thousand eight hundred fifty-five dollars ($1,855)~~. The penalty for failure to renew is one hundred fifty dollars ($150). The fee for an outsourcing facility temporary license is four thousand dollars ($4,000) ~~seven hundred fifteen dollars ($715)~~.

(x) The fee for the issuance of a nonresident outsourcing facility license is twenty-eight thousand five hundred dollars ($28,500) ~~three thousand three hundred thirty-five dollars ($3,335)~~. The fee for the annual renewal of a nonresident outsourcing facility is twenty-eight thousand five hundred dollars ($28,500) ~~three thousand one hundred eighty dollars ($3,180)~~. The penalty for failure to renew is one hundred fifty dollars ($150). The fee for a nonresident outsourcing facility temporary license is four thousand dollars ($4,000) ~~seven hundred fifteen dollars ($715)~~.

(y) The fee for the issuance of a correctional clinic license ~~that is not owned by the state~~ is six hundred twenty dollars ($620) ~~five hundred seventy dollars ($570)~~. The annual renewal application fee for a correctional clinic license is four hundred dollars ($400) ~~three hundred sixty dollars ($360)~~. The penalty for failure to renew is one hundred fifty dollars ($150).

(z) The application and initial license fee for operation of an EMSADDS is one hundred fifty dollars ($150) ~~one hundred dollars ($100)~~. The application fee for the annual renewal of an EMSADDS is two hundred dollars ($200) ~~one hundred dollars ($100)~~. The penalty for failure to renew is one hundred dollars ($100) ~~thirty-five dollars ($35)~~. The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency is eight hundred ten dollars ($810).

~~(aa) The application fee of a co-location clinic license is seven hundred fifty dollars ($750).~~

(aa ~~ab~~) The application and initial license fee for a designated paramedic license is three hundred fifty dollars ($350) ~~one hundred and forty dollars ($140)~~. The application fee for the biennial renewal of a designated paramedic license is two hundred dollars ($200) ~~one hundred forty dollars ($140)~~. The penalty for failure to renew a designated paramedic license is one hundred dollars ($100) ~~sixty-five dollars ($65)~~.

(ab) The application and initial license fee for a remote dispensing site pharmacy application is one thousand seven hundred thirty dollars ($1,730). The fee for the annual renewal for a remote dispensing site pharmacy license is one thousand twenty-five dollars ($1,025). The penalty for failure to renew a remote dispensing site pharmacy license is one hundred fifty dollars ($150). The fee for the issuance of any temporary remote dispensing site pharmacy license is eight hundred ninety dollars ($890).

(ac) The fee for the issuance of an ADDS license to a correctional clinic is five hundred dollars ($500). The fee for the annual renewal of an ADDS license issued to a correctional clinic is four hundred dollars ($400). The penalty for failure to renew is one hundred fifty dollars ($150).

(ad) The fee for the issuance of an ADDS license to all entities other than correctional clinics is five hundred twenty-five dollars ($525). The fee for the annual renewal of an ADDS license, issued to entities other than correctional clinics, is four hundred fifty-three dollars ($453). The penalty for failure to renew is one hundred fifty dollars ($150).

(ae) The fee for the issuance of a nonresident pharmacy license is two thousand four hundred twenty-seven dollars ($2,427). The fee for the annual renewal of a nonresident pharmacy license is one thousand twenty-five dollars ($1,025). The penalty for failure to renew is one hundred fifty dollars ($150). The fee for the issuance of a temporary nonresident pharmacy license is two thousand dollars ($2,000).

Authority cited: Sections 4005 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, 4119.11, 4120, 4127.1, 4127.15, 4127.2, 4128.2, 4129.1, 4129.2, 4129.8, 4130, 4160, 4161, 4180, ~~4180.5~~, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.

# Quality Assurance 16 CCR § 1711

**Proposal to Amend 16 CCR § 1711 as follows:**

**§ 1711. Quality Assurance Programs.**

(a) Each pharmacy shall establish or participate in an established quality assurance program that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1) The date, location, and participants in the quality assurance review;

(2) The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c)~~,~~ including:

(A) The date and approximate time or date range when the error occurred if known or can be determined. If it cannot be determined, the pharmacy shall note "unknown" in the record.

(B) The names of staff involved in the error.
(C) The use of automation, if any, in the dispensing process.
(D) The type of error that occurred. To ensure standardization of error reporting, the pharmacies' policies and procedures shall include the category the pharmacy uses for identifying the types of errors.
(E) The volume of workload completed by the pharmacy staff on the date of the error including clinical functions. If the date of the error is unknown, the average volume of workload completed daily shall be documented. For errors that occur in a community pharmacy, at a minimum the volume of workload records shall include the number of new prescriptions dispensed, the number of refill prescriptions dispensed, the number of vaccines administered, number of patient consultations given, and any other mandatory activities required by the pharmacy employer. Prescriptions filled at a central fill location and dispensed at the pharmacy must be documented separately from other prescriptions filled at the pharmacy.
(3) The findings and determinations generated by the quality assurance review; and,
(4) Recommend changes to pharmacy policy, procedure, systems, or processes, if any.
The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program. Documentation of the steps taken to prevent future errors shall be maintained as part quality assurance report.
(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least ~~one~~ three years from the date the record was created. Any quality assurance record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal of the facility license.
(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

NOTE: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125 and 4427.7, Business and Professions Code.

# Pharmacy Technicians 16 CCR § 1793.65

Proposed Amendment to 16 CCR § 1793.65 as follows:

§ 1793.65. Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:
(1) The Pharmacy Technician Certification Board, and
(2) The National Healthcareer Association.
(b) Approval of these programs is valid through ~~December 31, 2024~~ June 30, 2026.

**Credits**
NOTE: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

# Attachment 7

**Legislation and Regulation Committee**
**Regulation Timeline**

## XIV.h. Board-Approved Regulations – Board Staff Drafting Initial Rulemaking Documents

1. Proposed Regulation to Amend Title 16 CCR Sections 1715 and 1784 Related to the Community Pharmacy, Hospital Pharmacy, and Dangerous Drug Distributor Self-Assessment Forms

   **Timeline:**
   Approved by Board: February 8, 2024

# Community Pharmacy, Hospital Pharmacy, and Dangerous Drug Distributor Self-Assessments 16 CCR §§ 1715 and 1784

**California State Board of Pharmacy**
2720 Gateway Oaks Drive, Suite 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 SELF-ASSESSMENT/
## HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

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

The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.

**Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 pursuant to 16 CCR 1715). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 pursuant to 16 CCR 1735.2[k]).**

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding License# _____ Exp Date: _____

Licensed Remote Dispensing Site Pharmacy License # _____ Exp Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (if any): _____



_____
**PIC Initials**

**Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):**
Please use an additional sheet if necessary. APH=Advanced Practice Pharmacist, DEA=Drug Enforcement Administration.

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. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ TCH # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

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

**All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Additionally, Business and Professions Code is referenced as BPC.**

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

## 1. Facility

Yes No N/A

☐☐☐ 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714[a])

☐☐☐ 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, CCR 1714[b], [d])

☐☐☐ 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714[b])

☐☐☐ 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714[c])

☐☐☐ 1.5. The pharmacy sink has hot and cold running water. (CCR 1714[c])

☐☐☐ 1.6. The pharmacy has a readily accessible restroom. (CCR 1714[g])

☐☐☐ 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. A pharmacy may also or instead display the notice on a video screen. Additional "Notice to Consumers" in languages other than English may also be posted. (BPC 4122[a], CCR 1707.6)

☐☐☐ 1.8. "Point to Your Language" poster is posted or provided in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6[c])

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

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

Yes No N/A



**PIC Initials**

☐☐☐ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete the Compounding Self-Assessment as required by CCR 1735.2(k).)

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

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

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

☐☐☐ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (BPC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

☐☐☐ 1.16 In addition to the email notification, the pharmacy has provided to the Board the electronic mail address and must notify the Board within 30 days of any change in the electronic mail address. (CCR 1704)

☐☐☐ 1.16~~7~~. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

☐☐☐ 1.17~~8~~. The pharmacy informs the customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug unless the pharmacy automatically charges the

customer the lower price. Additionally, the pharmacy submits the claim to the health care service plan or insurer. (BPC 4079[a], [b])

Yes No N/A

☐☐☐ ~~1.18. A pharmacy that dispenses controlled substances shall display safe storage products (a device made with the purpose of storing prescription medications with a locking or secure mechanism for access by the patient, i.e., medicine lock boxes, locking medicine cabinets, locking medication bags, prescription locking vials, etc.) in a place on the premise that is located close to the pharmacy unless the pharmacy is owned and managed by pharmacists who owns 4 or less pharmacy. (BPC 4106.5[a], [b])~~

☐☐☐ 1.19. A community pharmacy does not require a pharmacist employee to engage in practice of pharmacy at any time the pharmacy is open to the public unless either another employee at the establishment is made available to assist the pharmacist at all times unless the pharmacy is exempted. (BPC 4113.5)

- ☐ 1.19.1. The pharmacy has designated the name(s) of personnel who will be available to assist the pharmacist; (CCR 1714.3[a][1])
- ☐ 1.19.2. Designated personnel are able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3, and is qualified to have access to controlled substances; (CCR 1714.3[a][2], [3])
- ☐ 1.19.3. Designated personnel respond and are able to assist the pharmacist within five minutes after the pharmacist's request; (CCR 1714.3[a][4])
- ☐ 1.19.4. The pharmacy has policies and procedures in compliance with CCR 1714.3; (CCR 1714.3[b])
- ☐ 1.19.5. All impacted pharmacy employees and designated persons have read and signed a copy of the policies and procedures. (CCR 1714.3[c])

☐☐☐ <u>1.20. The pharmacy has the capability to receive an electronic data transmission prescription on behalf of a patient. (BPC 688[b])</u>

- ☐ <u>1.20.1 The pharmacy shall not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy. (BPC 688[b][2])</u>
- ☐ <u>1.20.2 The pharmacy's staff is aware they may continue to dispense the medication from a legally valid written, oral or fax prescription and are not required to verify the prescription properly falls under one of the exceptions. (BPC 688[i])</u>

☐ 1.20.~~1~~3. For prescriptions for controlled substances, as defined by BPC section 4021 generation and transmission of the electronic data transmission prescription complies with Parts 1300, 1304, and 1311 of Title 21 of the Code of Federal Regulations. (BPC 688[c])

☐ 1.20.~~2~~4. At the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester, unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. (BPC 688[g]) ~~Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law~~. (21 CFR 1300, 1304, 1306, 1311, BPC 688[g])

☐ 1.20.3. If ~~the~~ pharmacy staff~~, or its staff~~, is aware that an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, pharmacy staff immediately notifies the prescribing health care practitioner. (BPC 688[h])

**Yes No N/A**

☐☐☐ 1.21. The pharmacy performs FDA approved or authorized tests that are classified as CLIA waived. (BPC 4119.10)

☐ 1.21.1. The pharmacy is appropriately licensed as a laboratory under Section 1265 of the Health and Safety Code. (BPC 4119.10[a])

CDPH (CLIA) Registration #:_____ Expiration: _____

☐ 1.21.2. The pharmacy maintains policies and procedures as specified in. (BPC 4119.10[b])

☐ 1.21.3. The tests are authorized to be administered by a pharmacist pursuant to BPC 4052.4(b)(1). (BPC 4119.10[c])

☐ 1.21.4. The pharmacist-in-charge reviews the policies and procedures annually, assesses compliance with its policies, documents corrective actions to be taken when noncompliance is found, and maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years. (BPC 4119.10[d])

☐ 1.21.5. The pharmacy maintains documentation related to performing tests, including the name of the pharmacist performing the test, the results of the test, and communication of results to the patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years. (BPC 4119.10[e])

☐☐☐ 1.22 If the pharmacy qualifies as a chain store as defined in BPC 4001, the chain community pharmacy does not establish a quota. (BPC 4113.7, BPC 4317)

