TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on October 20, 2014.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at the DCA Headquarters Building Two, 1747 North Market Blvd Room 186, Sacramento, CA 95834, on November 4, 2014, at 10:30 a.m.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Section 4005, 4057 and 4127 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4036, 4037, 4040, 4051, 4052, 4057, 4076, 4081, 4127, 4127.7, 4169, 4301, and 4332 of the Business and Professions Code, as well as Section 18944 of the California Health and Safety Code, the Board of Pharmacy is proposing to amend Articles 4.5 and 7 and add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board of Pharmacy ("Board") proposes to amend Sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8 and Sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, 1751.8, and 1751.10, as well as add Article 7.5 and Sections 1751.9, 1752, 1753, and 1754 of Division 17 of Title 16 of the California Code of Regulations ("CCR") for the purpose of amending the board's regulations specific to the compounding of drug products as part of the board's efforts to strengthen the regulation and enforcement of pharmacies that compound sterile drug products and as a result of Senate Bill (SB) 294 (Emmerson, Statutes of 2013, Chapter 565.), as specified below.

The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar

licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California.

SB 294 commencing July 1, 2014, expands these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board. SB 294 also specifies requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. SB 294 requires the board to adopt regulations to implement these provisions, and, on and after July 1, 2014, to review formal revisions to specified national standards relating to the compounding of sterile preparations to determine whether amendments to those regulations are necessary, as specified.

As specified in Business and Professions Code Section 4001.1, protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Included as part of the federal Drug Quality and Security Act (HR 3204) that became law on November 27, 2013, are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by "outsourcing facilities." The federal law sets forth voluntary requirements for licensure and enforcement of these entities. However, California's law is more restrictive than the federal law in several areas. California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with the board and comply with California requirements as sterile compounding pharmacies. She also indicated that FDA may also require or encourage licensure as an outsourcing facility.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Prior to the enactment of the Drug Quality and Security Act, compounding pharmacies were regulated by their respective states of residence. Compounding pharmacies also make drugs, but they are limited to producing small amounts in response to a specific patient's prescription, or to create a small supply for an identifiable patient population to ensure continuity of treatment. The state-by-state approach to regulating compounding organizations yields inconsistent standards and varying levels of enforcement on an industry that ships dangerous drugs across state lines.

Additionally, there are compounding professional standards that are used across the nation known as the United States Pharmacopeia and The National Formulary (USP–NF). USP-NF is a book of public pharmacopeial standards. It contains standards for (chemical and biological drug substances, dosage forms, and compounded preparations), excipients, medical devices, and dietary supplements. USP–NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary

supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF. The U.S. Federal Food, Drug, and Cosmetics Act designates the USP–NF as official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the standards in USP–NF to avoid possible charges of adulteration and misbranding.

In October 2012, the New England Compounding Center (NECC), based in Massachusetts, shipped contaminated product throughout the country, including California that resulted in the death of more than 60 people and 750 patients becoming ill from the tainted injections. NECC's compounding facility had obvious ongoing safety violations, but continued to operate and ship products despite employee whistleblower complaints to management. The compounding facility failed to maintain its clean room. The air intake for the clean room was contaminated and shared with the neighboring furniture recycling facility, and employees discovered mold on various work and storage surfaces several times per year. Yet, NECC remained accredited and was licensed to ship sterile compounded injectable products into California.

Because the board had to rely on third-party accreditation, the board did not have the opportunity or authority to inspect NECC or prevent NECC from shipping products into California until patients in other states had already been harmed.

NECC is not the only compounding pharmacy to have recently caused significant patient harm. In June 2012, a sterile injectable pharmacy located in Florida shipped contaminated product into California which resulted in significant patient harm, including blindness in some cases. Again, the board was only able to take action after patient harm had already occurred.

At the October 2013 Board Meeting, the board moved to initial notice of proposed changes in the California's compounding regulations (located in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq). The 45-day comment period ran from November 29, 2013 – January 13, 2014. A regulation hearing was held on January 16, 2014, to provide the public with an opportunity to provide comments in another forum.

During the notice period, the board received many written and oral comments. Board staff sorted all written and oral comments received by section number, to facilitate review all of related comments by section. This compilation document was available at the January 2014 board meeting and online. At the January 2014 board meeting, the board made a motion to allow the sterile compounding workgroup to work through the comments received and submit a second version of the proposed text based on comments.

After reviewing and considering the written and oral comments received, board staff recommended to the board to withdraw the current rulemaking file originally noticed November 29, 2013, and provide general guidance from the sterile compounding workgroup to develop new updated language based on substantive comments received by the board and notice the revised language as a new rulemaking. At the April 2014 Board meeting, the board

agreed with the recommendation. The board submitted a "Decision Not to Proceed" with the rulemaking file and was published in the California Notice Register on May 9, 2014.

The board's sterile compounding workgroup continued to work with stakeholders provide for revised languages that maintained the board's as well as addressed stakeholders' concerns. The board's proposal demonstrates the board's desire to ensure California compounding regulations reflect at minimum the compounding standards used in the profession. With the approval of SB 294 by the Legislature and Governor, parameters will be established and will provide uniformity for pharmacies that carry out compounding in general (including sterile injectable).

PROBLEM/BENEFITS STATEMENT APPLYING TO ALL SECTIONS:

The problem addressed is to ensure current compounding regulations reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). The board's proposal also addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 37 <797> and reducing such discrepancy for the compounding profession who are compounding drug products in California and shipping into California so as to ensure the safety of all consumers receiving compounded drugs in California. This is a real benefit to the people of the State of California particularly when the protection of public health and safety, worker safety, or the environment is involved.

Documents Incorporated by Reference: Chapters 71, 85, 151, 795, and 797 of the United States Pharmacopeia – National Formulary (USP37 – NF 32 through 2nd Supplement) (37th Revision, Effective December 1, 2014).

Amend 16 CCR §1735

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

The purpose of the board's proposal makes the following changes:

- Subdivision (4) adds "compounded" to clarify the type of drug preparation.
- Subdivision (4) deletes "product" and replaces with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (4) (b) adds a comma between rectal and topical to clarify the separate routes of administration.
- Subdivision (4) (b) adds "the sole act of" to clarify tablet splitting is not included in the compounding definition.
- Subdivision (4) (b) adds "or crushing, capsule opening," to clarify these routes are not included in the compounding definition.
- Subdivision (c) deletes "product" replaces with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates

it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (d) deletes "injectable" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation.

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 purpose of the board's proposal will add the following definitions or amend the following subdivisions as listed below.

- Subdivision (a) adds a definition of "anteroom" for purposes of compounding drug products. The definition clarifies and specifies "anteroom" means an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the buffer area and maintains air flows from clean to dirty areas.
- Subdivision (b) adds a definition of "batch" for purposes of compounding drug products. The definition clarifies and specifies "batch" means compounding of two or more finished drug preparation units produced during the same continuous cycle of compounding and shall include any multiple dose vials prepared for administration to more than one patient.
- Subdivision (c) adds a definition of "beyond use date" for purposes of compounding drug products. The definition clarifies and specifies "beyond use date" means the date or date and time after which a compounded drug preparation shall not be stored or transported, or administration begun.
- Subdivision (d) adds a definition of "buffer area" for purposes of compounding drug products. The definition clarifies and specifies "buffer area" means an area providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located.
- Subdivision (e) adds a definition of "bulk drug" for purposes of compounding drug products. The definition clarifies and specifies "bulk drug" means any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances.
- Subdivision (f) adds a definition of "cleanroom" for purposes of compounding drug products. The definition clarifies and specifies "cleanroom" means (which may also be

referred to as a buffer area) means a physically separate room with walls and doors providing at least an ISO Class 7 or better air quality where the primary engineering control is physically located. This room maintains segregation from the adjacent ante-area (ante-room) by means of specific pressure differentials. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area. The displacement concept shall not be used for high-risk compounding.

