DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Compounded Drug Products

Sections Affected:

- **Repeal** sections 1708.3, 1708.4, 1708.5 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR)[1].
- **Amend** title of Article 4.5 of Division 17 of Title 16 of the CCR, Nonsterile Compounding.
- **Repeal and Replace** sections 1735, 1735.2, 1735.1, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, and 1735.8 of Article 4.5 of Division 17 of Title 16 of the CCR, regarding Nonsterile Compounding.
- **Add** Sections 1735.9, 1735.10, 1735.11, 1735.12, 1735.13, and 1735.14 of Division 17 of Title 16 of the CCR, regarding Nonsterile Compounding.
- **Add** Article 4.6 to Division 17 of Title 16 of the CCR, Sterile Compounding
- **Add** Sections 1736 through 1736.21 and new titles to Article 4.6 of Division 17 of Title 16 of the CCR, regarding Sterile Compounding.
- **Add** Article 4.7 to Division 17 of Title 16 of the CCR, Hazardous Drugs.
- **Add** sections 1737 through 1737.17 and new titles to Division 17 of Title 16 of the CCR, regarding Hazardous Drugs.
- **Add** Article 4.8 to Division 17 of Title 16 of the CCR, Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging.
- **Add** sections 1738 through 1738.14 and new titles to Division 17 of Title 16 of the CCR, regarding Radiopharmaceutical Preparation, Compounding, Dispensing, and Repackaging.
- **Repeal** Article 7 and sections 1751-1751.10 of Article 7 of Division 17 of Title 16 of the CCR.

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on April 19, 2024, and ended on June 3, 2024. The Board held a regulation hearing on June 18, 2024. During the 45-day comment period and at the public hearing, the Board received numerous comments.

[1] All regulatory references are to Division 17 of Title 16 of the California Code of Regulations, unless otherwise noted.

At the July 31-August 1, 2024, Board meeting, the Board reviewed the comments received and staff-recommended responses to those comments and amendments based on those comments. Following a robust public discussion, including comments from stakeholders, the Board opted to delegate to Board Members Serpa and Barker to work with the executive officer and staff to incorporate additional modifications to the proposed modified text to reflect the Board's discussion at the meeting, and present the modified text to the Board at its meeting on September 12, 2024.

At the September 12, 2024, Board meeting, the Board had another robust public discussion, including stakeholder comments. The Board opted to delay a vote on the modified text to provide additional education on compounding to the Board members, and to continue the discussion at the November Board meeting.

At the November 6-7, 2024, Board meeting, educational presentations were made by board counsel and staff on federal law and the background work on the regulations. The Board voted to approve the Board staff's recommended responses to the initial comments from the 45-day comment period and regulation hearing, as well as the updated supplemental responses, as the responses of the Board. As part of the motion, the board also approved the recommended modified regulation text dated August 29, 2024, as presented, for a 30-day public comment period, which the board felt was more appropriate than 15-days for a regulation package with such a high level of interest. They further delegated to Members Serpa and Barker the authority to review comments received to the modified text during the 30-day public comment period with Board staff to present recommended changes and responses at a future Board meeting.

The initial statement of reasons (ISR) was amended to add additional clarity specific to providing reference to the United States Pharmacopeia (USP) and federal law and identifying the additional flexibility provided by the proposed text. Furthermore, the amended ISR expanded on the estimated economic impact on businesses. Finally, the amended ISR outlined additional documents were added to the rulemaking. Specifically:

18. Guidance for Industry, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (January 2018) https://www.fda.gov/media/90986/download
19. FDA to Compounders: Know Your Bulks and Excipients Suppliers, available at https://www.fda.gov/drugs/human-drug-compounding/fda-compounders-knowyour-bulks-and-excipients-suppliers
20. Pharmacy Compounding Advisory Committee (PCAC) Information – Glutathione
    - June 8, 2022 PCAC Meeting: https://www.fda.gov/advisorycommittees/advisorycommittee-calendar/june-8-2022-meeting-pharmacycompounding-advisory-committee-meeting-announcement-06082022#eventinformation
    - Briefing document: https://www.fda.gov/media/158541/download (glutathione information is tab 2)
    - Slide presentations: https://www.fda.gov/media/159042/download
    - PCAC Minutes: https://www.fda.gov/media/149084/download

21. FDA highlights concerns with using dietary ingredient glutathione to compound sterile injectables | FDA https://www.fda.gov/drugs/human-drugcompounding/fda-highlights-concerns-using-dietary-ingredient-glutathionecompound-sterile-injectables
22. FDA warns compounders not to use glutathione from Letco Medical to compound sterile drugs | FDA https://www.fda.gov/drugs/drug-safety-and-availability/fdawarns-compounders-not-use-glutathione-letco-medical-compound-sterile-drugs
23. PCAC Information - Methylcobalamin
    - June 9, 2021 PCAC Meeting: https://www.fda.gov/advisorycommittees/updated-agenda-information-june-9-2021-meeting-pharmacycompounding-advisory-committee-meeting#event-materials
    - Briefing document - https://www.fda.gov/media/149084/download (methylcobalamin information is tab 2)
    - Slide presentation - https://www.fda.gov/media/149084/download
    - PCAC Minutes: https://www.fda.gov/media/151410/download#:~:text=Committee%20Discussion%3A%20A%20majority%20of,to%20the%20503A%20Bulks%20List
24. FDA Inspection Findings
    - La Vita Pharmacy: https://www.fda.gov/media/137497/download
    - McGuff Compounding Pharmacy: https://www.fda.gov/media/133951/download
    - ACRX Specialty Pharmacy: https://www.fda.gov/media/153655/download
    - Infusion Systems of SW Florida - https://www.fda.gov/media/107273/download
    - Carolina Infusion - https://www.fda.gov/media/163087/download
    - Cantrell Drug - https://www.fda.gov/media/112675/download
25. California Board of Pharmacy Case: McGuff Compounding Pharmacy - https://www.pharmacy.ca.gov/enforcement/fy2122/ac217176

The 30-day comment period for the modified regulation text and the amended initial statement of reasons began November 8, 2024, and concluded on December 9, 2024. During the 30-day comment period, the Board received numerous comments. At the January 8, 2025, Board meeting, following consideration of the comments received, the Board voted to approve the Board staff's recommended responses to comments received during the 30-day comment period as their own; approved the recommended second modified text for a 15-day public comment period; and delegated to Members Serpa and Barker authority to review comments received with staff to offer recommendations to the Board for consideration at a future meeting.

The 15-day public comment period for the second modified text began January 10, 2025, and concluded on January 27, 2025.

Additionally, on January 10, 2025, the following documents were added to the rulemaking file and appropriate Notice was given of the availability of the following documents:

1. U.S. Food and Drug Administration Guidance Document, Compounding Animal Drugs from Bulk Drug Substances (CVM GFI #256), Guidance for Industry (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvmgfi-256-compounding-animal-drugs-bulk-drug-substances)

2. Federal Register, Vol. 87, No. 72. Published April 14, 2022, Food and Drug Administration, Compounding Animal Drugs from Bulk Drug Substances; Guidance for Industry; Availability. (https://www.federalregister.gov/documents/2022/04/14/2022-08092/compoundinganimal-drugs-from-bulk-drug-substances-guidance-for-industry-availability)

During this 15-day comment period, the Board received comments to the second modified text. At the February 5-6, 2025, Board meeting, following consideration of the comments received, the Board voted to approve the Board staff's recommended responses to comments received to the second modified text as their own; approved the recommended third modified text for a 15-day public comment period; and delegated to Members Serpa and Barker authority to review comments received with staff to offer recommendations to the Board for consideration at a future meeting.

This 15-day public comment period for the third modified text began February 6, 2025, and concluded on February 21, 2025.

Additionally, on February 6, 2025, the following documents were added to the rulemaking file and appropriate Notice was given of the availability of the following documents:

1. U.S. Food and Drug Administration Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry (https://www.fda.gov/media/124948/download)

2. Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting. (Call E, Bill B, McLean C, Call N, Bernkopf A, Oberg C. Hazardous Drug Contamination of Drug Preparation Devices and Staff: A Contamination Study Simulating the Use of Chemotherapy Drugs in a Clinical Setting. Hosp Pharm. 2017 Sep;52(8):551-558. doi: 10.1177/0018578717722870. Epub 2017 Aug 20. PMID: 29276288; PMCID: PMC5735723.) (https://pubmed.ncbi.nlm.nih.gov/29276288/)

The Board received comments during this 15-day public comment period for the third modified text. At the March 6, 2025, Board meeting, following consideration of the comments received, the Board voted to approve the Board staff's recommended responses to comments received to the third modified text as its own; approved the recommended fourth modified text for a 15-day public comment period; and delegated to Members Serpa and Barker authority to review comments received with staff to offer recommendations to the Board for consideration at a future meeting.

The 15-day public comment period for the fourth modified text began March 6, 2025, and concluded on March 21, 2025. The Board received comments during this 15-day public comment period for the fourth modified text. At the March 26, 2025, Board meeting, the Board voted to approve the Board staff's recommended responses to comments received to the fourth modified text as its own and adopted the fourth modified text. Lastly, the board delegated to the Executive Officer to make any technical, non-substantive changes necessary or required by the control agencies to obtain approval.

The final changes to the regulatory text from the modified Initial Statement of Reasons are described below. Interim modifications that were then again modified are described in the grids summarizing the comments received to each noticed modified text included as part of this rulemaking package.

Non-substantive changes were made throughout the document to correct grammar, punctuation, and numbering as necessary. Additionally, non-substantive changes were made as needed to ensure consistent use of terminology and precise identification of documents incorporated by reference. Finally, the introduction and scope sections of Articles 4.5 through 4.8 were amended to add language specifying the articles were applicable to compounding of a CNSP, CSP, hazardous drug, or radiopharmaceutical performed by or through a licensee of the Board, consistent with Pharmacy Law statutes, and such language does not materially alter any responsibility, right, requirement, or other regulatory element of the CCR.

Article 4.5 – Nonsterile Compounding

Section 1735

1735(a) – This subsection was amended to add “as applicable” to the definition of “approved labeling.” Labeling requirements under federal law are not always applicable, meaning not all FDA-approved information will apply in all circumstances. This makes the definition clearer regarding the applicability of federal law.

1735(b) – This subsection defining “designated person” was amended to add “Nothing in this definition prohibits the PIC from also serving as the designated person.” This sentence was added to clarify that licensees have the flexibility for the pharmacist-in-charge (PIC) to serve as the designated person and it was made in response to public comment. The language also allows for the PIC to designate a different licensee to serve as the designated person.

1735(d) – This subsection defining “essentially a copy” was amended to change “determined” to “verified and documented” and “prescribing practitioner” to “pharmacist.” The Board does not have regulatory authority over the prescribing practitioner. Additionally, pharmacists are always required to verify that a prescribed medication is clinically appropriate for a patient. These changes remove the potential confusion and concern that the Board is requiring the pharmacist to make an independent determination that a compounded preparation produces that clinically significant difference.