☐☐☐ 1.23 The pharmacy must report to the board any disciplinary action taken by any government agency since its last license issuance or last renewal. (CCR 1702.5)

Yes No N/A

☐☐☐ 1.24 When the pharmacy temporarily closes, the pharmacy must notify the board of the temporary closure as soon as closure exceeds three consecutive calendar days. A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days. (CCR 1708.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (BPC 4059.5[a], HSC 1120[a])

☐☐☐ 2.2. The pharmacy takes delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty ~~if~~ only when all of the following requirements are met: (BPC 4059.5[f])

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

Yes No N/A

☐☐☐ 2.3. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i])

☐☐☐ 2.4. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][1][A][ii])

☐☐☐ 2.5. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (21 USC sections 331, 351, 352, BPC 4342, HSC 111255, 111335, CCR 1714[b], 22 CCR 70263[q])

☐☐☐ 3.2. Dangerous drugs or dangerous devices are purchased, traded, sold, warehoused, distributed or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy, or manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5[b], 4169)

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

Yes No N/A

☐☐☐ 3.3. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

☐☐☐ 3.4. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

☐☐☐ 3.5. The pharmacy is aware that pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023, unit-level traceability. (21 USC 360eee-1[d][2], [g][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 4. Voluntary Drug Repository and Distribution Program (HSC 150200)

Yes No N/A

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

~~(If yes, complete Section 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)~~

☐☐☐ 4.2 The pharmacy that donates medications to or operates a voluntary county approved drug repository and distribution program meets all the requirements as specified in law. (HSC 150200, 150201, 150202, 150202.5, 150203, 150204, 150204.5, 150204.6, 150205, BPC 4169.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 5. Pharmacist-in-Charge (PIC)

Yes No N/A

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

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (BPC 4113[c], CCR 1709.1[b])

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

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

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

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101[a], 4113[d])

☐☐☐ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (BPC 1206.~~5~~6, 1209, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____



**PIC Initials** _____

## 6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. A pharmacist:

- ☐ transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
- ☐ administers drugs and biological products ordered by the prescriber; (BPC 4052[a][3])
- ☐ manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; (BPC 4052[a][7])
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
- ☐ provides professional information and participates in multidiscipline review of patient progress; (BPC 4052[a][9])
- ☐ furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, or prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations, HIV preexposure prophylaxis, HIV postexposure prophylaxis pursuant to a protocol; (BPC 4052 [a][10], 4052[a][11], 4052.01, 4052.02, 4052.03, 4052.3, 4052.8, 4052.9)
- ☐ dispenses aid-in-dying drugs; (HSC 443.5 [b][2])
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies; (BPC 4052 [a][12])
- ☐ initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority; and (BPC 4052 [a][13])
- ☐ provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law. (BPC 4052 [a][14])

Yes No N/A

☐☐☐ 6.2. In addition, a pharmacist:

- ☐ receives a new prescription order from the prescriber; (CCR 1793.1[a])
- ☐ consults with the patient; (BPC 4052[a][8], CCR 1707.2, CCR 1793.1[b])
- ☐ identifies, evaluates, and interprets a prescription; (CCR 1793.1[c])
- ☐ interprets the clinical data in a patient medication record; (CCR 1793.1[d])
- ☐ consults with any prescriber, nurse, health professional or agent thereof; (CCR 1793.1[e])
- ☐ supervises the packaging of drugs; (CCR 1793.1[f])
- ☐ checks the packaging procedure and product upon completion; (CCR 1793.1[f])

- ☐ is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e]) or
- ☐ performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (BPC 4052, 4052.02, 4052.03, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1 [g])

**Yes No N/A**

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

☐☐☐ 6.4. Pharmacists have obtained approval to access the CURES Prescription Drug Monitoring Program (PDMP). (HSC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraception only pursuant to the statewide protocol found in CCR 1746. (BPC 4052.3[b][1])

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (BPC 1206.6)

☐☐☐ 6.7. Only a pharmacist performs FDA-approved or authorized CLIA waived clinical laboratory tests as specified in law. ~~in BPC 4052.4~~ (BPC 4052.4, BPC 1206.6, BPC 4119.10)

CDPH (CLIA) Registration #: _____ Expiration: _____

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

☐☐☐ 6.9. ~~Effective July 1, 2022, a~~ A pharmacist who is authorized to initiate or adjust a Schedule II Controlled substance shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs. (BPC 4232.5[a])

☐☐☐ 6.10. All pharmacists have joined the board's email notification list. (BPC 4013)

☐☐☐ 6.11. Only a pharmacist may electronically enter a prescription or an order, as defined in BPC 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. This does not apply to prescriptions for Schedule II, III, IV or V controlled substances, except as permitted pursuant to HSC 11164.5. (BPC 4071.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 7. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 7.1. The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 7.1.1. Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a][1]-[3])
- ☐ 7.1.2. Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a][4])
- ☐ 7.1.3. Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[a][5], [b])
- ☐ 7.1.4. Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[a][5], [b])
- ☐ 7.1.5. Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])
- ☐ 7.1.6. Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist performs the functions of a pharmacist only under the direct supervision of a pharmacist. The pharmacist supervises no more than **two interns** at any one time. (BPC 4114, 4023.5, CCR 1726)

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

☐☐☐ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], CCR 1726)

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

☐☐☐ 8.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. Pharmacy technicians only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (BPC 4038, 4115[a], [f][1], CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies them as a pharmacy technician or pharmacy technician trainee. (BPC 680[a], 4115.5[e], CCR 1793.7[c])

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

☐☐☐ 9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 140 hours. (BPC 4115.5)

☐☐☐ 9.6. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

☐☐☐ 9.7 A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician. A certification only is not equivalent to being licensed by the board as a pharmacy technician. (BPC 4115[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 10. Duties of Non-Licensed Personnel

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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## PHARMACY PRACTICE

## 11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707.2)

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request;
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of their professional judgment; and
- ☐ 11.1.5. all of the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

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

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

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

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 12. Prescription Requirements

Yes No N/A

☐☐☐ 12.1. Prescriptions are complete with all the required information. (BPC 4040, 4070)

☐☐☐ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (BPC 4070, CCR 1717[c])

Yes No N/A

☐☐☐ 12.3. If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (BPC 4071)

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

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (BPC 4040[c])

☐☐☐ 12.7. Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (BPC 2290.5, 2242, 2242.1, 4067[a])

☐☐☐ 12.8. With the exception of those prescriptions written under HSC 11159.2 (terminally ill exemption), 11159.3 (declared emergency exemption) and 11167.5 (SNF, ICF, licensed home health agency and licensed hospice exemption), all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (HSC 11164[a], 11167.5, 11162.1, 11159.2, 11159.3)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 11164[a][1], 11166)

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR parts 1300, 1306, 1311)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (BPC 4076)

☐☐☐ 13.2. The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707.5)

☐☐☐ 13.3. The expiration dates of a drug's effectiveness is accurately identified on the label. (BPC 4076[a][9])

☐☐☐ 13.4. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record and includes the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (BPC 4076[a][1], CCR 1707.5[a][1], 1717[b][2])

☐☐☐ 13.5. Generic substitution is communicated to the patient. (BPC 4073)

☐☐☐ 13.6. When a biological product is substituted with an alternative biological product, all the requirements of BPC 4073.5 are met. (BPC 4073.5)

☐☐☐ 13.7. If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, before dispensing, the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or the identity of the reviewing pharmacist is recorded in a computer system by a secure means. (BPC 4115, 4115.5[b][3], CCR 1793.7, CCR 1712)

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

☐☐☐ 13.9. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717[a])

☐☐☐ 13.10. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.11. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.12. Medication guides are provided on required medications. (21 CFR 208.24[e])

☐☐☐ 13.13. The pharmacy furnishes dangerous drugs in compliance with:

- ☐ BPC 4119(b) to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency. (BPC 4119)
- ☐ BPC 4126.5(a) only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership.

☐☐☐ 13.14. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (BPC 4076[a][11])

☐☐☐ 13.15. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (HSC 11200[a])

☐☐☐ 13.16. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply. (HSC 11200[b])

☐☐☐ 13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, psychotropic medications and self-administered hormonal contraception, under the following provisions: (BPC 4064.5)

- ☐ 13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where: (BPC 4064.5[a])
  - ☐ 13.17.1.1. The prescriber has not indicated “no change to quantity” or words of similar meaning; (BPC 4064.5[d])
  - ☐ 13.17.1.2. The patient has completed an initial 30 day supply; (BPC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90 day supply. BPC 4064.5[b])
  - ☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
  - ☐ 13.17.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (BPC 4064.5[a][3])
  - ☐ 13.17.1.5. The pharmacist is exercising their professional judgment. (BPC 4064.5[a][4])
  - ☐ 13.17.1.6. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])

☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])

☐ 13.17.3. When requested by the patient, the pharmacist dispenses up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills. (BPC 4064.5[f][1])

☐ 13.17.4. When a pharmacist furnishes a self-administered hormonal contraceptive pursuant to BPC 4052.3 under protocols developed by the Board of Pharmacy, the pharmacist may furnish, at the patient's request, up to a 12-month supply at one time. (BPC 4064.5[f][2])

Yes No N/A

☐☐☐ 13.18. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[a], [b], 4076.7, CCR 1744)

☐☐☐ 13.19. The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[a], CCR 1744[b])

☐☐☐ 13.20. Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7)

☐☐☐ 13.21. When requested by a patient or patient representative, the pharmacy provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appears on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a])

Yes No N/A

☐☐☐ 13.22. When a pharmacist furnishes ~~naloxone~~ federal FDA-approved opioid antagonists pursuant to the board of pharmacy's approved protocol, the pharmacist complies with all the requirements listed in BPC 4052.01 and CCR 1746.3.

☐☐☐ 13.23. When the pharmacy furnishes naloxone or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code, it is furnished exclusively for use at a school district school site, county office of education school site, or charter school, and a physician or surgeon provides a written order specifying the quantity to be furnished. (BPC 4119.8)

☐☐☐ 13.24. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency exclusively for use by employees of the law enforcement agency, who have completed training provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists, and the records of

acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)

☐☐☐ 13.25. For each vaccine administered by a pharmacist, a patient vaccine administration record is 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's normal operating hours. A pharmacist provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of any vaccine. A pharmacist informs each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e). At the request of a patient, the pharmacist shall notify each patient's primary care provider or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. The pharmacist shall also notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days. (CCR 1746.4[d][e], [f])

☐☐☐ 13.26. The pharmacy furnishes epinephrine auto-injectors to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197a, and is furnished exclusively for use by, or in connection with, an authorized entity and an authorized health care provider provides a prescription specifying the quantity of the epinephrine auto-injectors to be furnished to the authorized entity. A new prescription is obtained for any additional epinephrine auto-injector required for use. The pharmacy complies with the requirements for labeling and records pursuant to BPC 4119.4.

☐☐☐ 13.27. When a pharmacist initiates and furnishes HIV preexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.02. (BPC 4052.02, CCR 1747)

☐☐☐ 13.28. When a pharmacist initiates and furnishes HIV postexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.03. (BPC 4052.03, CCR 1747).

☐☐☐ 13.29. When a pharmacist receives a prescription, which include the words "expedited partner therapy" or the letters "EPT" pursuant to HSC 120582, the pharmacists labels the drug without the name of the individual for whom the drug is intended (BPC 4076 [a], [f]).