- Subdivision (g) adds a definition of "controlled cold temperature" for purposes of compounding drug products. The definition clarifies and specifies "controlled cold temperature" means 2.2 degrees to 7.7 degrees C (36 degrees to 46 degrees F).
- Subdivision (h) adds a definition of "controlled freezer temperature" for purposes of compounding drug products. The definition clarifies and specifies "controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F).
- Subdivision (i) adds a definition of "controlled room temperature" for purposes of compounding drug products. The definition clarifies and specifies "controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).
- Subdivision (j) renumbers previous subdivision (a) as subdivision (j).
- Subdivision (k) adds a definition of "first air" for purposes of compounding drug products. The definition clarifies and specifies "first air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.
- Subdivision (l) adds a definition of "gloved fingertip sampling" for purposes of compounding drug products. The definition clarifies and specifies "gloved fingertip sampling" means a process where, compounding personnel lightly press each fingertip and thumb onto appropriate growth media, that are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.
- Subdivision (m) renumbers previous subdivision (b) as subdivision (m). Subdivision (m) amends the definition of "integrity" for the purposes of compounding drug products. The definition clarifies and specifies "integrity" means that all aspects of quality including sterility, packaging, chemical stability and potency, handling, and transport and storage are maintained throughout the drug preparation process, and until the beyond use date provided on the label. The revised definition removes "retention of potency" and changes "expiration" to "beyond use" as well as changes "noted" to "provided."
- Subdivision (n) adds a definition of "media-fill test" for purposes of compounding drug products. The definition clarifies and specifies "media-fill test" means a test that mimics compounding procedures using a growth-based media to demonstrate that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. Media fill tests are conducted on the most challenging and routine compounding procedures performed.

- Subdivision (o) adds a definition of “parenteral” for purposes of compounding drug products. The definition clarifies and specifies “parenteral” means a sterile preparation of drugs for injection or implantation through one or more layers of skin.
- Subdivision (p) adds a definition of “personal protective equipment” for purposes of compounding drug products. The definition clarifies and specifies “personal protective equipment” means clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
- Subdivision (q) renumbers previous subdivision (c) as subdivision (q). Subdivision (q) amends the definition of “potency” for the purposes of compounding drug products. The definition clarifies and specifies “potency” means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement, Effective December 1, 2014) of the labeled amount by adding “(or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement, Effective December 1, 2014).”
- Subdivision (r) adds a definition of “preparation” for purposes of compounding drug products. The definition clarifies and specifies “preparation” means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not contain sterile products.
- Subdivision (s) adds a definition of “prescriber’s office” or “prescriber office” for purposes of compounding drug products. The definition clarifies and specifies “prescriber’s office” or “prescriber office” means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment.
- Subdivision (t) adds a definition of “Primary Engineering Control (PEC)” for purposes of compounding drug products. The definition clarifies and specifies “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 environment or better through the use of unidirectional HEPA filtered first air.
- Subdivision (u) adds a definition of “process validation” for purposes of compounding drug products. The definition clarifies and specifies “process validation” means demonstrating that when a process is operated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.
- Subdivision (v) adds a definition of “product” for purposes of compounding drug products. The definition clarifies and specifies “product” means a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (w) renumbers previous subdivision (d) as subdivision (w). Subdivision (w) amends the definition of “quality” for the purposes of compounding drug products. The definition clarifies and specifies “quality” means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active and inactive ingredients other than those noted on the label by adding “and inactive” to the definition.
- Subdivision (x) adds a definition of “segregated compounding area” for purposes of compounding drug products. The definition clarifies and specifies “segregated compounding area” means a designated space where a device that provides

unidirectional airflow of ISO Class 5 air quality, including compounding aseptic isolators, is located within either a demarcated area (at least three foot perimeter) or room. Such area shall contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation, and shall not have a sink located within at least three feet of the ISO Class 5 PEC. This sterile compounding area will be restricted to preparing sterile-to-sterile compounded preparations.

- Subdivision (y) adds a definition of "smoke test" for purposes of compounding drug products. The definition clarifies and specifies "smoke test" means an analysis of the airflow in the ISO Class 5 PEC using a smoke generating device.
- Subdivision (z) renumbers previous subdivision (e) as subdivision (z). Subdivision (z) amends the definition of "strength" for the purposes of compounding drug products. The definition clarifies and specifies "strength" means amount of active ingredient per unit of a compounded drug preparation. The word "preparation" replaced the word "product" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

These changes are necessary is to ensure consistency in for all compounded drug products with sterile ingredients and not limit it to only those sterile drug products from one or more non-sterile ingredients.

Amend 16 CCR §1735.2

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) deletes "product" twice and replaces with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) deletes "product" replaces with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) deletes "as used in" and replaces with "furnished to a prescriber for office use by the prescriber as authorized by" to clarify the application of "reasonable quantity" in accordance with Business and Professions Code section 4052. The word "subdivision" is added to clarify the regulation refers to subdivision (a)(1) of the Section 4052 of the Business and Professions Code.
- Subdivision (c) deletes "product" and replaces with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates

it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (c) (1) further clarifies subdivision (c) and deletes “or application to patients in the prescriber’s office, or for distribution of not more than” and “to the prescriber’s patients, as estimated by the prescriber” and adds “ordered and paid for by the prescriber, using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber’s office for whom the drug is needed or anticipated, and the quantity for each patient that is”; “either office”; and “or furnishing of.”
- Subdivision (c) (2) further clarifies subdivision (c) by adding “is delivered to the prescriber office and signed for by the prescriber; and.”
- Subdivision (c) (3) further clarifies subdivision (c) by adding “is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 72-hour supply solely to the prescriber's own patients seen as part of regular treatment in the prescriber's office, as estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy; and.”
- Subdivision (c) (4) further clarifies subdivision (c) by adding “(4)” to “is reasonable considering the intended use of the compounded medication and the nature of the prescriber’s practice; and.”
- Subdivision (c) (5) further clarifies subdivision (c) by renumbering subdivision (c) (3) to subdivision (c) (5) and replacing “product” with “preparation; and” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) (6) further clarifies subdivision (c) by adding “does not exceed an amount the pharmacy can reasonably and safely compound.”
- Subdivision (d) adds the following language to specify when a pharmacy or pharmacist shall not compound a drug preparation by adding, “No pharmacy or pharmacist shall compound a drug preparation that:

  (1) is classified by the FDA as demonstrably difficult to compound;

  (2) appears on a FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

  (3) is a copy or essentially a copy of one or more drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense. The pharmacy shall retain a copy of the documentation of the shortage in the pharmacy records for three years.
- Subdivision (e) renumbers previous subdivision (d) as subdivision (e) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (e) (3) deletes “Expiration dating requirements.” and replaces with “The rationale or reference source for determining the maximum allowable beyond use date for this preparation.” to specify the requirement for determining the maximum allowable beyond use date.
- Subdivision (e) (5) deletes “Process and/or procedure” and replaces with “Specific compounding steps” to clarify the requirement for identifying what is used to prepare the drug of a master formula.
- Subdivision (f) renumbers previous subdivision (e) as subdivision (f) and replaces twice “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (g) renumbers previous subdivision (f) as subdivision (g) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (h) renumbers previous subdivision (g) as subdivision (h) and deletes the “l” in the word “compendial” making word “compendia” for accuracy.
- Subdivision (i) renumbers previous subdivision (h) as subdivision (i) and replaces “product(s)” with “preparation(s)” four times and adds “, stored, transported, or administration begun.” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. “An expiration” is changed to “A beyond use” and to clarify the date representing the date beyond which it is used.
- Subdivision (j) renumbers previous subdivision (i) as subdivision (j) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (k) renumbers previous subdivision (j) as subdivision (k) and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The reference “(Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. 02/12.)” is replaced with “as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations to better specify the reference. Deletes “injectable” twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. “Date” is

added to specify a self-assessment shall be completed within 30 days of the start date of a new pharmacist-in-charge and "or change of location" is added to specify a self-assessment shall be completed within 30 days of a change of location for the pharmacy.