Section 1735.1

1735.1(a) – This subsection was amended to state that nonsterile compounding performed by a pharmacy technician must be performed under “direct” supervision “and control” to mirror the statutory definition in Business and Professions Code section 4023.5 and reaffirm the that the level of supervision here requires more than indirect supervision. Direct supervision and control is required.

1735.1(b) – This subsection was struck from the language to avoid the potential overexpansion of the definition of non-sterile compounding to removing a dangerous drug from a manufacturer's bottle and placing it in a prescription vial is exempt from repackaging. Additionally, the requirement is sufficiently addressed within the USP Chapter. Relettering within the section followed.

1735.1(c) [initially subsection (d)] – This subsection was amended to change “as is necessary” to “it is necessary” and relocate it within the sentence to clarify that the “necessity” applies to the CNSP being prepared and stored in advance of the receipt of a patient specific prescription to ensure patient continuity of care, and not just to the quantity prepared. The change is nonsubstantive.

1735.1(d)(2) [initially subsection (e)(2)] – This subsection related to furnishing to a veterinary office for veterinary patients was amended to change the 7-day supply limitation, or up to 14 days for an antibiotic, to allow for a “14-day supply for an individual patient” and then added “an individual patient” at the end of the sentence. This change was made after consideration of public comment and after communication with an expert in veterinary practice who confirmed the need for some limitations on the volume of compounding while balancing the duration of treatment. As amended a 14-day supply may be provided to a veterinary patient irrespective of the type of compounded drug prescribed, antibiotic or otherwise.

1735.1(e)(1)(A) [initially subsection (f)(1)(A)] – This subsection related to the exceptions to the general prohibition against compounding a nonsterile drug that is “essentially a copy” of a commercially available drug was amended to add “Drug Shortage List” after American Society of Health-System Pharmacists (ASHP) as it was inadvertently omitted initially. The actual name of the list is necessary to appropriately reflect the full name of the reference licensees may use when considering if something is a copy. Additionally, “within 60 days of the end of the shortage” was added to allow a transition period from the time of the end of the shortage to ensure access to the medication. Finally, as manufacturers or wholesalers may run out of critical medications, the inability to procure medications may contribute to a heightened risk and safety concerns for in-patients. Because of this, the Board added language to allow a health care facility to compound as follows: “in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained.”

1735.1(e)(1)(B) [initially subsection (f)(1)(B)] – This subsection related to the exceptions to the general prohibition against compounding a drug that is “essentially a copy” of a commercially available drug was amended to change “determines” to “verifies” as the pharmacist should be verifying that the preparation produces a clinically significant difference but is not required make an independent determination, consistent with the amendment to section 1735(d). Additionally, the Board removed the requirement that could have potentially required two pharmacists to make independent determinations of a clinically significant difference. This requirement was removed following comments from the public and Board policy discussions.

1735.1(e)(2) [initially subsection (f)(1)(B)] – This subsection related to the general restrictions to compounding was amended to clarify that it applies to “veterinary” populations, which was previously implied with the reference to Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA). Additionally, as AMDUCA may not provide the level of detail needed for licensees, to ensure the regulated public understands the requirements for compounding veterinary medications, the following was added “When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compound shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.” The FDA developed and published GFI # 256, which serves as a list of active pharmaceutical ingredients permissible for use in compounding medications for animal patients. GFI 256 is intended to provide clarity to veterinarians and pharmacists about compounding from APIs. The Board underscores that pharmacists must exercise clinical judgment in determining what is appropriate, including in compounding for veterinary patients. This amendment was made after public comment and conferring with an expert in this area.

1735.1(g) [initially subsection (h)] – This subsection regarding patient consultation was amended to remove “shall be provided to the patient and/or patient’s agent concerning” because it is duplicative of language contained in section 1707.2(a) pertaining generally to consultations. Additionally, this language was added: “A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge compounded medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications that meets the requirements of Business and Professions Code Section 4074.” These exemptions to consultation for compounded medications were added to mirror the exemptions contained in section 1707.2(b)(2) regarding consultations with an inpatient of a healthcare facility and inmates in correctional or detention facilities.

1735.1(h) [initially subsection (i)] – This subsection regarding nonsterile preparations with human blood or blood derivatives was amended to change “prepared” to “compounded” for consistency within the regulatory text.

1735.1(i) [new] – This subsection regarding flavoring agents was added in the second modified text: “A facility that limits its compounding to combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of a prescriber, patient, or patient’s agent shall be exempt from the requirements established in subdivision (f) and Sections 1735.2 – 1735.13. A facility that performs any other form of nonsterile compounding at any time is not exempt as provided in this subdivision.” Adding a flavoring agent to a conventionally manufactured nonsterile product is considered compounding within USP chapter 795. Accordingly, initially the Board did not consider including any exemptions

to the nonsterile compounding requirements when the sole act of compounding was adding a flavoring agent. Many pharmacies, however, perform no other compounding other than adding a flavoring agent to such a product (which includes adding a flavoring agent to a reconstituted prescription pursuant to FDA-approved labeling). After consideration by the Board, it determined that compliance with the USP Chapter was sufficient when the sole act of compounding involves the adding of a flavoring agent as specified in the language. There are no exemptions to those requirements, however, for a pharmacy that performs any other type of nonsterile compounding at any time because of the higher risk involved, and because those pharmacies should already be in compliance with the requirements.

Section 1735.2

1735.2 – The opening paragraph was amended to mirror the opening paragraph of the other sections within the Article and changed from “In addition to the standards in the USP Chapter 795, the compounding of CNSP shall meet the following requirements of this article.” to “In addition to the standards in USP Chapter 795, the following requirements apply to nonsterile compounding.”

1735.2(a) – This subsection regarding training and competency procedures amended the reference to personnel with direct “oversight” to refer to personnel with direct “supervision and control” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision encompasses direct supervision and control as it is defined in statute. Additionally, “verifying, and/or handling a CNSP” was changed to “or verify compounding preparations” to remove the requirement for training by individuals who are just handling the completed compounded preparation. Those individuals only handle the finished compound, so the training would not be relevant to their task.

1735.2(b) – This subsection regarding demonstrating proficiency was stricken because it is sufficiently addressed within the USP Chapter. Relettering within the section followed.

1735.2(b) [initially subsection (c)] – This subsection regarding failing any aspect of training and evaluation amended the reference to personnel with direct “oversight” to refer to personnel with direct “supervision and control” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of a pharmacy technician encompasses direct supervision and control as it is defined in statute. Additionally, the language was amended to prohibit personnel who specifically fail any aspect of the training and evaluation “related to the USP Chapter 795’s core competencies” from being involved in compounding until being successful in the deficient areas. This language focuses the training requirements on those core competencies, as these are essential to performing compounding. The amendments also delete the prohibition of and now allow for the “oversight of the preparation” to continue in the event of failing any aspect of training and evaluation related to the core competencies. This allows for the continuation of oversight activities while retraining and competencies are reestablished ensuring continuity of patient care, while such retraining and competencies are performed.

Section 1735.3

1735.3(a) – This subsection regarding personnel with certain infections or other medical conditions entering the compounding area was amended to strike the following language: "Prior to admitting any personnel into a compounding area, the supervising pharmacist shall evaluate whether compounding personnel is experiencing any of the above conditions following: [rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition] …" and replace it with "Facilities shall require individuals entering the compounding area to report to the supervising pharmacist if they have [rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection, or any other medical condition] …." Additionally, "("contaminating condition")" was deleted at the end of the sentence and "per the facility's SOPs" was added there. These amendments place the requirement to report possible contaminating conditions on the staff in the manner set out in the standard operating procedures (SOPs) so that the supervising pharmacist is not required to inspect the staff involved in compounding. This reporting requirement must be included in the facility's SOPs to ensure that staff are aware of the requirement and follow the procedures.

1735.3(c) – This subsection relating to garb was amended to change the term "staff" to "personnel" for consistency throughout the Article. Additionally, the language was amended to change "All garb removed during a shift" to "Gowns intended for reuse during the shift" as garbs that are being disposed of and not reused would not need to remain in the compounding area. The language was amended in response to comments received and to provide clarity consistent with the recommendations from the public.

1735.3(e) – This subsection relating to the cleaning of garb and equipment was amended to change the term "Non-disposable" to "Reusable" to mirror the term used in USP. Additionally, the term "and equipment" was added after "garb" to ensure that all reusable items (e.g., goggles) are cleaned in the same way. Finally, amendments ensure that reusable items are cleaned and sanitized "at least daily and before use by different personnel to avoid the risk of cross contamination." "Before re-use" was deleted for grammatical reasons since the subsection now refers to reusable garb and equipment. Any reuseable gowns must be laundered, per the facility's SOPs before reuse" was added. This reminds licensees to launder gowns as their facility has outlined to minimize the risk of cross contamination.

Section 1735.4

1735.4(b) – This subsection regarding water for rinsing was amended to add "or higher quality water" to allow for additional types of water to be utilized for rinsing equipment and utensils, provided it is of higher quality than what had already been included (purified, distilled, or reverse osmosis water).. USP identifies various grades of water, including in Section 4.3 of the Chapter. The quality of water is of great significance for patient safety. For example, tap water may be contaminated with fungus, bacteria, and other elements that could contaminate the equipment or utensils used to prepare CNSPs and cannot be used under these requirements.

Section 1735.6

1735.6(a) – This subsection regarding compounding equipment was amended to add "where established by the manufacturer" after the reference to manufacturer's specifications to acknowledge that a manufacturer does not always establish specifications for its compounding equipment.

Section 1735.7

1735.7(c) – This subsection regarding a compounding record was amended to add that it shall be "maintained and, upon request, produced as" a single document to clarify the initial text that the compounding record shall be produced as a single document. The Board noted that the information that comprises a compounding record may be stored in different locations; when requested, however, the compounding record must be produced for the Board and include all of the required information in a single document. The Board needs to be able to easily review all the required information together for individual compounded preparations and not have to guess or wade through unrelated documents that are not part of the record.

1735.7(c)(1) – This subsection related to the beyond use date (BUD) was stricken. The Board noted that the Chapter requires the record to include the date and time compounding began, and provides that the BUD is determined from the date and time that the preparation of the CNSP is initiated. Given the specificity in the Chapter, the Board deleted subsection (c)(1) from the proposed text. Renumbering within the subsection followed.

1735.7(c)(3) [initially subsection (c)(4)] – This subsection relating to the elements of a compounding record was amended to add "or amount" after quantity to provide more clarity as to how preparation may be measured. Additionally, "where applicable" was added at the end of the phrase related the measurement of each unit to clarify that not each preparation will be made up of units. While the Board's regulation text is technologically neutral, the Board is aware of software that includes the ability to identify the quantity and such software/technology is commonly used.

1735.7(c)(4) [initially subsection (c)(5)] – This subsection relating to the elements of a compounding record was amended to change "each person" to "personnel" for consistency throughout the Article. Additionally, "the person" with supervision was changed to "the pharmacist" for clarity as the term "person" was too vague and it will always be a pharmacist supervising. Furthermore, the reference to the person with "direct oversight" was amended to read "direct supervision and control" to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of a pharmacy technician encompasses direct supervision and control as it is defined in statute. Finally, "if different" was added after the reference to the pharmacist verifying the final drug preparation, because it may or may not be the same pharmacist with direct supervision and control. This ensures both individuals are identified, if they are different.