**Yes No N/A**

☐☐☐ 13.30. When a pharmacist provides EPT the pharmacist provides written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions. (BPC 4076[a], [h]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (BPC 4063)

☐☐☐ 14.2. Refills are documented. (CCR 1717)

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

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (HSC 11200)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 15. Auto-Refill Program

Yes No N/A

☐☐☐ 15.1. The pharmacy offers a program to automatically refill prescriptions (CCR 1717.5). The pharmacy is aware ~~that effective July 1, 2022,~~ the following actions are required:

- ☐ 15.1.1. The pharmacy has policies and procedures describing the program. (CCR 1717.5[a][1])
- ☐ 15.1.2. Before a patient enrolls, the pharmacy provides a written or electronic notice summarizing the program to the patient or patient's agent. (CCR 1717.5[a][2])
- ☐ 15.1.3. The pharmacy obtains an annual renewal of each prescription from the patient or patient's agent for each prescription refilled through the program. (CCR 1717.5[a][3])
- ☐ 15.1.4. The pharmacy maintains a copy of the written or electronic consent to enroll on file for one year from date of dispensing. (CCR 1717.5[a][4])
- ☐ 15.1.5. The pharmacy completes a drug regimen review for each prescription refilled through the program at the time of refill. (CCR 1717.5[a][5])
- ☐ 15.1.6. Each time a prescription is refilled through the program, the pharmacy provides the patient or patient's agent with a written or electronic notice that a prescription was refilled through the program. (CCR 1717.5[a][6])

☐ 15.1.7. The pharmacy documents and maintains records of patient withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and provides confirmation to the patient or patient's agent. (CCR 1717.5[a][7])

☐ 15.1.8. The pharmacy provides a full refund to the patient, patient's agent or payer for any prescription refilled through the program if the pharmacy was notified that the patient did not want the refill, regardless of the reason, or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription medication. (CCR 1717.5[a][8])

☐ 15.1.9. The pharmacy makes available any written or electronic notification required by this section in alternate languages as required by state or federal law. (CCR 1717.5[a][9])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 16. Quality Assurance and Medication Errors

| Yes | No | N/A | |
|---|---|---|---|
| ☐ | ☐ | ☐ | 16.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC 4125, CCR 1711) |
| ☐ | ☐ | ☐ | 16.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c]) |
| ☐ | ☐ | ☐ | 16.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], [c][3]) |
| ☐ | ☐ | ☐ | 16.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3]) |
| ☐ | ☐ | ☐ | 16.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d]) |

| Yes | No | N/A | |
|---|---|---|---|
| ☐ | ☐ | ☐ | 16.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]) |

☐ 16.6.1. Date, location, and participants in the quality assurance review;

☐ 16.6.2. Pertinent data and other information related to the medication error(s) reviewed;

☐ 16.6.3. Findings and determinations; and

☐ 16.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

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

☐☐☐ 16.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with BPC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

☐☐☐ 17.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (HSC 11153)

☐☐☐ 17.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if the pharmacist knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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**18. Prescription Transfer**

Yes No N/A

☐☐☐ 18.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e])

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

☐☐☐ 18.3. For electronic data transmission prescriptions, at the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but

not dispensed to the patient, to an alternative pharmacy designated by the requester (BPC 688 (g)), unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. ~~Unfulfilled controlled substance prescriptions received as electronic data transmission prescriptions are transferred or forwarded in compliance with Federal Law.~~ (21 CFR 1300, 1304, 1306, and 1311)

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

☐☐☐ 18.4. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (21 CFR 1306.25, CCR 1717[e])

☐☐☐ 18.5. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], 21 CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 19. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ 19.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ 19.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

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

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

Yes No N/A

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

☐☐☐ 19.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

## 20. Record Keeping Requirements

Yes No N/A

☐☐☐ 20.1. All completed pharmacy self-assessments are on file in the pharmacy and maintained for three years. (CCR 1715[d])

☐☐☐ 20.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records. These records include (BPC 4081, 4105, 4169, 4333):

- ☐ 20.2.1. Prescription records (BPC 4081[a])
- ☐ 20.2.2. Purchase Invoices for all prescription drugs (BPC 4081[a])
- ☐ 20.2.3. Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 20.2.4. Biennial controlled substances inventory (21 CFR 1304.11[c], CCR 1718)
- ☐ 20.2.5. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 20.2.6. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05~~7~~)
- ☐ 20.2.7. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ 20.2.8. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081[a])
- ☐ 20.2.9. Record documenting transfers or sales to other pharmacies, licensees, prescribers, and reverse distributors (BPC 4081, 4105, CCR 1718)
- ☐ 20.2.10. Records of receipt and shipment (BPC 4081)

☐☐☐ 20.3. A pharmacist may sell hypodermic needles and syringes to a person without a prescription is limited to: (BPC 4145.5)

- ☐ 20.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need; (BPC 4145.5[a])
- ☐ 20.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established. (BPC 4145.5[c])
- ☐ 20.3.3. For industrial use, as determined by the board. (BPC 4144.5)
- ☐ 20.3.4. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (BPC 4145.5[b])

Yes No N/A

☐☐☐ 20.4. When hypodermic needles and syringes are furnished by a pharmacy without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis

C and safe disposal of sharps waste; and provide one or more of the following disposal options: (BPC 4145.5[e], [f])

☐ 20.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 20.4.2. Furnish or make available mail-back sharps containers.

☐ 20.4.3. Furnish or make available sharps containers.

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

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 20.6. The pharmacy furnishes an epinephrine auto-injector to a school district, county office of education, or charter school pursuant to Section 49414 of the Education Code if all of the following are met:

☐ 20.6.1. The epinephrine auto-injectors are furnished exclusively for use at a school district site, county office of education, or charter school (BPC 4119.2 [a][1]).

☐ 20.6.2. A physician and surgeon provide a written order that specifies the quantity of epinephrine auto-injectors to be furnished (BPC 4119.2[a][2]).

☐☐☐ 20.7. The pharmacy furnishes an epinephrine auto-injector to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197(a), provided that: (BPC 4119.3, 4119.4)

☐ 20.7.1. An authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed; (BPC 4119.3[a][1], 4119.4[a][2])

☐ 20.7.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation “Section 1797.197a responder” and “First Aid Purposes Only”, the dosage, use and expiration date; and. (BPC 4119.3[a], 4119.4[b])

☐ 20.7.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (BPC 4119.3[a][2][B], 4119.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 21. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

☐☐☐ 21.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[c])

☐☐☐ 21.2. Schedule II inventory is separate from Schedule III, IV and V. See also Section 22. (21 CFR 1304.04[h][1])

☐☐☐ 21.3. All completed inventories are ~~is~~ available for inspection for three years. (CCR 1718)

☐☐☐ 21.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a])

☐☐☐ 21.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])

☐☐☐ 21.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][4])

☐☐☐ 21.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

☐☐☐ 21.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all Schedule II controlled substances. When Schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form 222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])

☐☐☐ 21.9. When a pharmacy distributes Schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form 222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

Yes No N/A

☐☐☐ 21.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, a copy of the DEA Form 222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 21.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[a][1][iv]], Drug Supply Chain Security Act, BPC 4160)

☐☐☐ 21.12. When dispensed upon an “oral” order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Department of Justice within 144 hours of the failure to provide prescription. (HSC 11167[c], [d])

☐☐☐ 21.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ 21.14. ~~Any c~~Controlled substances drug loss is reported within one business day of discovery to the DEA and within 30 days ~~of discovery~~ to the Board of Pharmacy the discovery of any loss of controlled substances 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: ~~for the following:~~
(21 CFR 1301.74[c], CCR 1715.6)

21.14.1 Tablets, capsules, or other oral medication, 99 dosage units

21.14.2. Single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

21.14.3 Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers.

☐☐☐ 21.15. Do pharmacy staff hand initial prescription records or prescription labels, or (CCR 1712, 1717[b][1])

☐☐☐ 21.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist’s identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ 21.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES within one working day from the date the controlled substance is released to be patient. (HSC 11165[d])

☐☐☐ 21.18. Furnishing of dangerous drugs and controlled substances for physician office use is done under sales and purchase records that correctly give the date, names and addresses of supplier and buyer, the drug or device and its quantity. The prescription may not be used for obtaining dangerous drugs or controlled substances for supplying a practitioner for the purpose of dispensing to patients. (21 CFR 1306.04[b], HSC 11250, BPC 4059)

☐☐☐ 21.19. The pharmacy has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon

discovering a suspicious order or series of orders, notify the DEA and the Special Agent in charge of DEA in their area. (21 USC 832[a]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 22. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 22.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ 22.2. The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

☐☐☐ 22.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This report requires: (CCR 1715.65 [c])

- ☐ 22.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 22.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 22.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 22.3.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 22.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])
- ☐ 22.3.6 In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg, alprazolam 2mg, tramadol 50mg, and promethazine with codeine 6.25mg/10mg/5ml at least every 12 months. (CCR 1715.65[a][2])
- ☐ 22.3.7 An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the reportable loss. (CCR 1715.65)

☐ 22.3.8 Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])

☐ 22.3.9 The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file. (CCR 1715.65[e][1])

☐☐☐ 22.4. The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

☐☐☐ 22.5. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])

Yes No N/A

☐☐☐ 22.6. A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 23. Oral/Electronic Transmission and Partial Fill of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 23.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], HSC 11164)

☐☐☐ 23.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], HSC 11167.5)

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

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

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

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

☐☐☐ 23.3. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. The pharmacist shall notify the prescriber if the remaining portion of the prescription is not filled within 72 hours. (21 CFR 1306.13[a], CCR 1745[d])

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

☐☐☐ 23.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance when a partial fill is requested by the patient or practitioner. The pharmacist shall report to CURES only the actual amounts of drug dispensed. The total dispensed shall not exceed the prescribed quantity. (21 USC 829[f], BPC 4052.10)

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

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

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

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

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

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

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

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

☐☐☐ 23.14. Controlled substance prescriptions with the 11159.3 exemption during a declared local, state, or federal emergency, noticed by the board, may be dispensed if the following are met: (HSC 11159.3)

- ☐ The prescription contains the information specified in HSC 11164(a), indicates that the patient is affected by a declared emergency with the words "11159.3 exemption" or a similar statement, and is written and dispensed within the first two weeks of notice issued by the board.
- ☐ When the pharmacist fills the prescription, the pharmacist exercises appropriate professional judgment, including reviewing the patient's activity report from the CURES PDMP before dispensing the medication.
- ☐ If the prescription is a Schedule II controlled substance, the pharmacist dispenses no greater than the amount needed for a seven-day supply.
- ☐ The patient first demonstrates, to the satisfaction of the pharmacist, their inability to access medications, which may include, but not limited to, verification of residency within an evacuation area.

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 24. Automated Drug Delivery Systems

**Yes No N/A**

☐☐☐ 24.1. Does the pharmacy use an automated drug delivery system, automated patient dispensing system and/or automated unit dose system? (CCR 1713)

If yes, complete the biennial self-assessment for automated drug delivery systems.

Note: An ADDS license is not required for technology installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and devices. (BPC 4427.2[j]) or exempt AUDS operated by a licensed hospital pharmacy. (BPC 4427.2(i) As a reminder, a self-assessment form is required for an exempt AUDS.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 25. Repackaging by the Pharmacy

Yes No N/A

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

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

☐☐☐ 25.3. Drugs previously dispensed by another pharmacy are re-packaged at the patient's request and includes the name and address of both pharmacies and complies with the other requirements of BPC 4052.7.

☐☐☐ 25.4. The pharmacy only repackages and furnishes a reasonable quantity of dangerous drugs and devices for prescriber office use. (BPC 4119.5 [b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 26. Refill Pharmacy

Yes No N/A

☐☐☐ 26.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

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

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

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

If the answer to the three questions above is "no" or "not applicable" go to section 27.

