

## Board of Pharmacy

### Initial Statement of Reasons

Subject Matter of Proposed Regulation: Requirements for Pharmacies that Compound Medications

Sections Affected: Repeal sections

- 16 CCR 1716.1
- 16 CCR 1716.2

Add sections

- 16 CCR 1735
- 16 CCR 1735.1
- 16 CCR 1735.2
- 16 CCR 1735.3
- 16 CCR 1735.4
- 16 CCR 1735.5
- 16 CCR 1735.6
- 16 CCR 1735.7
- 16 CCR1735.8,

Amend sections

- 16 CCR 1751
- 16 CCR 1751.1
- 16 CCR 1751.2
- 16 CCR 1751.3
- 16 CCR 1751.4
- 16 CCR 1751.5
- 16 CCR 1751.6
- 16 CCR 1751.7
- 16 CCR 1751.8

#### Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to repeal sections 1716.1 and 1716.2, 1751.01, 1751.02; add sections 1735, 1735.1, 1735.2, 1735.3, 1735.4, 1735.5, 1735.6, 1735.7, 1735.8; and amend sections 1751, 1751.1, 1751.2, 1751.3, 1751.4, 1751.5, 1751.6, 1751.7, and 1751.8 of Division 17 of Title 16 of the California Code of Regulations.

The purpose for repealing the above sections is to remove duplication between Article 4.5 and Article 7 as to reorganize Article 7 to make it consistent with Article 4.5. The requirements currently in these sections are incorporated into new sections.

The purpose for adding the above sections is to address, among other items in compounding the strength, efficacy and quality as well as to require a quality assurance program for general compounding. Currently there is no provision that define these items for general compounding nor are any parameters established in pharmacy law detailing general compounding by a pharmacy.

The purpose for amending the above sections is to remove redundancies between the requirements for general compounding and sterile injectable compounding as well as to ensure consistent sequencing of related requirements items contained in both Articles.

This proposal would establish guidelines for distinguishing compounding from manufacturing and would provide uniformity in compounding for California consumers.

Below is a summary of each change as well as a brief justification for each change.

Repeal 16 CCR 1761.1. – Compounding Unapproved Drugs for Prescriber Office Use

The provisions in 1761.1 are now included within other sections of the regulation proposal.

Repeal 16 CCR 1761.2 – Record Requirements – Compounding for Future Furnishing.

The provisions in 1761.2 are not included within other sections of the regulation proposal.

Add 16 CCR 1735 – Compounding in Licensed Pharmacies

This new section will define the activities that constitute compounding identified by the workgroup, including board staff and board members.

Add 16 CCR 1735.1 – Compounding Definitions

This new section defines common terms referenced in the regulation proposal.

Add 16 CCR 1735.2 – Compounding Limitations and Requirements

This new sections places limitations on the conditions under which compounding can occur as well as allows for anticipatory compounding only under specified conditions. This section contains the provisions previously contained in section 1716.1 and specifies general requirements for compounding; including the requirement to maintain a master formula record, storage requirements, expiration date requirements and establishes the self-assessment form requirement.

Add 16 CCR 1735.3 – Records of Compounded Drug Products.

This new section details the pharmacy record requirements for each compounded drug, record requirements for the products used in compounding, as well as the duration of time records must be maintained.

Add 16 CCR 1735.4 – Labeling of Compounded Drug Products

This new section details the labeling requirements from compounded drugs in addition to the labeling requirements detailed in Business and Professions Code section 4076.

Add 16 CCR 1735.5 – Compounding Policies and Procedures

This new section establishes and defines the content of the policy and procedure manual that must be maintained by a pharmacy that compounds medications.

Add 16 CCR 1735.6 – Compounding Facilities and Equipment

This new section requires that the pharmacy maintain written documentation regarding the facilities and equipment used and specifies that all equipment (where applicable) shall be calibrated and the results documented in accordance with the manufacturers specifications.

#### Add 16 CCR 1735.7 – Training of Compounded Staff

This new section requires that the pharmacy maintain written documentation and an ongoing evaluation process to demonstrate pharmacy personnel assigned compounding duties are trained and possess the necessary skills.

#### Add 16 CCR 1735.8 – Compounding Quality Assurance

This new section requires that the pharmacy, as part of its written policies and procedures manual, include a quality assurance plan and specifies the required elements of the plan.

#### Amend 16 CCR 1751 – Sterile Injectable Compounding: Compounding Area

This section is amended to require pharmacies that engage in compounding sterile injectable drug products are required to comply with all requirements specified in 16 CCR 1735 – 1735.8 as well as all requirements specified in 16 CCR 1751 – 1751.8.