Section 1735.8

1735.8 – This subsection related to responsibility for the quality of the preparation was amended to add “the dispensing pharmacist” as a responsible party along with the pharmacist performing or supervising the compounding. A grammatical change was made for consistency. This change was necessary because the dispensing pharmacist must review and be responsible for the information on the patient's label. In addition, the language “provided the patient or the patient’s agent follows the label instructions provided on the CNSP for storage and handling after receiving the CNSP” was replaced with “so long as label instructions for storage and handling are followed after the preparation is dispensed.”. Integrity, strength, and quality can be impacted by improper storage and handling, which the pharmacy personnel will have no control over once the compounded drug product is dispensed.

Section 1735.9

1735.9(a) and (b) – These subsections regarding labeling of a CNSP were amended to add the term “also” to clarify that the items included in each subsection are in addition to the requirements of the USP Chapter and other labeling requirements, such as Business and Profession Code section 4076 and section 1707.5 of the regulations.

1735.9(c) – This subsection referring to other legal requirements for labeling was struck from the regulation text as unnecessary. CNSPs are drugs, so all the labeling requirements specified in BPC section 4076 and section 1707.5 apply.

Section 1735.10

1735.10(a) – This subsection related to beyond-use dates (BUDs) was amended to add “(23:59)” to reinforce the expiration time in the 24-hour clock format. This amendment was made in response to public comment.

1735.10(b)(3) – This subsection was amended to specify that a BUD may not exceed certain expiration dates “unless allowed by USP Chapter 795” to align with any exceptions provided in the USP.

1735.10(c) – This subsection regarding antimicrobial effectiveness testing was rewritten for ease of reading to add that testing must be compliant with USP Chapter 51, Antimicrobial Effectiveness Testing if provided by an FDA-registered drug establishment or outsourcing facility. If such testing is used, the rewritten section requires that the test in its entirety shall be readily retrievable; this added to the initial requirement that if relying upon current published peer-reviewed literature sources, the reference shall be readily retrievable. This amendment ensures that any testing is conducted in accordance with the requirements of USP and that the completed reference or test is readily retrievable, depending on what is used. For consistency the term “testing” was added to the first instance phrase “antimicrobial effectiveness,” to mirror the language in the subdivision.

Section 1735.11

1735.11(a)(2)(B) – This subsection related to a facility's SOPs handling of infectious materials was amended to add "If applicable," to clarify that procedures must only be included where applicable. If the facility is not dealing with infectious materials, the information within the subsection is not required.

1735.11(a)(2)(D) – This subsection regarding complying with other requirements in the article was stricken as it is redundant. Relettering within the subsection followed.

1735.11(a)(2)(D) [initially subsection (E)] – This subsection regarding shipping containers and transportation of CNSPs was amended to add "as applicable" in two places to clarify that such procedures must only be included where applicable. If the facility is not storing or transporting CNSPs, the information is not required.

1735.11(a)(2)(E) [initially subsection (F)] – This subsection was added: "The pharmacist responsible for the review of all complaints related to a potential quality problem with a CNSP in the event the PIC is not available within 72 hours of the receipt of the complaint or occurrence." Generally, the pharmacist in charge (PIC) is responsible for reviewing any complaint related to a potential quality problem or the occurrence of a potential quality problem with a CNSP within 72 hours. The added language is necessary to ensure that a pharmacist is identified within the SOPs to review a complaint about a potential quality issue or an occurrence of a potential quality problem timely should the PIC not be available.

1735.11(a)(2)(F) [initially subsection (G)] – This subsection was added: "Actions to be taken if the compounding area or equipment is rendered unusable or in a downtime situation." The added language is necessary to ensure the facility has procedures in place in the event of equipment failure or other condition making the compounding area unusable. Standard operating procedures are needed so that staff are aware of actions they must take in the event of an equipment failure.

1735.11(b) – This subsection regarding reviewing and updating the SOPs and documenting such was amended to require that documentation of compliance is maintained for three years. The Board determined three years is appropriate as it is consistent with other similar provisions of pharmacy law.

Section 1735.12

1735.12(a) – This subsection regarding a facility's quality assurance program was amended for grammatical simplicity. In addition, what was initially subsection (a)(1) was amended to remove "scheduled" before the word "action" as recalls or standards outside of expectations are not scheduled and happen unexpectedly.

1735.12(a)(2) – This subsection was stricken as existing regulations (section 1714(b)) require all pharmacies to ensure that medications are "safely and properly maintained and secured,"

which includes ensuring that proper temperatures are maintained. Because of the deletion, subsection (a)(1) was re-lettered as subsection (a).

1735.12(b) – This subsection was amended to change “72” to “96” hours for the time in which to notify the Board about potential quality problems involving a CNSP to provide additional flexibility for licensees while the facility reviews the possible quality problem. Additionally, “or the occurrence of an adverse drug event” was stricken as a conforming change to align with federal law.
1735.12(c) – This subsection regarding initiating a review of a complaint of a potential quality problem was amended from beginning with “All complaints” to begin with, “Consistent with the facility’s SOPs, a review shall be initiated of any complaints made to the facility” related to a potential quality problem with a CNSP within 72 hours of receipt of the complaint. This amendment requires facilities as part of their quality assurance programs to timely review complaints about potential quality problems and reminds them that any review must be completed consistent with their SOPs. Additionally, the review of “or occurrence of the adverse drug event” was stricken as a conforming change to align with federal law.

Section 1735.14

1735.14(b) – This subsection regarding documentation was amended to delete the first use of the word “created” as redundant. Additional amendments changed “to” [provide an audit trail] to “that will” [provide an audit trail] and added that records must be maintained “for at least three years from the date the record was created, modified, or relied upon,” and changed “the” changes to “all” changes. Lastly, identifying the individual who made “the” change was amended to “each” change in the last sentence. Consistent with other areas of pharmacy law, the Board determined that the records should be maintained for three years. Additionally, all changes need to be maintained, and the person who made each change to ensure a transparent audit trail.

Section 1735.15

1735.15 – This section was added in the second modified text and titled “Flavoring Agents” to establish requirements for facilities that limit nonsterile compounding activities to solely adding flavoring agents as specified. The section reads as follows:

(a) In addition to the standards in USP Chapter 795 and section 503a (21 U.S.C. §353a) of the Federal Food, Drug, and Cosmetic Act (FDCA) a facility that limits its compounding as described in Section 1735.1(i) shall establish the following SOPs:
(1) Provisions of accommodations as described in Personnel Preparation, Section 3.1 of USP Chapter 795.
(2) Provisions for cleaning and sanitizing designated compounding area when in use.
(3) Provisions to ensure documentation is available and maintained confirming that the quality of the medication is not impacted by adding the flavoring agent.
(4) Provisions for maintaining the elements of the compounding record to ensure information is readily retrievable upon request.
(5) Provisions to ensure the prescription label includes information that a flavoring agent was added.

(6) Provisions to ensure documentation is available to support the establishment of a BUD.

(7) Provisions for reporting to the Board the facility's receipt of a complaint of a potential quality problem involving the CNSP. At a minimum the provisions shall require notification to the Board within 96 hours of receipt of a complaint.

(b) A pharmacist may compound by combining a flavoring agent with a prescribed FDA approved drug in an oral liquid dosage form at the request of the patient or patient's agent without consultation with the prescriber or the prescriber's authorized agent. A pharmacist performing such compounding must document the compounding in the prescription or compounding record.

As discussed above in subsection 1735.1(i), adding a flavoring agent to a conventionally manufactured nonsterile product is considered compounding within USP chapter 795. While facilities that limit their compounding to adding flavoring as described in that subsection are exempt from many of the other regulations governing nonsterile compounding, the Board determined that their SOPs must still include procedures to ensure patient safety, specifically procedures that ensure quality, adequate documentation, and reporting to the Board complaints consistent with other CNSPs. The Board's proposal provides maximum flexibility for facilities to determine how to meet the USP Chapter through their SOPs.

Article 4.6 – Sterile Compounding

Section 1736

1736 – The opening paragraph of this section relating to definitions used within the sterile compounding article was amended to add "for compounded sterile preparations (CSPs)" at the end of the sentence. The amendment ensures consistent use of terminology throughout the Article and improves readability.

1736(a) - This subsection defining "compounding personnel" amended the reference to personnel with "oversight" to "direct supervision and control" to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of a pharmacy technician encompasses direct supervision and control as it is defined in the statute. Additionally, "compounding process" was amended to "preparation of CSPs" for consistency within the regulations and within the USP.

1736(b) – This subsection defining "designated compounding area or compounding area" was amended to limit access to the area to only "personnel" to clarify that the compounding area is a restricted location that limits access to mitigate environmental contamination.

1736(c) – This subsection defining "designated person(s)" was amended to add with respect to the required professional judgment "of a pharmacist" to clarify whose professional judgment the regulation refers to if the designated person is not a pharmacist. Additionally, the following sentence was added to clarify that the pharmacist-in-charge has the option to assign themselves to be the designated person: "Nothing in this definition prohibits the PIC from also serving as the designated person."

1736(e) – This subsection defining “essentially a copy” was amended to change “determined” to “verified and documented” and by the “prescribing practitioner” to “pharmacist.” The Board does not have regulatory authority over the prescribing practitioner. Additionally, pharmacists are always required to verify that a prescribed medication is clinically appropriate for a patient. These changes remove the potential confusion and concern that the Board is requiring the pharmacist to make an independent determination that a compounded preparation produces that clinically significant difference.

1736(g) – This subsection defining “quality” was amended to remove from the meaning, “the degree to which the components and preparation meets the intended specifications, complies with relevant law and regulation, and means” for consistency with the definition of “quality” related to nonsterile preparations in section 1735(f).

Section 1736.1

1736.1 – The opening paragraph was amended to make grammatical changes for ease of reading and for consistency throughout the regulation. Specifically, the opening now reads, “In addition to the standards set forth in USP Chapter 797 and section 503a (21 U.S.C. §353a) of the Federal Food Drug Cosmetic Act (FDCA) the following requirements apply throughout this article,” which is consistent with the structure in section 1735.1.

1736.1(a) – This subsection was amended to change that sterile compounding occurs under the “supervision” to under the “direct supervision and control” of a pharmacist for to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision encompasses direct supervision and control as defined in statute.

1736.1(b) – This subsection related to immediate use provisions of a compounded sterile preparation (CSP) was amended and split into subsections (b)(1) and (b)(2). Subsection (b)(1) retains the content of subsection (b) and was amended first to add at the beginning of the subsection: “Except as allowed in paragraph (2),” to note that subsection (2) contains exceptions and outside of those, the requirements within (b)(1) apply. Additionally, the third sentence setting out the required elements for documentation was amended to begin: “If not already documented in the patient’s medical record,” and the last sentence was amended to remove “may be available in the patient’s record and.” These changes were made to avoid unnecessary duplication of the information that must be documented. The “identification of the CSP” and “number of units compounded” were stricken as the specific compounding must be limited to the quantity necessary for the immediate need. Finally, the USP chapter number was inserted for clarity.

