

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Compounding Drug Products

Sections Affected: Amend § 1735 of Article 4 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1735.1 of Article 4 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1735.2 of Article 4 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1735.3 of Article 4 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1735.5 of Article 4 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.1 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.2 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.3 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.4 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.5 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.6 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.7 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.8 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Add § 1751.9 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.10 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.11 of Article 7 of Division 17 of Title 16 Cal.Code Reg.
 Amend § 1751.12 of Article 7 of Division 17 of Title 16 Cal.Code Reg.

Specific Purpose of the Proposed Changes/ Rationales/Problems Addressed

The Board of Pharmacy (“Board”) proposes to amend Sections 1735, 1735.1, 1735.2, 1735.3, 1735.5 and Sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, 1751.8, 1751.9, 1751.10, 1751.11, 1751.12 as well as add Section 1751.9 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.

Under the current federal regulatory system, drug manufacturers are regulated by the Food and Drug Administration (FDA). Compounding pharmacies are 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.

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.

It is possible that regulation may occur at the federal level, pre-empting state law on this issue. The FDA has been working with Congress to craft legislation authorizing increased federal oversight of compounding pharmacies. The FDA asserts that there should be minimum federal standards for firms that compound sterile drug products in advance of or without a prescription and ship them interstate. The FDA also wants clear authority to proactively inspect pharmacies to determine the scope and nature of their operations. However, at this time, there are no

such federal regulations. There are compounding professional standards that are used across the nation.

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).

Throughout the proposed text, there are amendments that occur in multiple places. In an effort to clarify these changes and eliminate redundancy in this document, they have been summarized below for consistency and nonduplication.

Multiple Occurrence of Amendment #1 - The board's proposal removes "injectable" and replaces the word with "drug" when referring to sterile injectable compounding. The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Multiple Occurrence of Amendment #2 - The purpose of the board's proposal replaces the phrase "expiration dating requirements" with "beyond use dating requirements." The purpose of the board's proposal is ensure the board's regulations accurately reflect the USP 36 <797> Standard used in the compounding profession. While "expiration dating requirements" and "beyond use dating requirements" may seem simple and inconsequential, there is a distinct and drastic difference. The "expiration dating requirements" is provided by a manufacturer to indicate the chemical stability of the drug product. The "beyond use dating requirements" references the likelihood of contamination after removing from the manufacturer's original packaging and manipulating the substance. To use an everyday example, an "expiration dating requirement" for a can of corn may be consumed a year from today. However, once that can of corn is opened, the "expiration date" is no longer a year from today as it has been opened and subjected to a different environment other than the manufacturer's original packaging. In the case of the can of corn, once the can is opened, the "expiration dating requirement" is no longer useful as it does not take into consideration temperature, atmospheric exposure or other similar factors. As such, a "beyond use dating requirements" is used once the original manufacturer's packaging has been opened to consider temperature, atmospheric exposure, and other such factors. While the can of corn is an oversimplified example, the concept remains the same. The "beyond use dating requirement" is used in the compounding industry because once the manufacturer's packaging has been opened and the drug product has been manipulated or exposed to an environment outside of the manufacturer's packaging, the

likelihood of contamination increases. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Multiple Occurrence of Amendment #3 – The board's proposal removes old references and replaces with updated and current references. The purpose is to update the following references:

- Chapter 797 of the United States Pharmacopeia – National Formulary (USP-NF) (35th Revision, Effective May 1, 2012) is updated to Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013);
- 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 is updated to NSF International Standard/American National Standard for Biosafety Cabinetry - Biosafety Cabinetry: Design, Construction, Performance, and Field Certification [NSF/ANSI 49-2012], as revised July 7, 2012 (available from the Chair, Joint Committee on Biosafety Cabinetry c/o NSF International, P.O. Box 130140, 789 N. Dixboro Road, Ann Arbor, MI 48105, USA, phone number (734) 769-8010);

This change is necessary to ensure alignment and consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring the board's regulations are aligned with the current compounding professional standards thereby ensuring the safety of all consumers receiving compounded drug products 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.

Multiple Occurrence of Amendment #4 – The board's proposal removes the phrase "clean room" and replaces it with "cleanroom." The purpose of the board's proposal is to reflect the current and updated references throughout Articles 4.5 and 7 of Division 17 of Title 16 of the California Code of Regulations. The necessity of this change is to ensure alignment and consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Multiple Occurrence of Amendment #5 – The board’s proposal removes the phrase “from one or more non-sterile ingredients.” The purpose of the board’s proposal is to enhance the type of sterile drug products the regulations apply. By removing this text, the regulations apply to all sterile drug products and not only those sterile drug products “from one or more non-sterile ingredients.” This change is necessary to ensure consistency in for all compounded drug products with sterile or non-sterile ingredients and not limit it to only those sterile drug products from one or more non-sterile ingredients. The board’s proposal addresses the problem of ensuring patient safety for all who receive compounded drug products. 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.

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 is to remove the word “injectable” when referring to sterile injectable compounding and to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations in accordance with implementation of SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

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 board’s proposal will add the following definitions or amend the following subdivisions as listed below.

- The purpose of the board’s proposal to add subdivision (a) is to add a definition of “anteroom” for purposes of compounding drug products. The definition clarifies and specifies “anteroom” as an ISO Class 8 or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, compounded sterile product labeling, and other high-particulate-generating activities are performed. It is a transition area that provides assurance that air flows from clean to dirty areas.
- The purpose of the board’s proposal to add subdivision (b) is to add a definition of “batch” for purposes of compounding drug products. The definition clarifies and specifies “batch” as more than one dose of a specific quantity of drug or other material that is intended to have uniform character and quality and is produced during the same continuous cycle of compounding.
- The purpose of the board’s proposal to add subdivision (c) is to add a definition of “beyond use date” for purposes of compounding drug products. The definition clarifies and specifies “beyond use date” as the date after which a compounded drug product should not be used.

