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Legislation and Regulation Committee

Greg Lippe, Public Member, Chair
Ryan Brooks, Public Member
Stan Weisser, RPh
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REGULATION REPORT AND ACTION

A. DISCUSSION AND POSSIBLE ACTION

Board Action to Adopt Amendments to Title 16 CCR 1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination; Confidentiality

ATTACHMENT A

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR §1721 and §1723.1 to strengthen the penalty an applicant would incur for dishonest conduct during an examination, as well as further clarify the penalty an applicant would incur for conveying or exposing any part of a qualifying licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2,000/item. Compromised test items pose not only a financial loss to the board, but also inhibit the board's ability to test for minimum competency and, if an otherwise incompetent applicant passes the exam because the exam has been compromised, such a breach is a public safety issue.

The formal rulemaking was noticed on October 30, 2009. The 45-day comment period concluded on December 14, 2009, and the board did not receive any comments to the proposed rulemaking. A copy of the board-approved language is attached.

B. FOR INFORMATION. Board Adopted Regulations – Approved by the Office of Administrative Law

ATTACHMENT B

Repeal Title 16 CCR Sections 1716.1 and 1716.2, Amend and Adopt Sections 1751 through 1751.8, and Adopt Sections 1735 through 1735.8 – Pharmacies that Compound

Current pharmacy law authorizes a pharmacist to compound drug products as well as compound injectable sterile drug products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that

compound sterile injectable products. There were no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. The proposal established guidelines to provide uniformity in compounding for California consumers. The rulemaking incorporates by reference Form 17M-39, Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment (Rev. 01/10).

Draft regulatory text was published at the end of August 2008, and a regulation hearing was held at the October 2008 Board Meeting. At the conclusion of the regulation hearing, the board voted to create a subcommittee of two board members to work with staff and fully consider all comments received both orally and in writing.

At its January 2009 Board Meeting, the board voted to pursue a 15-day comment period to exempt from some of the record keeping requirements detailed in Section 1735.3 those sterile products compounded on a one-time basis for administration within 2 hours, as specified. The modified text was noticed on February 26, 2009.

At the April 2009 Board Meeting, the board considered the comments received during the 45- and 15-day comment periods, along with a draft response to each. The board again considered modifications to proposed section 1735.3(a)(6) and subsequently voted to pursue a 2nd 15-day comment period to exempt from some of the record keeping requirements in proposed 1735.3(a)(6) those sterile products compounded on a one-time basis for administration within 24 hours, as specified. The 2nd 15-day comment period was noticed on May 4, 2009.

At the July 2009 Board Meeting, the board considered the comments received during the 2nd 15-day comment period, as well as a draft response to each comment. The board then voted to approve the subcommittee's recommendation to adopt the regulation text as noticed on May 4, 2009, and to specify that the requirements would not go into effect for six months following approval by the Office of Administrative Law to allow for implementation. The board further moved that staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

After staff compiled the final regulatory proposal, the department reviewed and approved the rulemaking which was transmitted to the Office of Administrative Law on November 19, 2009. OAL approved the rulemaking on January 6, 2010. As specified by the board, the rulemaking has an effective date six months following OAL approval: July 6, 2010. As directed by the board, staff will exercise its enforcement discretion for an additional six months to allow for education and transition.

A copy of the Adopted Text and Self-Assessment Form are attached.

C. FOR INFORMATION. Board Approved Regulations – Currently Noticed

Proposed Rulemaking to Add Title 16 Section 1707.2 to the California Code of Regulations – Fingerprint Requirements

ATTACHMENT C

At the October 2009 Board Meeting, the board considered and approved an Enforcement Committee recommendation to initiate the rulemaking process to require pharmacists to (1) report on license renewal applications prior convictions during the renewal period, and (2) require electronic submission of fingerprints for pharmacists with no prior history of electronic

fingerprints on file. The proposed rulemaking further specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The Initial Notice for the rulemaking was published on December 25, 2009, and the 45-day comment period concludes February 15, 2010.

A copy of the proposed regulatory language is attached.

D. FOR ACTION. Board Action to Initiate Rulemaking

Discussion and Possible Action to Amend Title 16 CCR Section 1746 – Emergency Contraception Protocol

ATTACHMENT D

In 2004, the board adopted a statewide protocol for dispensing emergency contraception products, resulting in the codification of Title 16 CCR Section 1746. The regulation became operative on December 2, 2004.

Staff recommends that an error be corrected in the 'chart' of Dedicated Emergency Contraception that is specified in 16 CCR §1746(b)(11) to correct the heading of "Ethinyl Estradiol per Dose (mg)." The heading should designate micrograms – not milligrams. While the board deems this to be a typographical error, the regulation (as originally adopted) specified milligrams, not micrograms. As a result, a formal regulation proposal is required to correct this heading. A copy of the current regulation with proposed amendments is attached.

E. FOR INFORMATION. Board Approved Regulations – Awaiting Notice

1. Proposed Addition to Title 16 CCR Section 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer

ATTACHMENT E-1

The adoption of Section 1785 of the California Code of Regulations would establish a self-assessment form for veterinary food-animal drug retailers and require the designated representative-in-charge to complete this form to ensure compliance with pharmacy law. This form would also aid these licensees in complying with legal requirements of their operations and therefore increase public safety as a result of this compliance.

The draft form was reviewed and approved at the September 2007 Enforcement Committee Meeting. During the October 2007 Board Meeting, the board voted to approve the regulation for the 45-day comment period.

The Licensing Committee is completing a program review of the Veterinary Food-Animal Drug Retailer program. Board staff does not anticipate proceeding with this regulation

change until the Licensing Committee completes its review of the Veterinary Food-Animal Drug Program for possible changes.

A copy of the approved text is attached.

2. Proposed Addition of Title 16 CCR §1751.xx – Accreditation Agencies for Pharmacies That Compound Injectable Sterile Drug Products

ATTACHMENT E-2

Business and Professions Code section 4127.1 requires a separate license to compound sterile injectable drug products. Section 4127.1(d) provides exemptions to the licensing requirement for pharmacies that have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board. Since the inception of this statute, the board has approved two such agencies.

The proposed regulation specifies the criteria the board will utilize to consider approval of those accrediting agency requests.

A copy of the approved text is attached.

F. FOR INFORMATION. Regulations Under Development

1. Proposed Amendment to Title 16 CCR §1780 – Update the USP Standards Reference Material

CCR §1780 sets minimum standards for drug wholesalers. Section 1780(b) references the 1990 edition of the United States Pharmacopeia Standards (USP Standards) for temperature and humidity. The USP Standards is updated and published annually. Consequently, this section requires an amendment to §1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards if determined appropriate.

Because of stated concerns about whether referencing the 2005 USP standards is an unreasonable burden on wholesalers, at the October 2008 Board Meeting, the board voted to address the issue of updating the USP Standards reference materials within this section.

President Schell may wish to consider filling the subcommittee vacancy created when former board member Jim Burgard's term concluded. This subcommittee has not held any meetings. Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting.

2. Proposed Amendment to 16 CCR §1732.2 – Continuing Education for Competency Committee Members

At the October 2008 Board Meeting, the board voted to award up to six hours of continuing education (CE) credit annually to complete on-line review of examination questions if the committee member is not seeking reimbursement for their time.

Competency Committee members serve as the board's subject matter experts for the development of the California Practice Standards and Jurisprudence Examination for Pharmacists. A committee member's term is generally about eight years.

