

Board of Pharmacy

Final Statement of Reasons

Hearing Date: June 25, 2015

Subject Matter of Proposed Regulation: Compounding Drug Preparations

Sections Affected: Amend § 1735 of Article 4.5 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1735.1 of Article 4.5 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1735.2 of Article 4.5 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1735.3 of Article 4.5 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1735.4 of Article 4.5 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1735.5 of Article 4.5 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.1 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.2 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.3 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.4 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.5 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.6 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.7 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.8 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Add § 1751.9 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Amend § 1751.10 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Add Article 7.5 of Division 17 of Title 16 Cal.Code Reg.
Add § 1752 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Add § 1753 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
Add § 1754 of Article 7 of Division 17 of Title 16 Cal.Code Reg.

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the Board of Pharmacy's (board) position regarding the adoption of the above sections, and is updated as follows:

The 45-day comment period began on May 8, 2015 and ended on June 22, 2015. The Board held a regulatory hearing on June 25, 2015 in Sacramento, California. The Board received 132 comments in response to the proposed regulation during the 45-day comment period and at the regulation hearing. These comments were addressed by modifying the text and additional clarifying changes were recommended by staff. The Board accepted the modifications at its July 28, 2015 meeting.

The modified text was noticed on the board's website and mailed on July 31, 2015. The 15-day public comment period began on July 31, 2015 and ended on August 15, 2015. The board received 174 comments which were addressed by modifying the text at its October 29, 2015 meeting.

The modified text was noticed on the board's website and mailed on November 20, 2015. The 15-day public comment period began on November 20, 2015 and ended on December 5, 2015. The board received 89 comments. The comments were reviewed and discussed at the January 19, 2016 Board meeting. No additional changes were made in response to the comments received during the second 15 day comment period.

During the process of completing this rulemaking, the U.S. Pharmacopeial Convention (USP) released a notice of intent to revise USP <800> (October 2015). Some sections of regulation text were modified to include changes made to USP <800>.

Additionally, during the process of completing this rulemaking, CETA revised their certification guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015). The regulation was updated to include reference to this revised document.

A non-substantive change was made to add "which is hereby incorporated by reference" in two locations following the reference to the CETA Certification Guide for Sterile Compounding Facilities.

Non-substantive changes were made throughout the regulation to correct punctuation and typographical errors, correct capitalization for consistency, corrections for grammar, and to update subdivision numbering as necessary for the addition or deletion of text.

Also, "buffer area or" was removed throughout the regulation text when next to "cleanroom" as both words have the same definition within these regulations.

Additionally, "policy and procedure" was changed throughout the regulation to "policies and procedures" as a pharmacy will have more than one policy and procedure.

Finally, "master formula record" was changed to "master formula document" throughout the regulation for clarity as there are several records within the document.

Amend 16 CCR §1735

Existing regulations at 16 CCR §1735 specify requirements related to the compounding of drug products in licensed pharmacies.

The following updates to the initial statement of reasons are made:

- Subdivision (b) was amended to remove "for oral, rectal, topical, or injectable administration" in response to a comment received. The Board determined that it was not necessary to list all the possible administration types.

Amend 16 CCR §1735.1

Existing regulations at 16 CCR § 1735.1 specify requirements related to the compounding of drug products, to include definitions of terms used throughout Articles 4.5 and 7.

The following updates to the initial statement of reasons are made:

- Subdivision (a) was amended to add “area with” for clarity and removed “buffer area or” as use of this term has been removed from the regulation text. Additionally, “ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room” was added to further align the regulation text with USP <797>.
- Subdivision (c) was amended to add “Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.” This requirement was added to align the regulation text with USP <800>.
- Subdivision (d) was removed. It was determined that the term “buffer area” was not needed in the regulation text and was removed for clarity. The Board viewed “cleanroom” and “buffer area” to have the same meaning, so the “buffer area” definition was removed and combined with “cleanroom.”
- Subdivision (f) was amended to combine “clean area or buffer area” with the definition of “cleanroom.” Additionally, “physically separate” and “with walls and doors” and “at least an” was removed for clarify the meaning of a cleanroom does not necessarily mean a separate room. Finally, “with HEPA-filtered air” was added to ensure that proper clean air is used as required by USP <797>.
- Subdivision (e)(1) is added to expand on the water column requirements. The new subdivision reads “For nonhazardous compounding a positive pressure differential of 0.02-to 0.05-inch water column relative to all adjacent spaces is required. This change aligns the regulation text with USP <797> and <800>.
- Subdivision (e)(2) is added and reads “For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.” This change is added for clarity based on comments and aligns the regulation text with USP <797> and <800>.
- Subdivision (f) was amended to add “unidirectional HEPA-filtered airflow” to the definition of “Compounding Aseptic Containment Isolator.” Additionally, “volatile” is removed, “should” is changed to “shall” and “building” is added before “ventilation.” Finally, “This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be re-circulated nor turbulent” was added. These changes are added for clarity based on comments and to further align the regulation text with USP <797>.
- Subdivision (g) was amended to add “non-hazardous” and “while bathed with unidirectional HEPA-filtered air.” Additionally, “Air within the CAI shall not be re-circulated nor turbulent.” These changes were added for clarity based on comments and to further align the regulation text with USP <797>.
- Subdivision (i) was amended from “35.6 degrees to 46.4 degrees” to “35 degrees to 46

degrees.” This change was made to accurately report the temperatures.