- The purpose of the board’s proposal to add subdivision (d) is to add a definition of “buffer area” for purposes of compounding drug products. The definition clarifies and specifies “buffer area” as an area where the ISO Class 5 hood is physically located.
- The purpose of the board’s proposal to add subdivision (e) is to add a definition of “cleanroom” for purposes of compounding drug products. The definition clarifies and specifies “cleanroom” as a separate room meeting an ISO Class 7 or better air quality.
- The purpose of the board’s proposal to add subdivision (f) is to add a definition of “controlled cold temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled cold temperature” as 2° to 8° C (36° to 46° F).
- The purpose of the board’s proposal to add subdivision (g) is to add a definition of “controlled freezer temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled freezer temperature” as -25° to -10° C (-13° to 14° F).
- The purpose of the board’s proposal to add subdivision (h) is to add a definition of “controlled room temperature” for purposes of compounding drug products. The definition clarifies and specifies “controlled room temperatures” as 20° to 25° C (68° to 77° F).
- The purpose of the board’s proposal to amend subdivision (i) from subdivision (a) for the definition of “equipment” is for alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (j) is to add a definition of “gloved fingertip sampling” for purposes of compounding drug products. The definition clarifies and specifies “gloved fingertip sampling” as the requirement that immediately after aseptic donning of sterile gloves compounding personnel will lightly press each fingertip and thumb onto appropriate growth media which will be incubated and then examined for growth of microorganisms.
- The purpose of the board’s proposal to amend subdivision (k) from subdivision (b) for the definition of “integrity” is for alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (l) is to add a definition of “parenteral” for purposes of compounding drug products. The definition clarifies and specifies “parenteral” as a sterile preparation of drugs for injection through one or more layers of skin.
- The purpose of the board’s proposal to add subdivision (m) is to add a definition of “personal protective equipment” for purposes of compounding drug products. The definition clarifies and specifies “Personal protective equipment” as clothing or devices that protect the employee from exposure to drug products and minimize the contamination of compounded sterile products and include shoe covers, head and facial hair covers, face masks, gowns, and gloves.
- The purpose of the board’s proposal to amend subdivision (n) from subdivision (c) for the definition of “potency” is for alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (o) is to add a definition of “process validation” for purposes of compounding drug products. The definition clarifies and specifies “Process validation” as establishing by objective evidence that a process consistently produces a result or product meeting its predetermined

specifications using microbiological simulation of an aseptic process with growth medium processed in a manner similar to the normal order of production and with the same container or closure.

- The purpose of the board’s proposal to changing subdivision (p) from subdivision (d) for the definition of “quality” is alphabetizing of the definitions and ease of readability.
- The purpose of the board’s proposal to add subdivision (q) is to add a definition of “segregated compounding area” for purposes of compounding drug products. The definition clarifies and specifies “segregated compounding area” as a designated space, either a demarcated area or room, that is restricted to preparing sterile-to-sterile compounded sterile products with a 12-hour or less beyond use date. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of compounded sterile products and shall be void of activities and materials that are extraneous to sterile compounding.
- The purpose of the board’s proposal to add subdivision (r) is to add a definition of “smoke test” for purposes of compounding drug products. The definition clarifies and specifies “smoke test” as an analysis of the airflow in the ISO Class 5 hood using a smoke generating device.
- The purpose of the board’s proposal to amend subdivision (s) from subdivision (e) for the definition of “strength” is for alphabetizing of the definitions and ease of readability.

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. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <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.

Amend 16 CCR §1735.2

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The purpose of the board’s proposal will add paragraph (4) to subdivision (c) to further define a “reasonable quantity” as not exceeding an amount the pharmacy can reasonably and safely compound. This change is necessary to further outline in regulation the requirement for compounding pharmacies compounding total volumes within their pharmacists’ and facility’s expertise. This addressed the problem of further clarifying reasonable quantity in the regulation to ensure the safety of Californian’s who receive compounded drugs from a compounding facility that is compounding within the facility’s ability to compound safely. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The purpose of the board’s proposal will amend paragraph (3) of subdivision (d) by removing the phrase “expiration dating requirements” and replacing it with “beyond use dating requirements.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #2” listed previously in this document. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The purpose of the board's proposal will amend subdivision (g) by removing "chemical, bulk drug substances." This change is necessary to eliminate redundant words in regulation as the meaning of "chemical and bulk drug substance" is found within the remaining verbiage of "drug products and other components." This addressed the problem of eliminating redundancy for ease of reading for the reader. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The purpose of the board's proposal will amend subdivision (h) by removing "expiration dating" and replacing "beyond use date." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #2" listed previously in this document. 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.