#### Amend 16 CCR 1751.1 – Sterile Injectable Recordkeeping Requirements.

This section was renumbered from CCR 1751.3 to 1751.1 to conform with the sequence of Article 4.5 (CCR 1735 – 1735.8). In addition, referenced sections were updated to also conform with the requirements in Article 4.5).

#### Amend 16 CCR 1751.2 – Sterile Injectable Labeling Requirements

This section is amended to include the specific references to labeling requirements contained in Business and Professions Code section 4076 as well as to conform with the labeling requirements in CCR 1735.4.

#### Amend 16 CCR 1751.3 – Sterile Injectable Policies and Procedures.

This section was renumbered from CCR 1751.02 and was consolidated to reduce confusion. In addition it was reordered to conform with the sequence of similar subject areas in Article 4.5. Subsection (c) was moved a slightly modified from former section 1751.6 to consolidate similar provisions.

#### Amend 16 CCR 1751.4 – Facility and Equipment Standards for Sterile Injectable Compounding

This section was renumbered from CCR 1751.01 and was consolidated with CCR 1751.1. In addition subsection (d) was moved and slightly modified from former section 1751.1, to consolidate similar provisions.

#### Amend 16 CCR 1751.5 – Sterile Injectable Compounding Attire

This section was renumbered from former section CCR 1751.4.

#### Amend 16 CCR 1751.6 – Training of Sterile Injectable Compounding Staff, Patient and Caregiver

This section was renumbered from former section CCR 1751.5.

#### Amend 16 CCR 1751.7 – Sterile Injectable Quality Assurance and Process Validation

This section is amended to require that end-product testing and process validation procedures are included in the quality assurance program and clarifies that the pharmacist-in-charge is responsible for determining periodic testing.

#### Amend 16 CCR 1751.8 – Sterile Injectable Compounding Reference Materials.

This section was renumbered from former section CCR 1751.9 and was slightly

modified to include similar language contained throughout Article 7.

As specified above, section 1735.2, in addition to other elements, establishes a requirement for the pharmacist-in-charge to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is a compilation of relevant pharmacy law citations and is used as both an educational tool for the PIC as well as to assist compounding pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. This proposal would make the pharmacy inspection process more meaningful and provide relevant information to pharmacies and their PIC.

### Factual Basis

In 2004 the Board of Pharmacy formed a Workgroup on Compounding comprised of board members, board staff and industry representative. The workgroup recognized that current pharmacy regulations addressing compounding only govern the physical circumstances, procedures and record keeping requirements for general compounding and do not address quality, strength or purity.

Below is a brief description of the relevant sections of state and federal law.

Business and Professions Code section 4005 provides that board with the authority to adopt rules and regulations.

Business and Professions Code section 4036 defines the term “pharmacist”.

Business and Professions Code section 4037 defines the term “pharmacy”.

Business and Professions Code section 4051 specifies that it is unlawful for any person to manufacture, compound, furnish, sell or dispense any dangerous drug or device or to dispense or compound any prescription pursuant to a prescriber unless he or she is a pharmacist.

Business and Professions Code section 4052 specifies permissible procedures by a pharmacist.

Business and Professions Code section 4059 specifies the conditions for furnishing dangerous drugs and devices upon a prescription as well as exemptions to the requirement.

Business and Professions Code section 4076 specifies the labeling requirements for prescription containers.

Business and Professions Code section 4081 specifies the requirements for records of dangerous drugs and devices.

Business and Professions Code section 4127 requires the board to adopt regulations establishing standards for sterile injectable compounding.

Business and Professions Code section 4127.7 specifies the requirements for compounding sterile injectable products from nonsterile ingredients.

Business and Professions Code section 4332 specifies that it is a misdemeanor to fail or refuse to maintain or produce records.

Health and Safety Code section 18944 requires state agencies to adopt regulations for publication in titles of the CCR containing other regulations of that agency to identify, the appropriate sections of the California Building Standards Code.

### Underlying Data

This proposal is based upon recommendations the Workgroup on Compounding as well as public comment to those recommendations at several board meetings and Licensing Committee Meetings.

### Business Impact

The board has not received any testimony as either part of the workgroup meetings or any public meetings that indicate a significant impact on pharmacies that perform general compounding or compounding of sterile injectable products.

### Specific Technologies or Equipment

This regulation does not create a new mandate the use of specific technologies or equipment.

### Consideration of Alternatives

No reasonable alternative to the regulation 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 than the proposed regulation.