- Subdivision (j) was amended to add “for that product” to clarify that the temperature can be changed based on the product.
- Subdivision (l) was amended to add “clinically” before “significant.” This change was added for clarity to further specify that the board is concerned with only those items that are clinically significant, which would be determined by the professional judgement of the pharmacist.
- Subdivision (m) was amended to add “except when daily monitoring or refrigerator and freezer temperature are required, then daily means every 24 hours.” This change was made for clarity based on a comment received as some compounded medication will require daily monitoring on temperature.
- New subdivision (m) adds the definition of “displacement airflow method” for the purposes of compounding drug products. The definition clarifies and specifies that displacement airflow method means “a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.” This definition is added for clarity.
- Subdivision (n) was amended to remove “except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered on dosage unit.” This was removed from the definition section as it is inappropriate to be in the definition of a term. This has been added to section 1751.7(e).
- Subdivision (q) was amended to add “of each hand” for clarity. This ensures that the gloved fingertip sampling is completed with each hand.
- Subdivision (s) was amended to remove “after it is dispensed.” This is necessary to clarify that the definition applies to pharmacies and hospitals and not just patients.
- Subdivision (u) was amended was clarity based on comments. The following was removed: “the mimics,” “to demonstrate,” and “that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. To be valid, media-fill tests must be conducted on both the most routine and the most challenging compounding procedures performed.” The revised definition reads “a test used to measure the efficacy of compounding personnel is aseptic techniques whereby compounding procedures are mimicked using growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.”
- Subdivision (v) adds a definition of “non-sterile-to-sterile batch” for the purposes of compounding drug products. The definition clarifies and specifies “non-sterile-to-sterile batch” means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

- Subdivision (w) was amended to remove “This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation.” Additionally, “It does not include topical, sublingual, rectal or buccal routes of administration” was added. These changes were made as the board determined it was clear to just list what is does not include instead of having a long list of what is included.
- Subdivision (x) was amended to change “drug products” to “compounding ingredients and/or potential toxins.” This change was made clarify the meaning of “drug products.”
- Subdivision (y) was amended to add “Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.” This section was added to account for possible reduced potency in a pre-mixed manufactured product.
- Subdivision (ab) was amended to remove “the exposure of critical sites when” and add “non-turbulent” and “sterile compounding automated robots.” These changes are added for clarity based on comments and to align with USP <797>. Additionally, it is necessary to include automated robots as they are now being used by pharmacies to perform these functions.
- Subdivision (af) was amended to change “preparing” to “preparation” and remove “non-hazardous” and add “of.” Hazardous compounding is permitted in a segregated sterile compounding area provided that it is done within the appropriate primary engineering control (PEC).
- New subdivision (af)(1) was added and reads “The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).” The above changes to Section 1735.1 were made to provide clarity and public safety to ensure that appropriate beyond use dates are assigned when preparations are produced in a segregated sterile compounding area
- New subdivision (af)(2) was added and reads “When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).” The above changes to Section 1735.1 were made to provide clarity and public safety to ensure that appropriate beyond use dates are assigned when preparations are produced in a segregated sterile compounding area

Amend 16 CCR §1735.2

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements; self-assessment.

The following updates to the initial statement of reasons are made:

- Subdivision (c)(1) was amended remove “and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation.” Additionally, “either” and

“or furnishing of a 72-hour supply” was removed. These changes were made based on comments to allow for someone other than the prescriber (i.e. a hospital) to pay for the preparation. The fair market value requirement was removed based on comments as it can be difficult to calculate. Additionally, the 72-hour supply was removed as prescriber dispensing needs to be done via a prescription or the preparation can be purchased from a federally licensed 503B facility. Pharmacies cannot prepare a compounded drug preparation for prescriber dispensing to a human without a prescription.

- Subdivision (c)(3) was amended to remove “a 72-hour supply for human medical practices, or” and add “veterinary” after “prescriber’s own.” This change was necessary as pharmacies cannot prepare a compounded drug preparation for prescriber dispensing without a prescription unless it is for a vet.
- Subdivision (c)(4) was re-written for clarity.
- Subdivision (e)(5) was amended and “and essential” was added. This term was added as for clarity based on a comment as there could be numerous compounding steps utilized; however, standardized steps used for every preparation do not need to be listed every time and can be documented in the policies and procedures. A pharmacist using his or her professional judgement will determine if something is essential.
- Subdivision (i) was amended and completely rewritten based on comments received and to align the regulation with USP <795>. New paragraphs and subparagraphs were added for clarity. Subdivision (i) now reads “Every compounded drug preparation shall be given an beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.”