Annually, committee members attend approximately 3-4 two-day meetings to assist in examination development. Each two-day meeting consists of approximately 2-4 hours of preparation time in addition to 16 hours of meeting time. Committee members also participate in 2-4 writing assignments based on the examination development need. Committee members spend approximately 50-80 hours preparing for and attending committee meetings on an annual basis in addition to multiple writing assignments and are compensated for time and travel.

One of the core functions of this committee is to complete an on-line review of all test questions prior to administration. As the test questions cover all aspects of pharmacy practice and law, this on-line review requires a significant amount of committee time to research items and confirm that a question and answer are valid. Given this, the committee requests that the board award up to six hours of CE annually for members that complete this on-line review. (Typically, committee members are not compensated for their time to complete this function. If a committee member is seeking reimbursement for this time, however, continuing education will not be awarded.)

Current pharmacy law requires pharmacists to earn 30 hours of approved CE every two years as a condition of license renewal. Currently, pharmacists can earn CE:

- Offered by approved providers (ACPE and the Pharmacy Foundation of California – 16 CCR §1732.05),
- Approved by Medical Board, Board of Podiatric Medicine, Board of Registered Nursing or Dental Board, if relevant to pharmacy practice (16 CCR §1732.2), and/or
- By petition of an individual pharmacist for a course that meets board standards for CE for pharmacists (16 CCR §1732.2).

Additionally, the board will award CE for:

- Attending one board meeting annually (6 hours of CE),
- Attending two committee meetings annually (2 hours of CE for each meeting, must be different committee meetings), and
- Completing the PSAM, which is administered by the National Association of Boards of Pharmacy (6 hours).

Board staff is drafting regulation language for consideration at a future Legislation and Regulation Committee meeting and in advance of the April 2010 Board Meeting.

3. Development of Enforcement Component of Security of Emergency Kits

ATTACHMENT F-3

AB 931 amended section 1261.5 of the Health and Safety Code to increase the number of oral dosage form and suppository dosage form drugs from 24 to 48 for storage within an emergency supplies container, as defined in Section 4119 of the Business and Professions Code. These "E-kits" are within the jurisdiction of the California Department of Public Health (CDPH), and the measure specifies that CDPH may limit the number of any doses of each drug available to not more than 16 doses of any separate drug dosage form. The bill

was signed by the Governor and Chapter 491 Statutes 2009 was filed with the Secretary of State on that date. The provisions of AB 931 became effective on January 1, 2010. A copy of the bill is attached.

Attachment A

*Proposed Amendment to
16 CCR §1721 and §1723.1
Dishonest Conduct on a Pharmacist Licensure
Examination; Confidentiality*

Order of Adoption
Board of Pharmacy
California Code of Regulations

**To Amend Division 17 of Title 16 CCR §1721 and
To Amend Division 17 of Title 16 CCR §1723.1**

Dishonest Conduct During Examination and Confidentiality of Examination Questions

Amend Section 1721 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1721. Dishonest Conduct During Examination.

An applicant for examination as a pharmacist who engages in dishonest conduct during the examination shall not have that examination graded, shall not be approved to take the examination for ~~twelve months~~ three years from the date of the incident, and shall surrender his or her intern card and license until eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

Amend Section 1723.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1723.1. Confidentiality of Examination Questions.

Examination questions are confidential. Any applicant for any license issued by the board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for a license. The applicant shall not be approved to take the examination for three years from the date of the incident and shall surrender his or her intern license until again eligible to take the examination. The applicant may not be issued a pharmacy technician license until the applicant is again eligible to take the examination.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 123 and 496, Business and Professions Code.

Virginia Herold
Executive Officer

Date

Attachment B

Approved Text
Amendments to 16 CCR §1751 - §1751.8 and
Addition of 16 CCR §1735 - §1735.8
Pharmacies that Compound

Form 17M-39
Community Pharmacy & Hospital Outpatient
Pharmacy Self Assessment

Order of Adoption
Board of Pharmacy
California Code of Regulations

**To Repeal Division 17 of Title 16 CCR §1716.1 and §1716.2 and
To Adopt Division 17 of Title 16 CCR §1735 and §1735.1 – §1735.8, and
To Amend Division 17 of Title 16 CCR §1751 and §1751.1 -- §1751.8
Requirements for Compounding and Sterile Injectable Compounding**

Repeal Section 1716.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.1. Compounding Unapproved Drugs for Prescriber Office Use.

~~As used in Business and Professions Code Section 4052(a)(1), the following terms have the indicated meaning concerning the compounding of unapproved drugs for prescriber office use:~~

- ~~(a) "Reasonable quantity" means that quantity of an unapproved drug which:~~
- ~~(1) is sufficient for that prescriber's office use consistent with the expiration date of the product as set forth in section 1716.2(a)(3); and~~
 - ~~(2) is reasonable considering the intended use of the compounded medication and nature of the prescriber's practice; and~~
 - ~~(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality and purity of the compounded medication.~~
- ~~(b) "Compounded medication" means medications actually compounded by the pharmacy supplying them to a prescriber.~~
- ~~(c) "Prescriber office use" means application or administration in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients as estimated by the prescriber.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4027, 4033, 4050, 4051, 4052, 4059, 4170 and 4171, Business and Professions Code.

Repeal Section 1716.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1716.2. Record Requirements--Compounding for Future Furnishing.

~~(a) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include, but are not limited to:~~

- ~~(1) The date of preparation.~~
- ~~(2) The lot numbers. These may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If the lot number is assigned by the pharmacy, the pharmacy must also record the original manufacturer's lot numbers and expiration dates, if known. If~~

~~the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components.~~

~~(3) The expiration date of the finished product. This date must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(4) The signature or initials of the pharmacist performing the compounding.~~

~~(5) A formula for the compounded product. The formula must be maintained in a readily retrievable form.~~

~~(6) The name(s) of the manufacturer(s) of the raw materials.~~

~~(7) The quantity in units of finished products or grams of raw materials.~~

~~(8) The package size and the number of units prepared.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4051, 4059, 4081 and 4332, Business and Professions Code.

Article 4.5. Compounding

Add Section 1735 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735. Compounding in Licensed Pharmacies.

- (a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:
- (1) Altering the dosage form or delivery system of a drug
 - (2) Altering the strength of a drug
 - (3) Combining components or active ingredients
 - (4) Preparing a drug product from chemicals or bulk drug substances
- (b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) for oral, rectal topical, or injectable administration, nor does it include tablet splitting or the addition of flavoring agent(s) to enhance palatability.
- (c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace.
- (d) The parameters and requirements stated by this Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile injectable compounding are stated by Article 7 (Section 1751 et seq.).

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

Add Section 1735.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.1. Compounding Definitions.

- (a) "Integrity" means retention of potency until the expiration date noted on the label.
- (b) "Potency" means active ingredient strength within +/- 10% of the labeled amount.
- (c) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.
- (d) "Strength" means amount of active ingredient per unit of a compounded drug product.

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

Add Section 1735.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.2. Compounding Limitations and Requirements.

- (a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.
- (b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.
- (c) A "reasonable quantity" as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:
 - (1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and
 - (2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and
 - (3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with

pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

- (d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:
- (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post-compounding process or procedures required, if any.
 - (6) Expiration dating requirements.
- (e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.
- (f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.
- (g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.
- (h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This "beyond use date" of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.
- (j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 01/10.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the

issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

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

Add Section 1735.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.3. Records of Compounded Drug Products.