Existing regulations at 16 CCR §1735.2 specify compounding limitations and requirements. The purpose of the board's proposal will amend subdivision (j) by removing "injectable" twice in the subdivision. The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations in accordance with implementation of SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

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 of Compounded Drug Products" to delineate the records are to be made and kept. This change is necessary to clarify the board's intentions with regard to recordkeeping regulations and addressed the problem of ensuring the board's licensees understand the board's intent with regard to recordkeeping. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board's proposal will change paragraph (6) of subdivision (a) to include the updated version of the reference for "Redispensed CSPS" found in Chapter 797 of the United States Pharmacopeia. The necessity of this change and the identification of

problem addressed is outlined in “Multiple Occurrence of Amendment #3” listed previously in this document. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board’s proposal will amend paragraph (8) of subdivision (a) by removing “expiration” and replacing “beyond use.” The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #2” listed previously in this document. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board’s proposal will amend subdivision (c) to remove “components” twice and move the corresponding “and” in the list of items with removed “components.” This change is necessary to eliminate redundancy as “components” is considered part of “chemicals, bulk drug substances, and drug products.” The word “component” is redundant and addressed the problem of reducing confusion among the regulated licensees. The board’s proposal will also amend subdivision (c) to require reliable suppliers of drug products for compounders to be FDA-registered. This change is necessary to add the requirement of “FDA-registered” to ensure that the supplier of drug products are adequately regulated by the Food and Drug Administration (FDA) and addressed the problem of the integrity of the purchased drug products by compounders providing compounded drug products to California consumers. The board’s proposal further clarifies by deleting “any available” and adding requirements for certificates of purity or analysis are to be matched to the product received. The requirement that all certifications of purity or analysis are to be kept and matched to the product received also includes the now required FDA-registered suppliers. This change is necessary to ensure a consolidated record for a compounded drug product that may have multiple ingredients from multiple FDA-registered suppliers. This addressed the problem of clarifying the requirements of recordkeeping for certificates of purity and analysis of drug products. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board’s proposal will add subdivision (d) to specify after receipt by the pharmacy, packages of ingredients that lack a supplier’s expiration date cannot be used after one (1) year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in compounded drug products. This change is necessary to identify for the board’s regulated licensees the maximum time a drug product can be used without appropriate inspection or testing if the manufacturer failed to provide an expiration date. This addressed the problem of clarity to the board’s regulated licensees and in accordance to compounding pharmacy professional standards USP 36 <797>. 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.

Existing regulations at 16 CCR §1735.3 specify requirements for recordkeeping of compounded drug products. The purpose of the board's proposal will change subdivision (d) to (e) as a result of the newly created subdivision (d). This change is necessary to provide for the newly added subdivision (d) and ensure there are not two subdivisions in the same section entitled (e). This addressed the problem of eliminating confusion for the board's regulated licensees so that no section has two subdivisions with the same letter. 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.

Amend 16 CCR §1735.5

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will add to subdivision (a) the requirement that the pharmacy shall follow its policies and procedures and failure to follow these policies and procedures shall be deemed unprofessional conduct. This change is necessary to specifying the requirement of not only maintaining compounding policies and procedures but also a requirement to following the pharmacy's policies and procedures. A requirement to have compounding policies and procedures but not follow the policies and procedures is not consistent with intent of the original regulation. This addressed the problem of the board being unable to enforce a requirement to maintain and follow compounding policies and procedures where only the requirement to maintain was outlined in regulation. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will amend subdivision (c) to add a semi-colon for the list of the subsequent requirements in paragraphs (1) through (7). This change is necessary to ensure the regulation is written in plain English. This addressed the problem of the board being accurate and clear to the board's regulated licensees. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will amend paragraph (4) of subdivision (c) to require documentation of the methodology be appropriate for the compounded drug products and to require this to be validated rather than tested. Additionally, the words "of compounded drug products" were stricken. This change is necessary to require documentation of the compounding formulas used for drug products compounded by the pharmacy. Additionally, "validate" is used instead of "test" to ensure that the compounded drug product's integrity, potency, quality, and labeled strength is corroborated rather than simply critically examined. The words "of compounded drug products" were stricken from the text as this was redundant with the addition of "appropriate to compound drug products." These changes addressed the problem of specifying and clarifying documentation requirements of methodology for the compounded drug product as well as clarifying the requirement of validation over testing of the compounded drug product. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will add paragraph (6) to subdivision (c) to require dates of annual reviews and signature/initials of the pharmacist-in-charge and dates of any revisions of policies and procedures. This change is necessary to clarify the times of reviews and documentation to verify the reviews have taken place. These changes addressed the problem of clarifying when and what is required at the time of review for the policies and procedures. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will amend paragraph (5) to subdivision (c) to delete "expiration" and replace with "beyond use." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #2" listed previously in this document. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will add paragraph (7) to subdivision (c) to require pharmacies that compound sterile drug products in the pharmacy at appropriate room, refrigerator, and freezer temperatures as required for each specific drug product as well as the daily documentation of the these temperatures. This change is necessary to ensure that compounded drug products are stored at appropriate temperatures for the specific compounded drug product and to prevent contamination or bacterial or fungal growth in compounded drug products. Daily documentation ensures the pharmacy documents in adherence to this subdivision. These changes addressed the problem of clarifying that storage and daily documentation of compounded drug products is required at specified temperatures as outlined in referenced temperatures. 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.

Existing regulations at 16 CCR §1735.5 specify requirements for compounding policies and procedures. The purpose of the board's proposal will add Business and Professions Code section 4301 to the reference cited for the regulation as failure for a pharmacy to follow its policies and procedures as outlined in subdivision (a) of section 1735.5 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations is deemed unprofessional conduct. This change is necessary to ensure that the appropriate statute reference is cited. This change addresses the problem to ensure adherence to the Administrative Procedure Act. 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.