- Subdivision (l) adds the following language to specify requirements for ingredients that are received without a supplier's expiration date, "Packages of ingredients that lack a supplier's expiration date are subject to the following limitations:

  (1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy unless either appropriate documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and

  (2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity."
- California Code of Regulations sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 are added to the References cited to ensure compliance with the Administrative Procedures Act.

The necessity of these changes is to make specific and further clarify the requirements for compounding limitations as well as self-assessment requirements.

Amend 16 CCR §1735.3

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board's proposal will change the section's title from "Records of Compounded Drug Products" to "Recordkeeping for Compounded Drug Preparations" to delineate the records are to be made and kept for compounded drug preparations. This change is necessary to clarify the board's intentions with regard to recordkeeping regulations and addresses the problem of ensuring the board's licensees understand the intent of the regulation.

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) replaces "product" with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word "the" is also deleted to correct grammar.
- Subdivision (a) (2) replaces "product" with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (a)(3) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “the” was replaced with “any” and the words “who compounded the” was replaced with “engaged in compounding the” to correct grammar.
- Subdivision (a) (4) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (5) replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (6) replaces “products” with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code” was moved for ease of readability. The reference “Chapter 797 of the United States Pharmacopeia – National Formulary (USP-NF) (35th Revision, Effective May 1, 2012)” was updated to the current reference of ““Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014)”
- Subdivision (a) (7) adds a hyphen to “pharmacy-assigned” to correct grammar. It also replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (8) deletes “expiration” and replaces with “beyond use” to specify the requirement for determining the maximum allowable beyond use date and replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (9) adds the word “final” to specify the final quantity or amount. The subdivision also replaces “product” with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “for dispensing” is also added to the subdivision to clarify the requirement for which the final quantity or amount of drug preparation compounded.
- Subdivision (a) (10) is added to include “Storage for the drug preparation” as a requirement for recordkeeping.

- Subdivision (c) is reorganized to add "Active pharmaceutical ingredients shall be obtained from a FDA registered supplier. All other c" and the "C" is deleted to the first sentence to require FDA register suppliers be used. The word "and" is inserted between "substance" and "drug" products while ", and components" is deleted to specify the requirements. The word "products" is replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrases ", whenever possible," is added; "reliable" is deleted; and "FDA-registered" qualifier is added to specify requirements for suppliers. In the second sentence, the words "any available" is deleted requiring certificate of purity or analysis for chemicals. The word "and" is added to include certificate of purity for both chemicals and bulk drug substances. The words ", drug products, and components" are deleted for redundancy. The sentence "Certificate s of purity or analysis are not required for drug products that are approved by the Food and Drug Administration." is deleted and the sentence "Certificates of purity or analysis are to be matched to the product received." is added requiring certificates of purity or analysis to be matched to the product received.
- Subdivision (d) is enhanced to add the sentence "If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c)." providing the requirement for electronic records maintenance.

The necessity of these changes in 16 CCR §1735.3 are required to update the recordkeeping for compounded drug preparation requirements.

Amend 16 CCR §1735.4

Existing regulations at 16 CCR §1735.4 specify requirements for labeling of compounded drug products. The purpose of the board's proposal will change the section's title from "Labeling of Compounded Drug Products" to "Labeling of Compounded Drug Preparations" to delineate the labeling requirements. This change is necessary to clarify the board's intentions with regard to labeling requirements in regulations for compounded drug preparations. The board's proposal addressed the problem of ensuring the board's licensees understand the intent of the regulation.

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) replaces "product" with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) replaces "products" with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase "the name of the compounding pharmacy and

dispensing pharmacy, if different," is added to specify the name(s) of the pharmacies required to be on the label of a compounded drug preparation. The word "expiration" is deleted and replaced with "beyond use" to specify the requirement for determining the maximum allowable beyond use date.

The necessity of these changes in 16 CCR §1735.4 are required to update the labeling for compounded drug preparation requirements.

Amend 16 CCR §1735.5

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) adds the sentence "The pharmacy shall follow its policies and procedures. Failure to follow these policies and procedures shall constitute grounds for disciplinary action." to ensure pharmacies are required to adhere to their own policies and procedures.
- Subdivision (b) adds the phrase "and such review shall be documented" to ensure that reviews to policies and procedures are completed and noted as such.
- Subdivision (c) addes a colon to the end of the text in the subdivision.
- Subdivision (c) (2) adds the requirement of "Evidence that staff have been educated and trained on all policies and procedures." to ensure compounding personnel are trained in accordance with policies and procedures.
- Subdivision (c) (3) renumbers previous subdivision (2) as subdivision (3) and deletes the phrase "Documentation of a" and replaces it with "A written" to clarify the requirement for a plan of recall. The word "product" is replaced with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase "of a compounded drug product" is deleted and the sentence "All affected doses can be accounted for as part of the recall." was added to further clarify the plan of recall requirement.
- Subdivision (c) (4) renumbers previous subdivision (3) as subdivision (4).
- Subdivision (c) (5) is added to include "The procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process." thereby providing further clarification on procedures.
- Subdivision (c) (6) renumbers previous subdivision (4) as subdivision (6) and adds the phrase "appropriate to compound drug preparations" as well as deleting "test" and replacing it with "validate" to further clarify documentation of methodology. The word "product" is replaced with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) (7) renumbers previous subdivision (5) as subdivision (7) and the word "expiration" is deleted and replaced with "beyond use" to specify the requirement for determining the maximum allowable beyond use date. The word "product" is replaced

with “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (c) (8), (9), (10) and (11) were added to further clarify requirements for compounding policies and procedures.

  (8) Dates of annual reviews of the policy and procedure manual by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.
  (9) Dates of any revisions to the policy and procedure manual approved by the pharmacist-in-charge, signed and dated by the pharmacist-in-charge.
  (10) Policies and procedures for storage of compounded sterile drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures.
  (11) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations.

- Business and Professions Code section 4301 is added to the References Cited to ensure compliance with the Administrative Procedures Act. The word “and” is deleted and replaced later in the citation for accuracy.

The necessity of these changes in 16 CCR §1735.5 are required to update the compounding policies and procedures requirements.

Amend 16 CCR §1735.6

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

The purpose of the board’s proposal makes the following changes:

- Subdivision (a) deletes the word “products” and replaces it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) deletes the word “products” and replaces it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) adds the phrase “that weighs, measures, or transfers ingredients” to specify what equipment this subdivision applies. The word “products” is deleted and replaces with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase “, per manufacturer’s specifications,” is added to require pharmacy personnel to ensure the manufacturer’s specifications are included.

The necessity of these changes in 16 CCR §1735.6 are required to update the compounding facilities and equipment for compounded drug preparation requirements.

Amend 16 CCR §1735.7

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

The purpose of the board's proposal makes the following changes:

- Subdivision (c) deletes the word "product" and replaces it with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

The necessity of these changes in 16 CCR §1735.7 are required to update the training of compounding staff for compounded drug preparation requirements.