The following subdivisions were added to address comment received and to align the beyond use date requirements with USP <795>.

- New subdivision (i)(1) reads “For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:”
- New subdivision (i)(1)(A) reads “the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,”
- New subdivision (i)(1)(B) reads “the chemical stability of any one ingredient in the compounded drug preparation;”
- New subdivision (i)(1)(C) reads “the chemical stability of the combination of all ingredients in the compounded drug preparation,”
- New subdivision (i)(1)(D) reads “180 days for non-aqueous formulations,”
- New subdivision (i)(1)(E) reads “14 days for water-containing oral formulations, and”
- New subdivision (i)(1)(F) reads “30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.”
- New subdivision (i)(2) reads “For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:”
- New subdivision (i)(2)(A) reads “The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,”

- New subdivision (i)(2)(B) reads “The chemical stability of any one ingredient in the sterile compounded drug preparation,”
- New subdivision (i)(2)(C) reads “The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and”
- New subdivision (i)(2)(D) reads “The beyond use date assigned for sterility in section 1751.8.”
- New subdivision (i)(3) reads “Extension of a beyond use date is only allowable when supported by the following:”
- New subdivision (i)(3)(A) reads “Method Suitability Test,”
- New subdivision (i)(3)(B) reads “Container Closure Integrity Test, and”
- New subdivision (i)(3)(C) reads “Stability Studies”
- New subdivision (i)(4) reads “In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.”
- New subdivision (i)(5) reads “Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.”
- Subdivision (k)(1) was amended to remove “unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packages and the storage conditions, and.” This text was removed for patient safety. The sterility of a preparation cannot be determined by inspection (simply looking at it) and the exclusion from the limitation was not necessary.
- Subdivision (k)(2) was amended to remove “unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packages and the storage conditions,.” This text was removed for patient safety. The sterility of a preparation cannot be determined by inspection (simply looking at it) and the exclusion from the limitations was not necessary.
-

Amend 16 CCR §1735.3

Existing regulations at 16 CCR §1735.3 specify recordkeeping for compounded drug preparations.

The following updates to the initial statement of reasons are made:

- Subdivision (a)(2) was amended to add “A compounding log consisting of a single document containing all of the following:.” This is added to provide a section to clearly list the requirements for recordkeeping requirements. The previous requirement listed in (a)(2) has been moved to (a)(2)(B).
- Subdivision (a)(2)(A) is added and reads “Name and Strength of the compounded drug

preparation.” This is necessary to ensure that the name and strength is recorded for accurate records.

- Subdivision (a)(2)(E) [formally (a)(5)] was amended to change “component” to “ingredient.” This is necessary for clarity as a component can be more than one ingredient.
- Subdivision (a)(2)(F)(i) [formally (a)(6)] was amended to add “(1735.3(a)(2)(F)). This is added for clarity to ensure the paragraph is accurately identified. Additionally, “an inpatient” was changed to “a patient” because patients being treated at a health care facility may not be categorized as an “inpatient.”
- Subdivision (a)(2)(G) [formally (a)(7)] was amended to add “unique” in front of reference. This ensures that the identification number is unique and not used for multiple preparations. The number needs to be unique for proper identification for testing.
- Subdivision (a)(2)(J) adds “Documentation of quality reviews and required post-compounding process and procedures.” This ensures that the records include the quality review information and the follow-up procedures. This information is necessary for accurate and complete records.
- Subdivision (c) was amended to change “product” to “chemical” and add “bulk drug substance, or drug products” to the last sentence. This is added to ensure that the purity documents required are maintained and to maintain consistency with the references to those items within the paragraph.
- Subdivision (d) was amended to change “created” to “last in effect.” This change was necessary to ensure that the documents are retained in the pharmacy. As previously written, the documents could be removed if more than 3 years old, even if they were still the relied upon and used.
- Subdivision (f) was amended to change “subdivision (k)” to “subdivision (l).” This change was necessary to ensure that regulations refer to the appropriate location within other sections.

Amend 16 CCR §1735.4

Existing regulations at 16 CCR §1735.4 specify labeling for compounded drug preparations.

This language within this section was stricken and the section has been re-written for clarity and patient safety.

The following updates to the initial statement of reasons are made:

- Subdivision (a) was amended and now reads “Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:” This section is added to specify that each preparation must be labeled.
- New Subdivision (a)(1) adds “Name of the compounding pharmacy and dispensing pharmacy (if different);” This is necessary to know which pharmacy compounded the preparation and which pharmacy dispensed the medication should a problem with the preparation be found.