Amend 16 CCR §1751

Existing regulations at 16 CCR specify the title of Article 7 to be "Sterile Injectable Compounding." As a result of SB 294, the name of Article 7 will be changed to "Sterile Compounding." The purpose of the board's proposal is to reflect changes in current law as a

result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulation at 16 CCR specifies the title of §1751 to be "Sterile Injectable Compounding; Compounding Area; Self-Assessment." As a result of SB 294, the name of §1751 will be changed to "Sterile Compounding; Compounding Area; Self-Assessment." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend subdivision (a) by striking "injectable" twice as a result of SB 294. The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend subdivision (b) by striking "injectable" once as well as replacing in another part of the subdivision "injectable" with "drug" in accordance with SB 294. Additionally, subdivision (b) is split into two sentences for ease of readability and to clarify the standards apply to the environments within the pharmacy. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. This change is necessary to allow for easier readability of the regulation and to

identify specifically the environment to which this subdivision pertains. The board's proposal addresses the problem of ensuring that board regulations are aligned with statute as well as be as clear as possible for the board's regulated licensees. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend paragraph (1) of subdivision (b) to replace "clean room" with "cleanroom." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #4" listed previously in this document. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend paragraph (3) of subdivision (b) to replace "be" with "The pharmacy shall be." This change is necessary to specify that the requirement pertains to the pharmacy rather than an unidentified environment. The board's proposal addresses the problem of ensuring that board regulations are as clear as possible for the board's regulated licensees so that there is no confusion as to what is required to be ventilated. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend paragraph (4) of subdivision (b) to replace "be" with "The ISO environment shall be" and "annually" is replaced with "at least six months." "Clean room" is replaced with "cleanroom." Additionally, "and whenever the device or cleanroom is relocated, altered, or a service to the facility is performed that would impact the cleanroom or device." is added. This change is necessary to specify that the certification pertains to the ISO environment rather than an unidentified environment. The change of certification requirements from annually to at least every six months and whenever the device or clean room is relocated, altered, or a service to the facility is performed that would impact the cleanroom or device is to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #4" listed previously in this document. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend paragraph (5) of subdivision (b) by replacing "injectable" with "drug." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend paragraph (6) of subdivision (b) by adding additional requirements that sinks and drains shall not be present in an ISO Class 7 or better cleanroom, in buffer area, nor adjacent to an ISO Class 5 hood in a segregated compounding area. A sink may be located in an anteroom. This change is necessary as sinks and drains are sources of contamination. In order to maintain a sterile environment for compounding, the sinks and drains may not be present in a cleanroom, buffer area nor adjacent to a hood in a segregated compounding area. Sinks may be located in an anteroom. When sterile compounding is being conducted, compounding tasks are done in an order to minimize contamination. Simultaneously, compounding tasks are also done in certain areas to minimize contamination. The board's proposal addresses the problem to ensure that contamination does not occur in the sterile compounding area and the compounding pharmacist is aware of where a sink and drain may or may not be located. Failure to do so would allow for a contamination source to be directly inside a sterile environment where sterile compounding is occurring for injection, inhalation or application to the eye by a California consumer. 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.

Existing regulations at 16 CCR §1751 specify requirements for sterile compounding; compounding area; self-assessment. The purpose of the board's proposal will amend subdivision (c) by replacing "injectable" with "drug." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Amend 16 CCR §1751.1

Existing regulation at 16 CCR specifies the title of §1751.1 to be "Sterile Injectable Recordkeeping Requirements." As a result of SB 294, the name of §1751.1 will be changed to "Sterile Compounding Recordkeeping Requirements." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (a) by replacing "injectable" with "drug." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) by adding to sterile "compounded drug" products and striking "compounded from one or more non-sterile ingredients." This change is necessary to ensure that sterile compounding regulations encompass drug products compounded from non-sterile to sterile ingredients as well as sterile to sterile ingredients. As the regulation is currently written, this only applies to drug products compounded from non-sterile to sterile. By including drug products compounded from sterile to sterile ingredients, the regulations are applied to all sterile compounding and not only drug products compounded from non-sterile to sterile ingredients. This change addresses the problem of regulations for sterile compounding being applied to those drug products compounding from non-sterile to sterile ingredients. The same regulations must apply to drug products compounded from sterile to sterile ingredients as well. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to add a new paragraph (2) to require recordkeeping requirements for the results of gloved fingertip testing and aseptic technique media fill assessments. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to add a new paragraph (3) to require recordkeeping requirements for the results of viable volumetric air and surface sampling. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety

of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to renumber the former paragraph (2) to (4) and amend the paragraph to require recordkeeping requirements for the daily documentation of room, refrigerator, and freezer temperatures as appropriate for drug preparations consistent with the temperatures defined in section 1735.1. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to renumber the former paragraph (3) to (5) regarding certification of the sterile compounding environment. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to add a new paragraph (6) to require recordkeeping requirements for the logs of room pressure differentials. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to renumber the former paragraph (4) to (7) regarding other facility quality control logs specific to the pharmacy's policies and procedures. This change is necessary to ensure numeric

consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to renumber the former paragraph (5) to (8) regarding inspections for expired or recalled pharmaceutical products or raw ingredients. The purpose of the board's proposal will add an "s" to "Inspection" in order to require recordkeeping for all inspections rather than a singular inspection. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.1 specify requirements for sterile compounding recordkeeping requirements. The purpose of the board's proposal will amend subdivision (b) to renumber the former paragraph (6) to (9) regarding preparation records including master work sheet, the preparation work sheet, and records of end-product evaluation results. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Amend 16 CCR §1751.2

Existing regulation at 16 CCR specifies the title of §1751.2 to be "Sterile Injectable Labeling Requirements." As a result of SB 294, the name of §1751.1 will be changed to "Sterile Compounding Labeling Requirements." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.2 specify requirements for sterile compounding labeling requirements. The purpose of the board's proposal will amend the section by striking "injectable" and replacing it with "drug" three times throughout the section. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Amend 16 CCR §1751.3