Amend 16 CCR §1735.8

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) deletes the word "products" and replaces it with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (c) deletes the word "products" twice and replaces it with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (d) deletes the word "product" and replaces it with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e) is added to require "The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations, including for preparations furnished to patient care areas." to ensure policies and procedures address out-of-range temperature variations.

The necessity of these changes in 16 CCR §1735.8 are required to update the compounding quality assurance requirements.

Amend 16 CCR §1751

Existing regulations at 16 CCR §1751 specify requirements for sterile injectable compounding. The purpose of the board's proposal will change the section's title from "Sterile Injectable Compounding" to "Sterile Compounding" to delineate the sterile compounding requirements. This change is necessary to clarify the board's intentions with regard to sterile compounding requirements in regulations and addressed the problem of ensuring the board's licensees understand the intent of the regulation.

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) deletes "injectable" twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (a) also deletes "products" and replaces with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) deletes "injectable" twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (b) also deletes "products" and replaces with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. This subdivision also deletes "designated" and adds "compounding" and "designated." The word "drug" is added before preparation. These changes clarify the compounding area designated for the preparation of sterile drug preparations. The following phrase and sentence is added to enhance the understanding of the compounding area designated for the preparation of sterile drug preparations, "preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The buffer area, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.12 of Title 24, Part 4, Chapter 5 of the California Code of Regulations." The phrase "which shall meet the following standards:" was deleted and replaced with "The environments within the pharmacy shall meet the following standards:" for clarity.
- Subdivision (b) (1) – (4) was deleted and (4) was written as the current subdivision (b) (1) to state, "Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations. Certification records must be retained for at least 3 years." This ensured the requirements for certification of ISO environments are done at least every six months in accordance with Section 1751.4 of Title 16, Division 17, of the California Code of Regulations.
- Subdivision (b) (2) renumbers previous subdivision (5) as subdivision (2). The following sentence was deleted, "The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations." The word

"injectable" was deleted once and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (b) also deletes "products" and replaces with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (b) (3) renumbers previous subdivision (6) as subdivision (3). The following sentence was added to specify the location of sinks and drains, "Sinks and drains shall not be present in an ISO Class 7 or better buffer area, nor within three feet of an ISO Class 5 PEC or better located in segregated compounding areas. A sink may be located in an ante-area."
- Subdivision (b) (4) renumbers previous subdivision (7) as subdivision (4). In subdivision (b) (4), a comma was added and the "/or" was removed. Inserted after the comma is the phrase "where appropriate, a." A comma was inserted after the word "freezer." The phrase "or freezing" was added to the last sentence. These changes clarified the refrigerator/freezer requirements.
- Subdivision (c) deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. Subdivision (b) also deletes "products" and replaces with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Sections 1735, 1735.1-1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations is added to the References Cited to ensure compliance with the Administrative Procedures Act.

The necessity of these changes in 16 CCR §1751 are required to update the sterile compounding; compounding area; and self-assessment requirements for sterile compounded drug preparations.

Amend 16 CCR §1751.1

Existing regulations at 16 CCR §1751.1 specify requirements for sterile injectable recordkeeping requirements. The purpose of the board's proposal will change the section's title from "Sterile Injectable Recordkeeping Requirements" to "Sterile Compounding Recordkeeping Requirements" to delineate the sterile compounding recordkeeping requirements. This change

is necessary to clarify the board's intentions with regard to sterile compounding requirements in regulations and addressed the problem of ensuring the board's licensees understand the intent of the regulation.

The purpose of the board's proposal makes the following changes:

- Subdivision (a) is deleted in its entirety, "Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber." This subdivision text is added as the new subdivision (b).
- Subdivision (b) is renumbered to (a) with the deletion of reference to the former subdivision (a) by deleting the following phrase "and subdivision (a)." The phrase "compounded drug" is added while "products" is deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. Additionally, "compounded from one or more non-sterile ingredients" is deleted to further clarify this requirement.
- Subdivision (a) (1) deleted "product" and replaced it with "preparation" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (2) was added to include results of gloved fingertip testing assessments, "Results of hand hygiene and garbing assessment with integrated gloved fingertip testing."
- Subdivision (a) (3) was added to include aseptic technique assessments, "Results of assessments of personnel for aseptic techniques including results of media fill tests and gloved fingertip testing performed in association with media fill testing."
- Subdivision (a) (4) was added to include viable volumetric air and surface sampling, "Results of viable volumetric air and surface sampling."
- Subdivision (a) (5) was renumbered from (2) as the current (5) to include additional documentation of refrigerator and freezer temperature requirements. "Daily documentation of room" was added to the beginning of the sentence with the "R" for refrigerator being changed to a lowercase "r" and a comma being added after refrigerator. The phrase was added to the end of the sentence and included the following temperatures, "appropriate for drug preparations consistent with the temperatures listed in section 1735.1 for:
    (A) Controlled room temperature.
    (B) Controlled cold temperature.
    (C) Controlled freezer temperature."
    The period after the colon was deleted for accuracy.
- Subdivision (a) (6) was renumbered from (3) as the current (6) and added an "s" to "certification" to include all certifications for the sterile compounding environment.
- Subdivision (a) (7) was added to include requirements for air pressure differentials and air velocity documentation, "Daily documentation of air pressure differentials or air velocity between adjoining all ISO rooms or areas and measurement between all ISO

rooms or areas, including those associated with compounding aseptic (containment) isolators."

- Subdivision (a) (8) was renumbered from (4) as the current (8).
- Subdivision (a) (9) was renumbered from (5) as the current (9) to add the requirement of "Logs or other documentation" of inspections for expired or recalled pharmaceutical products or raw ingredients for better patient health and safety. The "I" from "Inspection" was changed to "l" and an "s" was added to "inspection" for accuracy.
- Subdivision (a) (10) was renumbered from (6) as the current (10).
- Subdivision (b) was moved from the previous subdivision (a) and stated as, "Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name of the compounded drug preparation, lot number, amount, and date on which the preparation was provided to a prescriber."
- Subdivision (c) added the following sentence to address requirements for electronically stored data, "If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c)."

The necessity of these changes in 16 CCR §1751.1 are required to update the sterile compounding recordkeeping requirements.

Amend 16 CCR §1751.2

Existing regulations at 16 CCR §1751.2 specify sterile injectable labeling requirements. The purpose of the board's proposal will change the section's title from "Sterile Injectable Labeling Requirements" to "Sterile Compounding Labeling Requirements" to delineate the sterile compounding labeling requirements. This change is necessary to clarify the board's intentions with regard to sterile compounding requirements in regulations and addressed the problem of ensuring the board's licensees understand the intent of the regulation.

The purpose of the board's proposal makes the following changes:

- "California Code of Regulations" was added to ensure the correct citation for section 1735.4. The word "injectable" was deleted twice and replaced twice with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted twice and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014,

required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. A few minor grammatical changes were made in changing "for" to "to" and "of" to "by."

- Subdivision (b) deleted the "s" on concentrations. Subdivision (b) deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (d) deleted the word "cytotoxic" and replaced it with "hazardous." The phrase "Chemotherapy – Dispose of Properly" was deleted and moved to the end of the sentence with the addition of ", if applicable." The word "Cytotoxic" was deleted and replaced with "Hazardous." The word "or" was deleted.

The necessity of these changes in 16 CCR §1751.2 are required to update the sterile compounding labeling requirements for compounded drug preparation requirements.