- (a) For each compounded drug product, the pharmacy records shall include:
- (1) The master formula record.
 - (2) The date the drug product was compounded.
 - (3) The identity of the pharmacy personnel who compounded the drug product.
 - (4) The identity of the pharmacist reviewing the final drug product.
 - (5) The quantity of each component used in compounding the drug product.
 - (6) The manufacturer and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted.
Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.
 - (7) The equipment used in compounding the drug product.
 - (8) A pharmacy assigned reference or lot number for the compounded drug product.
 - (9) The expiration date of the final compounded drug product.
 - (10) The quantity or amount of drug product compounded.
- (b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.
- (c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.
- (d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

Add Section 1735.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.4. Labeling of Compounded Drug Products.

- (a) In addition to the labeling information required under Business and Professions Code section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active ingredient(s).
- (b) A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.
- (c) Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight, pharmacy reference or lot number, and expiration date.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Add Section 1735.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.5. Compounding Policies and Procedures.

- (a) Any pharmacy engaged in compounding shall maintain a written policy and procedure manual for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding.
- (b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge and shall be updated whenever changes in processes are implemented.
- (c) The policy and procedure manual shall include the following
 - (1) Procedures for notifying staff assigned to compounding duties of any changes in processes or to the policy and procedure manual.
 - (2) Documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product.
 - (3) The procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

- (4) Documentation of the methodology used to test integrity, potency, quality, and labeled strength of compounded drug products.
- (5) Documentation of the methodology used to determine appropriate expiration dates for compounded drug products.

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

Add Section 1735.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.6. Compounding Facilities and Equipment.

- (a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products. Where applicable, this shall include records of certification(s) of facilities or equipment.
- (b) Any equipment used to compound drug products shall be stored, used, and maintained in accordance with manufacturers' specifications.
- (c) Any equipment used to compound drug products for which calibration or adjustment is appropriate shall be calibrated prior to use to ensure accuracy. Documentation of each such calibration shall be recorded in writing and these records of calibration shall be maintained and retained in the pharmacy.

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

Add Section 1735.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.7. Training of Compounding Staff.

- (a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.
- (b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.
- (c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

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

Add Section 1735.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1735.8. Compounding Quality Assurance.

- (a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug products.
- (b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.
- (c) The quality assurance plan shall include written standards for qualitative and quantitative integrity, potency, quality, and labeled strength analysis of compounded drug products. All qualitative and quantitative analysis reports for compounded drug products shall be retained by the pharmacy and collated with the compounding record and master formula.
- (d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality, or labeled strength.

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

Article 7 Sterile Injectable Compounding

Amend Section 1751 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751. Sterile Injectable Compounding; Compounding Area.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile injectable compounding.
- (b) The Any pharmacy doing sterile injectable compounding shall have a designated area for the preparation of sterile injectable products which shall meet the following standards:

- (1) Clean Room and Work Station Requirements, shall be in accordance with Section ~~490A.3.1~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations.
- (2) Walls, ceilings and floors shall be constructed in accordance with Section ~~490A.3.1~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations.
- (3) Be ventilated in a manner in accordance with Section 505.12₂ of Title 24, ~~Part 4~~, Chapter 5 of the California Code of Regulations.
- (4) Be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration. Certification records must be retained for at least 3 years.
- (5) The pharmacy shall be arranged in accordance with Section ~~490A.3.1~~ 1250 of Title 24, Part 2, Chapter 4A 12, of the California Code of Regulations. Items related to the compounding of sterile injectable products within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.
- (6) A sink shall be included in accordance ~~in~~ with Section ~~490A.3.1~~ 1250 of Title 24, Part 2, ~~Chapter 4A~~ of the California Code of Regulations.
- (7) There shall be a refrigerator and/or freezer of sufficient capacity to meet the storage requirements for all material requiring refrigeration.

(c) Any pharmacy compounding a sterile injectable product from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127 and 4127.7, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Renumber section 1751.3 to new section 1751.1 and amend section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§~~1751.3~~, 1751.1. Sterile Injectable Recordkeeping Requirements.

- (a) Pharmacies compounding sterile injectable products for future use pursuant to section ~~4746.4~~ 1735.2 shall, in addition to those records required by section ~~4746.2~~ 1735.3, ~~have~~ make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.
- (b) In addition to the records required by section 1735.3 and subdivisions (a), for sterile products compounded from one or more non-sterile ingredients, the following records must be ~~maintained for at least three years~~ made and kept by the pharmacy:
 - (1) The training and competency evaluation of employees in sterile product procedures.
 - (2) Refrigerator and freezer temperatures.

- (3) Certification of the sterile compounding environment.
- (4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).
- (5) Inspection for expired or recalled pharmaceutical products or raw ingredients.
- (6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

(c) ~~Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years~~ Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

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

Amend Section 1751.2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.2. Sterile Injectable Labeling Requirements.

~~In addition to existing labeling requirements to the labeling information required under Business and Professions Code section 4076 and section 1735.4,~~ a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states "Chemotherapy -Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Renumber section 1751.02 to new section 1751.3 and amend section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.02. 1751.3. Sterile Injectable Policies and Procedures.

- (a) ~~Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include, but not be limited to~~ Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy

and procedure manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:

- (1) Compounding, filling, and labeling of sterile injectable compounds.
 - (2) Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.
 - (3) Equipment and supplies.
 - (4) Training of staff in the preparation of sterile injectable products.
 - (5) Procedures for handling cytotoxic agents.
 - (6) Quality assurance program.
 - (7) Record keeping requirements.
- (b) The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.
- (c) Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- (d) Pharmacies compounding sterile injectable products from one or more non-sterile ingredients must have written policies and procedures that comply with the following:
- (1) All written policies and procedures shall be immediately available to all personnel involved in these activities and board inspectors.
 - (2) All personnel involved must read the policies and procedures before compounding sterile injectable products, and any additions, revisions, and deletions to the written policies and procedures must be communicated to all personnel involved in sterile compounding.
 - (3) Policies and procedures must address at least the following:
 - (A) Competency evaluation.
 - (B) Storage and handling of products and supplies.
 - (C) Storage and delivery of final products.
 - (D) Process validation.
 - (E) Personnel access and movement of materials into and near the controlled area.
 - (F) Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).
 - (G) Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.
 - (H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.

- (I) For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.
- (J) Sterilization.
- (K) End-product evaluation and testing.

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

Renumber section 1751.01 to new section 1751.4 and amend section 1751.4 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.04. 1751.4. Facility and Equipment Standards for Sterile Injectable Compounding from Non-Sterile Ingredients.

- (a) No sterile injectable product shall be ~~prepared~~ compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile injectable drug products.
- (b) During the preparation of sterile injectable products, access to the designated area or cleanroom must be limited to those individuals who are properly attired.
- (c) All equipment used in the designated area or cleanroom must be made of a material that can be easily cleaned and disinfected.
- (d) 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.
- (e) Pharmacies preparing parenteral cytotoxic agents shall do so in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a laminar air flow hood. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code; and Section 18944 Health and Safety Code.

Repeal Section 1751.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.1. Laminar Flow Biological Safety Cabinet.

~~Pharmacies preparing parenteral cytotoxic agents shall be in accordance with Section 4-1106(b) of Title 24 of the California Administrative Code. The hood must be certified annually by a qualified technician who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code; and Section 18944(a), Health and Safety Code.

Repeal Section 1751.3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.3. Recordkeeping Requirements.

- ~~(a) Pharmacies compounding sterile injectable products for future use pursuant to section 1716.1-1735.2 shall, in addition to those records required by section 1716.2-1735.3, have records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~
- ~~(b) In addition to the records required by subdivisions (a), for sterile products compounded from one or more non-sterile ingredients the following records must be maintained for at least three years:~~
- ~~(1) The training and competency evaluation of employees in sterile product procedures.~~
 - ~~(2) Refrigerator and freezer temperatures.~~
 - ~~(3) Certification of the sterile compounding environment.~~
 - ~~(4) Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).~~
 - ~~(5) Inspection for expired or recalled pharmaceutical products or raw ingredients.~~
 - ~~(6) Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.~~
- ~~(c) Pharmacies shall maintain records of validation processes as required by Section 1751.7 (b) for three years.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

Renumber section 1751.4 to new section 1751.5 and amend section 1751.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.4. 1751.5. Sterile Injectable Compounding Attire.