Subsection 1736.1(b)(2) – This subsection also related to immediate use provisions was added to allow all facilities in limited circumstances a short period of time in which to use the provisions without the showing that loss of life or intense suffering of a patient could result that is required in subsection (b)(1). Specifically, if sterile compounding equipment or the environment fail and the facility is not able to remediate the failure(s) after following their

SOPs to try to do so, they may compound a CSP for immediate use for the next 48 hours. The Board considered a shorter time of 24 hours but determined that a 48-hour period was more reasonable and allowed for greater patient access to needed medications. In addition, a suggestion to increase the allowable time to use such provisions as permitted for critical access hospitals in subsection (b)(3) was rejected because critical access hospitals face unique needs not faced by other facilities. The subsection was further amended to require that the facility report to the Board any failures requiring the immediate use provisions within 72 hours of transitioning to their use to ensure the Board's ability to timely track any abuses of this provision.

1736.1(b)(3) -- This subsection also related to immediate use provisions was added to allow critical access hospitals in limited circumstances a period of time in which to use the provisions without the showing that loss of life or intense suffering of a patient could result that is required in subsection (b)(1). Specifically, if sterile compounding equipment or the environment fail and the hospital is not able to remediate the failure(s) after following their SOPs to try to do so, a critical access hospital may compound a CSP for immediate use for the next 120 hours. The Board considered determined that a 120-hour period was more reasonable and allowed for greater patient access to needed medications because of the unique circumstances faced by critical care hospitals. The subsection was further amended to require that the facility report to the Board any failures requiring the immediate use provisions within 72 hours of transitioning to their use to ensure the Board's ability to timely track any abuses of this provision.

1736.1(d) – This subsection related to compounded sterile preparations being furnished to a veterinary office amended "compounded drug preparation" to "CSP" to ensure consistency of terminology throughout the Article.

1736.1(d)(2) – This subsection related to compounded sterile preparations being furnished to a veterinary office was amended to change a "120-hour" supply to "7-day" supply after consultation with veterinary experts informed the Board's policy that a longer period allowed for greater flexibility and greater patient safety and added "for an individual patient" to ensure that the 7-day supply is for a specific veterinary patient. Subsection (d)(2)(A) was amended to insert the word "Chapter" before 797 because it had been inadvertently omitted.

1736.1(e)(1)(A) - This subsection related to the exceptions to the general prohibition against compounding a sterile drug that is "essentially a copy" of a commercially available drug was amended to add "Drug Shortage List" after American Society of Health-System Pharmacists (ASHP) and "of drugs" was added after "Database" as it was inadvertently omitted initially. The actual name of the list is necessary to accurately reflect the full name of the reference licensees that may be used when considering whether something is a copy. Additionally, as manufacturers or wholesalers may run out of critical medications, the inability to procure medications may contribute to a heightened risk and safety concerns for in-patients. Because of this, the Board added language to allow a health care facility to compound as follows: "in a health care facility licensed pursuant to Health and Safety Code Section 1250 where the drug product cannot be obtained from the manufacturer or wholesaler and documentation is maintained.

1736.1(e)(1)(B) – This subsection related to the exceptions to the general prohibition against compounding a sterile drug that is “essentially a copy” of a commercially available drug was amended to change “the preparation produces a clinically significant difference” to “The pharmacist verifies and documents that” [the preparation produces a clinically significant difference], as the pharmacist must verify that the compounded preparation produces a clinically significant difference. The Board considered using “determines” that the preparation produces a clinically significant difference but changed it to “verifies and documents” as pharmacist must verify a clinically significant difference but is not required make an independent determination of such, consistent with the amendment to section 1736(e). The pharmacist must also document that the compounding produces a clinically significant difference within pharmacy records to support the reasoning that the preparation was compounded. Additionally, the Board removed the requirement that could have potentially required two pharmacists to make independent determinations of a clinically significant difference. This requirement was removed following comments from the public and discussions with the Board.

1736.1(e)(2) – This subsection related to the general restrictions to compounding was amended to clarify that it applies to “veterinary” populations, which was previously implied with the reference to Animal Medicinal Drug Use Clarification Action of 1994 (AMDUCA), by changing the term “patient” to “veterinary”. Additionally, as AMDUCA may not provide the level of detail needed and to ensure the regulated public understands the requirements for compounding veterinary medications, the following was added “When a veterinarian, acting within a valid veterinarian-client-patient relationship (VCPR), determines there is no medically appropriate human or animal drug that is FDA-approved, conditionally approved, or indexed to treat the animal, a pharmacy may use a bulk drug substance to compound an animal drug. This compounding shall be in compliance with the Center for Veterinary Medicine Guidance for Industry #256 – Compounding Animal Drugs from Bulk Drug Substances issued August 2022.” The FDA developed and published GFI # 256, which serves as a list of active pharmaceutical ingredients permissible for use in compounding medications for animal patients. GFI 256 is intended to provide clarity to veterinarians and pharmacists about compounding from APIs. The Board underscores that pharmacists must exercise clinical judgment in determining what is appropriate, including in compounding for veterinary patients.

1736.1(e)(3) – This subsection related to the restriction on compounding a CSP with a non-sterile component was amended to remove “and appropriate for the intended CSP” and add “unless the CSP master formula supports such use and is appropriate for the intended CSP.” The Board considered requiring that such compounding of a CSP with a non-sterile component be either in full compliance with USP Chapter 797 Category 3 requirements or the sterile component was in short supply. Rather, however, these amendments provide flexibility for pharmacists to use their clinical judgment to determine under which USP Category the CSP must be prepared. A pharmacist, using professional clinical judgment, will be responsible for determining the USP category. Pharmacists must remain knowledgeable of the industry's current practice standards and legal requirements while exercising their professional judgment.

1736.1(g) - This subsection regarding patient consultation was amended to remove “shall be provided to the patient and/or patient’s agent concerning” because it is duplicative of language contained in section 1707.2. Additionally, “includes” was added prior to the enumerated elements of a consultation for grammatical clarity.

1736.1(g) – This subsection was added and reads, “A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge compounded medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications that meets the requirements of Business and Professions Code Section 4074.” These exemptions to consultation for compounded medications were added to mirror the exemptions contained in section 1707.2(b)(2) regarding consultations with an inpatient of a healthcare facility and inmates in correctional or detention facilities.

1736.1(h) – This subsection regarding sterile preparations with human blood or blood derivatives was amended to add this sentence: “This shall not apply to the compounding of an FDA-approved human whole blood or human whole blood derivative product.” This addition was added in response to public comment to clarify that it does not apply to any human whole blood or human whole blood derivative that is already FDA-approved and manufactured. This is consistent with FDA guidance in this area.

Section 1736.2

1736.2(a) - This subsection regarding training and competency procedures amended the reference to personnel with direct “oversight” to refer to personnel with direct “supervision and control” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of pharmacy technicians encompasses direct supervision and control as it is defined in statute. Additionally, “compounding personnel” was changed to “personnel performing compounding” for greater clarity as some personnel may not perform compounding duties.

1736.2(b) – This subsection related to aseptic manipulation training and competency documentation amended the competencies that may be used from one premises to another. “Aseptic qualifications” that may be used for another premises now reads “Garbing and hand hygiene competencies and aseptic manipulation competencies” from one premises may be used for another premises. This is to provide additional clarification regarding the transferring or allowance for the necessary hand hygiene and garbing competencies (observational competency and gloved fingertip and thumb sampling) under specified conditions. Such provisions help reduce costs by leveraging competencies from one compounding area to another similar area as specified.

1736.2(d) – This subsection regarding failing any aspect of aseptic training and evaluation amended the reference to personnel with direct “oversight” or “oversight over” to refer to personnel with direct “supervision and control of” in three instances to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision encompasses direct supervision and control as it is defined in statute. An additional amendment removed “oversight of the preparation” from the first sentence. This change allows for the individual to continue oversight of staff performing the compounding for a limited time if they fail competency evaluation. The second sentence of the subsection was amended to increase that allowable direct supervision and control after failing competency evaluation from a period of 14 to 30 days. This allows for additional time for the pharmacist to complete the necessary training and competency evaluations while still providing supervision to staff.

Section 1736.3

1736.3(a) and (b) – These subsections related to allowing personnel into the compounding area amended the term “overseeing” to “supervision and control of” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision encompasses direct supervision and control as it is defined in statute.

1736.3(c) – This subsection regarding donning garb and gloves was amended to add “With the exception of sterile gloves,” at the beginning of the first sentence. Additionally, “Sterile gloves shall be donned in a classified room or SCA.” was added. These changes are consistent with USP, which requires that sterile gloves be donned in a classified room or SCA.

Section 1736.4

1736.4(e) – This subsection related to airflow was struck from the regulation text. The Board determined that the language was not necessary as the requirement in subsection 1736.4(d) was adequate to control the airflow between compounding areas.

1736.4(e) [initially subsection (f)] – This subsection prohibiting compounding in the event of a failure in the environment was amended to add “unless such compounding is being performed consistent with immediate use provisions.” This addition is necessary for consistency to allow for immediate use compounding, as specified in section 1736.1(b).

Section 1736.5

1736.5(a) – This subsection was amended to add “October” to the CETA revision date. This addition was made to match the associated revision date specified on the document. This is a nonsubstantive change as it is the only version of the document published within the year.

Section 1736.6

1736.6(a) – This subsection was struck from the regulation text. In response to comments to the modified text, the Board determined that air and surface sampling monitoring, as required by the USP Chapter, was sufficient, and this requirement was removed from the regulation text. As a result, there are no longer subsections within section 1736.6

1736.6(b) – This subsection regarding environmental sampling was amended into a single paragraph and is no longer subsection (b) due to subsection (a) being deleted. Additionally, the Controlled Environment Testing Association's Certification Application (CETA) Guide, incorporated by reference, was amended to reference the correct version and title of the CETA guide that applies to this section. CETA guidelines establish an industry-based minimum set of criteria appropriate for performance evaluation and certification of facility and environmental controls used for compounding sterile preparations. This minimum set of criteria are necessary to ensure consistent and repeatable testing at all facilities.

Section 1736.9

1736.9(b) – This subsection regarding incubators was amended to add this sentence: "Temperatures must be monitored either manually or by a continuous recording device during incubation, and the results shall be reviewed and documented as described in the facility's SOPs." This addition was made for consistency between Articles 4.6 and 4.8 related to the use of incubators.

1736.9(d) – This subsection regarding components in a compound was amended to remove "and excipient components" in two instances. The regulation text only applies to active pharmaceutical ingredients (APIs) and not excipient (inert) components. A grammatical change of adding "An" [API] was made as a result. An excipient is not expected to cause a pharmacological response as, ideally, they are pharmacologically inactive, and, as such, do not need to be held to the same rigorous requirements as an API related to Certificate of Analysis (COAs).