Amend 16 CCR §1751.3

Existing regulations at 16 CCR §1751.3 specify requirements for sterile injectable policies and procedures. The purpose of the board's proposal will change the section's title from "Sterile Injectable Policies and Procedures" to "Sterile Compounding Policies and Procedures" to delineate the sterile compounding policy and procedures requirements.

The purpose of the board's proposal makes the following changes:

- Subdivision (a) deleted the word "injectable" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation and to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (a) (1) deleted the words “injectable compounds” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.) and replaced with “drug preparations.” California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “compounds” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (2) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “product” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (a) (3) added “Proper use of” and deleted the “E” replacing it with a “e” to further clarify the proper use of equipment and supplies.
- Subdivision (a) (4) added “all aspects of” as well as deleted “injectable” replacing it with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “product” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The subdivision (a) (4) is extended to include specific requirements for training and knowledge competency of staff, “including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; cleaning and disinfection of controlled compounding areas and proper aseptic technique.”
- Subdivision (a) (5) was added to include hand hygiene and garbing, “Hand hygiene and garbing.”
- Subdivision (a) (6) was added to include cleaning and maintenance, “Cleaning and maintenance of ISO environments and segregated compounding areas.”

- Subdivision (a) (7) was added to include environmental sampling plan and procedures, "An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling."
- Subdivision (a) (8) was added to include manufacture's purge times, "For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time."
- Subdivision (a) (9) was added to include media fill testing procedures, "Media fill testing procedure."
- Subdivision (a) (10) was added to include stability and beyond use dating, "Compounded sterile drug preparation stability and beyond use dating."
- Subdivision (a) (11) was added to include final quality checks, "Visual inspection and other final quality checks of sterile drug preparations."
- Subdivision (a) (12) was renumbered from (5) as the current (12). The phrase ", compounding and disposal of" was added while "cytotoxic" was replaced with "hazardous" to allow for more descriptive requirement for handling of hazardous agents.
- Subdivision (a) (13) was renumbered from (6) as the current (13).
- Subdivision (a) (14) was renumbered from (7) as the current (14).
- Subdivision (c) deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted twice and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word "cytotoxic" was deleted and replaced with the word "hazardous" as this is a more commonly used nomenclature.
- Subdivision (d) deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase "from one or more non-sterile ingredients" was deleted to require written policies and procedures for drug preparations from one non-sterile ingredient.
- Subdivision (d) (2) deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014,

required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (d) (3) (A) added "Orientation, training, and" and the "C" was changed to "c" as well as added "of compounding personnel." This clarifies requirements for competency evaluation.
- Subdivision (d) (3) (D) added "Media fill testing and" while deleting "P" and replacing it with "p" for process validation to clarify the requirement of process validation.
- Subdivision (d) (3) (E) deleted "Personnel access and movement of materials into and near the controlled area" and added "Conduct of personnel in controlled areas and aseptic technique overview." to further define personnel conduct.
- Subdivision (d) (3) (F) deleted "environmental control devices" and replaced with the new definition of "PEC." "Critical" was deleted and replaced with "direct compounding" and "manipulation of sterile products" was deleted and replaced with "compounding of sterile drug preparations." The parenthetical "(e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations)." was deleted.
- Subdivision (d) (3) (G) deleted "Regular" and replaced with "Daily and monthly" to cleaning and added "and disinfection" to increase the requirements for cleaning and disinfecting. The phrase "and the alteration of disinfectants" was deleted and replaced with the correct citation of "as specified in California Code of Regulations section 1751.4." The sentence regarding exemptions was deleted, "Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision."
- Subdivision (d) (3) (H) deleted the sentence, "Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area." and replaced it with "Non-viable particle testing" to further define the testing requirement.
- Subdivision (d) (3) (I) deleted the sentence, "For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation." and replaced it with "Viable air sampling." to further specify the viable air sampling.
- Subdivision (d) (3) (J) deleted "Sterilization" and replaced it with "Surface sampling" to further define the requirements for surface sampling.
- Subdivision (d) (3) (K) deleted "End-product evaluation and testing." and replaced with "Airflow considerations and pressure differential monitoring." to further specify airflow differential monitoring.
- Subdivision (d) (3) (L) added requirements for temperature and humidity monitoring, "Temperature and humidity monitoring in compounding and controlled storage areas."

- Subdivision (d) (3) (M) added requirements for facility management, “Facility management including certification and prevention maintenance of controlled environments and related equipment.”
- Subdivision (d) (3) (N) added requirements for sampling, “Gloved fingertip sampling.”
- Subdivision (d) (3) (O) added requirements for stability and assignment of beyond use dating, “Compounded sterile product stability and assignment of beyond use dating.”
- Subdivision (d) (3) (P) added requirements for automated compounding devices, “Use of automated compounding devices (if applicable).”
- Subdivision (d) (3) (Q) added requirements for hazardous drug compounding, “Hazardous drug compounding (if applicable).
    (i) Hazardous drug employee training and safety program.
    (ii) Hazardous drug handling, storage, labeling and transport.
    (iii) Hazardous drug compounding techniques.
    (iv) Hazardous drug spill, deactivation and waste management.”
- Subdivision (d) (3) (R) added requirements for sterile solutions, “Preparing sterile solutions from nonsterile components (if applicable).”
- Subdivision (d) (3) (S) added requirements for hand hygiene and garbing, “Hand hygiene and garbing.”
- Subdivision (d) (4) (A) added requirements for disposal and sanitation, “Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.”
- Subdivision (d) (4) (B) added requirements for sterile batch compounding, “For sterile batch compounding:,
    (i) use of master formulas and compounding work sheets;
    (ii) appropriate documentation; and
    (iii) appropriate sterility and bacterial endotoxin testing.”
- Subdivision (d) (4) (C) added requirements for non-sterile to sterile compounding, “For non-sterile to sterile compounding:
    (i) Sterilization methods
    (ii) End-product evaluation and testing.”
- Subdivision (d) (4) (D) added requirements for action levels for colony-forming units, “Action levels for colony-forming units (CFUs) detected during viable surface testing, glove fingertip and volumetric air sampling.”

The necessity of these changes in 16 CCR §1751.3 are required to update the sterile compounding policies and procedures for compounded drug preparation requirements.

Amend 16 CCR §1751.4

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile injectable compounding. The purpose of the board’s proposal will change the section’s title from “Facility and Equipment Standards for Sterile Injectable Compounding” to “Facility and Equipment Standards for Sterile Compounding” to delineate the facility and equipment standards for sterile compounding.

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) deleted the word "injectable" twice and replaced with "drug" once referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products(s)" was deleted twice and replaced with "preparation(s)" twice to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) added "compounding of" and removed "preparation of" to further clarify when this subdivision applied. Subdivision (b) also deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word "areas" was added and "area or cleanroom" was deleted prior to the addition of "for compounding" to further clarify the area in which this subdivision applies.
- Subdivision (c) added the word "areas" and "area or cleanroom" was deleted prior to the addition of "for compounding" to further clarify the area in which this subdivision applies.
- Subdivision (d) added the following to clarify where cleaning and disinfecting should take place, "Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:
    (1) at the beginning of each shift;
    (2) before and after each batch;
    (3) after each spill; and
    (4) when surface contamination is known or suspected."
- Subdivision (e) was renumbered from (d) as the current (e). The sentence, "Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination." was deleted and the following inserted to be more specific in what must be disinfected, "Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and

disinfected with a suitable agent (e.g., sterile isopropyl alcohol) daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent (e.g., sterile isopropyl alcohol) monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination."