- (a) When preparing cytotoxic agents, gowns and gloves shall be worn.
- (b) When compounding sterile products from one or more non-sterile ingredients the following standards must be met:
 - (1) Cleanroom garb consisting of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.
 - (2) Cleanroom garb must be donned and removed outside the designated area.
 - (3) Hand, finger, and wrist jewelry must be eliminated. If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.
 - (4) Head and facial hair must be kept out of the critical area or be covered.
 - (5) Gloves made of low-shedding materials are required.
- (c) The requirements of this subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.

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

Renumber section 1751.5 to new section 1751.6 and amend section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.5. 1751.6. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.

- (a) Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy.
- (b) The pharmacist-in-charge shall be responsible to ensure all pharmacy personnel engaging in compounding sterile injectable drug products shall have training and demonstrated competence in the safe handling and compounding of sterile injectable products, including cytotoxic agents if the pharmacy compounds products with cytotoxic agents.
- (c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.
- (d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile injectable products.
- (e) Pharmacies that compound sterile products from one or more non-sterile ingredients must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

- (A) Aseptic technique.
- (B) Pharmaceutical calculations and terminology.
- (C) Sterile product compounding documentation.
- (D) Quality assurance procedures.
- (E) Aseptic preparation procedures.
- (F) Proper gowning and gloving technique.
- (G) General conduct in the controlled area.
- (H) Cleaning, sanitizing, and maintaining equipment used in the controlled area.
- (I) Sterilization techniques.
- (J) Container, equipment, and closure system selection.

(2) Each person assigned to the controlled area 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.

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

Repeal Section 1751.6 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.6. Disposal of Waste Material.

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.~~

Note: Authority cited: Section 4005 Business and Professions Code. Reference: Section 4005 Business and Professions Code.

Amend 1751.7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.7. Sterile Injectable Compounding Quality Assurance and Process Validation.

- (a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, ~~There shall be~~ a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The Quality Assurance Program shall include at least the following:
- (1) Cleaning and sanitization of the parenteral medication preparation area.
 - (2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.
 - (3) Actions to be taken in the event of a drug recall.
 - (4) Written justification of the chosen expiration dates for compounded sterile injectable products.
- (b) Each individual involved in the preparation of sterile injectable products must first successfully complete a validation process on technique before being allowed to prepare sterile injectable products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials are must be involved. Completed medium samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated. Personnel competency must be revalidated at least every twelve months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.
- (c) Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens.
- (d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.

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

Renumber section 1751.9 to new section 1751.8 and amend section 1751.8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9. 1751.8. Sterile Injectable Compounding Reference Materials.

In any pharmacy engaged in compounding sterile injectable drug products, There shall be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.

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

Virginia Herold
Executive Officer

Date



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STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug product to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in entirety and may be completed online, printed and retained in the pharmacy. Do not copy a previous assessment.

Note: If a hospital pharmacy dispenses prescriptions for outpatient use, a Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment.

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner Partnership Corporation LLC
 Non-Licensed Owner Other (please specify) _____

Permit #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding Permit # _____ or Accredited by: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: Daily _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

- 2. _____ RPH # _____ Exp. Date: _____
- 3. _____ RPH # _____ Exp. Date: _____
- 4. _____ RPH # _____ Exp. Date: _____
- 5. _____ RPH # _____ Exp. Date: _____
- 6. _____ RPH # _____ Exp. Date: _____
- 7. _____ INT # _____ Exp. Date: _____
- 8. _____ INT # _____ Exp. Date: _____
- 9. _____ INT # _____ Exp. Date: _____
- 10. _____ TCH # _____ Exp. Date: _____
- 11. _____ TCH # _____ Exp. Date: _____
- 12. _____ TCH # _____ Exp. Date: _____
- 13. _____ TCH # _____ Exp. Date: _____
- 14. _____ TCH # _____ Exp. Date: _____
- 15. _____ TCH # _____ Exp. Date: _____
- 16. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY & HOSPITAL OUTPATIENT PHARMACY COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

COMPOUNDING

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

The pharmacy compounds prescriptions as defined in CCR 1735.

The compounding pharmacist understands the definitions of integrity, potency, quality and strength as defined in CCR 1735.1.

2. Compounded Limitations and Requirements (CCR 1735.2)

The pharmacy does not compound drug product prior to receipt of a valid prescription unless under the following conditions. (CCR 1735.2[a])

Yes No N/A

The pharmacy prepares and stores a limited quantity of a compounded drug product in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified patient population as defined. (CCR 1735.2[b])

The pharmacy compounds a reasonable quantity of drug product that is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2 (c) that:

Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 72-hour supply, (CCR 1735.2[c][1])

Is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice, (CCR 1735.2[c][2]) AND

Is an amount, which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength for any individual prescriber or for all prescribers taken as a whole. (CCR 1735.2[c][3])

The pharmacy does not compound medication until it has prepared a written master formula that includes the following elements (CCR 1735.2[d][1-6]):

Active ingredients used.

Inactive ingredients used.

Process and/or procedure used to prepare the drug.

Quality reviews required at each step in the preparation of the drug.

Post-compounding process or procedures if required.

Expiration dating requirements.

The master formula for a drug product that is not routinely compounded by the pharmacy is recorded on the prescription document itself. (CCR 1735.2 [e])

All chemicals, bulk drug substances, drug products and other components for compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2 [g])

Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. The "beyond use date" of the compounded drug product does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

3. Records of Compounded Drug Products (CCR 1735.3)

Yes No N/A

A record for each compounded drug product includes the following (CCR 1735.3[a][1-10]):

The master formula record.

The date the drug product was compounded.

The identity of the pharmacy personnel who compounded the drug product.

The identity of the pharmacist reviewing the final drug product.

The quantity of each component used in compounding the drug product.

The manufacturer or supplier and lot number of each component. Exempt from this requirement are sterile drug products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

The equipment used in compounding the drug product.

The pharmacy assigned reference or lot number for the compounded drug product.

The expiration date of the final compounded drug product.

The quantity or amount of drug product compounded.

- The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products and components used in compounding. (CCR 1735.3 [b])
- Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c])
- The pharmacy acquires and retains any available certificates of purity or analysis for chemicals, bulk drug substances, drug products and components used in compounding. (This is not a requirement for drug products approved by the FDA.) (CCR 1735.3 [c])
- The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3 [d]).

4. Labeling of Compounded Drug Products (CCR 1735.4)

Yes No N/A

- The label of the compounded drug product contains the generic name(s) of the principle active ingredient(s). (CCR 1735.4[a])
- The prescription label contains all the information required in B&PC 4076. (CCR 1735.4[a])
- The container or receipt contains a statement that the drug has been compounded by the pharmacy. (CCR 1735.4[b])
- Drug products compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of [a] and [b] are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and expiration date. (CCR 1735.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

- The pharmacy maintains a written policy and procedure manual for compounding that establishes the following (CCR 1735.5 [a]):

Procurement procedures.

Methodologies for the formulation and compounding of drugs.

Facilities and equipment cleaning, maintenance and operations.

Other standard operating procedures related to compounding.