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

☐☐☐ 26.5. Refill prescription label meets requirements of BPC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

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

☐☐☐ 26.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 26.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

**Yes No N/A**

☐☐☐ 27.1. The pharmacy is a provider of blood clotting products for home use in compliance with HC 125286.20 and 125286.25. (HSC 125286.20, 125286.25)

~~☐ 27.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])~~

~~☐ 27.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])~~

~~☐ 27.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])~~

~~☐ 27.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])~~

~~☐☐☐ 27.2. The pharmacy meets the following requirements:~~

~~☐ 27.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])~~

~~☐ 27.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])~~

~~☐ 27.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])~~

~~☐ 27.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])~~

~~☐ 27.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])~~

☐ ~~27.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])~~

☐ ~~27.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])~~

☐ ~~27.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])~~

☐ ~~27.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])~~

☐ ~~27.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])~~

☐ ~~27.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])~~

☐ ~~27.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[*l*])~~

## 28. Policies and Procedures

Yes No N/A

☐☐☐ 28.1. There are written policies and procedures in place for:

☐ 28.1.1. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects their ability to practice the profession or occupation authorized by their license, including the reporting to the board within 14 days of receipt or development; (BPC 4104[a],[c])

☐ 28.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (BPC 4104[b], [c])

☐ 28.1.3. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to HSC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (BPC 4074[a], CCR 1707.2[b][2])

☐ 28.1.4. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, the

pharmacist's responsibilities for checking all work performed by ancillary staff, and the pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 28.1.5. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ 28.1.6. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (BPC 4059.5[f][1])

☐ 28.1.7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ 28.1.8. A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection; (BPC 733[b][3])

☐ 28.1.9. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; (BPC 733[b][1])

☐ 28.1.10. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language; and (CCR 1707.5[d])

☐ 28.1.11. Inventory reconciliation reporting requirements. (CCR 1715.65[b])

Yes No N/A

☐☐☐ 28.2. Does your pharmacy employ the use of a common electronic file? (CCR 1717.1)

☐ 28.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1[e])

☐☐☐ 28.3. Does your pharmacy furnish emergency contraceptives pursuant to BPC 4052.3[b][1]? (BPC 4052, CCR 1746)

If yes, does the pharmacy:

☐ 28.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746[b])

☐ 28.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746[b][4])

☐ 28.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746[b][8])

☐ 28.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (BPC 4052.3[b][2], CCR 1746[b][10])

☐ 28.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (BPC 773[b], CCR 1746[b][5])

☐ 28.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (BPC 733[b])

☐ 28.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified their employer in writing? (BPC 733[b][3], 4052.3)

Yes No N/A

☐☐☐ 28.4. Furnishes ~~naloxone hydrochloride~~ federal FDA-approved opioid antagonists in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.01[a], CCR 1746.3)

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

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

☐☐☐ 28.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.9, CCR 1746.2)

☐☐☐ 28.6. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.3, CCR 1746.1)

☐☐☐ 28.7. Does your pharmacy furnish travel medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50 states and the District of Columbia pursuant to section BPC 4052(a)(10)(A)(3)? If yes, does the pharmacy do the following: (CCR 1746.5[a], [c])

☐ 28.7.1. Keep documentation on site and available for inspection by the board, pharmacist(s) completion of an immunization training program that meets the requirements on BPC 4052.8(b)(1), completion of a travel medicine training program, consisting of at least 10 hours of training and cover each element of the International Society of Travel Medicine's Body of Knowledge for the Practice of Travel Medicine (2012) completion of the CDC Yellow Fever Vaccine Course; and current basic life support certification. (CCR 1746.5[c])

☐ 28.7.2. Pharmacists complete two hours of ongoing continuing education focused on travel medicine, separate from continuing education in immunization and vaccines, from an approved provider once every two years. (CCR 1746.5[d])

☐ 28.7.3. Prior to furnishing travel medications, the pharmacist performs a good faith evaluation of the patient, including evaluation of the patient's travel history using destination-specific travel criteria. The travel history includes all the information necessary for a risk assessment during pre-travel consultation, as identified in the CDC Yellow Book. (CCR 1746.5[e])

☐ 28.7.4. The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient within 14 days of the date of furnishing, or enters the appropriate information in the patient record system shared with the primary care provider, as permitted by the primary care provider. If the patient does not have a primary care provider, or is unable to provide contact information for their primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice. (CCR 1746.5[f])

☐ 28.7.5. A patient medication record is maintained and securely stored in a physical or electronic manner for each travel medication furnished, such that the information required under section 300aa-25 of title 42 of the United States Code is readily retrievable during the pharmacy's or facility's normal operating hours and the pharmacist provides the patient with written documentation that reflects the clinical assessment and travel medication plan. (CCR 1746.5[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 29. Compounding

Yes No N/A

☐☐☐ 29.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" required by CCR 1735.2[k].

## 30. Nuclear Pharmacy

Yes No N/A

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

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

☐☐☐ 30.3. The pharmacy possesses a current Sterile Compounding Permit (BPC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, required by CCR 1735.2[k].

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 31. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Yes No N/A

☐☐☐ 31.1. Pharmacy provides telepharmacy services and has obtained a remote dispensing site pharmacy license from the board. (BPC 4130[e], 4044.6, 4044.3[a])

If the answer is "yes", name the remote dispensing site pharmacy and license number:

Name: _____ License No.: _____

List the names of all qualified remote dispensing site pharmacy technician:

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

If the answer to the question above is “no” or “not applicable” go to section 32.

Yes No N/A

☐☐☐ 31.2. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board . (BPC 4131[b])

☐☐☐ 31.3. Both the supervising and remote dispensing site pharmacies operate in accordance with BPC 4130, 4131, 4132, 4133, 4134, 4135, 4044, 4044.3, 4044.6, 4044.7, 4059.5.

☐☐☐ 31.4. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130[h])

~~31.2. The supervising pharmacy uses a telepharmacy system for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at the remote dispensing site pharmacy. (BPC 4130[a], BPC 4044.7)~~

~~☐☐☐ 31.3. The remote dispensing site pharmacy is located in a medically underserved area unless otherwise approved by the board. (BPC 4130[c])~~

~~☐☐☐ 31.4. The remote dispensing site pharmacy does not employ any unlicensed personnel. (BPC 4130[d])~~

~~☐☐☐ 31.5. The supervising pharmacy has only obtained one remote dispensing site pharmacy license. (BPC 4130[e])~~

☐☐☐ 31.6. The remote dispensing site pharmacy is not operated by the state and is not located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. (BPC 4130[f])

☐☐☐ 31.7. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130[h])

☐☐☐ 31.8. The supervising pharmacy provides telepharmacy services for only one remote dispensing site pharmacy. (BPC 4131[a])

☐☐☐ 31.9. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board. (BPC 4131[b])

☐☐☐ 31.10. The supervising pharmacy and the remote dispensing site pharmacy are under common ownership. (BPC 4131[c])

☐☐☐ 31.11. The remote dispensing site pharmacy is staffed by a pharmacist, or at least one registered pharmacy technician meeting the qualifications of BPC section 4132 (BPC 4130[d]).

☐☐☐ 31.12. Pharmacy technicians working at a remote dispensing site pharmacy remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. (BPC 4131[d])

☐☐☐ 31.13. The supervising pharmacists utilizes a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy. (BPC 4131[d])

☐☐☐ 31.14. The designated pharmacist-in-charge of the supervising pharmacy is also the pharmacist-in-charge at the remote dispensing site pharmacy. (BPC 4131[e])

☐☐☐ 31.15. The pharmacist -in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy are responsible to ensure that both the supervising pharmacy and the remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare. (BPC 4130[f])

☐☐☐ 31.16. In addition to the requirements of BPC 4202, a pharmacy technician working at the remote dispensing site pharmacy has met the requirements required by BPC 4132. (BPC 4132[a])

- ☐ Possess a pharmacy technician license that is in good standing.
- ☐ Possess and maintain a certification issued by the board-approved pharmacy technician certification program.



**PIC Initials**

- ☐ Possess one of the following: a minimum of an associated degree in pharmacy technology, a minimum of a bachelor's degree in any subject, or a certification of completion from a course of training specified by regulations adopted by the board pursuant to BPC 4202.
- ☐ Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

☐☐☐ 31.17. Registered pharmacy technicians may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at the remote dispensing site pharmacy under the supervision of a pharmacist at the supervising pharmacy using a telepharmacy system. (BPC 4132[b])

☐☐☐ 31.18. Pharmacy technicians at the remote dispensing site pharmacy do not do any of the following:

- ☐ 31.18.1. Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law. (BPC 4132[c][1])
- ☐ 31.18.2. Consult with a patient or their agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart. (BPC 4132[c][2])
- ☐ 31.18.3. Identify, evaluate, or interpret a prescription. (BPC 4132[c][3])
- ☐ 31.18.4. Interpret the clinical data in a patient medication record system or patient chart. (BPC 4132[c][4])
- ☐ 31.18.5. Consult with any prescriber, nurse, or other health care professional or authorized agent thereof. (BPC 4132[c][5])
- ☐ 31.18.6. Supervise the packaging of drugs and check the packaging procedures and product upon completion. (BPC 4132[c][6])
- ☐ 31.18.7. Perform any function that requires the professional judgment of a licensed pharmacist. (BPC 4132[c][7])
- ☐ 31.18.8. Compound drug preparations. (BPC 4132[c][8])

Yes No N/A

☐☐☐ 31.19. A pharmacist at the supervising pharmacy supervises no more than two pharmacy technicians at each remote dispensing site pharmacy. The pharmacist may also supervise pharmacy technicians at the supervising pharmacy. (BPC 4132[d])

☐☐☐ 31.20. The supervising pharmacy's telepharmacy system maintains a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients. (BPC 4133[a])

☐☐☐ 31.21. The telepharmacy system facilitates adequate pharmacist supervision and allows the appropriate exchange of visual verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs. (BPC 4133[b])

☐☐☐ 31.22. Patient counseling is provided using audio-visual communication prior to all prescriptions being dispensed from the remote dispensing site pharmacy. (BPC 4133[c])

☐☐☐ 31.23. The telepharmacy system is able to do all of the following:

- ☐ 31.23.1. Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription. (BPC 4133[d][1])
- ☐ 31.23.2. Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription. (BPC 4133[d][2])
- ☐ 31.23.3. Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed. (BPC 4133[d][3])
- ☐ 31.23.4. Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing. (BPC 4133[d][4])
- ☐ 31.23.5. Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery. (BPC 4133[d][5])

Yes No N/A

☐☐☐ 31.24. The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191). (BPC 4133[e])

☐☐☐ 31.25. All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription. (BPC 4133[f])

☐☐☐ 31.26. A pharmacist from the supervising pharmacy completes a monthly in-person, self-inspection of each remote dispensing site pharmacy using the form designated by the board and retains all inspection reports. (BPC 4134[a])

☐☐☐ 31.27. A perpetual inventory is kept for all controlled substances stored at the remote dispensing site pharmacy. (BPC 4134[b])

☐☐☐ 31.28. All controlled substances stored at the remote dispensing site pharmacy are stored in a secure cabinet or safe that is locked. (BPC 4134[c])

☐☐☐ 31.29. A pharmacist from the supervising pharmacy performs inventory and inventory reconciliation functions at the remote dispensing site pharmacy to detect and prevent the loss of any controlled substances. (BPC 4134[d])

☐☐☐ 31.30. The pharmacist-in-charge of the remote dispensing site pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of any controlled substances. (BPC 4134[e])

☐☐☐ 31.31. A pharmacist from the supervising pharmacy compiles an inventory reconciliation report of all Schedule II controlled substances at the remote dispensing site pharmacy at least once every three months. (BPC 4134[f]) This compilation shall include the following:

- ☐ 31.31.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. (BPC 4134[f][1])
- ☐ 31.31.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report. (BPC 4134[f][2])
- ☐ 31.31.3. A comparison of the two above-mentioned items to determine if there are any variances. (BPC 4134[f][3])
- ☐ 31.31.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form. (BPC 4134[f][4])

☐☐☐ 31.32. The remote dispensing site pharmacy reports in writing, any identified losses of controlled substances and possible causes of losses to the board within 31 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report is made within 14 days of discovery. If the remote dispensing site pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4134[g])