- Subdivision (f) was renumbered from (e) as the current (f). The following was added to clarify requirements for pharmacies preparing sterile compounded preparations requiring the use of a PEC that provides ISO Class 5 or better, "Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012). Certification records must be retained for at least 3 years. Compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 buffer area if the isolator meets the following criteria:

  (1) particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
  (2) not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.
  (3) recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.
  Compounding aseptic isolators or compounding aseptic containment isolators that do not meet the requirements as outlined in this subdivision and are not located within an ISO Class 7 buffer area may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations."
- Subdivision (g) deleted "parenteral cytotoxic" and replaced with "sterile hazardous" to specify the agents required to adhere to Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations. The words "laminar air flow head" was replaced with negative pressure PEC" and "hood" was replaced with "negative pressure PEC" for clarification of the equipment. Certification was clarified when "annually" was deleted and "every six months" replaced it. The reference of "the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications." was deleted and replaced with "CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-11, Revised January 31, 2012)" to update the requirement reference. The sentence "Certification

records must be retained for at least 3 years." was deleted and these sentences were added to further define the requirement for the subdivision, "Any drug preparation that is compounded in a hazardous drug PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur, complete with hair cover, facemask, beard cover (if applicable), polyprophylen or low shedding gown that closes in the back, shoe covers, and two layers of gloves that have been tested to meet ASTM 6978-05 with the outermost glove that contacts the sterile drug preparation."

- Subdivision (h) was added to provide requirements if compounding aseptic isolators are used, "If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again."
- Subdivision (i) was added to provide clarity on viable surface sampling and volumetric air sampling requirements, "Viable surface sampling shall be done at least monthly for low and medium risk-level compounding and weekly for high-risk compounding. Volumetric air sampling by impaction shall be done at least once every six months for low and medium risk-level compounding and weekly for high-risk compounding. Viable surface and volumetric air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation. Remediation shall include an immediate investigation of cleaning and compounding operations and facility management."
- Subdivision (j) was added to provide clarity for the working environment of compounding personnel, "The pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. Humidity levels should be consistent ASHRAE Standard 55 (30-65% RH)."

The necessity of these changes in 16 CCR §1751.4 are required to update the facility and equipment standards for sterile compounding requirements.

Amend 16 CCR §1751.5

Existing regulations at 16 CCR §1751.5 specify requirements for sterile injectable compounding attire. The purpose of the board's proposal will change the section's title from "Sterile

Injectable Compounding Attire" to "Sterile Compounding Attire" to delineate the sterile compounding attire requirements.

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) is deleted and later rephrased in the new subdivision (b) to further define the requirements for appropriate attire when preparing hazardous agents.
- Subdivision (a) was renumbered from (b) as the current (a). The word "drug" was added and "products" was replaced with "preparations" as well as "from one or more non-sterile ingredients" was deleted to clarify when compounding sterile drug preparation standards must be met.
- Subdivision (a)(1) replaced the words "Cleanroom garb" with "Personal protective equipment" as well as "low" changed to "non" and "coverall" changed to "gown" to describe the type of attire required during sterile compounding. The phrases "facial hair covers (if applicable)," and ", unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing are not required" were added to further describe the requirements as well as allow for the manufacturer's specifications of compounding aseptic isolator or compounding aseptic containment isolator.
- Subdivision (a)(2) deleted "Cleanroom garb" and replaced with "Personal protective equipment" as well as replaced "outside the designated area" with "in an ante-area or immediately outside the segregated compounding area" to further clarify what must be donned and removed when preparing sterile compounding.
- Subdivision (a)(3) added the following sentences to further clarify the order in which personal protective equipment must be donned, "Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown."
- Subdivision (a) (4) was renumbered from (a) (3) as the current (a) (4) and added "Compounding personnel shall not wear." The "h" was changed to "H" and the word "and" was changed to "or" while the phrase "must be eliminated" was deleted. All changes were made to specify who should not wear jewelry during compounding.
- Subdivision (a) (4) was deleted for duplication.
- Subdivision (a) (5) was added in lieu of Subdivision (a) (4) by striking, "Gloves made of low-shedding materials are required" and adding, "Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or buffer area. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and

after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected." to further specify the requirements for sterile gloves to be worn during sterile compounding.

- Subdivision (a) (6) was added to specify personnel who are not allowed to participate in sterile compounding when the following applies, "Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from the compounding areas until their conditions are remedied."
- Subdivision (c) was deleted as previous subdivisions (a) and (b) were altered and subdivision (c) no longer applied.
- Subdivision (b) was added to specify attire to be required while preparing hazardous agents as, "When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator)."

The necessity of these changes in 16 CCR §1751.5 are required to update the sterile compounding attire for compounded drug preparation requirements.

Amend 16 CCR §1751.6

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile injectable compounding staff, patient, and caregiver for sterile injectable compounding. The purpose of the board's proposal will change the section's title from "Training of Sterile Injectable Compounding Staff, Patient, and Caregiver." to "Sterile Compounding Consultation; Training of Sterile Compounding Staff." to further clarify requirements on sterile compounding consultation and training of staff.

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

The purpose of the board's proposal makes the following changes:

- Subdivision (a) added the phrase, ", storage, handling, and disposal" to further clarify direction that should be provided to the patient and/or caregiver about instructions for taking sterile compounded drugs. The subdivision also deleted the word "injectable" and replaced with "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (b) deleted the phrase "be responsible to" and added "that" to further clarify the pharmacist-in-charge's responsibilities for training of compounding staff.

The subdivision also deleted the word “injectable” twice and replaced with “drug” once referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “shall” was deleted as it was redundant. The word “products” was deleted twice and replaced with “preparations” twice to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The word “cytotoxic” was deleted twice and replaced with “hazardous” twice to be more specific in the requirements of specific agents.

- Subdivision (d) deleted the word “injectable” and replaced with “drug” referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word “products” was deleted and replaced with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e) deleted the phrase “products from one or more non-sterile ingredients” and replaced it with “preparations” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e) (1) (C) deleted the word “product” and replaced with the word “preparation” to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.
- Subdivision (e) (1) (E) added the phrase “using media fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the selected manipulations” to further specify the requirements for aseptic procedures.
- Subdivision (e) (1) (F) added “hand hygiene” to further specify the requirements for proper techniques required.
- Subdivision (e) (1) (G) added the “t” to the word “the” as it was previously left out and corrects the spelling.
- Subdivision (e) (1) (H) added the words “of the” and “and” and deleted “used in” to clarify the requirement for cleaning, sanitizing, and maintaining the equipment and the controlled area.

- Subdivision (e) (1) (I) added "for compounding sterile drug preparations from one or more non-sterile ingredients" to further specify the sterilization technique requirement.
- Subdivision (e) (2) deleted the phrase "assigned to the controlled area" and replaced with the phrase "engaged in sterile compounding" as well as added the phrase "at least" to clarify the requirement for practical skills training in aseptic technique and aseptic area practices.

The necessity of these changes in 16 CCR §1751.6 are required to update the sterile compounding consultation and training of sterile compounding staff requirements.

Amend 16 CCR §1751.7

Existing regulations at 16 CCR §1751.7 specify requirements for sterile injectable compounding quality assurance and process validation. The purpose of the board's proposal will change the section's title from "Sterile Injectable Compounding Quality Assurance and Process Validation." to "Sterile Compounding Quality Assurance and Process Validation." to further clarify requirements on sterile compounding quality assurance and process validation.
Existing regulations at 16 CCR §1751.7 specify sterile compounding quality assurance and process validation.