- New Subdivision (a)(2) adds “Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;” This is necessary to identify what the preparation is and what it contains for identification and safety.
- New Subdivision (a)(3) adds “Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;” This is necessary for patient safety. Patients must know how to store, handle, and administer their prescriptions.
- New Subdivision (a)(4) adds “The beyond use date for the drug preparation;” This is necessary to know when the preparation must be disposed of for patient safety.
- New Subdivision (a)(5) adds “The date compounded; and” This is necessary to know when the preparation was compounded and to calculate the beyond use date.
- New Subdivision (a)(6) adds “The lot number or pharmacy reference number.” This is necessary in the advent there is a sterility issue with a lot. All preparations from that lot must be able to be identified.
- Subdivision (b) was amended and now reads “Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.” This section is added to ensure that the label contains the other legal requirements. This information was originally in subdivision (a).
- Subdivision (c) was amended and now reads “Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.” This section was originally in subdivision (b).
- New Subdivision (d) was added and reads “Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).” This section is added to specify the labeling requirements for those containers that are too small to comply with (a)-(c) for this section.
- New Subdivision (e) was added and reads “All hazardous agents shall bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly.”” This section is added to ensure proper labeling of hazardous agents. This section replicates 1751.2(c).

Amend 16 CCR §1735.5

Existing regulations at 16 CCR §1735.5 specify compounding policies and procedures.

Throughout this section “policy and procedure manual” was changed to “policies and procedures.”

The following updates to the initial statement of reasons are made:

- Subdivision (a) was amended to add “material” before “failure.” This change was made for clarity based on comments received. Whether the failure is material will be determined by the pharmacist’s professional judgement.
- Subdivision (c)(2) and was amended to add “and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).” This is added to ensure that the pharmacy has a plan in place to identify the proper patients that need to be contacted to retrieve recalled preparations.
- Subdivision (c)(11) adds “Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.” This is added to ensure that garbing requirements are included in the policies and procedures.

Amend 16 CCR §1735.6

Existing regulations at 16 CCR §1735.6 specify compounding facilities and equipment.

The following updates to the initial statement of reasons are made:

- Subdivision (e) adds “Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:” to include the facility and equipment requirements for hazardous compounding and align the regulation with USP <797> and USP <800>.
- Subdivision (e)(1) adds “Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and” to align the regulation with USP <800>.
- Subdivision (e)(2) adds “Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and” to align the regulation with USP <800>.
- Subdivision (e)(3) adds “Each PEC in the room shall also be externally vented; and” to align the regulation with USP <800>.
- Subdivision (e)(4) adds “All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.” to align the regulation with USP <800>.
- Subdivision (f) adds “Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.” This section is added to provide a waiver process in order to allow facilities to request additional time for construction following the implementation date. A decision to approve a waiver will be made on a case by case basis after considering the waiver request, including any supporting documentation provided.

Amend 16 CCR §1735.7

Existing regulations at 16 CCR §1735.7 specify training of compounding staff requirements.

The following updates to the initial statement of reasons are made:

- Subdivision (a) was amended and rewritten. The proposed text language was deleted and new text language was added as follows: “A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.” This section was amended for clarity based on comments to ensure that the training requirements apply to the appropriate compounding related staff. The pharmacy is responsible for ensuring those personnel involved in compounding have both the skills and training required to perform their assigned responsibilities and documenting the skills and training. Trained personnel should be better able to ensure public safety; requiring the pharmacy to document the skills and training provides a means for the board to verify that it occurred. The pharmacy must also have documentation that all personnel involved in compounding are trained in all aspects of policies and procedures because an understanding of the overall process should help ensure public safety. This language clarifies that the pharmacy determines the specific training appropriate for its staff; through other laws and regulations, the pharmacist-in-charge of the pharmacy will determine specific training based on his or her professional judgment in the setting. The regulatory language does not specify that a person must be able to perform any specific physical tasks (such as manipulating needles); it does, however, require that individuals, including those requesting a reasonable accommodation, demonstrate to the pharmacy how they will accomplish their roles and functions in the sterile compounding process. The language does not prohibit such demonstration from also occurring with a reasonable accommodation for a disability, because, like other employer functions, all training and demonstration requirements are subject to the reasonable accommodation requirements of the American with Disabilities Act (ADA) and related state statutes, and as such would be accepted by the board to meet these requirements.

Amend 16 CCR §1735.8

Existing regulations at 16 CCR §1735.8 specify compounding quality assurance requirements.

The following updates to the initial statement of reasons are made:

- Subdivision (c) was amended to remove “of compounded drug preparations” from the first sentence as it was redundant. Additionally, “compounding record” was changed to

“compounding log” and “document” was added after master formula in the second sentence for clarity. Finally, “specified” is added after “analysis of” to clarify that not all products need a testing schedule. The facilities will need to identify the products as appropriate for their location.

- Subdivision (d) was amended to change “below” to “outside.” As preparations may a standard range for integrity, potency, quality, or labeled strength, this change is necessary to ensure that the quality assurance plan includes procedures on what to do if the preparation is below or above that standard range.
- Subdivision (e) was amended to change “or” to “and” because temperature variations need to be responded to both in the pharmacy and patient care areas where compounded preparations may be stored.