Yes No N/A

☐☐☐ 31.33. Possible causes of overages are identified in writing and incorporated into the inventory reconciliation report. (BPC 4134[h])

☐☐☐ 31.34. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy, and is readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (BPC 4134 [i])

☐☐☐ 31.35. While closed, the remote dispensing site pharmacy utilizes an alarm or other comparable monitoring system. (BPC 4135[a])

☐☐☐ 31.36. The remote dispensing site pharmacy is not open and its employees are not allowed access at times when the supervising pharmacy is closed. (BPC 4135[b])

☐☐☐ 31.37. The remote dispensing site pharmacy's security system tracks entries into the remote dispensing site pharmacy and the pharmacist-in-charge periodically review the record of entries. (BPC 4135[b])

☐☐☐ 31.38. Pharmacy services are not provided at the remote dispensing site pharmacy if the telepharmacy system is unavailable. (BPC 4135[b])

☐☐☐ 31.39. The remote dispensing site pharmacy retains a recording of facility surveillance excluding patient communications, for a minimum of 120 days. (BPC 4135[c])

☐☐☐ ~~31.40. Dangerous drugs and devices and controlled substances ordered by the remote dispensing site pharmacy are signed for and received by a pharmacist or a registered pharmacy technician, who meets the qualifications of Section 4132. (BPC 4059.5[g])~~

☐☐☐ ~~31.41. A controlled substance signed for by a pharmacy technician under BPC section 4059.5 is stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. (BPC 4059.5[g])~~

☐☐☐ ~~31.42. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to BPC section 4059.5 is captured on video, and the video is accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days. (BPC 4059.5[g])~~

~~CORRECTIVE ACTION OR ACTION PLAN: _____~~

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## 32. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 32.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to the federal, state and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)
If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that applies to the type of program(s):

- ☐ Mail back envelopes or package service. (CCR 1776.2)
- ☐ Collection receptacles in the pharmacy. (CCR 1776.3)
- ☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

If the answer to the question above is “no” or “not applicable” go to section 33.

Yes No N/A

☐☐☐ 32.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[f])

☐☐☐ 32.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) are not collected as part of the pharmacy’s drug take-back service. (CCR 1776.1[f])

☐☐☐ 32.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 32.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed of as part of the pharmacy’s drug take-back services. (CCR 1776.1[g][3])

**Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)**

☐☐☐ 32.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])

☐☐☐ 32.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

☐☐☐ 32.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

☐☐☐ 32.9. The preaddressed envelope and package contain a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 32.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):

DEA Collector Registration Number: _____ Expiration Date: _____

Yes No N/A

☐☐☐ 32.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], [g][1])

**Pharmacies with Collection Receptacles in the Pharmacy (CCR 1776.1, 1776.3)**

Yes No N/A

☐☐☐ 32.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

☐☐☐ 32.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i][1])

Date the board was notified: _____

☐☐☐ 32.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 32.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported: _____

☐☐☐ 32.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

☐☐☐ 32.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

☐☐☐ 32.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[a])

☐☐☐ 32.19. The collection receptacle is securely fastened to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 32.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter. (CCR 1776.3[b])

☐☐☐ 32.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

**Yes No N/A**

☐☐☐ 32.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 32.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D1709 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR 1776.3[f])

- ☐ 32.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle. (CCR 1776.3[f][1], [2])
- ☐ 32.23.2. The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]
- ☐ 32.23.3. The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 32.23.4. The liner is removable as specified pursuant to CCR 1776.3.

☐☐☐ 32.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[g])

☐☐☐ 32.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling, and transport. (CCR 1776.3[h])

☐☐☐ 32.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

☐☐☐ 32.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 32.28. The pharmacy maintains records for collected unwanted drugs from consumers for three years, including the records for each liner identified in 1776(a). (CCR 1776.3[k], 1776.6[a])

☐☐☐ 32.29. The pharmacy seals the inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premises. (CCR 1776.3[l])

Yes No N/A

☐☐☐ 32.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) are not to be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

### Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 32.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or person lawfully entitled to dispose of resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 32.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the pharmacy requires the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 32.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs. (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

_____

☐☐☐ 32.34. Was the board notified in writing within 30 days of establishing a collection receptacle? (CCR 1776.4[b][2])

☐☐☐ 32.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4], [5])

☐ If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

☐☐☐ 32.36. When the pharmacy license was renewed, did the pharmacy provide ~~the list~~ a current list of collection receptacles? (CCR 1776.4[b][6])

☐☐☐ 32.37. The skilled nursing facility places patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

☐☐☐ 32.38. The collection receptacle is located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner? (CCR 1776.4[e][f][g])

**Yes No N/A**

☐☐☐ 32.39. The liner certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes, waterproof, tamper evident, tear resistant, opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 32.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 32.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 32.42. The rigid container is disposable, reusable, or recyclable. The rigid container is leak resistant, has sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 32.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) cannot be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

☐☐☐ 32.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 32.45. The installation, removal, transfer, and storage of inner liners is performed only by: (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

☐☐☐ 32.46. Sealed inner liners placed in a container are stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

☐☐☐ 32.47. Liners housed in a rigid container are delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

**Record Keeping Requirements for Board Licensees Providing Drug Take Back Services**

**Yes No N/A**

☐☐☐ 32.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 32.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

- ☐ 32.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])
- ☐ 32.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])
- ☐ 32.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])
- ☐ 32.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner

stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])

☐ 32.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~**33. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program**~~

~~Yes No N/A~~

~~☐☐☐ 33.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets all requirements as specified in the laws.: (HSC 150202, 150202.5, 150204, BPC 4169.5)~~

~~☐ 33.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (HSC 150202.5)~~

~~☐ 33.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)~~

~~Yes No N/A~~

~~☐☐☐ 33.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (BPC 4169.5)~~

~~☐☐☐ 33.3. No controlled substances shall be donated. (HSC 150204[c][1])~~

~~☐☐☐ 33.4. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])~~

~~☐ 33.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])~~

~~☐ 33.4.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])~~

~~☐ 33.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])~~

☐ 33.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

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

## 34. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 34.1. The pharmacy conducts a county-approved drug repository and distribution program. (HSC 150201[b][1], 150204)

☐ 34.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (HSC 150201[b][1])

☐ 34.1.1.1. Is county owned (HSC 150201[b][1]) or

☐ 34.1.1.2. Contracts with the county to establish a voluntary drug repository and distribution program. (HSC 150201[b][1], 150200, 150204[b][1])

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

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

Issued By: _____ Date: _____

Yes No N/A

☐☐☐ 34.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (HSC 150204[a][3])

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

Date last quarterly report was submitted: _____

☐☐☐ 34.5. The pharmacy complies with the county's established written procedures. (HSC 150204[b])

### *Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Drugs and Maintenance of Drug Stock*

Yes No N/A

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

☐☐☐ 34.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (HSC 150204[k])

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

☐☐☐ 34.9. Donated medications received are unused, unexpired and meet the following requirements: (HSC 150202, 150202.5, 150204[c])

- ☐ 34.9.1. Are received from authorized sources. (HSC 150202, 150203)
- ☐ 34.9.2. No controlled substances are received. (HSC 150204[c][1])
- ☐ 34.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (HSC 150204[c][2])
- ☐ 34.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (HSC 150204[c][3])
- ☐ 34.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 150204[d])
- ☐ 34.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (HSC 150204[i])
- ☐ 34.9.7. For donated medication that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

☐☐☐ 34.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (HSC 150204[d][1], 150204[h])

***Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Transferring Donated Drugs From One Participating Entity to Another***

~~Yes No N/A~~

☐☐☐ 34.11. The pharmacy transfers donated medication to another participating county-owned pharmacy within an adjacent county. (HSC 150204[g][4])

☐☐☐ 34.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (HSC 150204[g][4][A])

Adjacent counties to which donated medication are transferred:

_____
_____

☐☐☐ 34.13. Donated medication is not transferred by any participating entity more than once. (HSC 150204[g][4][B])

☐☐☐ 34.14. When transferring donated medication, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (HSC 150204[g][4][C])



**PIC Initials** _____

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

***Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Dispensing to Eligible Patients***

Yes No N/A

☐☐☐ 34.16. Donated medications that are dispensed to an eligible patient who presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (HSC 150204[i])

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

**PHARMACIST-IN-CHARGE CERTIFICATION:**

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

Signature _____ _____ Date
(Pharmacist-in-Charge)

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

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment 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
Pharmacy Owner or Hospital Administrator

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

- Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 3 – Clinical Laboratory Technology
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
- CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
- CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice Combat Methamphetamine Epidemic Act of 2005. Pub. L. 109-177. 120 Stat. 256.9 Mar. 2006
- Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
- HSC, Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- HSC, Division 106, Part 5, Chapter 2 – Genetic Disease Services
- HSC, Division 116 – Surplus Medication Collection and Distribution
- United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
- USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control

**California State Board of Pharmacy**
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Sacramento, CA 95833
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www.pharmacy.ca.gov

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

# HOSPITAL PHARMACY SELF-ASSESSMENT

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

**The self-assessment must be completed in its entirety. It may be completed online, printed, initialed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. Do not copy a previous assessment.**

**Notes: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, pursuant to 16 CCR 1715) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 pursuant to 16 CCR 1735.2(k).)**

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

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

Licensed Sterile Compounding License #_____ Expiration: _____

Accredited by (optional):_____ From: _____ To: _____

Centralized Hospital Packaging #: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays*_____ *Sat.*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

**Pharmacy staff (pharmacists, interns, technicians):**
APH= Advanced Practice Pharmacist, DEA = Drug Enforcement Administration.

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. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____



_____
PIC
Initials

## HOSPITAL PHARMACY SELF-ASSESSMENT

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

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

### 1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, 4117, CCR 1714)

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

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

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

☐☐☐ 1.5. The pharmacy maintains a supply of medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714[b])

☐☐☐ 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714[c])

☐☐☐ 1.8. The pharmacy sink has hot and cold running water. (CCR 1714[c])

☐☐☐ 1.9. The pharmacy has a readily accessible restroom. (CCR 1714[g])



PIC Initials

Yes No N/A

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

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

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?

(If yes, complete the Compounding Self-Assessment required by CCR 1735.2[k])

☐☐☐ 1.13. The pharmacy is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

☐☐☐ 1.15. All medicinal cannabis is stored in a locked container in the patient's room, other designated areas, or with the patient's primary caregiver and is retrieved, administered, handled, removed and disposed in accordance with HSC 1649.1, 1649.2, 1649.3, 1649.4.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 2. Nursing Stations

Yes No N/A

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

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

☐ 2.2.1. An intern pharmacist shall report any irregularities to the pharmacist. (BPC 4119.7[c])

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____



PIC Initials _____

## 3. Delivery of Drugs

Yes No N/A

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

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

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

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

☐☐☐ 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i])

☐☐☐ 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][1][A][ii])



PIC Initials

☐☐☐ 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])

☐☐☐ 3.7. ~~The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023 unit-level traceability~~. The pharmacy has lot level traceability and by November 27, 2023 will have unit level traceability in accordance with the Drug Quality and Security Act (DQSA). (21 USC 360eee-1[d][2] and 582[g][1])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

## 4. Drug Stock

**Yes No N/A**

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (21 USC sections 331, 351, 352, BPC 4169[a][2]-[4], 4342, HSC 111255, 111335, CCR 1714 (b), 22 CCR 70263[q])

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. Records of drugs taken from the drug stock or drug supplies must be maintained and the pharmacist must be notified. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales) or to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need. (BPC 4380, CCR 1710[a])

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (BPC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (BPC 4119.7[b]

☐☐☐ 4.6. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy or a manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169, CCR 1718.1)

- ☐ 4.6.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.
- ☐ 4.6.2. Are not known or reasonably should not be known to the pharmacy as being misbranded.
- ☐ 4.6.3. Are not expired.