The purpose of the board's proposal makes the following changes:

- Subdivision (a) deleted the word "injectable" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The words "Quality Assurance Program" were changed to "quality assurance program" to correct the grammar.
- Subdivision (a) (1) added the words "Procedures for" in the beginning of the sentence; changed the "C" to "c" in cleaning; deleted the words "parenteral medicine" and added the word "sterile" to further specify the procedures for cleaning and sanitizing the sterile preparation area.
- Subdivision (a) (2) deleted in its entirety.
- Subdivision (a) (2) was renumbered from (a) (3) as the current (a) (2).
- Subdivision (a) (3) was renumbered from (a) (4) as the current (a) (3). Subdivision (a) (3) deleted "Written justification of" and replaced with "Documentation justifying" to specify the requirement for documentation justifying the chosen beyond use dates. The word "expiration" was replaced with "beyond use" to specify the use of beyond use instead of expiration date. Subdivision (a) (3) also deleted the word "injectable" and added the word "drug" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter

565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted and replaced with "preparations" to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

- Subdivision (b) deleted the word "injectable" three times and added the word "drug" twice referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted three times and replaced with "preparations" three times to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase "demonstrate competency by successfully performing aseptic media fill tests" replaced "complete a validation process on technique" to specify the completion of a successful aseptic media fill test. The following was deleted as this is captured in identifying the aseptic media fill test, "The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare." The following was added to indicate the level of complexity of the required media fill testing process, "The media fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount of volume transferred during the compounding process." This sentence was added to provide qualifications for a successful media test, "Media used must have demonstrated the ability to support and promoted growth." The word "medium" was corrected to state "media" for correct grammar. The phrase "in a manner consistent with the manufacturer's recommendations" was added to incorporate inclusion of manufacture's recommendations into the qualifications for successful media testing. The words "employee's" and "and documented" were added as well as "media fill testing" replaced "validation process" to further clarify procedures when microbial growth was found in an employee's sterile preparation process. The phrase "for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients" was added to specify competency revalidation for sterile to sterile compounding and non-sterile to sterile compounding. The word "is" was changed to "are" to correct the grammar.
- Subdivision (c) was added to specify and clarify what procedures are included in the initial competency evaluation, "All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand

hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations."

- Subdivision (d) was added to specify and clarify the components and time specific elements of re-evaluation, "Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients."
- Subdivision (e) was renumbered from (c) as the current (e). Subdivision (e) deleted the word "injectable" referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted once and replaced with "preparations" once to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA. The phrase "shall be subject to documented end product testing for sterility" was replaced with "that are exposed longer than 12 hours at 2 to 8 degrees C and longer than 6 hours at warmer than 8 degrees C before they are sterilized shall meet the sterility test in accordance with methodologies and processes found in Chapter 71 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014)," specifies requirements for sterility testing. The words "testing for" was added before "pyrogens" and "in accordance with the methods of Chapters 85 and 151 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference," was added after "pyrogens" to specify that testing is required and to what standard the testing must be. The words "before dispensing" were added to clarify the testing for pyrogens must occur prior to dispensing. This sentence was added to further when end product testing shall apply, "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." The following was added to clarify parameters for dispensing prior to receipt of the results of the testing, "In a circumstance where a batch-produced sterile drug preparation compounded from one or more non-sterile ingredients is necessary for immediate dispensing where failure to dispense could result in loss of life or intense suffering, the drug preparation may be dispensed before receipt of test results so long as the pharmacy complies with a written procedure included in the pharmacy's policies and procedures that includes:
    (1) Prior to dispensing:
    (A) Notifying the prescriber of the inability to conduct testing;
    (B) Suggesting an available alternative product to the prescriber; and
    (C) Securing the prescriber's written consent to dispense.

(2) And subsequent to dispensing:
(A) Daily observation of the incubating test specimens; and
(B) Immediate recall of the dispensed compounded sterile preparation's when there is any evidence of microbial or pyrogen growth in the test specimens. Any such dispensing shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures."

- Subdivision (d) was deleted as it was redundant.

The necessity of these changes in 16 CCR §1751.7 are required to update the sterile compounding quality assurance and process validation requirements.

Amend 16 CCR §1751.8

Existing regulations at 16 CCR §1751.8 was added as "Beyond Use Dating for Sterile Compounded Drug Preparations" to specify beyond use dating requirements. The necessity of these changes in 16 CCR §1751.8 are required to update the sterile compounding quality assurance and process validation requirements. The regulation that previously held 16 CCR §1751.8 was changed to 16 CCR §1751.10.

The purpose of the board's proposal makes the following changes to add the following section as 16 CCR §1751.8:

"1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that conforms to the following limitations, except that the beyond use date shall not exceed any expiration date or beyond use date provided by the manufacturer for any component in the preparation.
(a) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations
(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using only sterile ingredients, products, components, and devices; and
(2) the compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and
(3) compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing
in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby

incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 48 hours at controlled room temperature; 14 days at controlled cold temperature; and 45 days at controlled freezer temperature.
(b) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations
(1) entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
(2) the compounding process involves complex aseptic manipulations other than the single-volume transfer; and
(3) the compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing
in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 30 hours at controlled room temperature; 9 days at controlled cold temperature; and 45 days at controlled freezer temperature.
(c) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations entirely within an ISO Class 5 PEC located in an ISO Class 7 buffer area with an ante-area, using non-sterile ingredients, including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed the following: 24 hours at controlled room temperature; 3 days at controlled cold temperature; and 45 days at controlled freezer temperature.
For the purposes of this paragraph, “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.
(d) Where the sterile compounded drug preparation was compounded solely with aseptic manipulations
(1) entirely within an ISO Class 5 PEC that is located in a segregated compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and
(2) the compounding process involves simple transfer of not more than three

commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and
(3) the compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify a more extended beyond use date, the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours in a laminar air flow workbench or biological safety cabinet.
(e) Where the sterile compounded drug preparation was compounded
(1) using or containing hazardous drugs or components; and
(2) in facilities that prepare a low volume of hazardous drugs, where low volume is defined as five or less per a week, the use of two tiers of containment (e.g., closed system transfer device within a biological safety cabinet or compounding aseptic containment isolator that is located in a non-negative pressure room)
the beyond use date shall specify that storage and exposure periods cannot exceed 12 hours.
(f) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation.
Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

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

The necessity of these changes in 16 CCR §1751.8 are required to add the beyond use dating for sterile compounded drug preparation requirements.

Add 16 CCR §1751.9

Existing regulations at 16 CCR §1751.9 was added as "Single-Dose and Multi-Dose Containers; Limitations on Use" to specify single-dose and multi-dose containers and limitations on use requirements. The necessity of these changes in 16 CCR §1751.9 are required to add the single-dose and multi-dose containers and limitations on use requirements.

The purpose of the board's proposal makes the following changes to add the following section as 16 CCR §1751.9:

> "1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use
>
> (a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.
> (b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents discarded within the following time limit, depending on the environment:
> (1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;
> (2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours.
> (c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such condition.
> Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code."

The necessity of these changes in 16 CCR §1751.9 are required to add the single-dose and multi-dose containers and limitations on use requirements.

Renumber 16 CCR §1751.8 to §1751.10

Existing regulations at 16 CCR §1751.8 specify sterile injectable compounding reference materials. 16 CCR §1751.8 was renumbered to 16 CCR §1751.10 and changed from "Sterile Injectable Compounding Reference Materials" to "Sterile Compounding Reference Materials." The word "injectable" was deleted from the title referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation.