- The policy and procedure manual is reviewed on an annual basis by the pharmacist-in-charge and is updated whenever changes in process are implemented. (CCR 1735.5 [b])
- The policy and procedure manual includes procedures for notifying staff assigned to compounding duties of any changes in process or to the policy and procedure manual. (CCR 1735.5[c][1])
- The manual includes documentation of a plan for recall of a dispensed compounded drug product where subsequent verification demonstrates the potential for adverse effects with continued use of a compounded drug product. (CCR 1735.5[c][2])
- The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[c][3])
- The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[c][4])
- The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[c][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

- The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounded drug products to include records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])
- All equipment used to compound drug products is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])
- All equipment used to compound drug products is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])
- Documentation of each calibration is recorded in writing and maintained and retained in the pharmacy. (CCR 1735.6[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

The pharmacy maintains written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform assigned responsibilities relating to compounding. (CCR 1735.7[a])

The pharmacy develops and maintains an on-going competency evaluation process for pharmacy personnel involved in compounding. (CCR 1735.7[b])

Documentation on any and all such training for pharmacy personnel is maintained. (CCR 1735.7[b])

Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

The pharmacy maintains as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.8[a])

The pharmacy's quality assurance plan includes the written procedures and standards for the following:

Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])

Qualitative and quantitative integrity, potency, quality and labeled strength analysis of compounded drug products. (CCR 1735.8[c])

Such reports are retained by the pharmacy and collated with the compounding record and master formula. (CCR 1735.8[c])

Scheduled action in the event any compounded drug product is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])

COMPOUNDING STERILE INJECTABLE DRUGS

FOR PHARMACIES THAT COMPOUND STERILE INJECTABLE DRUGS

Yes No N/A

Pharmacy has a board issued Licensed Sterile Compounding permit or has current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other board approved accreditation agency. (B&PC 4127.1[a] and 4127.1[d])

LSC # _____ OR

Name of accreditation agency _____

9. Compounding Drug for Other Pharmacy for Parenteral Therapy (B&PC 4123)

Yes No N/A

The pharmacy contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy.

The contractual arrangement is reported to the board within 30 days of commencing that compounding.

10. Sterile Injectable Compounding; Compounding Area (CCR 1751)

Yes No N/A

If the pharmacy compounds sterile injectable drugs from a nonsterile source, the pharmacy has a designated area or cleanroom for the preparation of sterile products that has one the following:

An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. A positive air pressure differential in the cleanroom that is relative to adjacent areas; (B&PC 4127.7[a])

An ISO class 5 cleanroom (B&PC 4127.7[b])

A barrier isolator that provides an ISO class 5 environment for compounding. (B&PC 4127.7[c])

The cleanroom walls, ceiling and floors are made of non-porous, cleanable surfaces and the room is well ventilated (CCR 1751)

The laminar airflow hoods and clean room are certified annually; (CCR 1751)

Supplies are stored in a manner, which maintains integrity of an aseptic environment; (CCR 1751)

A sink with hot and cold running water; (CCR 1751)

A refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration. (CCR 1751)

CORRECTIVE ACTION OR ACTION PLAN: _____

11. Sterile Injectable Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

Pharmacy records are made and kept for sterile injectable products produced for future use (pursuant to section 1735.2), in addition to record requirements of section 1735.3, contain the name, lot number, amount, and date on which the products were provided to a prescriber. (CCR 1751.1[a])

Records for sterile products compounded from one or more non-sterile ingredients are made and kept and contain the following: (CCR 1751.1[b][1-6])

The training and competency evaluation of employees in sterile product procedures;

Refrigerator and freezer temperatures;

Certification of the sterile compounding environment;

Other facility quality control logs specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment);

Inspection for expired or recalled pharmaceutical products or raw ingredients; and

Preparation records including the master work sheet, the preparation work sheet, and records of end-product evaluation results.

The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years from the date the record was created. (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

12. Sterile Injectable Labeling Requirements (CCR 1751.2)

Yes No N/A

In addition to the labeling information required under Business and Professions Code section 4076 and 16 CCR 1735.4, the pharmacy's compounded sterile injectable product labels contain: (CCR 1751.2[a-d])

Telephone number of the pharmacy, unless dispensed for a hospital in-patient;

Name and concentrations of ingredients contained in the product;

Instructions for storage and handling; and

A special label that states "Chemotherapy—Dispose of Properly" for all cytotoxic agents.

CORRECTIVE ACTION OR ACTION PLAN: _____

13. Sterile Injectable Policies and Procedures (CCR 1751.3)

Yes No N/A

The pharmacy has a written manual documenting the policies and procedures associated with the preparation and dispensing of sterile injectable products and, in addition to the elements required by section 1735.5, includes: (CCR 1751.2[a][1-7])

Compounding, filling, and labeling of sterile injectable compounds;

Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration;

Equipment and supplies;

Training of staff in preparation of sterile injectable products;

Training of patient and/or caregiver in the administration of compounded sterile injectable products;

Procedures for the handling and disposal of cytotoxic agents;

Quality assurance program; and

Record keeping requirements.

Ingredients and compounding process for each preparation is determined in writing and reviewed by a pharmacist before compounding begins. (CCR 1751.3[b])

Policies and procedures address the disposal of infectious materials and/or materials containing cytotoxic residues and include cleanup of spills in conformance with local health jurisdictions. (CCR 1751.3 [c])

If compounding sterile injectable products from one or more non-sterile ingredients, the pharmacy has written policies and procedures that comply with the following: (CCR 1751.3[d][1-3])

Policies and procedures are immediately available to all compounding personnel and board inspectors (CCR 1751.3[d][1]); and

All compounding personnel have read the policies and procedures, any additions, revisions, and deletions before compounding. (CCR 1751.3 [d][2])

Policies and procedures address the following: (CCR 1751.3 [d][3] [A-K])

Competency evaluation;

Storage and handling of products and supplies;

Storage and delivery of final products;

Process validation;

Personnel access and movement of materials into and near the controlled area;

Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations);

A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules;

Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area;

For sterile batch compounding, written policies and procedures for the use of master formulas and work sheets and for appropriate documentation;

Sterilization; and

End-product evaluation and testing.

CORRECTIVE ACTION OR ACTION PLAN: _____

14. Facility & Equipment Standards for Sterile Injectable Compounding (CCR 1751.4)

Yes No N/A

The compounding environment meets criteria specified in the pharmacy's written policies and procedures for safe compounding of sterile injectable drugs. (CCR 1751.4[a])

Only those who are properly attired pursuant to (CCR 1751.5) are allowed in the cleanroom during the preparation of sterile injectable products. (CCR 1751.4[b])

All equipment used in the designated area or cleanroom is made of easily cleaned and disinfected material. (CCR 1751.4[c])

Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools are disinfected weekly and after any unanticipated event that could increase risk of contamination (CCR 1751.4[d])

The preparation of parenteral cytotoxic agents is done in accordance with Section 505.12.1 of Title 24, Chapter 5, of the California Code of Regulations and includes: (CCR 1751.4[e])

A laminar airflow hood, which is certified annually.