1736.9(e) – This subsection regarding sterile compounding components was amended. Initially, the text required that a bulk drug substance or API used to compound be FDA approved unless authorized by a public official in an emergency use situation for a patient-specific compound. The subsection was ultimately replaced with this language: "All APIs and other components used must be evaluated for suitability for use in sterile drug preparations, as provided in USP 797, Section 9.3 Components, and follow the USP drug monograph if one exists. Components labeled with "not for pharmaceutical use,", "not for injectable use,", "not for human use" or other equivalent statement must not be used to compound for these purposes." While a pharmacist must evaluate any component for suitability, the Board adopted this approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards, as the most appropriate and flexible. The Board determined that this approach is necessary to preserve access to compounded preparations using bulk substances currently under evaluation by the FDA.

1736.9(f) – This subsection regarding sterile compounding with bulk substances was amended. As set out above, initially the text in subsection (e) required that a bulk drug substance or API used to compound be FDA approved unless authorized by a public official in an emergency use situation for a patient-specific compound. The Board received comments to the earlier versions, however, that such a limited exception was contrary to patient health in that it did not allow sufficient access to certain bulk drug substances that have not been FDA approved. The subsection was ultimately replaced with this language: "If a component included on the published 503A Category 1 bulk substances list is used, it must be found suitable for sterile drug preparations following USP Chapter 797, Section 9.3 Components. The facility's SOPs must establish a process to determine the quality of the API." The Board adopted this approach that relies on a pharmacist's knowledge of compounding, including an understanding of federal law, guidance documents, and the national standards, as the most appropriate and flexible. The Board had considered an approach that permitted the use of bulk drug substances if they were nominated for inclusion on the FDA list in 21 CFR section 216.23(a) and if they had undergone stability testing and their use was supported by the stability data obtained from that testing. The Board determined that it's approach in the adopted regulation text is necessary to preserve access to compounded preparations using bulk substances currently under evaluation by the FDA.

Section 1736.10

1736.10 – The beginning statement of this subsection related to sterilization was amended to add "where applicable" to the end of the sentence. This addition clarified that not all requirements will apply in every instance. The applicability will depend on the serialization method being used.

1736.10(f) – This subsection was amended to delete "/or" for clarity, as all supplies and container-closure systems must follow the same sterilization process of USP Chapter 1229. It is not an either/or situation, as such, the use of "/or" was not appropriate.

Section 1736.11

1736.11(c) – This subsection regarding a compounding record was amended to add that it shall be "maintained and, upon request, be produced as a" single document to clarify the initial text that the compounding records shall be produced as a single document. The Board noted that the information that comprises a compounding record may be stored in different locations; when requested, however, the compounding record must be produced for the Board and include all of the required information in a single document. The Board needs to be able to easily review all the required information together for individual compounded preparations and not have to guess or wade through unrelated documents that are not part of the record. This addition mirrors the language in section 1735.7.

1736.11(c)(1) – This subsection use date (BUD) was stricken. The Board noted that the Chapter requires the record to include the date and time compounding began, and provides that the BUD is determined from the date and time that the preparation of the CSP is initiated.

Given the specificity in the Chapter, the Board deleted subsection (c)(1) from the proposed text. Renumbering within the subsection followed.

1736.11(c)(4) [initially subsection (c)(5)] – This subsection relating to the elements of a compounding record was amended to change “each person” to “personnel” for consistency throughout the Article. Additionally, “the pharmacist” replaced “that” to clarify which individual has direct oversight and it will always be a pharmacist supervising. Furthermore, the reference to the person with “direct oversight” was amended to change “oversight” to “direct supervision and control” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of a pharmacy technician encompasses direct supervision and control as it is defined in statute. Finally, “if different” was added after the reference to the pharmacist verifying the final drug preparation, because it may or may not be the same pharmacist with direct supervision and control; this ensures both individuals are identified, if they are different.

Section 1736.12

1736.12(a), (b), and (c) – These subsections related to responsibility for testing were amended to change a pharmacist “supervising sterile compounding” to “who has direct supervision and control of compounding personnel” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of a pharmacy technician encompasses direct supervision and control as it is defined in statute.

Section 1736.13

1736.13(a) – This subsection related to labeling was amended to add the term “also” before “include all of the following” to clarify that the items included in each subsection are in addition to the requirements of the USP Chapter.

1736.13(a)(2) – This subsection related to label information was amended to remove “if applicable” and add “For CSPs administered by infusion” at the beginning of the sentence as the Board determined that the label only needs to include the solution utilized if the CSP is administered through infusion. This specificity provides clarity on when the information is needed and “if applicable” then became redundant.

1736.13(a)(3)(A) – This subsection related to instructions was amended to remove “an admixed” [CSP] and add CSP’s “administered by infusion” as the Board determined that the label only needed to include the instructions for administration if the CSP is administered through infusion. Additionally, this sentence was added: “A health care facility licensed pursuant to Health and Safety Code Section 1250 may reference the patient’s chart in lieu of rate of infusion when a patient’s condition requires a variable rate.” This addition allows for flexibility in operationalize the requirements depending on the functionality and integration of their electronic medical record (EMR) systems.

1736.13(b) – This subsection related to labeling for CSPs that are dispensed was first reworded for clarity as “The label for a”[ny CSP] was moved to the beginning of the subsection as the information is required of the CSPs dispensed or ready to be dispensed. This sentence was also added: “A CSP that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility, or a juvenile detention facility shall be labeled with the patient’s name, the directions for the use of the drug, and the date of issuance, but is otherwise exempt from these requirements.” These exemptions to the labeling were added as the medication is being administered to the patient in a health care facility and not being dispensed to the patient.

Section 1736.14

1736.14(a)(1)(A) – This subsection regarding establishing a beyond-use date (BUD) was moved within the subsection from (a)(1)(A) to (a)(3). This relocation was made as the language was originally put in the wrong location of the text. An exemption for the use of pH adjusters is included in the USP Chapter in certain circumstances when establishing a BUD.

1736.14(b) – This subsection regarding BUDs was amended to add “(23:59)” to reinforce the expiration time in the 24-hour clock format. This change was made in response to public comment.

1736.14(c) – This subsection regarding sterility and endotoxin testing was rewritten and amended for clarity. As rewritten, the first sentence deleted “Prior to furnishing a CSP,” and added: “When sterility or endotoxin testing is required, the pharmacist performing or with direct supervision and control of personnel compounding is responsible for ensuring such testing is performed.” When sterility testing is required in the Chapter to establish a BUD for the compounded preparation, and this subsection clarifies who is responsible to ensuring it has been completed. Additionally, “must” was changed to “shall” for consistency in how the terms are used; however, this change does not have a regulatory effect.

Section 1736.17

1736.17(a)(2)(B) – This subsection related to standard operating procedures (SOPs) was amended to add “If applicable” to the beginning of the subsection as it is specific to infectious materials and not all facilities may compound or handle infectious materials.

1736.17(a)(2)(C) – This subsection related to SOPs for approving components of CSPs was amended consistent with the changes to section 1736.9(f) regarding compounding bulk substances. The Board considered specific SOPs requiring specific testing of bulk substances (subsection 1736.17(a)(2)(E), now deleted), but ultimately determined that the SOPs shall define the types of tests that must be performed incompliance with the Chapter and Federal guidance. The Board determined that it’s approach in the adopted regulation text is necessary to preserve access to compounded preparations using bulk substances currently under evaluation by the FDA.

1736.17(b) – This subsection related to SOPs if areas fail to meet standards was amended to add after classified area “including PEC,”. This addition is necessary so that the facility has SOPs established in case the PEC fails to meet the appropriate ISO classification. A second sentence was added and reads, “This subsection shall also include actions to be taken if the compounding area or equipment is rendered unusable or in downtime situations.” Standard operating procedures are needed so that staff are aware of actions they must take in the event of an equipment failure.

1736.17(d) – This subsection related to cleaning equipment was amended to change “dwell” [time] to “contact” [time] to mirror the USP Chapter that refers to “contact time.” Additionally, the requirement to include “how dwell time will be monitored and documented” was amended to read “the method to ensure contact time is achieved.” As the methods that facilities use may vary, the Board is not mandating specific technology on how to monitor dwell time, rather that the dwell time must be monitored and documented.

1736.17(f) – A new subsection was added as (f) and the prior (f) was moved to (h), and re-lettering resulted after that. The new subsection reads, “The SOPs shall specify which pharmacist is responsible for the review of all complaints related to a potential quality problem with a CSP and all adverse drug experiences in the event that the PIC is not available within 72 hours of the receipt of the complaint or occurrence.” SOPs must identify who is responsible for reviewing complaints if the PIC is unavailable so that staff know who to speak with and the pharmacist knows that they must perform the review. Failure to have someone assigned could lead to complaints not being reviewed timely, which could result in patient harm if there is, in fact, a quality issue.

1736.17(h) [prior subsection (f)] – This subsection related to reviewing the SOPs was amended to include the following: “Documentation of compliance with the subdivision shall be maintained for three years.” The Board determined three years was appropriate as it is consistent with other areas of pharmacy law.

Section 1736.18

1736.18(a) – This subsection related to a quality assurance program was amended to add the “facility’s quality assurance” before “program” for additional clarity with respect to what “program” the Board is referring to in this section.

1736.18(a)(1) – This subsection was amended to remove “scheduled” before the word “action” as recalls or standards outside of expectations are not scheduled and happen unexpectedly.

1736.18(b) – This subsection regarding recalls was amended to change adverse “event” to adverse “drug experiences, as defined in 21 CFR 310.305(b),” to ensure that recalls and adverse drug experiences are reported appropriately according to federal law. Additionally, “must” was changed to “shall” for consistency in how those terms are used in the regulations; however, this change does not have a regulatory effect.

1736.18(c) – This subsection related to complaints was rewritten from “all” [complaints made to the facility related to a potential quality problem with a CSP and] “all” adverse “events” to the “pharmacist-in-charge shall initiate a review of any” [complaints related to a potential quality problem] and “any” adverse “drug experience” within 72 hours of the receipt of the complaint or occurrence. This allows for flexibility to complete the complaint investigation beyond the 72 hours, as long as the review is initiated within that time. Additionally, the change from adverse “events” to adverse “drug experiences” was made to align with federal law.

Section 1736.19

1736.19 – This subsection regarding CSP packaging materials was amended to remove “contamination, degradation, and adsorption” as the requirements are specified with the USP Chapter. Minor grammatical changes were also made as a result.

Section 1736.20

1736.20 – This subsection related to documentation was amended to remove the first reference to the term “created” for grammatical purposes as it is duplicative. Additionally, the subsection was modified to add “, for at least three years from the date the record was created, modified, or relied upon,” in the second sentence regarding prior versions of each record. Consistent with other areas of pharmacy law, the Board determined that the records should be maintained for three years. Lastly, “the” was added before “individual who made the change” as a minor grammatical edit that ensures a transparent audit trail.