The purpose of the board's proposal makes the following changes:

- The word "injectable" was deleted twice and the word "drug" was added once referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). California law prior to July1, 2014, required a sterile compounding license for sterile compounding administered by route of injection only. SB 294 adds sterile compounding licensing requirements for sterile compounded drug products to include route of administration of injection as well as route of administration into the eye or inhalation. The word "products" was deleted twice and replaced with "preparations" two times to clarify the drug or nutrient compounded is compounded in a licensed pharmacy where product indicates it is a commercially manufactured drug or nutrient that has been evaluated for safety and efficacy by the FDA.

The necessity of these changes in 16 CCR §1751.10 are required to update the sterile compounding reference materials requirements.

Article 7.5 Furnishing for Home Administration

Article 7.5 Furnishing for Home Administration was added as the remaining sections pertained to furnishing for home administration and not sterile compounding.

- *Renumber 16 CCR §1751.10 to 16 CCR §1752*
- *Renumber 16 CCR §1751.11 to 16 CCR §1753*
- *Renumbered 16 CCR §1753 deleted "and" from the Authority Cited section as this was a duplicate and was removed to correct the grammar.*
- *Renumber 16 CCR §1751.12 to 16 CCR §1754*

The necessity of these changes in 16 CCR Article 7.5 is required to remove them from the Article 7 pertaining to Sterile Compounding as they are not related to the topic. The problem addressed is to ensure accuracy in the regulations in that the article titles reflect the content of the article. This is a real benefit to the people of the State of California particularly when the protection of public health and safety, worker safety, or the environment is involved as pharmacist and the people working in the industry will be able to better identify code sections based on the naming convention.

After conducting a review of regulations that are related to or would affect this area, the board has determined that the regulatory proposal is not inconsistent nor incompatible with existing state regulations.

FISCAL IMPACT ESTIMATES

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None

Effect on Housing Costs: None

Local Mandate: None

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the Notice and are consistent with compounding industry standards.

The proposed amendments to Articles 4.5 and 7 are intended to protect the people of California by ensuring consumers receiving compounded drug products that have been compounded in accordance with the highest safety standards. Additionally, the board understands that compounding in California and throughout the nation is compounded in accordance with USP standards. The board is establishing and incorporating these standards into California regulation. As a result, there may be cost to implement these regulations but the board does not anticipate a statewide adverse economic impact directly affecting businesses. The board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant. Article 7.5 is separated from Article 7 based on the content of the sections.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs businesses or the expansion of businesses in the State of California.

Small Businesses: The board's proposal may affect small businesses; however, the board does not have nor does it maintain data to determine if any of its licensed pharmacies are "small businesses" as defined in Government Code Section 11342.610.

Cost Impact on Representative Private Person or Business: The board understands that compounding in California and throughout the nation is compounded in accordance with USP standards. In the event a pharmacy compounding or shipping into California is not compounding in accordance with standards, the cost impacts a business could incur in becoming compliant with the proposed action are reasonable and outlined in the Economic Impact Assessment in the Underlying Data for the Initial Statement of

Reasons. This determination is based the board's understanding of compounding in California and the nation.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The proposed amendments to Articles 4.5 and 7 are intended to protect the people of California by ensuring consumers receiving compounded drug products have been compounded in accordance with the highest safety standards. However, the board does not have any information indicating that the proposed amendments will in and of itself have any effect on the (1) creation or elimination within the State of California, (2) creation of new businesses or the elimination of existing businesses within the State of California, or (3) expansion of businesses currently doing business within the State of California. The board does not have any information indicating the adoption of proposed amendments to Articles 4.5 and 7 would actually have a positive effect on the creation of jobs and new businesses within California and the expansion of businesses currently doing business in California. Consideration by the board as to whether the benefit to the consumers of California outweighs any negative effect on affected businesses is not anticipated to eliminate jobs or existing businesses. The board concludes that the economic impact, including the ability of California businesses to compete with businesses in other states will not be significant. This initial determination is based on the fact that the proposed changes will help protect the public health based on the proposed changes described in the Notice and are consistent with compounding industry standards. The addition of Article 7.5 provides for ease of finding sections related to furnishing for home administration.

Creation or Elimination of Jobs within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or elimination of existing jobs in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Creation of New Businesses within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new businesses in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Elimination of Existing Businesses within California: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the elimination of existing businesses in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Expansion of Businesses Currently Doing Business within the State: The Board of Pharmacy has determined that this regulatory proposal will not have a significant

impact on the expansion of businesses currently doing business in the State of California. The assessment and conclusions are outlined in the Economic Impact Assessment of the Underlying Data for the Initial Statement of Reasons.

Benefits of the Regulation to the Health and Welfare of California Residents, Worker Safety, and the State's Environment: The board's proposal demonstrates the board's anticipated benefit to ensure the health and welfare of California Residents, Worker Safety, and the State's environment to ensure California compounding regulations reflect at minimum the compounding standards used in the profession. With the approval of SB 294 by the Legislature and Governor, parameters will be established and will provide uniformity for pharmacies that carry out sterile and non-sterile compounding.

Occupations/Businesses Impacted: The Board of Pharmacy has made an initial determination that this regulatory proposal will impact pharmacies and specialty sterile compounding pharmacies. As of July 2014, the board had approximately 7,500 pharmacies (sites) with current licenses issued by the board. Of those 7,500 pharmacies, the board issued approximately 989 specialty sterile compounding permits.

Reporting Requirements: None

Comparable Federal Regulations:
Included as part of the federal Drug Quality and Security Act (HR 3204) that became law on November 27, 2013, are provisions that establish provisions for federal regulation and oversight of large scale drug compounding by "outsourcing facilities." The federal law sets forth voluntary requirements for licensure and enforcement of these entities. However, California's law is more restrictive than the federal law in several areas. California will continue to require any pharmacy that is compounding sterile products for California residents or practitioners to possess licensure with the board and comply with California requirements as sterile compounding pharmacies. She also indicated that FDA may also require or encourage licensure as an outsourcing facility.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Prior to the enactment of the Drug Quality and Security Act, compounding pharmacies were regulated by their respective states of residence. Compounding pharmacies also make drugs, but they are limited to producing small amounts in response to a specific patient's prescription, or to create a small supply for an identifiable patient population to ensure continuity of treatment. The state-by-state approach to regulating compounding organizations yields inconsistent standards and varying levels of enforcement on an industry that ships dangerous drugs across state lines.

Additionally, there are compounding professional standards that are used across the nation known as the United States Pharmacopeia and The National Formulary (USP–NF). USP-NF is a book of public pharmacopeial standards. It contains standards for

(chemical and biological drug substances, dosage forms, and compounded preparations), excipients, medical devices, and dietary supplements. USP–NF is a combination of two compendia, the United States Pharmacopeia (USP) and the National Formulary (NF). Monographs for drug substances, dosage forms, and compounded preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF. The U.S. Federal Food, Drug, and Cosmetics Act designates the USP–NF as official compendia for drugs marketed in the United States. A drug product in the U.S. market must conform to the standards in USP–NF to avoid possible charges of adulteration and misbranding.

Benefits: Business and Professions Code section 4005 states that "the board may adopt rules and regulations….pertaining to the practice of pharmacy…." Further, Business and Professions Code 4001.1 states that the "protection of the public shall be the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."

The board's proposal demonstrates the board's anticipated benefit to ensure California compounding regulations reflect at minimum the compounding standards used in the profession. With the approval of SB 294 by the Legislature and Governor, parameters will be established and will provide uniformity for pharmacies that carry out sterile and non-sterile compounding.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposal described in this Notice.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site http://www.pharmacy.ca.gov.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7913
Fax No.:	(916) 574-8618
E-Mail Address:	Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name:	Anne.Sodergren@dca.ca.gov
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Telephone No.:	(916) 574-7910
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Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.