Certification records are maintained for at least three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

15. Sterile Injectable Compounding Attire (CCR 1751.5)

Yes No N/A

When preparing cytotoxic agents, gowns and gloves are worn.(CCR 1751.5[a])

When compounding sterile products from one or more non-sterile ingredients and a barrier isolator is not used: (CCR 1751.5[b][1-5])

Cleanroom garb is donned and removed outside the designated area; (CCR 1751.5[b][2])

Individuals in the cleanroom wear a low-shedding coverall, head cover, face mask, and shoe covers; (CCR 1751.5[b][1])

No hand, finger, or wrist jewelry is worn or if the jewelry cannot be removed, it is cleaned and covered with a sterile glove; (CCR 1751.5[b][3])

Head and facial hair is kept out of critical area or covered (CCR 1751.5[b][4]); and

Gloves of low-shedding material are worn. (CCR 1751.5[b][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

16. Training of Sterile Injectable Compounding Staff, Patient, and Caregiver (CCR 1751.6)

Yes No N/A

Consultation is available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy. (CCR 1751.6[a])

The pharmacist-in-charge ensures that all pharmacy personnel engaging in compounding sterile injectable drug products has training and demonstrated competence in the safe handling of those products, including cytotoxic agents if the pharmacy compounds such agents. (CCR 1751.6[b])

Records of training and demonstrated competence are available for each individual and are retained for three years beyond the employment period. (CCR 1751.6[c])

The pharmacist-in-charge ensures the continuing competence of pharmacy personnel engaged in compounding sterile injectable products. (CCR 1751.6[d])

When compounding sterile products from one or more non-sterile ingredients, the pharmacy complies with the following training requirements: (CCR 1751.6[e])

The pharmacy follows a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation addresses the following: (CCR 1751.6[e][1][A-J])

Aseptic technique;

Pharmaceutical calculations and terminology;

Sterile product compounding documentation;

Quality assurance procedures;

Aseptic preparation procedures;

Proper gowning and gloving technique;

General conduct in the controlled area;

Cleaning, sanitizing, and maintaining equipment used in the controlled area;

Sterilization techniques; and

Container, equipment, and closure system selection.

Each person assigned to the controlled area successfully completes practical skills training in aseptic technique and aseptic area practices. (CCR 1751.6[e][2])

Evaluation includes written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. (CCR 1751.6[e][2])

Each person's proficiency and continuing training is reassessed every 12 months. (CCR 1751.6[e][2])

Results of these assessments are documented and retained in the pharmacy for three years. (CCR 1751.6[e][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

17. Sterile Injectable Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures that the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

The Quality Assurance Program contains at least the following: (CCR 1751.7[a][1-4])

Cleaning and sanitization of the parenteral medication preparation area;

The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature;

Actions to be taken in the event of a drug recall; and

Written justification of the chosen expiration dates for compounded sterile injectable products in accordance with CCR 1735.2[h]).

Each individual involved in the preparation of sterile injectable products successfully completes a validation process on technique before being allowed to prepare sterile injectable products. (CCR 1751.7[b])

The validation process is carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. (CCR 1751.7[b])

The validation process is representative of all types of manipulations, products and batch sizes the individual is expected to prepare. (CCR 1751.7[b])

The same personnel, procedures, equipment, and materials are involved. (CCR 1751.7[b])

Completed medium samples are incubated. (CCR 1751.7[b])

If microbial growth is detected, the sterile preparation process is evaluated, corrective action taken, and the validation process is repeated. (CCR 1751.7[b])

Personnel competency is revalidated and documented at least every 12 months, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever aseptic techniques are observed. (CCR 1751.7[b])

Batch produced sterile injectable drug products compounded from one or more non-sterile ingredients are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. (CCR 1751.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Sterile Injectable Compounding Reference Materials (CCR 1751.8)

Yes No N/A

Current and appropriate reference materials regarding the compounding of sterile injectable products are maintained or immediately available to the pharmacy. (CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____
(Pharmacist-in-Charge)

Date _____

Attachment C

*Proposed Text to
Add §1707.2 to Title 16 CCR*

Pharmacist Fingerprint Requirements

Title 16. Board of Pharmacy Proposed Language

To Add Section 1702 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Section 1702. Pharmacist Renewal Requirements

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's renewal date that occurs on or after ([OAL insert effective date]).

(1) A pharmacist shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the Board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, omitting traffic infractions under \$500 not involving alcohol, dangerous drugs, or controlled substances.

(c) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1, 4005 Business and Professions Code.
Reference: Sections 490, 4036, 4200.5, 4207, 4301, 4301.5, 4311, and 4400, Business and Professions Code; and Sections 11105(b)(10), and 11105(e), Penal Code.

Attachment D

*Draft Regulatory Text to Amend
16 CCR §1746
Emergency Contraception Protocol*

**Title 16. Board of Pharmacy
Proposed Language**

To Amend Section 1746 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1746. Emergency Contraception.

(a) A pharmacist furnishing emergency contraception pursuant to Section 4052 (a)(8)(ii) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.

(2) Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

(4) The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medication record by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code section 4052b(3).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception

<i>Dedicated Emergency Contraception</i>				
Brand	Manufacturer	Tablets per Dose	EthinylEstradiol per Dose (mg mcg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Duramed	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Duramed	1 tablet per dose	0	0.75
Preven	Duramed	2 tablets per dose	100	0.50
<i>Oral Contraceptive Pills</i>				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg mcg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

(12) Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
<i>Non-prescription Drugs</i>		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4052 and 4052.3, Business and Professions Code.

Attachment E-1

*Board-Approved Text to Add
16 CCR §1785
Self-Assessment of a Veterinary Food-Animal
Drug Retailer*

Board of Pharmacy
Specific Language to Add Section 1785

Add Section 1785 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1785. Self-Assessment of a Veterinary Food-Animal Drug Retailer by the Designated Representative-in-Charge.

(a) The designated representative-in-charge of each veterinary food-animal drug retailer as defined under section 4041 of the Business and Professions Code shall complete a self-assessment of the wholesaler's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new veterinary food-animal drug retailer permit is issued, or

(2) There is a change in the designated representative-in-charge. The new designated representative-in-charge of a wholesaler is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a veterinary food-animal drug retailer to a new address.

(c) The components of this assessment shall be on Form 17M-40 entitled "Veterinary Food-Animal Drug Retailer Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.

(d) Each self-assessment shall be kept on file in the licensed premises for three years after it is completed.

(e) The veterinary food-animal drug retailer is jointly responsible with the designated representative-in-charge for compliance with this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4201, and 4196 Business and Professions Code.

Attachment E-2

Board-Approved Text to Add

16 CCR §1751.xx

*Accreditation Agencies for Pharmacies that
Compound Injectable Sterile Drug Products*

Board of Pharmacy
Specific Language to Add Section 1751.xx

Add Section 1751.xx to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.xx – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1 or section 4127.2 shall provide evidence satisfactory to the board that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least every three years.

(2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standards-setting organizations.

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation.

(4) The accrediting agency is recognized by at least one California healthcare payors (e.g., HMOs, PPOs, PBGH, CalPERS).

(5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board to become an approved accrediting agency must submit a comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding. The applicant agency's request will not be processed unless the comparison demonstrates the agency's standards are in compliance with California Pharmacy Law.

(c) The board shall consider the length of time the agency has been operating as an accrediting agency.

(d) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies.

(e) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.

(f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Attachment F-3

*AB 931 (Fletcher)
Emergency Supply Kits*

Assembly Bill No. 931

CHAPTER 491

An act to amend Section 1261.5 of the Health and Safety Code, relating to health facilities.

[Approved by Governor October 11, 2009. Filed with
Secretary of State October 11, 2009.]

LEGISLATIVE COUNSEL'S DIGEST

AB 931, Fletcher. Emergency supplies.

Existing law provides for the licensing and regulation by the State Department of Public Health of health facilities, including, but not limited to, skilled nursing facilities and intermediate care facilities.

Existing Pharmacy Law provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy and establishes requirements for the dispensing of drugs.

Existing law authorizes a pharmacy to furnish dangerous drugs or devices to a licensed health facility for storage in a secure emergency pharmaceutical supplies container that is maintained within the facility under regulations of the department. Existing law limits the number of oral dosage form and suppository dosage form drugs for storage within this container to 24. It also authorizes the department to limit the number of doses of each drug available to a skilled nursing facility or intermediate care facility to not more than 4 doses of any separate drug dosage form in each emergency supply.