Amend 16 CCR §1751

Existing regulations at 16 CCR §1751 specify sterile compounding requirements.

The following updates to the initial statement of reasons are made:

- Subdivision (b)(3) was amended to add “with the exception of emergency eye-rinsing stations” to the second sentence. This was added based on comments received to allow for the exception of eye-rinsing stations. Additionally, “When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).” Was added to the end of the paragraph. This was added to allow for the exception for using a CAI or CACI in a segregated compounding area.

Amend 16 CCR §1751.1

Existing regulations at 16 CCR §1751.1 specify requirements for sterile injectable recordkeeping requirements.

The following updates to the initial statement of reasons are made:

- Subdivision (a) was amended to change “make and keep” to “maintain” and add “which must be readily retrievable” for clarification that the records must be maintained in the pharmacy. The records need to be maintained and retrievable in the pharmacy for inspector review during inspections.
- Subdivision (a)(4) was amended to remove “volumetric” for clarity to align the regulation with USP <797>.
- Subdivision (a)(5) adds “Video of smoke studies in all ISO certified spaces” for clarity to align the regulation with USP <797>.
- Subdivision (a)(6) [formally (a)(5)] was amended to change “recordation” to “documentation” for clarity.
- Subdivision (a)(11) [formally (a)(10)] was amended to change “master work sheet” to “master formula document” and “preparation work sheet” to “preparation

compounding log” to clarification the identity of the two documents. Additionally, “testing and” was added after evaluation to clarify that the testing needs to be recorded as well and not just the result.

- Subdivision (b) was amended to add “type and” after “license” to ensure that the license type of the prescriber is recorded. This is necessary should the identity of the prescriber need to be confirmed or should the prescriber need to be contacted.

Amend 16 CCR §1751.2

Existing regulations at 16 CCR §1751.2 specify sterile injectable labeling requirements.

The following updates to the initial statement of reasons are made:

- The initial statement was amended to add “title 16” and “1707.5 and” to clarify the appropriate CCR reference sections.
- Subdivision (a) was amended to change “dispensed” to “administered” and “patients” was changed back to “inpatients.” This change was made to clarify when the telephone number from the label for preparations administered to inpatients within a hospital.
- Subdivision (b) was removed from the regulation. This information has been added to CCR 1735.4 and duplicated in this section.
- Subdivision (c) was amended to add “and administration” to ensure the administration instructions are included on the label for sterile compounded drug preparations.

Amend 16 CCR §1751.3

Existing regulations at 16 CCR §1751.3 specify sterile compounding policies and procedures.

The following updates to the initial statement of reasons are made:

This section was alphabetized for clarity and a few amendments were made. Below are the amendments:

- Subdivision (a) was amended to add “Any material failure to follow the pharmacy’s written policies and procedures shall constitute a basis for disciplinary action.” This is added to reiterate disciplinary action can be taken for failing to follow the policies and procedures and align the section with 1735.5. Additionally, “there shall be” was added for grammatical clarity.
- Subdivision (a)(1) [formerly (a)(19)] was amended to add “and actions to be taken when the levels are exceeded.” This is added to ensure the policies and procedures define what needs to occur if action levels are exceeded.
- New Subdivision (a)(8) adds “Depyrogenation of glassware (if applicable).” This is added to ensure that the policies and procedures include the process to remove pyrogens from glassware used to compound preparations.
- Subdivision (a)(13) [formerly (a)(5)] was amended to read “Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.” This is added to ensure that the supervising pharmacists and staff know and understand the methods used to ensure the

preparation quality.

- Subdivision (a)(14) [formerly (a)(12)] was amended to add “demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.” This is added to specify that a pharmacy’s written policies and procedures addressing the orientation, training and competency evaluation include the topic of aseptic practices (previously listed at (a)(5)) and to reflect that relevant personnel must perform the media-fill test, to demonstrate that such personnel know how to conduct the test to ensure the accurate evaluation of the safety and efficacy of a compounded preparation.
- Subdivision (a)(15) [formerly (a)(11)] was amended to add “This shall include sterilization method suitability testing for each master formula document.” This is added to ensure that the method suitability testing is included in the policies and procedures.
- Subdivision (a)(19) [formerly (a)(6)] was amended to add “compliant with sections 1711, 1735.8, and 1751.7.” This information is added for clarity to ensure the quality assurance programs meets the regulatory requirements.

Amend 16 CCR §1751.4

Existing regulations at 16 CCR §1751.4 specify facility and equipment standards for sterile compounding.