Existing regulation at 16 CCR specifies the title of §1751.3 to be “Sterile Injectable Policies and Procedures.” As a result of SB 294, the name of §1751.3 will be changed to “Sterile Compounding Policies and Procedures.” The purpose of the board’s proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.3 specify requirements related sterile compounding policies and procedures. The purpose of the board’s proposal is to remove the word “injectable” when referring to sterile injectable compounding in §1751.3 subdivision (a) and paragraph (1) of subdivision (a). The purpose of the board’s proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations in accordance with implementation of SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board’s proposal will amend the section by striking “injectable” and replacing it with “drug” five times throughout the section. The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #1” listed previously in this document. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board’s proposal will add paragraph (5) of subdivision (a) to include in the policies and procedures the training of staff in the cleaning and maintenance of an ISO environment and segregated compounding areas. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by

applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will add paragraph (6) of subdivision (a) to include in the policies and procedures a viable and nonviable sampling plan. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will renumber paragraph (5) to (8) of subdivision (a) as the result of adding a new paragraph (5) to subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will renumber paragraph (6) to (9) of subdivision (a) as the result of adding a new paragraph (5) to subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will renumber paragraph (7) to (10) of subdivision (a) as the result of adding a new paragraph (5) to subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will add paragraph (7) of subdivision (a) to include in the policies and procedures must documentation of the manufacturer's recommended purge time for barrier isolators. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the

regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will amend subdivision (d) by striking "from one or more non-sterile ingredients." This change is necessary to ensure that sterile compounding regulations encompass drug products compounded from non-sterile to sterile ingredients as well as sterile to sterile ingredients. As the regulation is currently written, this only applies to drug products compounded from non-sterile to sterile. By including drug products compounded from sterile to sterile ingredients, the regulations are applied to all sterile compounding and not only drug products compounded from non-sterile to sterile ingredients. This change addresses the problem of regulations for sterile compounding being applied to those drug products compounding from non-sterile to sterile ingredients. The same regulations must apply to drug products compounded from sterile to sterile ingredients as well. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will amend subparagraph (G) of paragraph (3) of subdivision (d) to strike "Regular" and replace with "Daily" cleaning and to add "and disinfection" schedule for controlled area of any equipment in the controlled area and to strike "and the alternation of disinfectants" and replace with "as specified in section 1751.4." This will also strike "subdivision" and replace with "subparagraph" as the reference in current regulation was incorrect. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will amend subparagraph (I) of paragraph (3) of subdivision (d) to enhance the requirement for sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets by striking ", and for" and adding ", and for sterility and bacterial endotoxin testing." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36

<797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will move the contents of subparagraphs (J) and (K) of paragraph (3) of subdivision (d) to a new subparagraph (J) entitled "For non-sterile to sterile compounding" of paragraph (3) of subdivision (d). This change is necessary to clarify the requirements of policies and procedures for non-sterile to sterile compounding to include sterilization and end-product evaluation and testing. The board's proposal addresses the problem of ensuring clarity for the board's regulated licensees and reducing such discrepancy for the compounding profession who are compounding drug products in California and shipped 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.

Existing regulations at 16 CCR §1751.3 specify requirements for sterile compounding policies and procedures. The purpose of the board's proposal will add a new subparagraph (K) of paragraph (3) of subdivision (d) to add the requirement for policies and procedures for action levels of colony-forming units (CFUs) detected during viable surface testing and volumetric air sampling. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.4

Existing regulation at 16 CCR specifies the title of §1751.4 to be "Facility and Equipment Standards for Sterile Injectable Compounding." As a result of SB 294, the name of §1751.3 will be changed to "Facility and Equipment Standards for Sterile Compounding [from Non-Sterile Ingredients]." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The purpose of the board's proposal will amend the section by striking "injectable" and replacing it with "drug" two times throughout the section and striking "injectable" from "sterile injectable drug products" one time. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The purpose of the board's proposal will add subdivision (d) to specify cleaning and disinfecting surfaces in the ISO Class 5 hood shall occur frequently, including: at the beginning of each shift; before each batch; every 30 minutes during continuous compounding of individual compounded sterile drug products; after each spill; when surface contamination is known or suspected; and when switching between cytotoxic and non-cytotoxic ingredients. This change outlines minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The purpose of the board's proposal will renumber subdivision (d) to (e) and strike "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." and replacing with "Counters, cleanable work surfaces and floors shall be cleaned and disinfected daily. Walls, ceiling, storage shelving, tables and stools are to be cleaned and disinfected monthly. Cleaning shall occur after any unanticipated event that could increase the risk of contamination. Cleaning shall include the periodic use of a sporicidal agent." This change outlines minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The purpose of the board's proposal will renumber subdivision (e) to (f) and to specifically delete "parenteral" and replace with "sterile" when referring to pharmacies preparing sterile cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Administrative Code requiring a laminar air flow hood. Additionally, the board's proposal will change the hood certification from annually to every six months. The board's proposal updates the reference and contact information for the National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry to NSF International Standard/American National Standard for Biosafety Cabinetry – Biosafety Cabinetry: Design, Construction, Performance, and Field Construction. The board's proposal removes the requirement that certification records must be retained for at least three years and specifies that the hood shall be decontaminated when switching between cytotoxic and non-cytotoxic ingredients. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #3" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The purpose of the board's proposal will add subdivision (g) to specify that pharmacies preparing sterile cytotoxic agents shall use a biological safety cabinet or compounding aseptic containment isolator that provides an ISO Class 5 environment during dynamic compounding conditions which is maintained in accordance with the manufacturer's recommendations and which is certified every six months. If a compounding aseptic containment isolator meeting the above criteria is located outside of an ISO Class 7 area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 air changes per hour. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements to prevent worker inhalation or contamination of cytotoxic (chemotherapy) air escapes the controlled environment of the biological safety cabinetry or compounding aseptic containment isolator. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.4 specify requirements for facility and equipment standards for sterile compounding. The purpose of the board's proposal will add subdivision (h) to specify that viable surface and volumetric air sampling by impaction shall occur at least every six months by a qualified technician 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. Exceeded action levels shall prompt an immediate investigation of cleaning and compounding operations and facility management. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.5