This bill would increase the storage container limit to 48, as specified. The bill would also increase the authorized dosage amount available to a skilled nursing facility or intermediate care facility.

The people of the State of California do enact as follows:

SECTION 1. Section 1261.5 of the Health and Safety Code is amended to read:

1261.5. (a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section 4119 of the Business and Professions Code, shall be limited to 48. The State Department of Public Health may limit the number of doses of each drug available to not more than 16 doses of any separate drug dosage form in each emergency supply.

(b) Not more than four of the 48 oral form or suppository form drugs secured for storage in the emergency supplies container shall be

psychotherapeutic drugs, except that the department may grant a program flexibility request to the facility to increase the number of psychotherapeutic drugs in the emergency supplies container to not more than 10 if the facility can demonstrate the necessity for an increased number of drugs based on the needs of the patient population at the facility. In addition, the four oral form or suppository form psychotherapeutic drug limit shall not apply to a special treatment program service unit distinct part, as defined in Section 1276.9. The department shall limit the number of doses of psychotherapeutic drugs available to not more than four doses in each emergency supply. Nothing in this section shall alter or diminish informed consent requirements, including, but not limited to, the requirements of Section 1418.9.

(c) Any limitations established pursuant to subdivisions (a) and (b) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs.

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

<p>Objective 3.1</p>	<p>Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.</p>
<p>Measure:</p>	<p>100 percent successful enactment of promoted legislative changes.</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date. <ul style="list-style-type: none"> <i>Sept. 30, 2006:</i> Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008. <i>June 2007:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process. <i>July 2008:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments. <i>Sept. 2008:</i> Governor signs SB 963 (Chapter 385, Statutes of 2008) <i>Sept. 2009:</i> Sunset extension amended into AB 1071. Bill enrolled and sent to Governor. <i>Oct. 2009:</i> Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013. 2. Sponsor legislation to update pharmacy law. <ul style="list-style-type: none"> <i>Enacted - 1st Qtr. 08/09:</i> SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions <i>Oct. 2007:</i> Board sponsors omnibus provisions for 2008. Four types of changes are discussed. <ol style="list-style-type: none"> (1) Changes specific to the PIC and DRC requirements <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4161 – Nonresident wholesaler • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts (2) Changes to allow for the use of mobile pharmacies <ul style="list-style-type: none"> • Section 4062 – Furnishing Dangerous Drugs During an Emergency. • Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership. (3) General changes <ul style="list-style-type: none"> • Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions. • Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory • Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy. • Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee. • H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

Jan. 2008: *Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.*

Board approved language for omnibus bill.

April 2008: *Some provisions of omnibus bill removed:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

Oct. 2008: *Governor vetoes SB 1779*

1st Qtr. 08/09: *Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change:*

(1) Changes specific to the PIC and DRC requirements

- *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*
- *Section 4036.5 – Pharmacist-in-Charge*
- *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*
- *Section 4329 – Nonpharmacists; Prohibited Acts*
- *Section 4330 – Proprietors; Prohibited Acts*

(2) Changes to allow for the use of mobile pharmacies

- *Section 4062 – Furnishing Dangerous Drugs During an Emergency.*
- *Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.*

(3) *General changes*

- *Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.*
- *Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory*
- *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.*
- *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.*
H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.

(4) *Changes based on recodification of Business and Professions Code section 4052*

- *Section 733 – Dispensing Prescription Drugs and Devices*
- *Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
- *Section 4040 – Prescription; Content Requirements*
- *Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist*
- *Section 4060 – Controlled Substance – Prescription Required, Exceptions*
- *Section 4076 – Prescription Container – Requirements for Labeling*
- *Section 4111 – Restrictions on Prescriber Ownership*
- *Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner*
- *H&SC 11150 – Persons Authorized to Write or Issue a Prescription*

1st Qtr. 08/09: Board seeks to introduce additional changes:

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

New Provisions

- *4200.1 – Pharmacist Examination; Remedial Education*
- *4112 – Non-resident Pharmacy; Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

2nd Qtr. 08/09: Provisions contained in SB 821:

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*

- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*

New Provisions

- *4112 – Non-resident Pharmacy: Registration Required*
- *4146 – Return and Disposal of Sharps*
- *4013 – Subscriber Alert*

3rd Qtr. 08/09: *Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.*

Jan 2010: *Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.*

Omnibus Proposal #1:

- (1) *Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)*
 - * *§650.1 – Lease Prohibition – Hospitals or Prescribers*
 - * *§652 – Violation of Unprofessional Conduct*
 - * *§4017 – Authorized Officers of the Law*
 - * *§4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities*
 - * *§4028 – Definition of Licensed Hospital*
 - * *§4037 – Definition of Pharmacy*
 - * *§4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations*
 - * *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions.*
 - * *§4072 – Oral or Electronic Transmission of Prescription – Health Care Facility*
 - * *§4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies*
 - * *§4127.1 – License to Compound Injectable Sterile Drug Products Required*
 - * *§4169 – Prohibited Acts (also, strike operative date of 2008)*
 - * *§4181 – License Requirements; Policies and Procedures; Who May Dispense*
 - * *§4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs*
- (2) *Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)*
 - * *§4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions*
- (3) *Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)*

- * §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
- * §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

- (1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative in Charge
- (2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)
- (3) Add §4362 – Pharmacists Recovery Program

3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).

Sept. 30, 2006: Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.

4. Secure statutory standards for pharmacies that compound medications (AB 595).

Aug. 2006: Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.

Aug. 2008: Regulatory effort initiated. (See Objective 3.2, Task 12)

Oct 2009: Board approves regulatory language for Initial Notice.

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.

Sept. 2006: Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.

Sept. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.

*Oct. 2007: Governor signs the following:
 AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.
 SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*

	<p>SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal. Governor vetoes the following: AB 249 (Eng) Healing Arts: Settlement Agreements. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure. AB 1025 (Bass) Professions and Vocations: Denial of Licensure. SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</p> <p>Oct. 2008: Governor signs the following: AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review Governor vetoes the following: AB 501 (Swanson) Pharmaceutical Devices AB 865 (Davis) State Agencies AB1574 (Plescia) Surgical Clinics: Licensure</p> <p>Jan. 2009: Legislation introduced affecting Pharmacy law: (New Session) AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections. SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.</p> <p>April 2009: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing Arts Practice AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD) AB 1370 (Solorio) "Best Before" Date on a Prescription Label AB 1458 (Davis) Drugs: Adverse Effects Reporting SB 26 (Simitian) Home-Generated Pharmaceutical Waste SB 43 (Alquist) Cultural and Linguistic Competency SB 238 (Calderon) Medical Information SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs</p>
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	<p>SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus</p> <p>SB 484 (Wright) Ephedrine Products to Schedule V</p> <p>SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews</p> <p>SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>June 2009: AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012</p> <p>AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid</p> <p>AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container</p> <p>AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)</p> <p>SB 389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus</p> <p>SB 484 (Wright) Ephedrine Products to Schedule V</p> <p>SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews</p> <p>SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>July 2009: Governor signs SB 762 (Aanestad) Professions and Vocations; Healing Arts</p> <p>Oct. 2009: Governor signs SB 819 (Omnibus)</p> <p>Governor signs SB 821 (Omnibus)</p> <p>Governor signs SB 470 (Corbett) - "Purpose"</p> <p>Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset</p> <p>Governor signs AB 931 (Fletcher) - Emergency Supplies Container</p> <p>Governor signs AB 830 (Cook) Drugs and Devices; references to Compendia</p>
7.	<p>Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.</p> <p>March 2007: Licensing Committee considers and approves concept. More work is required.</p> <p>June 2007: Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.</p> <p>Sept. 2007: Licensing Committee forwards to full board legislative proposal.</p> <p>Oct. 2007: Board approved draft legislation.</p> <p>Nov. 2007: Staff meeting with stakeholders to elicit support for the proposal.</p> <p>Dec. 2007: Staff develop fact sheets and work with experts in immunizations.</p> <p>Feb. 2009: Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.</p> <p>April 2009: Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.</p> <p>May 2009: Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)</p> <p>Jan 2010: Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.</p> <p>Jan 2010: AB 977 passes out of Assembly Health Committee</p>