Yes No N/A

☐☐☐ 4.7. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

☐☐☐ 4.8. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

☐☐☐ 4.9. An automated unit dose system (AUDS) operated by a licensed hospital pharmacy as defined by BPC 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility shall be exempted from the requirement of obtaining an ADDS license if the hospital pharmacy owns or leases the AUDS and owns the dangerous drugs or devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS (i.e. Security, Record keeping, Self-Assessment, Quality Assurance, etc.) and maintain a list of the location of each AUDS it operates. (BPC 4119.11[b][3], 4427.2, 4427.65)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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

Yes No N/A

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

~~(If yes, complete Section 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)~~

☐☐☐ 5.2 The pharmacy that donates medications to or operates a voluntary county approved drug repository and distribution program meets all the requirements as specified in law. (HSC 150200, 150201, 150202, 150202.5, 150203, 150204, 150204.5, 150204.6, 150205, BPC 4169.5)

~~5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202, 150202.5, 150204)~~

- ~~☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, and (HSC 150202.5)~~
- ~~☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)~~

~~☐☐☐ 5.2. No controlled substances shall be donated. (HSC 150204[c][1])~~



PIC Initials

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])

- ☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])
- ☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])
- ☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

Yes No N/A

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (HSC 150204[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (BPC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

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

☐☐☐ 6.3. Is the PIC in charge of another pharmacy?

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

If yes, name of other pharmacy _____

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101, 4330)

☐☐☐ 6.5. The PIC is not concurrently serving as the designated representative-in-charge for a wholesaler or veterinary food-animal drug retailer. (CCR 1709.1[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

## 7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. A pharmacist: (BPC 4019, 4051, 4052, 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)

- ☐ 7.1.1. Receives a chart order for an inpatient; (BPC 4019, 4051 [b], 4052, 4052.2, CCR 1717, CCR 1793.1[a])
- ☐ 7.1.2. Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- ☐ 7.1.3. Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], 4052.2[a][4], CCR 1793.1[d])
- ☐ 7.1.4. Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- ☐ 7.1.5. Calculates drug doses; (BPC 4052 [a][3], 4052.2 [a][3], 4052.2 [a][4])
- ☐ 7.1.6. Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- ☐ 7.1.7. Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e])
- ☐ 7.1.8. Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (BPC 4052, 4052.2, CCR 1793.1[g])

Yes No N/A

☐☐☐ 7.2. Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (BPC 4027, 4051, 4052, 4052.2)

- ☐ 7.2.1. Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- ☐ 7.2.2. Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052.1[a][2], [3]; 4052.2[a][2], [3])
- ☐ 7.2.3. Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])
- ☐ 7.2.4. Performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in BPC section 4052.2[d]. (BPC 4052.4)
- ☐ 7.2.5. A pharmacist may perform any aspect of any FDA-approved or authorized test that is classified as waived pursuant to the federal Clinical

Laboratory Improvement Amendments of 1988 (42 USC Sec 263a) and the pharmacist completes the testing in a pharmacy laboratory that is licensed in California as a laboratory pursuant to BPC section 1265 unless otherwise authorized in law. The pharmacist has completed necessary training as specified in the pharmacy's policies and procedure maintained in subsection be of BPC section 4119.10 and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition or disease being tested as applicable. (BPC 4052.4)

Yes No N/A

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

☐☐☐ 7.4. All pharmacists have submitted an application to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient. Upon approval, the DOJ shall release to the pharmacist or their delegate the CURES information for an individual under the pharmacist's care. (HSC 11165.1)

☐☐☐ 7.5. All pharmacists have joined the board's email notification list. (BPC 4013)

☐☐☐ 7.6 The hospital pharmacist (or pharmacy technician or an intern pharmacist if both requirements of BPC 4118.5(b) are met) shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patients if the hospital has more than 100 beds, the accurate medication profile is acquired during hospital pharmacy's hours of operation. (BPC 4118.5)

☐☐☐ 7.7. The pharmacist may initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority. (BPC 4052[a][13], [14])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 8. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 8.1 The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a])
- ☐ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a])

- ☐ 8.1.3 Initiate, adjust or discontinue drug therapy and shall promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[a][5], [b])
- ☐ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[b])
- ☐ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])
- ☐ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 9. Duties of an Intern Pharmacist

**Yes No N/A**

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (BPC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

- ☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (BPC 4119.6)
- ☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty-free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], [c], [d]; CCR 1726)

☐☐☐ 9.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

## 10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793.2, CCR 1793.7)

☐☐☐ 10.2. The ratio is not less than one pharmacist on duty for two technicians when filling prescriptions for an inpatient of a licensed health facility. (BPC 4115[f], CCR 1793.7[f])

☐☐☐ 10.3. When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[f], CCR 1793.7[f])

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

☐☐☐ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies them as a pharmacy technician or pharmacy technician trainee. (BPC 680, BPC 4115.5[e], CCR 1793.7[d])

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

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

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

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.

PIC Initials

☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.

☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

Yes No N/A

☐☐☐ 10.9. Pharmacy technician duties include the following:

☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (BPC 4119, 4115[i])

☐ 10.9.2. Seal emergency containers for use in the health care facility. (BPC 4115[i])

☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (BPC 4115[i])

☐☐☐ 10.10. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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### 11. Duties of Non-Licensed Personnel

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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## PHARMACY PRACTICE

### 12. Pharmaceutical Service Requirements

Yes No N/A

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



PIC Initials

☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
☐ 12.1.2. Repackaging and compounding records;
☐ 12.1.3. Physician orders;
☐ 12.1.4. Wards, nursing stations and night stock medications;
☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
☐ 12.1.6. Bedside medications;
☐ 12.1.7. Emergency drug supply;
☐ 12.1.8. Pass medications;
☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
☐ 12.1.10. Routine distribution of inpatient medications;
☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
☐ 12.1.12. Handling of medication when pharmacist not on duty; and
☐ 12.1.13. Use of electronic image and data order transmissions.

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

☐ 12.2.1. Destruction of controlled substances; and
☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263)

CORRECTIVE ACTION OR ACTION PLAN: _____

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**13. Medication/Chart Order**

**Yes No N/A**

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (BPC 688, 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by BPC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (BPC 688, 4019, 4040, 22 CCR 70263[g])

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. An order for controlled substance for use by a patient in a county or licensed hospital shall be in the patient's records and the record of such orders shall be maintained as a hospital record for a minimum of seven years. (HSC 11159, BPC 4081, 4105, 4333)

**Yes No N/A**

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (BPC 4119.7)

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PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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**14. Labeling and Distribution**

Yes No N/A

☐☐☐ 14.1. Unit dose medication are properly labeled and include the information as required by BPC 4076, or the information is otherwise readily available at the time of drug administration. (BPC 4076[b])

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (BPC 4126.5[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

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**15. Duration of Drug Therapy**

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

☐☐☐ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (BPC 4040, CCR 1764, Civil Code 56 et seq.)

☐☐☐ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (BPC 688, CCR 1717.4)

☐☐☐ 16.5. Records regarding dangerous drugs and dangerous devices stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. (BPC 4105, CCR 1707)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 16.6. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (BPC 4105, CCR 1707)

CORRECTIVE ACTION OR ACTION PLAN: _____

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**17. Quality Assurance and Medication Errors**

**Yes No N/A**

☐☐☐ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC 4125, CCR 1711)

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

☐☐☐ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

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

Yes No N/A

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

☐☐☐ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

- ☐ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 17.6.3. Findings and determinations;
- ☐ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

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

☐☐☐ 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with BPC 4073 (generic substitution). (CCR 1716)

☐☐☐ 17.9. The PIC is reporting the quality assurance review reports for medication errors for all ADDS to the Board at the time of annual renewal of the hospital pharmacy license. (CCR 1711[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. All completed pharmacy self-assessments are on file in the pharmacy and are maintained for three years. (CCR 1715)

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. These records include:

- ☐ 18.2.1. Prescription records (BPC 4081[a])
- ☐ 18.2.2. Purchase Invoices and sales records for all prescription drugs (BPC 4081)
- ☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 18.2.4. U.S. Official Order Forms (DEA Form-222) (21 CFR 1305.13, 21 CFR 1305.22)
- ☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05)
- ☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

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PIC Initials

☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)

☐ 18.2.8. Record documenting transfers or sales to other pharmacies, ~~and~~ prescribers, and reverse distributors. (BPC 4059, 4081, 4105, 4332, CCR 1718)

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (HSC 150200, 150202[a][1], 150204[k], BPC 4105[c]).

Yes No N/A

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Drug Supply Chain Security Act (DSCSA), BPC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, DSCSA, BPC 4160)

☐☐☐ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

☐☐☐ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

~~☐☐☐ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)~~

☐☐☐ 18.11. Any Controlled substance drug loss is reported within one business day of discovery to the DEA and within 30 days to the Board of Pharmacy the discovery of any loss of controlled substances 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: (21 CFR 1301.74[c], CCR 1715.6)

21.14.1 Tablets, capsules, or other oral medication, 99 dosage units



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PIC Initials

21.14.2. Single-dose injectable medications, lozenges, film, such as oral, Buccal and sublingual, suppositories, or patches, 10 dosages units.

21.14.3 Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers.

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

☐☐☐ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 19. Inventory Reconciliation Report of Controlled Substances

**Yes No N/A**

☐☐☐ 19.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. Inpatient hospital pharmacy reports shall include controlled substances stored within the pharmacy, within each satellite location, and within each drug storage area in the hospital (CCR 1715.65[a], CCR 1715.65[g])

☐☐☐ 19.2 The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65[b])

☐☐☐ 19.3 A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65[c])

☐ 19.3.1 A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the

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PIC Initials

biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])

- 19.3.2 A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- 19.3.3 A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- 19.3.4 All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- 19.3.5 Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

☐ 19.3.6 In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg, alprazolam 2mg, tramadol 50mg, and promethazine with codeine 6.25mg/10mg/5ml at least every 12 months. (CCR 1715.65[a][2])

☐ 19.3.7 An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the reportable loss. (CCR 1715.65)

☐ 19.3.8 Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])

☐ 19.3.9 The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file. (CCR 1715.65[e][1])

☐☐☐ 19.4 The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4104, CCR 1715.65[d], CCR 1715.6)

**Yes No N/A**

☐☐☐ ~~19.5 The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])~~

☐☐☐ 19.6 A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also



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completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

☐☐☐ ~~The inpatient hospital pharmacy shall prepare an inventory reconciliation report(s) covering the federal controlled substances for A separate inventory reconciliation report shall be required for federal Schedule II controlled substances and alprazolam 1 mg, alprazolam 2mg, tramadol 50 mg and promethazine/codeine 6.25 mg/10mg on quarterly basis. The report(s) shall include controlled substances stored within the pharmacy, within each pharmacy satellite location and withing each drug storage area in the hospital under the pharmacy's controlled. stored within the pharmacy and for each pharmacy satellite location and within each drug storage area in the hospital under the pharmacy's control. (CCR 1715.65 [g]~~

☐☐☐ ~~19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that: (CCR 1715.65[h])~~

- ~~19.8.1 All controlled substances added to an automated drug delivery system are accounted for; (CCR 1715.65[h][1])~~
- ~~19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel; (CCR 1715.65[h][2])~~
- ~~19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and (CCR 1715.65[h][3])~~
- ~~19.8.4 Confirmed losses of controlled substances are reported to the board. (CCR 1715.65[h][4])~~

☐☐☐ 19.8. The inpatient hospital pharmacy uses an ADDS, inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. (CCR 1715.65[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 20. After-Hours Supply of Medication

**Yes No N/A**

☐☐☐ 20.1 The pharmacy has a system assuring the prescribed medications are available in the hospital 24 hours a day. (22 CCR 70263[e])

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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**21. Drug Supplies for Use in Medical Emergencies**

Yes No N/A

☐☐☐ 21.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ 21.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1], BPC 4115, 4119.6))

☐☐☐ 21.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ 21.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. The inspection can be done by a pharmacy technician or pharmacy intern as defined in the pharmacy's written inspection policies and procedures. (22 CCR 70263[f][3], BPC 4115[i][3], 4119.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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**23. Emergency Room Dispensing**

Yes No N/A

☐☐☐ 23.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (BPC 4068[a])

- ☐ 23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 23.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 23.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or ~~IV~~ V controlled substance, transmits the dispensing data to the Department of Justice within one working day from the date the controlled substance is released to the patient. (HSC 11165[d])
- ☐ 23.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ☐ 23.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;
- ☐ 23.17. If an ADDS is located in the emergency room and is used for dispensing to patients upon discharge, the ADDS is licensed with the Board. (BPC 4427.2(i).