Existing regulation at 16 CCR specifies the title of §1751.5 to be "Sterile Injectable Compounding Attire." As a result of SB 294, the name of §1751.3 will be changed to "Sterile Compounding Attire." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will delete subdivision (a) removing the requirement for gowns and gloves to be worn when preparing cytotoxic agents. The section is further expanded the addition of requirements for gowns and gloves to be worn for all sterile compounding and not only compounding of cytotoxic agents. These changes outline minimum safety requirements and the required documentation for the minimum safety requirements. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident

pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will renumber subdivision (b) to (a). The new subdivision (a) will provide for the standards that must be met when compounding sterile drug products. The board's proposal will add "drug" so that compounding sterile products is now compounding sterile drug products. The board's proposal will also remove "from one or more non-sterile ingredients." This change is necessary to add "drug" is and further specify that compounded sterile products referenced in this section apply to compounded sterile drug products rather than other types of products such as food. The board's proposal addresses the problem of ensuring that board regulations are clear to the board's regulated licensees. Additionally, the necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #5" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will amend paragraph (1) of subdivision (a) to specify cleanroom garb requirements. Specifically, the "low-shedding coverall" is revised to a "non-shedding gown." The change is required to prevent particles from the gown worn during compounding to fall off the gown and into the compounded drug products. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will amend paragraph (2) of subdivision (a) to specify where cleanroom garb must be donned and removed. Specifically, "in an anteroom" is added to where cleanroom garb must be donned and removed. Additionally, "outside the designated area" is removed and "in a designated area immediately outside the segregated compounding area" is added as the other option to where cleanroom garb must be donned and removed. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will add paragraph (3) of subdivision (a) to specify the donning of personal protective equipment. Specifically, "Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. 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 and then the donning of a non-shedding gown. Cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves must occur within the buffer area, not prior to entering. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol after contact with non-sterile objects." This change is required to further clarify and specify for the board's regulated licensees the requirement for personal protective equipment during the sterile compounding of drug products. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will renumber paragraph (3) to (4) of subdivision (a) to specify where what personal property may be worn by compounding personnel. Specifically, the paragraph is revised by making grammar changes and deleting "must be eliminated" to read "Compounding personnel shall not wear hand, finger, or wrist jewelry. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove." is added as the other option to where cleanroom garb must be donned and removed. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will delete the former paragraph (4) of subdivision (a) to specifically removed "Head and facial hair must be kept out of the critical care area or be covered." This change is necessary in that it is redundant with the requirement set forth in paragraph (1) of subdivision (a). Further, this change aligns the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are

aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will amend paragraph (5) of subdivision (a) to specify sterile glove requirements. Specifically, the paragraph is revised by deleting "Gloves made of low-shedding materials are required." and replacing with "Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected." This is required in order to ensure that the gloves used by compounding personnel do not interact with isopropyl alcohol as isopropyl alcohol is the product used for disinfection. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will add paragraph (6) of subdivision (a) to specify that "Individuals experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections, or those wearing cosmetics shall be excluded from working in ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied." This is required to protect both the compounding personnel from contamination with open wounds on their body as well as protect the consumer of California receiving the compounded drug product to ensure that bodily fluids are not included in the compounded drug product. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board's proposal will delete subdivision (c) specifically deleting "The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients." The purpose of the board's proposal is to enhance the type of sterile drug products the regulations apply. By removing this

text, the regulations apply to all sterile drug products and not only those sterile drug products “from one or more non-sterile ingredients.” This change is necessary 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. The board’s proposal addresses the problem of ensuring patient safety for all who receive compounded drug products. 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.

Existing regulations at 16 CCR §1751.5 specify requirements sterile compounding attire. The purpose of the board’s proposal will add subdivision (b) to specify “When preparing cytotoxic agents, appropriate gowns and personal protective equipment shall be worn.” This further specifies that in addition to the compounding attire outlined in subdivision (a), compounding personnel must ensure appropriate personal protective equipment for cytotoxic agents is donned when preparing cytotoxic agents. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.6

Existing regulation at 16 CCR specifies the title of §1751.6 to be “Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.” As a result of SB 294, the name of §1751.3 will be changed to “Training of Sterile Compounding Staff, Patient, and Caregiver.” The purpose of the board’s proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board’s compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board’s proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The purpose of the board’s proposal will amend the section by striking “injectable” and replacing it with “drug” three times throughout the section and striking “injectable” from “sterile injectable drug products” one time. The necessity of this change and the identification of problem addressed is outlined in “Multiple Occurrence of Amendment #1” listed previously in this document. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The purpose of the board's proposal will amend the subdivision (a) to add ", storage, handling, and disposal" to the requirements for consultation and will be stated as "Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile injectable drug products and related supplies furnished by the pharmacy." This change is necessary to provide for increased consultation to be provided to the patient and/or primary caregiver. This will assist the patient and/or primary caregiver by increasing the information provided related to the proper use, storage, handling, and disposal of compounded sterile drug products. The problem addressed is to increase knowledge for the consumers of California with regard to the compounded sterile products they inject, inhale and apply to their eyes. Increased information assists with medication compliance as well as reduces the number of medication errors with regards to medication compliance. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The purpose of the board's proposal will amend subdivision (e) to remove "from one or more non-sterile ingredients." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #5" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The purpose of the board's proposal will amend subparagraph (E) of paragraph (1) of subdivision (e) to add additional information to the aseptic preparation procedures. Specifically, the subparagraph will read as "Aseptic preparation procedures 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 compounding process." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The purpose of the board's proposal will amend subparagraph (I) of paragraph (1) of subdivision (e) to add additional information to the sterilization techniques. Specifically, the subparagraph will read as "Sterilization techniques for compounding sterile drug products from one or more non-sterile ingredients." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>.