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.
- Oct. 2007: Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.
- Apr. 2008: First public forum held in Fremont.
- May 2008: Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.
- June 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.
- July 2008: Staff attends community events, interview attendees about prescription label and distribute surveys.
- Oct. 2008: Staff continues to attend community events, interview attendees about prescription label and distribute surveys.
Public Education Committee updated on the status of survey results.
- Feb. 2009: Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.
- May 2009: Bill passes out of the Senate
- Oct. 2009: Governor signs SB 470 (Chapter 590, Statutes of 2009).
- Oct 2009: Board approves regulatory language for notice.
- Nov 2009: Regulatory effort initiated (See Objective 3.2, Task 16)
9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the boards statutory obligations as a consumer protection agency.
- Dec. 2008: Board receives findings of independent fee audit.
- Jan. 2009: Board votes to pursue fee increase.
- Feb. 2009: Assembly Member Emmerson authors AB 1071 which establishes new application and renewal fees.
- June 2009: Bill passes out of the Assembly.
- Sept. 2009: Bill is enrolled and sent to the Governor.
- Sept. 2009: Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.
- Oct. 2009: Governor signs AB 1071 (Chapter 270, Statutes of 2009)
- Jan 2010: Statutory fee schedule implemented (supercedes 16 CCR 1749)
10. Advocate legislation to enhance the board's enforcement activities.
- Jan 2010: Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):
- Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory,
- Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.
- Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> 3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.</i> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> 4. Repeal the requirement to post a notice regarding electronic files (section 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 5. Revise and update Disciplinary Guidelines revision and update (section 1760). <i>Aug. 2006: Final changes to Disciplinary Guidelines being compiled by staff.</i> <i>Dec. 2006: Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.</i> <i>June 2007: Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.</i> <i>Sept. 2007: Enforcement Committee approves Disciplinary Guidelines and recommends board approval.</i> <i>Oct. 2007: Board approves Disciplinary Guidelines for 45-day comment period.</i> <i>Feb. 2008: Regulation released for 45 days of public comment.</i> <i>April 2008: Board adopts regulation.</i> <i>Sept. 2008: Rulemaking file submitted for review by the administration.</i> <i>Jan. 2009: Board pursues 15-day comment to eliminate an optional provision contained in the guidelines.</i> <i>March 2009: Rulemaking compiled and resubmitted for review by the administration.</i> <i>May 2009: Regulation takes effect.</i> 6. Self-assessment of a wholesaler by the designated representative (section 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> 7. Exempt the address of records of interns from display on the board's website (section 1727.1). <i>Sept. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> 8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i>

9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2).
- Feb. 2007: Board notices regulation for 45 days comment period.*
- April 2007: Board considers comments submitted during public comment period and modifies text regulation to reflect comments.*
- May 2007: New section 1707.2 released for 45 days of public comment.*
- July 2007: Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review.*
- Sept. 2007: File submitted to the Office of Administrative Law for review.*
- Oct. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Regulation changes takes effect.*
- Nov. 2007: Staff solicits design submissions from graphic designers.*
- Jan. 2008: Communication and Public Education Committee make recommendations on design submissions.*
- Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.*
10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.
- Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:*
- 1707 – Waiver of requirements for off-site storage of records*
 - 1709.1 – Designation of pharmacist-in-charge*
 - 1715 – Self-assessment of a pharmacy by the pharmacist-in-charge*
 - 1717 – Pharmacy practice*
 - 1746 – Emergency contraception*
 - 1780.1 – Minimum standards for veterinary food-animal drug retailers*
 - 1781 – Exemption certificate*
 - 1787 – Authorization to distribute dialysis drugs and devices*
 - 1790 – Assembling and packaging*
 - 1793.8 – Technician check technician*
 - Repeal section 1786 – Exemptions*
- March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.*
11. Increase fees to keep the board's contingency fund solvent and maintain operations.
- Nov. 2007: Office of Administrative Law approves rulemaking.*
- Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.*
- Jan. 1, 2008: New fees take effect.*
- Oct. 2009: Governor signs AB 1071, new fee schedule.*
- Jan 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)*

12. Secure regulatory standards for pharmacies that compound.
- Dec. 2006: Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.*
- March 2007: Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.*
- May 2007: Licensing Committee holds detailed discussion on compounding regulations.*
- Sept. 2007: Licensing Committee forwards regulation proposal to the board for review.*
- Nov. 2007: Board releases language for the 45-day comment period.*
- Jan. 2008: Board held regulation hearing and considers written comments and oral testimony.*
- April 2008: Board votes to withdraw rulemaking.*
- Aug. 2008: Board releases new language for the 45-day comment period.*
- Oct. 2008: Board holds regulation hearing to elicit additional comments.*
- Jan. 2009: Board votes to pursue 15-day notice.*
- April 2009: Board releases second 15-day comment period.*
- May 2009: Board releases second 15-day comment period.*
- July 2009: Board votes to approve regulation.*
- Aug. 2009: Rulemaking submitted for review by the administration.*
- Nov 2009: Rulemaking submitted for review by Office of Administrative Law.*
- Jan 2010: Office of Administrative Law approves regulation.*
13. Establish an ethics course.
- April 2007: Board establishes a subcommittee to examine the development of an ethics course.*
- Oct. 2007: Board votes to pursue regulation change to establish program components.*
- Sept. 2008: Board notices regulation for 45-day comment period.*
- Oct. 2008: Board votes to pursue 15-day comment period and, absent any negative comments, authorizes the Executive Officer to complete the rulemaking file.*
- March 2009: Rulemaking submitted for review by the administration.*
- Aug. 2009: Office of Administrative Law approves regulation.*
- Sept. 2009: Regulation takes effect.*
14. Pharmacist Renewal Requirements
- Dec 2009: Board notices regulation for 45-day comment period.*
15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions
- Oct 2009: Board notices regulation for 45-day comment period.*
- Jan 2010: Board considers adoption of regulation as noticed.*
16. Standardized, Patient-Centered Prescription Labels
- Oct 2009: Board approves language to initiate rulemaking.*
- Nov 2009: Board notices regulation for 45-day comment period.*
- Jan 2010: Regulation hearing scheduled.*
17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC)
- Jan 2010: Board to consider approval of draft regulation to correct a typographical error in the Emergency Contraception Protocol regulation (16 CCR §1746(b)(11)).*

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007: Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</i></p> <p><i>Oct. 2007: Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</i></p> <p><i>Jan. 2008: Board approves omnibus language recommended by Legislation and Regulation Committee.</i></p> <ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i> <p><i>April 2008: The following provisions are not incorporated into omnibus bill.</i></p> <ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> <p><i>Sept. 2008: Governor vetoes SB 1779.</i></p> <p><i>Jan. 2009: Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</i></p> <p><i>Sept. 2009: SB 819 and SB 821 enrolled and sent to the Governor.</i></p> <p><i>Oct. 2009: Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</i></p>