The following updates to the initial statement of reasons are made:

- Subdivision (d) was amended for clarity based on comments received and to align the regulation with USP <797>. Subdivision (d) now reads: “Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.” This was formally in subdivision (e).
- New subdivision (d)(1) reads “All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.” This change was made for clarity based on comments received and to align the regulation with USP <797>.
- New subdivision (d)(2) reads “Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.” This change was made for clarity based on comments received and to align the regulation with USP <797>.
- New subdivision (d)(3) reads “Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.” This change was made for clarity based on comments received and to align the regulation with USP <797>.
- New subdivision (d)(4) reads “All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.” This change was made for clarity based on comments received and to align the regulation with USP <797>.
- New Subdivision (e) reads “Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:” This change was made for

clarity based on comments received and to align the regulation with USP <797>.

- Subdivision (e)(2) [formally (d)(2)] was amended to add “At least every 30 minutes when compounding involving human staff is occurring or” and remove “and after” for clarity based on comments received and to align the regulation with USP <797>.
- Former subdivision (e) is removed in its entirety as the requirements are now more clearly detailed in subdivision (d).
- Subdivision (f) was amended to update the reference to the CETA Certification Guide to the most recent version (CAG-003-2006-13, Revised May 20, 2015). This version of the Guide was released after the 45-day comment period began. Additionally, “Unidirectional” was added before “compounding aseptic isolators” for clarity as the CAI and CACI need to be unidirectional to align with USP <797>. Finally, “is certified to” to ensure that the CAI and CACI are appropriately certified.
- Subdivision (f)(3) was amended to remove “or compounding aseptic containment isolators” to align the regulation with USP <800>. Only a CAI can have the beyond use dates listed in 1751.8(d).
- Subdivision (g) was amended to add “Additionally, each PEC used to compound hazardous agents shall be externally vented” to align the regulation with USP <797>. Additionally, the subdivision was amended to update the reference to the CETA Certification Guide to the most recent version (CAG-003-2006-13, Revised May 20, 2015). This version of the Guide was released after the 45-day comment period began.
- Subdivision (g) was further amended to add subsection (1) for the hazardous compounding section. Subsection (g)(1) was amended to split the first sentence into two separate sentences by removing “complete with” and adding “Garbing shall include” as a beginning of the new sentence. Additionally, “two layers of gloves with the outermost glove tested to meet ASTM 6978-05” was changed to “two pairs of sterile ASTM D6978-05 standard gloves” for clarity. The double glove requirement is in accordance with USP <800> for operator safety when working with hazardous compounds. Based on comments received, “Where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply” was removed for operator safety. The Board agreed that a manufacturer should not override the need for protective garbing.
- New subdivision (i) adds “Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.” This section was added to align the regulation with USP <800> and ensure appropriate air flow for patient and operator safety.
- Subdivision (j) [formally subdivision (i)] was amended to change “quarterly” to “every six months” and “monthly” to “quarterly” based on USP <797>. Additionally, “Volumetric” was changed to “Viable” and “shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and” was added and “impaction” was removed based on the CETA Certification Guide and USP <797>. “Viable” was added in front of “surface sampling” to maintain consistency in the paragraph. Furthermore, “pursuant to its policies and procedures” was added to identify how an investigation should be conducted. Finally, “at minimum” was added to allow

for additional investigation outside of the required to be completed.

- Subdivision (k) [formally (j)] was amended to add “sterile compounding area in the” and change the temperature requirements from “20 degrees Celsius (68 degrees Fahrenheit)” to “20-24 degrees Celsius (68-75 degrees Fahrenheit)” based on comments received to allow for flexibility in the temperature.

Amend 16 CCR §1751.5

Existing regulations at 16 CCR §1751.5 specify compounding policies and procedures.

The following updates to the initial statement of reasons are made:

- Subdivision (a)(1) was amended to remove “unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment” as the Board determined that the need for protective garbing is always necessary to protect both the process and staff performing the functions, irrespective of the type of equipment that is used.
- Subdivision (a)(4) was amended to add “other visible jewelry, piercing, headphones, earbuds, or personal electronic device” and remove “If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.” These changes were made to align the regulation with USP <797>.
- Subdivision (a)(6) was amended to add “exposed” before rashes, “or other communicable disease” after infections, and “nail polish, or artificial nails” after cosmetics based on comments received and to align the regulation with USP <797>.

Amend 16 CCR §1751.6

Existing regulations at 16 CCR §1751.6 specify sterile compounding consultation and training of sterile compounding staff.

The following updates to the initial statement of reasons are made:

- Subdivision (e)(1)(E) was amended to remove “using media-fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount or greater of volume transferred during the selected manipulations.” This section has been moved to 1751.7(b)(1).
- Subdivision (e)(1)(G) was amended to add “(aseptic area practices)” to ensure clarity in training requirements.
- Subdivision (e)(2) was amended to add “using models that are comparable to the most complex manipulations to be performed by the individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations.” This is added to address comments received and ensure that the appropriate staff have proper training and the skills to ensure preparation sterility for patient safety. The language does not require every individual to perform each physical

action, but that each individual perform the most complex manipulation that person might do in the compounding practice in a training setting so that mistakes or errors can be identified in a situation that poses no risk to the public. It also requires that each pharmacist responsible for, or supervising and controlling other staff, demonstrate those skills that will be used to ensure the sterility of compounded drug preparations. No specific skills are specified, because those will be determined as appropriate to each environment by the pharmacy, through its pharmacist-in-charge.