Section 1736.21

1736.21 – This section was amended to change “sterile compounding” to “allergenic extracts” in the opening sentence as the requirements of this section are very specific in the type of compounding being performed.

1736.21(a) – This subsection was amended to add “allergenic extract compounding area (AECA) or” to the places where such compounding maybe performed. It was further modified to remove “No other CSP may be made in this PEC.” This limitation was replaced with this: “No other CSP may be made in this PEC at the same time allergenic extract compounding is occurring. Work surface of the PEC must be cleaned and disinfected immediately after allergenic extract compounding.” This amendment was made to align with the requirements of the USP Chapter.

1736.21(b) – This subsection was amended to remove “and the conditions limited to Category I and Category 2 CSPs as specified in USP Chapter 797” for consistency with USP Chapter 797 and to conform to the changes made in subsection (a).

1736.21(c) – This subsection related to stock allergy solutions was stricken from the regulatory text as the USP Chapter does not allow compounding allergenic stock solutions.

Article 4.7 – Hazardous Drugs

Section 1737

1737 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in sections 1735 and 1736. The new paragraph reads, “In addition to the requirements in United States Pharmacopeia (USP) General Chapter 800 (USP Chapter 800), Hazardous Drugs – Handling in Healthcare Setting, this article applies to the compounding of Hazardous Drugs (HDs) or crushing or splitting tablets or opening capsules of antineoplastic HDs.” As initially noticed, this section applied to the “handling” of hazardous drugs; however, the scope of regulation text was narrowed to remove “handling” and replaced with “compounding of Hazardous Drugs.” The Board is focusing on the safety of the drug products and not employee safety, which is under the purview of Cal/OSHA (Division of Occupational Safety and Health). The Board added “crushing or splitting tablets or opening capsules of antineoplastic HDs” because performing these functions also requires compliance with the USP Chapter and the regulations to ensure patient safety by reducing the risk of cross contamination. Even if the facility is not compounding HDs, there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing “other manipulations included in Table 1 of the Chapter” but instead thought identifying the functions was clearer and easier for licensees to understand.

The section was divided into two subsections. Subsection (a) contains the originally proposed language requiring compliance with the article as well as non-sterile and sterile compounding requirements as applicable.

New subsection (b) was added and reads, “Additional safety and health requirements are included in the California Code of Regulations, Title 8, and are enforced by the Division of Occupational Safety and Health.” This addition serves as a reminder to licensees of the additional requirements under the purview of Cal/OSHA. This ensures that licensees are aware that additional requirements exist to protect employees and aligns with a statutory requirement under Labor Code 144.8 for Cal/OSHA to develop a regulation for the safe handling of anti-neoplastic drugs. This amendment was made as a result of written comments received from Cal/OSHA.

Section 1737.1

1737.1 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in sections 1735 and 1736. The new paragraph reads, “In addition to the requirements in USP Chapter 800, the following requirements apply to the compounding of Hazardous Drugs.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

Additionally, this section regarding patient consultation was amended to change “providing consultation in compliance with” to “the provisions in” and to remove “shall be provided to the patient and/or patient’s agent concerning” because this language is duplicative of language

contained in section 1707.2(a) pertaining generally to consultations. The words “included” and “compounded” were added to the first sentence to clarify that consultation includes, in addition to other requirements, handling and disposal of hazardous drugs and only applies to those that were compounded. A further addition provides: “A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge compounded medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge compounded medications that meets the requirements of Business and Professions Code Section 4074.” These exemptions to consultation for compounded medications were added to mirror the exemptions contained in section 1707.2(b)(2) regarding consultations with an inpatient of a healthcare facility and inmates in correctional or detention facilities.

Section 1737.2

1737.2 - The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.2(a) – This subsection related to a list of a facility’s hazardous drugs (HDs) was amended to remove the authority of the designated person to review and approve the facility’s list of HDs. This amendment was necessary as the PIC, professional director of a clinic, or the designated representative-in-charge are the individuals solely responsible for operational compliance. As such, it is appropriate for only those three individuals to approve the facility’s HD list. In addition, this sentence was moved from the end of the initial paragraph when the remainder of the paragraph was split off into subsection 1737(a)(1), described below: “Approval shall be documented at least every 12 months.”

1737.2(a)(1) – This is a new subsection, split off from prior subsection (a) to address the activities of the designated person, and “In a pharmacy,” was added at the beginning, to make clear that the paragraph only applies to pharmacies. Additionally, as it is common for multiple people to assume the responsibilities of the designated person and to align with sections 1735 and 1736, which define the designated person(s) as “one or more individuals,” reference to “a single individual” was stricken.

Section 1737.3

1737.3 - The opening paragraph of this section was amended and rewritten to mirror the opening paragraph within other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP Chapter 800, the following requirements apply to a facility that compounds HDs or crushes or splits tablets or opens capsules of antineoplastic

HDs." The Board added "crushes or splits tablets or opens capsules of antineoplastic HDs because performing these functions also requires compliance with the USP Chapter and the regulations to ensure patient safety. Even if the facility is not compounding HDs, there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing "other manipulations included in Table 1 of the Chapter" but instead thought identifying the functions was clearer and easier for licensees to understand.

Additionally, the second paragraph was amended to strike "Each premises where HDs are handled" and add "Any facility where compounding of HDs is performed or where crushing or splitting tablets or opens capsules of antineoplastic HDs is performed." The Board determined that it was necessary to broaden the description of functions and added "crushing or splitting tablets or opening capsules of antineoplastic HDs" because there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing "other manipulations included in Table 1 of the Chapter" but instead thought identifying the functions was clearer and easier for licensees to understand.

Section 1737.4

1737.4 - The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, "In addition to the standards in USP Chapter 800, the following requirements apply to the compounding of HDs or performing crushing or splitting tablets or opening capsules of antineoplastic HDs." The Board added "crushing or splitting tablets or opening capsules of antineoplastic HDs because, if the facility is not compounding HDs, there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing "other manipulations included in Table 1 of the Chapter" but instead thought identifying the functions was clearer and easier for licensees to understand.

Section 1737.5

1737.5 - The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, "In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed. A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.5(c) – This subsection regarding a containment secondary engineering control was stricken from the regulation as a result of a change in the building standards. This ensures consistency between the Board's regulations and the California Building Standards Code, California Code of Regulations, Title 24.

1737.5(c) [initially subsection (d)] – This subsection related to pass-throughs was amended from providing “Where a pass-through door is installed or replaced in a secondary engineering control” to “Where there is a pass-through in a containment secondary engineering control (C-SEC),” in order to align with the requirements of the USP Chapter. Additional changes removed “[OAL insert effective date] the door shall be a HEPA purge type” to “the doors must be gasketed and interlocking by January 1, 2027.” Further, the Board established a delayed implementation for requiring interlocking doors to allow facilities to develop the process to operationalize the requirements by a date certain.

1737.5(d) – This subsection was added and reads, “On or after January 1, 2028, prior to installing a new pass-through, a facility shall consider the use of a HEPA purge type pass-through. Documentation shall be maintained showing compliance with this requirement if such a pass-through is not used.” The Board added this evaluation to ensure that facilities consider HEPA purge-type pass-throughs. While the Board and USP do not require this type of pass-through, consideration should be given as they protect against particle contamination. This is especially important when transferring materials between ISO-classified and unclassified areas to maintain a controlled environment and prevent contamination.

1737.5(e) – This subsection regarding pressure monitoring equipment was amended to add “Where sterile hazardous compounding is performed” at the beginning of the sentence and strike “and air changes per hour” for consistency with the requirements within CETA Guidelines CAG-003:2022. Additionally, this subsection was amended to add “October” to the CETA revision date. This addition was made to match the associated revision date specified on the document. This is a nonsubstantive change as it is the only version of the document published within the year.

Section 1737.6

1737.6 - The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.6(a) – This subsection was amended and is no longer labeled (a) since subsection (b) was deleted as described below. The section regarding environmental wipe sampling was amended from requiring the SOPs of a premises where HDs are handled to address environmental wipe sampling including frequency, areas of testing, levels of measurable contamination to now read, “The premises shall consider environmental wipe sampling. SOPs shall describe the consideration of and provisions for environmental wipe sampling for HD surface residue. Nothing in this section is intended to require the use of environmental wipe sampling.” The Board amended the language to provide clarity on the intent of the language. The Board notes that the proposed regulation does not require a facility to perform environmental wipe sampling with any specified frequency. The proposed text requires the facility to develop SOPs that include provisions for the consideration of the use of wipe

sampling for their specific facility. It is incumbent upon the PIC (or their designated person) to use their professional judgment to determine when or if wipe sampling occurs and under what conditions.

1737.6(b) – 1737.6(b)(4) – These subsections regarding procedures when contamination is found have been stricken from the regulation text. As a result of the clarifying changes in subsection (a) and the clarification that wipe sampling is not required, the requirements within subsection (b) are no longer necessary.

Section 1737.7

1737.7 – The opening paragraph of this section regarding personal protective equipment (PPE) was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.7(a) and (b) – These subsections regarding chemotherapy gloves were stricken from the regulation text as the requirements are generally covered in the USP Chapter and some of the requirements specifically fall under the purview of Cal/OSHA. Additionally, the Board decided that the requirements established in subdivision (a) and (b) were more directed at personnel safety, which is generally the purview of Cal/OSHA. The Board’s regulations focus on patient and product safety. Re-lettering within the section followed.

1737.7(a) [initially subsection (c)] – This section regarding outer gloves was amended to delete that they shall be “changed between each different HD preparation” to read that they shall be “carefully removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC as established in USP 800 Section 7.6.” This amendment aligns the regulation text with the language from the USP Chapter, as specified. The Board considered requiring that they be changed between each different HD preparation unless the preparations were of the same drug, or different drugs for the same patient. In response to a number of comments received regarding the potential cost impact associated with changing of gloves, the Board decided on language more closely in step with language from the USP Chapter.

1737.7(b) [initially subsection (d)] – This subsection regarding removing PPE was amended for clarity. The proposed text was amended to change PPE “shall be removed” [to avoid transferring contamination] to say PPE “removal process shall be done in a manner” [to avoid transferring contamination]. Additionally, “Outer” was added to the second sentence to describe the PPE to be disposed of. This addition clarifies that the PPE worn when compounding HDs, specifically, the outer layer, must be disposed of consistent with the requirements of the USP Chapter, which states “Consider all PPE worn when handling HDs to be contaminated with, at minimum, trace quantities of HDs. PPE must be placed in an appropriate waste container and further disposed of per local, state, and federal regulations.

PPE worn during compounding should be disposed of in the proper waste container before leaving the C-SEC."

Section 1737.8

1737.8 – The opening paragraph of this section regarding hazard communication programs was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, "In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed." A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

The section was further amended from providing that the designated person shall "develop" [the premise's hazardous communication program] to provide that the designated person shall "be involved in" [the premise's hazardous communication program] to clarify that the designated person must be involved in the facility's hazardous communication plan but does not necessarily need to be the specific individual who develops the plan. Comments received noted that depending on the type of facility, e.g. a hospital, a committee may be response for developing the communication program. The Board's proposed regulation ensure that the designated person is involved in the process.