This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.6 specify requirements for training of sterile compounding staff, patient, and caregiver. The purpose of the board's proposal will amend of paragraph (2) of subdivision (e) to add additional information to the requirement outlining who of the compounding personnel must complete practical skills training in aseptic technique and aseptic area practices. Specifically, the board's proposal strikes "assigned to the controlled area" and replaces with "who handles compounded sterile drug products" so that the paragraph will read as "Each person who handles compounded sterile drug products must successfully complete practical skills training in aseptic technique and aseptic area practices. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years." In addition to enhancing worker competency and safety, this change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Amend 16 CCR §1751.7

Existing regulation at 16 CCR specifies the title of §1751.7 to be "Sterile Injectable Compounding Quality Assurance and Process Validation." As a result of SB 294, the name of §1751.3 will be changed to "Sterile Compounding Quality Assurance and Process Validation." The purpose of the board's proposal is to reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565.). Current law requires 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. This change is necessary to align the board's compounding regulations with the provisions in SB 294 commencing July 1, 2014. The board's proposal addresses and eliminates the problem of board regulations being inconsistent with statute. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will amend the section by striking "injectable" six times and replacing it with "drug" four times throughout the section. The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #1" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will amend of paragraph (1) of subdivision (a) to delete "parenteral medication" and replace with "sterile" so that the paragraph reads "Cleaning and sanitization of the sterile preparation area." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will delete paragraph (2) of subdivision (a) as this has been moved to 16 CCR §1751.1 entitled Sterile Compounding Recordkeeping Requirements. This change is necessary for ease of readability for the board's regulated licensees as this documentation requirement has been moved to the section for recordkeeping. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will renumber paragraph (3) to (2) of subdivision (a) as a result of deleting the former paragraph (2) of subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will renumber paragraph (4) to (3) of subdivision (a) as a result of deleting the former paragraph (2) of subdivision (a). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring

consistency within the order of the regulations. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will amend paragraph (4) of subdivision (a) by removing "expiration dating requirements" and replacing "beyond use dating requirements." The necessity of this change and the identification of problem addressed is outlined in "Multiple Occurrence of Amendment #2" listed previously in this document. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will amend subdivision (b) to remove the following text "The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare." and replace the text to read "The validation process shall be as complicated as the most complex manipulations performed by staff and which contain the same amount of volume transferred during the compounding process." This requires the validation process to be as extreme as the most difficult compounding manipulation performed at the pharmacy. The board's proposal will also increase the requirement of the medium samples to be incubated by adding "in a manner consistent with the manufacturer's recommendations and demonstrated to promote growth." This requires the compounding pharmacy to follow the manufacturer's guidelines to ensure the validation is being conducted according to manufacturer's standards. The board's proposal increases the requirement for personnel competency's re-evaluation at least every twelve months by adding "for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients." This requires those compounding from non-sterile products to sterile products to be tested twice a year. This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will add subdivision (c) to read as follows "All compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the hand hygiene and garbing procedure, all compounding personnel must successfully complete a gloved fingertip sampling procedure (zero colony forming units) at least three times before initially being allowed to compound sterile drug products." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment

ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will add subdivision (d) to read as follows "Re-evaluation of garbing and gloving competency shall occur at least annually for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients." This change is necessary to align the board's compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board's proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board's proposal will renumber subdivision (c) to (e) as a result of adding subdivisions (c) and (d). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations. The purpose of the board's proposal is to include references for Chapter 71 of the United States Pharmacopeia-National Formulary and Chapters 85 and 151 of the United States Pharmacopeia-National Formulary. This change is necessary to ensure that the most current and up to date citations are referenced in the board's regulation. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board's proposal addresses the problem of ensuring the board's regulations are aligned with the current compounding professional standards thereby ensuring the safety of all consumers receiving compounded drug products 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. The board's proposal additionally clarifies the requirements for end product testing confirming sterility and acceptable levels of pyrogens to be before dispensing. This is to ensure that contaminated compounded drug products are not dispensed to California consumers. Additionally, the board's proposal requires samples for sterility testing to be taken at the beginning, middle and end of the compounding process. This change is necessary to ensure testing is done on compounded drug products compounded throughout the entire process to ensure sterility and acceptable levels of pyrogens prior to dispensing to California consumers. The board's proposal addresses the problem of ensuring the board's regulations are aligned with the current compounding professional standards thereby ensuring the safety of all consumers receiving compounded drug products in California.

Existing regulations at 16 CCR §1751.7 specify requirement for sterile compounding quality assurance and process validation. The purpose of the board’s proposal will renumber subdivision (d) to (f) as a result of adding subdivisions (c) and (d). This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board’s proposal addresses the problem of ensuring consistency within the order of the regulations.

Amend 16 CCR §1751.8

The amended and proposed regulation at 16 CCR specifies the title of §1751.8 to be “Beyond Use Dating for Sterile Compounded Drug Products.” The purpose of the board’s proposal will outline for the board’s regulated licensees conducting sterile compounding the requirement for every compounded drug product to be given and labeled with a beyond use date. Subdivisions (a), (b), (c), and (d) outline beyond use date requirements for sterile compounded drugs compounded solely with aseptic manipulations meeting the outlined specifications. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Add 16 CCR §1751.9

The proposed regulation at 16 CCR specifies the title of §1751.9 to be “Single-Dose and Multi-Dose Containers; Limitations on Use.” The purpose of the board’s proposal will outline the requirements for the use of single-dose containers in accordance with the usage and intended use of one time when meeting the outlined requirements. The board’s proposal will also outline the restriction of a multi-dose container absent the manufacturer’s specifications. This change is necessary to align the board’s compounding regulations in accordance with compounding standards in USP 36 <797>. This alignment ensures consistency between the standards used in the profession and the regulations for the profession. The board’s proposal addresses the problem of ensuring that board regulations are aligned with compounding standards in USP 36 <797>. The board’s proposal ensures the safety of all consumers receiving compounded drugs in California by applying these compounding standards to both in-state and nonresident pharmacies. 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.