Amend 16 CCR §1751.7

Existing regulations at 16 CCR §1751.7 specify sterile compounding quality assurance and process validation.

The following updates to the initial statement of reasons are made:

- Subdivision (b) was deleted in its entirety and is incorporated in parts into a new subdivision (b) and its subsections.
- New Subdivision (b)(1) was added and reads “The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer’s recommendations. If microbial growth is detected, then each individual’s sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.” This section is added to ensure the appropriate competency and validation processes when preparing sterile drug preparations and includes portions of the previous subdivision (b). Additionally, this section was added for clarity based on comments received. The regulatory language does not specify that a person must be able to perform any specific physical tasks (such as manipulating needles); it does, however, require that certain individuals, including those requesting a reasonable accommodation, demonstrate to the pharmacy how, physically, they will accomplish their roles and functions in the sterile compounding process. The language also does not prohibit that such demonstration from also occurring with a reasonable accommodation for a physical disability, because, like other employer functions, all training and demonstration requirements are subject to the reasonable accommodation requirements of the American with Disabilities Act (ADA) and related state statutes, and

as such would be accepted by the board to meet these requirements.

- New Subdivision (b)(2) adds “Each individual’s competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.” This section remains from the previous subdivision (b) and is not newly text.
- New Subdivision (b)(3) adds “The pharmacy’s validation process on aseptic technique and aseptic area practices must be revalidated whenever:” This section remains from the previous subdivision (b) and has been reworded for clarity.
- New Subdivision (b)(3)(A) adds “the quality assurance program yields an unacceptable result,” and this section is original text.
- New Subdivision (b)(3)(B) adds “there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.” Again, this section contains original text; however “repaired or” is added back into the regulation text as revalidation is necessary following a repair to confirm the equipment was accurately repaired.
- New Subdivision (b)(4) adds “The pharmacy must document the validation and revalidation process.” This section contains original text and is reworded for clarity.
- Subdivision (c) was amended to change “all compounding personnel” to “each individual who may be required to do so in practice” to ensure that the proper personnel complete the gloved fingertip process. Those who do not perform relevant duties would not need to complete the process. Additionally, “(all fingers on both hands)” was added after “fingertip” for clarity to ensure that all fingers are sampled.
- Subdivision (e) was removed and a new subdivision (e) was added.
- New Subdivision (e)(1) adds “Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.” This section is added for clarity to clearly define the end product testing requirements and exemptions. This section aligns the regulation with USP <71>, USP <85>, and USP <797>.
- New Subdivision (e)(2) adds “The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:” This section is added to define the exemptions for non-sterile-to-sterile drug preparations.
- New Subdivision (e)(2)(A) adds “Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to

a prescription.” The section provides the exemption for ophthalmic drops. USP <797> references batches of 25; the Board determined that a 30 day or less supply was sufficient and a supply for longer than 30 days needs to be tested for patient safety.

- New Subdivision (e)(2)(B) adds “Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.” This section was added to address a patient’s immediate medical need. It will provide a patient at least 5 days of an emergency inhaled drug and allow the patient and/or doctor to find a supply from another source.

Amend 16 CCR §1751.8

16 CCR §1751.8 was amended and now contains provisions relating to “Beyond Use Dating for Sterile Compounded Drug Preparations” to specify beyond use dating requirements. The provisions that were previously contained in 16 CCR §1751.8 were amended into 16 CCR §1751.10.

The following updates to the initial statement of reasons are made:

- The initial paragraph was amended for clarity and to further align the regulation with USP <797>. The language of “the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation” was added and “the expiration date or beyond use date provided by the manufacturer for any component in the preparation.”
- Subdivision (a) was amended to in response to a comment received to change “at controlled freezer temperature” to “in solid frozen state” for clarity.
- Subdivision (a)(1) was amended to add “or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3)” to include the exemption from 1751.4.
- Subdivision (a)(3) was amended to add “or spiked transfer devices” after “syringes” in response to a comment received to include the use of these devices.
- Subdivision (b) was amended to in response to a comment received to change “at controlled freezer temperature” to “in solid frozen state” for clarity.
- Subdivision (b)(1) was amended to add “or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3)” to include the exemption from 1751.4.
- Subdivision (c) was amended to in response to a comment received to change “at controlled freezer temperature” to “in solid frozen state” for clarity. Additionally, “regardless of intervening sterilization of that ingredient and the following applies:” was added and “including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives. For the purposes of this subdivision, “non-sterile” includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation, transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour” was

removed to make clear that regardless of any preparation that has been terminally sterilized and is now considered “sterile,” if the preparation/compound was non-sterile at one point it would still be considered non-sterile. Therefore, the beyond use date for sterile-to-sterile would not be applicable to said compound and they would have to use the beyond use date in 1751.8(c).