Yes No N/A

☐☐☐ 23.2. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the four required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 23.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (BPC 4068[b])

☐☐☐ 23.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (BPC 4076, CCR 1717)

☐☐☐ 23.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 23.6. Prescriptions are dispensed in new, senior-adult ease-of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15., CCR 1717)

☐☐☐ 23.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

☐☐☐ 23.8. The pharmacy provides patients with required Black Box Warning Information. (21 CFR 201.57[c])

☐☐☐ 23.9. Medication guides are provided on required medications. (21 CFR Part 208)

☐☐☐ 23.10. Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” (BPC 4076.7).

☐☐☐ 23.11. A pharmacist may dispense a drug prescribed pursuant to HSC Section 120582 and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words “expedited partner therapy” or the letters “EPT” and shall provide written notification that describes the right of an individual who received EPT to consult with a pharmacist about the medication dispensed and possible drug interactions. (BPC 4076[f], [h])

Yes No N/A

☐☐☐ 23.12. If emergency department patient dispensing is done via AUDS, the AUDS is licensed by the Board. (BPC 4427.2[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

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**24. Discharge Medication/Consultation Services**

Yes No N/A

☐☐☐ 24.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (BPC 4074, CCR 1707.2)

☐☐☐ 24.2. Prescriptions are transmitted to another pharmacy as required by law. (BPC 4072, CCR 1717[c], [f], 1717.4)

☐☐☐ 24.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the four required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 24.4. The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074 [a], [b], CCR 1744[a][1]-[7])

☐☐☐ 24.5 The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The

label may be printed on an auxiliary label affixed to the prescription container (BPC 4074[a], CCR 1744[b][1]-[6]).

☐☐☐ 24.6. The trade name or generic name and manufacturer of the prescription drug is accurately identified in the prescription record. (CCR 1717)

☐☐☐ 24.7. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (BPC 4073)

☐☐☐ 24.8. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product or can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means and is immediately retrievable in the pharmacy. (CCR 1712, 1793.7)

**Yes No N/A**

☐☐☐ 24.9. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 24.10. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473, 16 CFR 1700.15, CCR 1717)

☐☐☐ 24.11. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 24.12. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])

☐☐☐ 24.13. Medication guides are provided on required medications. (21 CFR Part 208)

☐☐☐ 24.14. Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7).

☐☐☐ 24.15. ~~Effective January 1, 2022, t~~ The pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients. (BPC 688)

☐☐☐ 24.16. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or V controlled substance, transmits the dispensing data to the Department of Justice within one working day from the date the controlled substance is released to the patient. (HSC 11165[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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**25. Central Filling of Patient Cassettes For Other Hospital Pharmacies**

**Yes No N/A**

☐☐☐ 25.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy within this state receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

☐☐☐ 25.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy:
If the answer to this and the previous question is "no" or "not applicable" go to Section 26.

☐☐☐ 25.3. Prescription information is electronically transferred between the two pharmacies. (CCR 1710[b][6])

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

☐☐☐ 25.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ 25.6. Each cassette or container meets the requirements of Business and Professions Code section 4076. (BPC 4076[b], [c], [d], CCR 1710[b][3])

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

**26. Centralized Hospital Packaging Pharmacy**

Yes No N/A

☐☐☐ 26.1 Prior to engaging in centralized hospital packaging, the pharmacy in addition to the hospital pharmacy license, has obtained a Centralized Hospital Packaging specialty license from the Board (BPC 4128.2a)

License Number: _____

☐☐☐ 26.2. The pharmacy prepares medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located within a 75-mile radius: (BPC 4128)

*Hospitals to which central packaged unit dose medications are provided:*

- ☐ 26.2.1. _____ Distance (miles): _____
- ☐ 26.2.2. _____ Distance (miles): _____
- ☐ 26.2.3. _____ Distance (miles): _____
- ☐ 26.2.4. _____ Distance (miles): _____
- ☐ 26.2.5. Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to BPC 4128.4.

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- 26.2.6. Prepares sterile compounded unit dose drugs for administration to inpatients, if each compounded unit dose drug is barcoded pursuant to BPC 4128.4.
- 26.2.7. Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

☐☐☐ 26.3. The pharmacy prepares and stores limited quantities of unit dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (BPC 4128.3)

☐☐☐ 26.4. Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded to be machine readable at the inpatient's bedside using barcode medication administrative software. (BPC 4128.4)

- ☐ 26.4.1. The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. (BPC 4128[a])
- ☐ 26.4. The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient. [BPC 4128(b)]

☐☐☐ 26.5. Any label for each unit dose medication produced by a centralized hospital packaging pharmacy displays a human-readable label that contains the following: (BPC 4128.5[a])

- 26.5.1. The date the medication was prepared.
- 26.5.2. The beyond-use date
- 26.5.3. The established name of the drug.
- 26.5.4. The quantity of each active ingredient.
- 26.5.5. The lot number or control number assigned by the centralized hospital packaging pharmacy.
- 26.5.6. Special storage or handling requirements.
- 26.5.7. The name of the centralized hospital packaging pharmacy.

**Yes No N/A**

☐☐☐ 26.6. The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])

- 26.6.1. The components used in the drug product.
- 26.6.2. The expiration date of each of the drug's components.
- 26.6.3. The National Drug Code Directory number.

☐☐☐ 26.7. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (BPC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 27. Policies and Procedures

Yes No N/A

☐☐☐ 27.1. There are written policies and procedures in place for:

- ☐ 27.1.1. Oral consultation for discharge medication to an inpatient of a health care facility licensed pursuant to HSC 1250. The assurance that each patient received information regarding each medication given at the time of discharge. (BPC 4074[e], CCR 1707.2[b][2])
- ☐ 27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects their ability to practice the profession or occupation authorized by their license. (BPC 4104[a])
- ☐ 27.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (BPC 4104[b])
- ☐ 27.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (BPC 4104[b])
- ☐ 27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in BPC 4104[c][1]-[6].
- ☐ 27.1.6. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])
- ☐ 27.1.7. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])
- ☐ 27.1.8. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)
- ☐ 27.1.9. Inventory reconciliation reporting requirements. (CCR 1715.65)
- ☐ 27.1.10. Pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility and reporting irregularities within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility. (BPC 4115[i][3])

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- ☐ 27.1.11. Intern pharmacist, under the direct supervision and control of a pharmacist, may inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])
- ☐ 27.1.12. Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided. (BPC 4119.7[a])
- ☐ 27.1.13. Storing and maintaining drugs in accordance with national standards regarding storage areas, refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. (BPC 4119.7[b], 22 CCR 70263 [c][1], [q][6])
- ☐ 27.1.14. Establishing the supply contents, procedure for use, restocking and sealing of emergency drug supply. (CCR 70263[f][1])
- ☐ 27.1.15. If applicable, dispensing, storage and records of use if bedside medications are allowed. No controlled substances shall be left at bedside. (22 CCR 70263[*l*])
- ☐ 27.1.16. The use of investigational drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interaction and symptoms of toxicity shall be available in the pharmacy and the nursing station. The pharmacist is responsible for the proper labeling, storage and distribution of such drug pursuant to the investigator's written orders. (22 CCR 70263[o]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 28. Compounding

Yes No N/A

☐☐☐ **Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment"as required by CCR 1735.2. (CCR 1735.2)**

## 29. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 29.1. The hospital pharmacy operates automated drug delivery systems that are automated unit dose systems (AUDS) for doses administered at the facility and approved services listed on the hospital's license and the ADDS is/are exempt from licensure with the board. <u>The AUDS must comply with all other requirements for an ADDS in Article 25.</u> (BPC 4427.2[i])

☐☐☐ 29.2. The hospital pharmacy operates automated drug delivery systems that are automated patient delivery dispensing systems (APDS) for doses dispensed to patients at the facility and approved services listed on the hospital's license and the ADDS is/are licensed with the board. (BPC 4427.2[a])

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☐☐☐ 29.3. If the pharmacy operates an automated drug delivery system, the pharmacist-in-charge has completed the self-assessment for automated drug delivery systems pursuant to CCR 1715. The pharmacy shall comply with all recording keeping and quality assurance requirements and maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. (BPC 4427.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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## 30. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 30.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to the federal, state and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)

If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that apply to the type of program(s):

- ☐ Mail back envelopes or package service. (CCR 1776.2)
- ☐ Collection receptacles in the pharmacy. (CCR 1776.3)
- ☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

☐☐☐ 30.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[f])

Yes No N/A

☐☐☐ 30.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) are not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

☐☐☐ 30.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 30.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed as part of the pharmacy's drug take-back services. (CCR 1776.1[g][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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### Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)

Yes No N/A

☐☐☐ 30.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])



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☐☐☐ 30.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

☐☐☐ 30.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

☐☐☐ 30.9. The preaddressed envelope and package contains a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 30.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):
DEA Collector Registration Number: _____
Expiration Date: _____

☐☐☐ 30.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], [g])

CORRECTIVE ACTION OR ACTION PLAN: _____

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**Pharmacies with Collection Receptacles in the Pharmacy/Hospital (CCR 1776.1, 1776.3)**

Yes No N/A

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

☐☐☐ 30.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i])

Date the board was notified: _____

☐☐☐ 30.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 30.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported: _____

☐☐☐ 30.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

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If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

☐☐☐ 30.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

☐☐☐ 30.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[a], [d])

☐☐☐ 30.19. The collection receptacle is securely fastened to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 30.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter or is located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle is locked so that drugs are not deposited into the collection receptacle. (CCR 1776.3[b], [c])

☐☐☐ 30.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

**Yes No N/A**

☐☐☐ 30.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 30.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR1776.3[f])

- ☐ 30.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle. (CCR 1776.3[f])
- ☐ 30.23.2 The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[g])
- ☐ 30.23.3 The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 30.23.4 The liner is removable as specified pursuant to CCR 1776.3. (CCR 1776.3[f][2])

☐☐☐ 30.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and

liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[d], [e], [g])

☐☐☐ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR 1776.3[h])

☐☐☐ 30.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

☐☐☐ 30.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 30.28. The pharmacy maintain records for collected unwanted drugs from consumers for three years, including the records for each liner. (CCR 1776.3[k], 1776.6[a])

☐☐☐ 30.29. The pharmacy seals the inner liners and their contents are shipped to a reversed distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premise. (CCR 1776.3[l])

**Yes No N/A**

☐☐☐ 30.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) shall not to be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

**Onsite Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities**

**Yes No N/A**

☐☐☐ 30.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or persons lawfully entitled to dispose of a resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 30.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 30.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs? (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.
If yes, continue answering the questions in this section.
List the location(s) of the collection receptacle:

_____
_____

☐☐☐ 30.34. The board was notified in writing within 30 days of establishing a collection receptacle. (CCR 1776.4[b][2])

☐☐☐ 30.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4], [5])

- If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

☐☐☐ 30.36. When the pharmacy license was renewed, the pharmacy provide the list a current list of collection receptacles. (CCR 1776.4[b][6])

☐☐☐ 30.37. The skilled nursing facility places a patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

**Yes No N/A**

☐☐☐ 30.38. The collection receptacle is located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, has a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner. (CCR 1776.4[e][f][g])