Renumber 16 CCR §1751.8 to §1751.10

Existing regulation at 16 CCR specifies the title of §1751.8 to be “Sterile Compounding Reference Materials.” The purpose of the board’s proposal will make a nonsubstantive change and renumber the section from 1751.8 to 1751.10 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency of the number of paragraphs

within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Renumber 16 CCR §1751.10 to §1751.11

Existing regulation at 16 CCR specifies the title of §1751.10 to be "Furnishing to Parenteral Patient at Home." The purpose of the board's proposal will make a nonsubstantive change and renumber the section from 1751.10 to 1751.11 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Renumber 16 CCR §1751.11 to §1751.12

Existing regulation at 16 CCR specifies the title of §1751.11 to be "Furnishing to Home Health Agencies and Licensed Hospices." The purpose of the board's proposal will make a nonsubstantive change and renumber the section from 1751.11 to 1751.12 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Renumber 16 CCR §1751.12 to §1751.13

Existing regulation at 16 CCR specifies the title of §1751.12 to be "Obligations of a Pharmacy Furnishing Portable Containers." The purpose of the board's proposal will make a nonsubstantive change and renumber the section from 1751.12 to 1751.13 as a result of adding sections 1751.8. and 1751.9. This change is necessary to ensure numeric consistency of the number of paragraphs within this section. The board's proposal addresses the problem of ensuring consistency within the order of the regulations.

Factual Basis

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4057 generally authorizes the board to provide exceptions to the application of Division 2 of Chapter 9 of the Business and Professions Code.

Business and Professions Code section 4127 requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.

Business and Professions Code section 4169 generally authorizes the board to subject the person or entity that has committed the violation of Business and Professions Code section 4169 a fine not to exceed the amount specified in section 125.9 for each occurrence, pursuant to a citation issued by the board.

Economic Impact Assessment

The board conducted an Economic Impact Assessment and 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 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.

Evidence Supporting Finding of No Significant Statewide Adverse Economic Impact Directly Affecting Business

SB 294 was approved by the Legislature. AB 294 was signed and approved by the Governor. There was no public opposition on record for the bill.

Technical, Theoretical, and/or Empirical Study, Report, or Documents

The Board of Pharmacy relied on Chapters 71, 85, 151, 795, and 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013) and NSF International Standard/American National Standard for Biosafety Cabinetry - Biosafety Cabinetry: Design, Construction, Performance, and Field Certification [NSF/ANSI 49-2012], as indicated in the Underlying Data.

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 believes the regulatory changes as described in the Notice will

serve to protect the public health by ensuring the board's regulations regarding compounded drug products are aligned with the compounding profession's compounding standards in Chapters 71, 85, 151, 795, and 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement). By reducing such discrepancy for the compounding profession who are compounding drug products in California and shipped into California, the board is ensuring the safety of all consumers receiving compounded drugs in California.

Consideration of Alternatives

The Board of Pharmacy has made an initial determination that no reasonable alternative to adopting or amending the regulations would be either 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 the Notice.

Specific Technologies or Equipment

This regulation does not mandate the use of specific equipment as outlined in Chapters 71, 85, 151, 795, and 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013) and NSF International Standard/American National Standard for Biosafety Cabinetry - Biosafety Cabinetry: Design, Construction, Performance, and Field Certification [NSF/ANSI 49-2012], as indicated in the Underlying Data. The types of compounding equipment outlined in the above referenced documents are industry and performance standards for the practice and profession of compounding drug products.

Underlying Data

1. Senate Bill 294 (Emmerson, Statutes of 2013, Chapter 565.)
2. Senate Floor Analyses for SB 294 (September 10, 2013).
3. Chapter 71 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013).
4. Chapters 85 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013)
5. Chapters 151 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013)
6. Chapter 795 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013).
7. Chapter 797 of the United States Pharmacopeia – National Formulary (USP36-NF31 through 1st Supplement) (36th Revision, Effective August 1, 2013).
8. NSF International Standard/American National Standard for Biosafety Cabinetry - Biosafety Cabinetry: Design, Construction, Performance, and Field Certification [NSF/ANSI 49-2012], as revised July 7, 2012.
9. "Multistate Fungal Meningitis Outbreak Investigation." *Centers for Disease Control and Prevention*. Centers for Disease Control and Prevention, 23 Oct. 2013. Web. 19 Nov. 2013.

10. "Standards for Classification of Cleanroom," *www.icccs.net*, Published February 2005 on <http://www.icccs.net/news/ClassificationOfCleanrooms2005.pdf>.
11. Relevant Meeting Materials and Minutes from the Board of Pharmacy Enforcement Committee Meetings Held June 4, 2013 and September 10, 2013.
12. Relevant Meeting Materials and Minutes from the Board of Pharmacy Board Meetings held October 25-26, 2012; December 13, 2012; February 5-6, 2013; April 24-25, 2013; and July 30-31, 2013.
13. Relevant Meeting Materials and Minutes from the Board of Pharmacy Compounding Subcommittee Meeting held March 19, 2013.
14. Economic Impact Assessment