- New Subdivision (c)(1) adds “The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).” This section is added to include the exception listed in 1751.4.
- Subdivision (f) was renumbered to subdivision (e) and the subdivision was split into two subsections for clarity.
- New Subdivision (f) adds “The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.” This section was added in response to comments received to address the beyond use dates for allergen extracts.

Amend 16 CCR §1751.9

16 CCR §1751.9 was amended and now contains provisions relating to “Single-Dose and Multi-Dose Containers; Limitations on Use” to specify single-dose and multi-dose containers and limitations on use requirements.

The following updates to the initial statement of reasons are made:

- Subdivision (b) was amended to add “shall be labeled with a beyond use date and” and removed “BUD” to ensure the containers are properly labeled for patient safety and to prevent accidental use after the BUD.
- Subdivision (b)(2) was amended to add “A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.” This is added for patient safety. Bacterial growth can occur if the container is removed from an appropriate air quality location.
- New Subdivision (b)(3) adds “If the puncture time is not noted on the container, the container must immediately be discarded.” This section is added for patient safety and to ensure that containers are properly discarded if the time of puncture is unknown.
- Subdivision (c) was amended to “shall be labeled with a beyond use date and” and removed “BUD” to ensure the multi-Dose containers are properly labeled for patient safety and to prevent accident use after the BUD. Additionally, “If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.” was added to ensure that containers are appropriately discarded if the beyond use date is unknown.

Amend 16 CCR §1754

The following updates to the initial statement of reasons are made:

- Subdivisions (a) and (b) were amended to change section “1751.11” to section “1753.”

This change was necessary as the sections were renumbered.

On January 19, 2016, after having considered all comments in the record, the Board itself adopted the regulation with the revisions above and authorized the Executive Officer to make any non-substantive changes necessary to complete the rulemaking file.

Local Mandate

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

Small Business Impact

This action may have an adverse economic impact on small businesses; however, the board does not have nor does it maintain data to determine how many, if any, of its licensed pharmacies are “small businesses” as defined in Government Code Section 11342.610.

Consideration of Alternatives

No reasonable alternative which was considered or that has otherwise been identified and brought to the attention of the board would be more effective in carrying out that purpose for which it was proposed or would be as effective and less burdensome to private persons than the adopted regulation or would be more cost effective to affected private person and equally effective in implementing the statutory policy or other provision of law. The following alternative was considered and was rejected for the reasons set forth below:

- (1) Do not seek a regulatory change

Reason for rejection: The board’s highest priority is the protection of the public while exercising its licensing, regulatory, and disciplinary functions. Without this regulatory change, the board would not be aligned with federal compounding standards in USP 37 <797>. Additionally, the board would not be able to ensure the protection of public health and safety, worker safety, or the environment for the people of the State of California.

Objections or Recommendations/Responses

Please see the attachments containing the comments and the Board’s responses.

During the 45-day comment period and regulation hearing (May 8, 2015-June 22, 2015 [Regulation hearing June 25, 2015]), the Board received 132 comments. On July 28, 2015, the comments were reviewed and discussed at its Board meeting. Numerous changes were made to address some of these comments and the Board voted to initiate a 15-day comment period.

During the first 15-day comment period (July 31, 2015 – August 15, 2015), the Board received 174 comments. Numerous changes were made to address some of these comments. On

October 29, 2015, the comments were reviewed and discussed at its Board meeting. Numerous changes were made to address some of these comments and the Board voted to initiate a second 15-day comment period.

During the second 15-day comment period (November 20, 2015 – December 05, 2015), the Board received 89 comments. On January 19, 2016, the comments were reviewed and discussed at its Board meeting. No changes were made in response to these comments.

On January 19, 2016, after having reviewed all the comments submitted, the Board voted to adopt the compounded drug preparation regulation text as it was noticed on November 20, 2015.

On February 24, 2016, after discussion, the Board voted to set a regulation effective date of January 1, 2017. This date was set to provide a firm effective date for facilities to begin planning and construction processes.

Incorporation by Reference

The incorporation by reference method was used because it would be impractical and cumbersome to publish Chapters 71, 85, 151, 795, and 797 of the United States Pharmacopeia – National Formulary (USP) in the California Code of Regulations (CCR) as the USP was used as a guideline and the regulation is not an exact replication. Additionally, the USP is voluminous and is the compounding professional pharmacopeial standard used across the United States for compounded drug preparations. If the guidelines were incorporated into the CCR, it would substantially increase the size of Title 16 and may cause confusion to the user. The USP is the professional industry standard and is commonly known to be available through the United States Pharmacopeial Convention. Finally, CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015) is also incorporated by reference. The CETA certification is industry standard and required by USP 797 for the proper use, cleaning, and certification of PECs and buffer areas. As with the USP, the CETA Certification Guide is voluminous and may cause confusion to the user if it were added into the CCR.