☐☐☐ 30.39. The liner is certified by the manufacturer to meet the American Society for Testing Materials(ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922standards for tear resistance of 480 grams in both parallel and perpendicular planes, is waterproof, tamper evident, tear resistant, and opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 30.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription

drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 30.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 30.42. The rigid container is either disposable, reusable, or recyclable. The rigid container is leak resistant, has sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 30.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) can not be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

☐☐☐ 30.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 30.45. The installation, removal, transfer, and storage of inner liners is performed only by (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

☐☐☐ 30.46. Sealed inner liners placed in a container are stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

Yes No N/A

☐☐☐ 30.47. Liners housed in a rigid container are delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

**Record Keeping Requirements for Board Licensees Providing Drug Take Back Services**

Yes No N/A

☐☐☐ 30.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 30.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

- ☐ 30.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])

- 30.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])
- 30.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])
- 30.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])
- 30.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

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 _____ (date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ _____ Date
(Pharmacist-in-Charge)

**ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:**

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment

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
(Hospital Administrator)

_____
PIC
Initials

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

- Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions
- BPC, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
- CCR, Title 22, Division 5, Chapter 1 – General Acute Care Hospitals
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
- CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
- CFR, Title 21, Chapter I, Subchapter C, Part 290 – Controlled Drugs
- CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
- CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice
- Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act
- HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
- HSC, Division 116 – Surplus Medication Collection and Distribution
- United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
- USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

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

# WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

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

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS = Wholesaler
- 3PL = Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR = Designated Representative, Designated Representative-3PL, and Designated Representative Reverse Distributor

Licensed Premises Name: _____

Address: _____

Phone: _____

Licensed Premises Email address: _____

Ownership: Please mark one

○ sole owner ○ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify) _____

License #_____ Expiration Date_____

Other License #_____ Expiration Date_____
*(Use additional sheets if needed.)*

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours ○

DRIC / RM _____

DR License # / RPH License #_____ Expiration Date_____

Website Address (optional): _____

**Other Licensed Staff (DR, pharmacist (RPH)):**

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

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

**1. Ownership/Location**

Yes No N/A

☐ ☐ ☐ 1.1. Review the current WLS/3PL license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (BPC 4160[a], [c], [f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082) **Please attach a copy of the list to this document.** (This list should be dated.)

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

☐ ☐ ☐ 1.3. Has there been a transfer of the management or control over the WLS/3PL to a person or entity who did not have management or control over the license at the time the original license was issued? Written notification to the board is required of within 30 days of the transfer (CCR 1709[b]) **Please attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.4. Is there any beneficial interest of the WLS/3PL held in a trust? (CCR 1709[d]) **Please attach a copy of the trust document and any related amendments to this document.**

CORRECTIVE ACTION OR ACTION PLAN _____

_____

**2. Facility**

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly
☐ ☐ ☐ 2.1.2. Are well ventilated
☐ ☐ ☐ 2.1.3. Are free from rodents and insects
☐ ☐ ☐ 2.1.4. Are adequately lit
☐ ☐ ☐ 2.1.5. Have plumbing in good repair

Yes No N/A

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see the standards set forth in the latest edition of the USP) (CCR 1780[b])

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

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (BPC 4167, CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs or dangerous devices are stored limited to authorized personnel? (BPC 4116, 4167, CCR 1780[c])

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

_____

_____

_____

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

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

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

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

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

Explain how your security system complies with these requirements.

_____

_____

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers, or others, by receiving, inventorying, and managing the disposition of outdated or nonsaleable dangerous drugs or dangerous devices? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices. (BPC 4163[~~(~~c]~~)~~)

Date of approval from the board: _____

☐ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

☐ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

**3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities**

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the DRIC/RM are both equally responsible for maintenance of the records and inventory of the facility. (BPC 4081[b])

☐ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the compliance with all state and federal laws for the distribution of drugs? The DRIC may be a pharmacist. (BPC 4160[d], 4053.1[b], 4053.2)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of a proposed new DRIC/RM within 30 days of the termination of the former DRIC/RM. (BPC 4160[f], 4160[g], 4331[c]) The appropriate form for this notification is available on the board's website.

☐ ☐ ☐ 3.5. The DRIC/RM who ends their employment at a licensed premises, must notify the board within 30 days. (BPC 4305.5[c], 4101[b][c]). This notification is in addition to that required of the owner.

☐ ☐ ☐ 3.6. The DRIC/RM has provided an electronic mail address to the board and shall maintain a current electronic mail address, if any, with the board and must notify the board within 30 days of any change of electronic mail address, giving both the old and new electronic mail address. (CCR 1704[b])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

**4. Ordering Drugs by this Business for Future Sale/Transfer or Trade**

Yes No N/A

☐ ☐ ☐ 4.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (BPC 4163[b], 4169)

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

☐ ☐ ☐ ~~4~~.3. For license verification, the licensed premises may use the licensing information displayed on the board's Internet web site. (BPC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

**5. Receipt of Drugs by this Business**

Yes No N/A

☐ ☐ ☐ 5.1. When drugs are received by your business, are they delivered to the licensed premises, and received by and signed for only by a DR or a pharmacist? (BPC 4059.5[a])

☐ ☐ ☐ 5.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

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

**6. Drug Stock**

Yes No N/A

☐ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

☐ ☐ ☐ 6.2. Are all drugs you order maintained in a secure manner at your licensed premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (BPC 4167)

☐ ☐ ☐ 6.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (BPC 4342[a])

☐ ☐ ☐ 6.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 6.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e][1])

☐ ☐ ☐ 6.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e][2])

☐ ☐ ☐ 6.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e][3])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

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

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

Yes No N/A

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

7.2. Describe how you verify a business or person is appropriately licensed. (BPC 4059.5[a], [b],[d],[g], BPC 4169)

_____

_____

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

_____

_____

Yes No N/A

☐ ☐ ☐ 7.4. Are drugs only furnished by your business to an authorized person? (BPC 4163[a]) Note: An authorized person can be a business or natural person.

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

☐ ☐ ☐ 7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a])

Yes No N/A

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

☐ ☐ ☐ 7.6.1. transacted with a business licensed with this board as a WLS/3PL or pharmacy?

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

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

☐ ☐ ☐ 7.6.4. **confirmed** to not be beyond their use date (expired drugs)? (BPC 4169)

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

_____

_____

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

Yes No N/A

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

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

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

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

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

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

_____

_____

Yes No N/A

☐ ☐ ☐ 7.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])

☐ ☐ ☐ 7.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)

Yes No N/A

☐ ☐ ☐ 7.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (BPC 4341, BPC 651, CCR 1766)

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

_____

_____

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

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

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

**8. Donations of Medication to Voluntary Drug Repository and Distribution Programs (HSC 150200, 150203, 150204)**

**Yes No N/A**

☐☐☐ 8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (HSC 150203, 150204)

☐☐☐ 8.2. No controlled substances shall be donated. (HSC 150204[c][1])

☐☐☐ 8.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150204[c])

- ☐ 8.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 8.3.2. Have never been in the possession of a patient or individual member of the public. (HSC 150204[c][3])
- ☐ 8.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])

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

**9. Outgoing Shipments of Drugs**

Yes No N/A

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

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

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

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

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

**10. Delivery of Drugs**

Yes No N/A

☐ ☐ ☐ 10.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (BPC 4059.5[a])

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

☐ ☐ ☐ 10.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (BPC 4059.5[c])

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

CORRECTIVE ACTION OR ACTION PLAN _____

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**11**. **Controlled Substances**

Yes No N/A

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

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

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

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

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

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

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

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

_____

_____

Yes No N/A

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

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

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

Yes No N/A

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

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

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

_____

_____

Yes No N/A

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

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

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

☐ ☐ ☐ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

Yes No N/A

☐ ☐ ☐ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received, and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a], [b], and HSC 11252, 11253)

☐ ☐ ☐ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 11.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.74[g])

☐ ☐ ☐ 11.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

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

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

☐ ☐ ☐ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency. (21 USC 832[a][3], 21 USC 802[57], 21 CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

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**12. Policies and Procedures**

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

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs

☐ ☐ ☐ 12.1.2. Security of drugs

☐ ☐ ☐ 12.1.3. Storage of drugs (including maintaining records to document proper storage)

☐ ☐ ☐ 12.1.4. Inventory of drug (including correcting inaccuracies in inventories)

☐ ☐ ☐ 12.1.5. Distributing drugs

☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 12.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 12.1.9. drugs that have been partially used

☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN _____

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**13. Training**

Yes No N/A

☐ ☐ ☐ 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

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

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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**14. Dialysis Drugs**

Yes No N/A

☐ ☐ ☐ 14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (BPC 4054, 4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ 14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (BPC 4059[d])

☐ ☐ ☐ 14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☐ 14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ 14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient's name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

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**15. Record Keeping Requirements**

Yes No N/A

☐ ☐ ☐ 15.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (BPC 4059[b])

☐ ☐ ☐ 15.2. Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☐ ☐ ☐ 15.3. Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (BPC 4081~~[a]~~, 4105[c], 4332)

☐ ☐ ☐ 15.4. Are all purchase and sales records retained in a readily retrievable form? (BPC 4105[a])

☐ ☐ ☐ 15.5. Is a current accurate inventory maintained for all dangerous drugs? (BPC 4081, 4332, CCR 1718)

☐ ☐ ☐ 15.6. If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (BPC 4105[b])

☐ ☐ ☐ 15.7. Are required records stored off-site only if a board issued written waiver has been granted?

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

Date _____ Address_____

☐ ☐ ☐ 15.9. Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

Yes No N/A

☐ ☐ ☐ 15.10. If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 15.11. Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (BPC 4105[d][2])

☐ ☐ ☐ 15.12. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

☐ ☐ ☐ 15.13. Has this licensed premises, or the designated representative-in-charge/responsible manager, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation (BPC 4162[a][5]):

_____

_____

☐ ☐ ☐ 15.14. Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (BPC 4083)

☐ ☐ ☐ 15.15. Has this licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (BPC 4315[f])

☐ ☐ ☐ 15.16. If this licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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

**16. Reporting Requirements to the Board**

Yes No N/A

☐ ☐ ☐ 16.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (BPC 4101[b], 4305.5[c].

☐ ☐ ☐ 16.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager. (BPC 4305.5[a])

☐ ☐ ☐ 16.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 16.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

☐ ☐ ☐ 16.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 16.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (BPC 4201[j], CCR 1709[b])

- ☐ 16.6.1. identify any transfer, in a single transaction or in a serious of transaction, 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 of the original license was issued
- ☐ 16.6.2. identify any transfer of the management or control over a business entity licensed by the board to a person or entity who did not have management or control over the license at the time the original license was issued
- ☐ 16.6.3. identify any new ownership and their application to the board of licensure in advance of the proposed transaction taking place

Yes No N/A

☐ ☐ ☐ 16.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (BPC 4164[a])

☐ ☐ ☐ 16.8. The wholesaler maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

- ☐ 16.8.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities
- ☐ 16.8.2. identify purchases of any dangerous drugs at preferential or contract prices
- ☐ 16.8.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (BPC 4164[b])

☐ ☐ ☐ 16.9. I understand that this license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (BPC 4201[g])

☐ ☐ ☐ 16.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver

appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 16.11. If this business requires a temporary closure, the owner must notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. (CCR 1708.1)

☐ ☐ ☐ 16.12. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☐ ☐ ☐ 16.13. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by BPC 4169.1.

CORRECTIVE ACTION OR ACTION PLAN _____

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**17. Additional Licenses/Permits Required**

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

_____

_____

**DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:**

I, (please print) _____, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). Any deficiency identified herein will be corrected by _____(Date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager (RM)

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

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

Signature _____ Date _____

**Legal References**

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov, at the California State Law Library, or at other libraries or Internet websites:

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulations (CCR), Title 16, Division 17 – California State Board of Pharmacy

Code of Federal Regulations (CFR), Title 21, Chapter 2 – Drug Enforcement Administration, Department of Justice

Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law, Chapter 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)