Section 1737.9

1737.9 – The opening paragraph of this section regarding personnel training was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, "In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs." The Board added "crushing or splitting tablets or opening capsules of antineoplastic HDs is performed" because even if the facility is not compounding HDs, there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing "other manipulations included in Table 1 of the Chapter" but instead thought identifying the functions was clearer and easier for licensees to understand.

1737.9(b) – This subsection regarding personnel evaluation and training was amended from referring to personnel who "handle" or are "handling" HDs to those who "compound" or are "compounding" HDs as ongoing training and evaluation is relevant to those compounding, but not necessarily to those just handling the finished product. The Board added "or crushing or splitting tablets or opening capsules of antineoplastic HDs" and "or perform crushing or splitting tablets or opening capsules of antineoplastic HDs" because there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to "other manipulations" but instead thought identifying the functions was clearer and easier for licensees to understand. Additionally, to mirror the competency requirements throughout all compounding articles, "Any failure in personnel competency shall comply with the provisions of sections 1735.2(c)

or 1736.2(d), as applicable." was added to this subsection. Including this cross reference improves clarity on the requirements for personnel when there is a failure of competency.

Section 1737.10

1737.10 – The opening paragraph of this section related to receiving HDs was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, "In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed." A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

Additionally, the section was amended to change referring to all HD APIs and antineoplastic HDs "shipped and received from" to "transported by" to clarify that the requirements apply to suppliers of HD APIs and antineoplastic HDs, as pharmacies may have limited control over how products are transported from the supplier.

Section 1737.11

1737.11 – The opening paragraph of this section related to labeling, packaging, transport and disposal was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, "In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding of HDs is performed." A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.11(a) – This subsection was amended to add "The label for" to the beginning of the first sentence to clarify that the subsection is specific to the label requirements. Additionally, a second sentence was added and reads, "A compounded HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility, or a juvenile detention facility shall be labeled with the patient's name, the directions for the use of the drug, and the date of issuance, but is otherwise exempt from these requirements." This exemption was added because inpatients and inmates have this medication administered to them and the medication is not directly dispensed to them.

1737.11(b) – This subsection regarding transportation was amended to delete "HD APIs and" from the requirements to only all "compounded" antineoplastic HDs as this subsection applies to a pharmacy compounding antineoplastic HD products (primarily chemotherapy drugs) and not distributors of all other HD APIs. APIs are distributed from a supplier and covered by 1737.10. Additionally, the requirement for the label was amended to specifically state "Hazardous Drugs" instead of "HD." Lastly, "unless the label is visible through the outer container" was added to clarify that a second label is not required if the hazardous label is available through the outer container.

1737.11(c) – This subsection was added and reads, “When furnishing a compounded antineoplastic HD for administration within a health care facility licensed pursuant to Health and Safety Code section 1250, the HD shall be placed in a plastic container and labeled as a hazardous drug on the outside of the container or with a label that is visible through the outer container.” This addition clarifies that those compounded antineoplastic HDs that will be administered to patients must still be labeled as a hazardous drug to ensure that it is understood that it is an HD product during administration. This requirement was in section 1737.14(a)(1) in the initial proposed text related to administering, but the Board determined that is more appropriate in this section.

Section 1737.12

1737.12 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP 800, the following requirements apply to a facility where compounding of HDs is performed.” A return was added after the opening sentence for ease of reading the requirement. A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

Section 1737.13

1737.13 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP 800, the following requirements apply to a facility where compounding of HDs is performed.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.13(a) – This subsection regarding compounding mats was amended from requiring that “A disposable preparation mat shall be placed on the work surface of the C-PEC when compounding HD preparations” to requiring that “If a disposable preparation mat is used for compounding a CSP it must be sterile and it must be changed immediately if a spill occurs, after each different HD preparation unless multiple preparations of the same drug or for a single patient is occurring, and at the end of the daily compounding activity.” In response to public comment expressing concern about cost impacts, the Board determined that the use of a disposable preparation mat should not be mandated, which is consistent with the USP Chapter. This amendment added “unless multiple preparations of the same drug or for a single patient is occurring” from the initial requirement to clarify that a mat can continue to be used if the HD preparations are for a single patient or if the HD preparations use the same drug. This provides flexibility for facilities to continue using mats under specific conditions while preserving patient protections and establishing a minimum threshold to prevent cross contamination.

1737.13(b) – This subsection allowing only one HD preparation to be handled in a C-PEC at a time was amended to add “, unless the multiple HD preparations are of the same drug, or are multiple HD preparations for a single patient.” This addition aligns this subsection with the amendment made in subsection (a). This provides flexibility for facilities to operationalize their

processes to allow for the compounding multiple HD preparations that are of the same drug or a single patient without a risk of cross-contamination.

Section 1737.14

1737.14 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP 800, the following requirements apply to a facility where compounding of HDs is performed.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

1737.14(a) – This subsection requiring that when “dispensing an HD to a patient or patient’s agent” [for administration] the “pharmacy” [shall] was amended to to requiring that when “furnishing an infused compounded antineoplastic HD” [for administration] the “facility” [shall] and deleted “to a patient or patient’s agent,” as the section is specific to administering substances, which are not dispensed. Additionally, “infused” was added for specificity as not all antineoplastic HDs are infused and the regulation text does not apply to non-infused products. These amendments were made to be consistent with the USP Chapter, which is focused on antineoplastics and the use of CSTDs (closed-system drug-transfer device), specifically related to administration.

1737.14(a)(1) – This subsection was stricken as the language was relocated to subsection 1737.11(c) as described above.

1737.14(a)(2) – This subsection was deleted as its own subsection and edited to be consistent with and combined with subsection (a).

1737.14(b) – This subsection requiring when “furnishing an antineoplastic HD” [a sufficient supply of gloves that meet the ASTM D-6978 standard must be provided] was amended to require when “dispensing a compounded antineoplastic HD to a patient or patient’s agent, the pharmacy shall provide, or offer for purchase, a sufficient supply of ASTM D-6978 standard chemotherapy gloves to allow for appropriate handling, and disposal of the HD. A compounded antineoplastic HD preparation that is administered to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code is exempt from this requirement.” Specifically, amending the term “furnishing” to “dispensing” clarified that chemotherapy gloves needed to be provided or offered for purchase when compounded antineoplastic HDs are dispensed to a patient or patient’s agent. The term furnishing is too broad a term for when the patient or patient’s agent receives the preparation for self-administration. Additionally, language specifically allowing the pharmacy to offer gloves for purchase was added to clarify that the requirement to provide gloves means the pharmacy can charge for any or all pairs. Finally, a health care facility licensed pursuant to section 1250 of the Health and Safety Code that is administering the preparation to an inpatient is exempt from this requirement as the inpatient is not taking the preparation with them for private home use and will not need gloves to handle it.

Section 1737.15

1737.15 – The title of this section was amended to change the term “Deactivation” to “Deactivating” for grammatical clarity, as “deactivating” is a verb tense. The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.” The Board added “crushing or splitting tablets or opening capsules of antineoplastic HDs” because, if the facility is not compounding HDs, there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing “other manipulations included in Table 1 of the Chapter” but instead thought identifying the functions was clearer and easier for licensees to understand.

1737.15(a) – This subsection related to cleaning agents of all types used in accordance with manufacturers’ specifications was amended to add “, or subsequent manufacturer approved studies.” This addition is necessary to provide flexibility in the use of a specified agent, based upon emerging manufacturer’s scientific studies that would support such use.
1737.15(b) – This subsection related to cleaning agents of all types used in areas involved in HD handling was amended to delete HD “handling” and add “compounding of” HDs and “or performing crushing or splitting tablets or opening capsules of antineoplastic HDs.” This addition makes the language consistent throughout the article where there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to “other manipulations” but instead thought identifying the functions was clearer and easier for licensees to understand. Additionally, “and shall not be applied or delivered to the wipe by use of a spray bottle to avoid spreading HD residue” was removed as it is specified with the USP Chapter and does not need to be duplicated here.

1737.15(c) – This subsection was stricken from the language as the requirement is already included in the SOP section of the regulation text.

Section 1737.16

1737.16 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP 800, the following requirements apply to a facility where compounding of HDs is performed.” A similar narrowing of the language was made to refer to compounding of hazardous drugs instead of handling for the reasons identified above.

Additionally, the section regarding spill control was amended to remove the first sentence that provided: “The premises shall maintain a list of properly trained and qualified personnel able to clean up an HD spill.” Instead, the SOPs must outline how a person qualified to clean up HD spills will be available when HDs are compounded. As the regulation text was narrowed to apply to compounding HDs, the Board determined that having an SOP that outlines how a

qualified person will be available is appropriate. Such an approach provides flexibility to a facility to determine the best means to ensure a qualified person is available. In that sentence, the word “such” [a qualified person] was deleted because there is no longer the list in the first sentence that “such” refers back to. In addition, an amendment replaced while HDs are “handled” while they are “compounded.”

Section 1737.17

1737.17 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, and 1737. The new paragraph reads, “In addition to the standards in USP Chapter 800, the following requirements apply to a facility where compounding HDs is performed or where crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.” The Board added “crushing or splitting tablets or opening capsules of antineoplastic HDs because, if the facility is not compounding HDs, there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to performing “other manipulations included in Table 1 of the Chapter” but instead thought identifying the functions was clearer and easier for licensees to understand.

1737.17(a) – This subsection related to SOPs was amended to remove “Any premises engaged in the compounding or handling of HDs” [shall maintain and follow written SOPs] and replaced with “A facility” [shall maintain and follow written SOPs] “for all situations in which HDs are compounded or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed.” The Board added this language to be more specific about what situations the SOPs are to cover. The Board considered referring to “other manipulations” but instead thought identifying the functions was clearer and easier for licensees to understand. Additionally, “handling” was removed as it is too broad.

1737.17(b) – This subsection related to SOPs was amended to replace “The SOPs for compounding or handling of HDs shall” [include the list that follows] with “A facility where compounding of HDs is performed or where or crushing or splitting tablets or opening capsules of antineoplastic HDs is performed shall have SOPs that” [include the list that follows]. The Board added “crushing or splitting tablets or opening capsules of antineoplastic HDs because, if the facility is not compounding HDs,” there is still a safety risk associated with airborne particles that may be produced when crushing or splitting tablets or opening capsules. The Board considered referring to “other manipulations” but instead thought identifying the functions was clearer and easier for licensees to understand. Additionally, “handling” was removed as as it is too broad.

1737.17(b)(3), (4), (5), (11), (14), (15), (16) – These subsections regarding the elements of the SOPs were amended to add “if compounding” to clarify that the SOPs must include that specific information only if compounding. The information would not apply outside of compounding. Additionally, “manipulation” was added to 1737.17(b)(8) as manipulation under USP refers to activities like crushing tablets and opening capsules, so including hand hygiene and use of PPE for this activity in the SOPs would be necessary.

1737.17(c) – This subsection regarding review of SOPs was amended to change “entity’s” to “facility’s” to ensure consistent use of the terminology throughout the Articles. “HD handling” was removed as the SOPs are specific to compounding. Finally, “Documentation of compliance with the subdivision shall be maintained for three years” was added as the Board determined three years was appropriate as it is consistent with other areas of pharmacy law.

1737.17(d) – This subsection was amended to remove “handling” as the SOPs are specific to compounding.

Article 4.8 – Radiopharmaceutical- Preparation, Compounding, Dispensing, and Repackaging

Section 1738

1738 – The opening paragraph of this section regarding definitions was amended and rewritten to mirror the format of the opening paragraphs in sections 1735, 1736, and 1737. The new paragraph reads, “In addition to the terms defined in United States Pharmacopeia (USP) General Chapter 825 (USP Chapter 825), titled Radiopharmaceuticals- preparation, compounding, dispensing, and repackaging, the following definitions apply to this article and supplement the definitions provided in USP Chapter 825 radiopharmaceutical processing activities.” This language was originally included under 1738.1.

1738(c) – This subsection defining “designated person” was amended to add “Nothing in this definition prohibits the PIC from also serving as the designated person.” This sentence was added to clarify that licensees have the flexibility for the pharmacist-in-charge (PIC) to serve as the designated person and it was made in response to public comment. The language also allows for the PIC to designate a different licensee to serve as the designated person.

Section 1738.1

1738.1 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.2

1738.2 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.4

1738.4 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph

reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

1738.4(b) – This subsection regarding demonstrating proficiency amended the reference to the pharmacist with “oversight” to refer to the pharmacist with “supervision and control” to mirror the statutory definition in Business and Professions Code section 4023.5 and to reaffirm the Board's expectation that the level of supervision of a pharmacy technician encompasses direct supervision and control as it is defined in statute.

1738.4(g) – This subsection regarding the person providing training was added and reads, “Any person assigned to provide the training specified in this article shall have demonstrated competency in the skills in which the person will provide training or observe and measure competency described in the facility’s SOPs as referenced in section 1738.14. Documentation must be maintained demonstrating compliance with training requirements and demonstrating competency must be maintained.” This addition was added for consistency with the requirements within 1737.9, although addressing radiopharmaceutical compounding. The requirement is necessary to ensure that the individual assigned to provide the training to personnel has sufficient knowledge and expertise to provide the training. Additionally, documentation must be maintained for review during board staff inspections to ensure appropriate training has been provided in the interest of patient safety.

1738.4(h) – This subsection regarding failing ongoing evaluation was added and reads, “All personnel working with radiopharmaceuticals who fail any aspect of ongoing evaluation and training in personnel qualifications shall not work with radiopharmaceuticals until after successfully passing reevaluations in the deficient area(s), as detailed in the facility’s SOPs.” If personnel fail ongoing training and evaluation, patient safety must take priority and those individuals must not be involved with radiopharmaceuticals as it poses a risk to patient safety and employee safety.

Section 1738.5

1738.5 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

1738.5(d)(3) – This subsection prohibiting compounding in the SRPA was stricken from the language as the Chapter already specifically details what activities can be done in an SRPA, and duplication is unnecessary.

1738.5(j) – This subsection regarding smoke pattern tests was stricken from the language as the requirement for smoke studies are established in the Chapter, and duplication is unnecessary.

Section 1738.6

1738.6 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

1738.6(b) – This subsection was stricken from the language as the requirements are identified within the USP Chapter and additional clarity is unnecessary. Re-lettering within the section followed.

1738.6(c) [initially subsection (d)] – This subsection was amended to reference the correct version and title of the CETA guide that applies to this section, which is incorporated by reference. CETA guidelines establish an industry-based minimum set of criteria appropriate for performance evaluation and certification of facility and environmental controls used for compounding sterile preparations. This minimum set of criteria are necessary to ensure consistent and repeatable testing at all facilities. This change was necessary and non-substantive in nature because the document version identified in the regulation text does not exist. The Board attempted to make the update during the second modified text when section 1736.6 was amended; however, the amendment was inadvertently not made.

1738.6(d) [initially subsection (e)] – This subsection regarding incubators was amended to change “must” to “shall” for consistency with how those terms are used. Additionally, “cleaned, maintained” were added to the first sentence regarding care for an incubator. This requires that the incubators are cleaned and maintained appropriately based on the manufacturer’s specifications to ensure that they are in appropriate working condition. Further, “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” was added. This addition ensures consistency with the requirements outlined in 1736.9(b) to maintain similar requirements across the compounding Articles.

Section 1738.7

1738.7 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.8

1738.8 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.9

1738.9 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

1738.9(b) – This subsection was amended to add “maintained and, upon request, be produced as” for consistency with the requirements within section 1735.7(c) and section 1736.11(c) to ensure the requirements are similar across the compounding Articles.

1738.9(d) – This subsection regarding documentation was amended to delete the first use of the word “created” for grammatical purposes as it was duplicative. Additionally, the subsection was amended to add “for a least three years from the date the record was created, modified or relied upon” regarding prior versions of each record for consistency with the requirements within section 1735.14 and section 1736.20 to ensure the requirements are similar across the compounding Articles. The Board needs to be able to easily review all the required information together and not have to guess or wade through unrelated documents that are not part of the record.

Section 1738.10

1738.10 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

1738.10(c) – This subsection regarding preparations with minor deviations was amended to strike the second sentence beginning with “Such circumstances…” for clarity, as the intent of the proposed regulation is to ensure the facility has an SOP defining the conditions for minor deviations. While the language specifically referring to a pharmacist’s clinical judgement was removed, it is important to note that the change should not be interpreted as the Board suggesting that a pharmacist does not need to exercise clinical judgment. To the contrary, pharmacists, as licensed health care providers, must always exercise professional judgment in their practice. This requirement is memorialized in Business and Professions Code section 4306.5.

Section 1738.11

1738.11 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.12

1738.12 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.13

1738.13 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

Section 1738.14

1738.14 – The opening paragraph of this section was amended and rewritten to mirror the opening paragraphs in other sections of 1735, 1736, 1737, and 1738. The new first sentence of the paragraph reads, “In addition to the standards in USP Chapter 825, the processing of radiopharmaceuticals shall meet the requirements of this section.”

1738.14(b) – This subsection regarding notifying the Board of a complaint was amended to change “72” to “96” hours and clarifying language was added that reads, “the facility’s receipt of a complaint, excluding delivery delays,” to provide additional clarity that the facility must notify the Board of the receipt of the complaint, not necessarily that outcome of any associated investigation, within that time period. The hour change resulted from Board discussion in response to comments received to provide additional flexibility for licensees while the facility reviews the possible quality problem. Additionally, the language was amended to add “drug experiences as defined in 21 CFR section 310.305(b)” to replacing adverse “events” because that term is defined in federal regulations.

1738.14(c) – This subsection regarding initiating a review of a complaint of a potential quality problem amended “all complaints” [related to a potential quality problem] … and “all adverse events” to read “the pharmacist-in-charge shall initiate a review of any complaints made to the facility” [related to a potential quality problem]and “any reported adverse drug experiences” within 72 hours to clarify that the PIC must begin a review of any complaint within the specified time and not necessarily complete any associated investigation. “Adverse events” was changed to “adverse drug experience” to align with federal law. Finally, the subsection was amended to add, “In the event the PIC is not available within 72 hours, the PIC will define in the SOPs the pharmacist who will be required to review.” This addition resulted from Board discussion and concern about the PIC being unavailable or on vacation. The Board determined that the facility should identify a backup to review complaints when the PIC is unavailable due to the risk to patient safety.

1738.14(d) – This subsection regarding SOPs in the event of a failure to meet standards was amended to add “This subsection shall also include actions to be taken if the compounding

area or equipment is rendered unusable or in downtime situations" for consistency with the requirements within 1735.11 and 1736.17 to ensure the requirements are similar across the compounding Articles. Standard operating procedures are needed so that staff are aware of actions they must take in the event of an equipment failure.

1738.14(e) – This subsection was amended to remove "compounding" for grammatical clarity and change "CSP" to radiopharmaceutical to appropriately apply the requirement to this section of law. Further, "Documentation of compliance with the subdivision shall be maintained for three years" was added as the Board determined three years was appropriate as it is consistent with other areas of pharmacy law.

All the documents relied upon for this rulemaking (including Board meeting attachments) were made available to the Board in connection with this rulemaking. Additionally, if any public members requested to view the documents relied upon, all of the documents in the rulemaking file would have been made available.

Incorporation by Reference

Controlled Environment Testing Association (CETA) Certification Guide for Sterile Compounding Facilities (CAG-003, Revised October 2022).

Controlled Environment Testing Association (CETA) Certification Guide USP <797> Viable Environment Monitoring for Sterile Compounding Facilities (CAG-009, Revised September 2020)

U.S. Food and Drug Administration Guidance Document, Compounding Animal Drugs from Bulk Drug Substances (CVM GFI #256), Guidance for Industry (Revised August 2022)

Incorporation by reference method was used for these documents because it would be impractical and cumbersome to publish the documents in the California Code of Regulations. If the guidelines were incorporated into the CCR, it would increase the size of Title 16 and may cause confusion. The documents were made available to the public upon request and are available through the U.S. Food and Drug Administration or CETA.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a "small business," as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action will not affect small businesses as the proposal aligns the Board's regulation with the national minimum standard. While the board does, in some instances, establish a higher standard, the Board determined that this standard will not have a significant adverse impact.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, as effective and less burdensome to affected private persons than the adopted regulation, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board considered the following:

- Option 1: The Board considered not implementing the proposed regulations. The Board opted not to pursue this option as the current regulations of the CCR would be inconsistent with the current national standards set by USP. Not implementing this proposal would cause confusion and discrepancy throughout the industry.

- Option 2: The Board considered not establishing additional regulatory standards beyond the minimum national standards set by USP. The Board opted not pursue this option because BPC 4126.8 gives the board authority to adopt regulations to impose additional standards above the minimum national standards set by USP and adopting these additional regulatory standards beyond the minimum national standards set by USP provides clarification to the Board's regulated public and benefits the health and welfare of California residents.

Objections or Recommendations/Responses to Comments

(The summarized comments and Board responses are attached following this document)

45-Day and Public Hearing Comment Period

The 45-day comment period began on April 19, 2024, and ended on June 3, 2024. Additionally, the Board held a regulation hearing on June 18, 2024. The Board received numerous comments during the 45-day comment period and at the public hearing.

30-Day Comment Period for Modified Text

The 30-day comment period began on November 8, 2024, and ended on December 9, 2024. During this period, the board received numerous comments.

15-Day Comment Period for Second Modified Text

The first 15-day comment period began on January 10, 2024, and ended on January 27, 2024. During this period, the board received numerous comments.

15-Day Comment Period for Third Modified Text

The second 15-day comment period began on February 6, 2025, and ended on February 21, 2025. During this period, the board received numerous comments.

15-Day Comment Period Fourth Modified Text

The third 15-day comment period began on March 6, 2025, and ended on March 21, 2025. During this period, the board received numerous comments.