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

## **Legislation and Regulation Committee**

**Greg Lippe, Public Member, Chair**  
**Ryan Brooks, Public Member**  
**Robert Swart, PharmD**  
**Stan Weisser, RPh**  
**Shirley Wheat, Public Member**

### ***Part 1: REGULATION REPORT AND ACTION***

#### **A. DISCUSSION AND POSSIBLE ACTION to Amend Title 16 CCR §1749 – Board Fees**

##### **ATTACHMENT A-1**

The board sponsored AB 1071, authored by Assembly Member Emmerson, to adjust application and renewal fees to ensure that the Board of Pharmacy has sufficient funds to fulfill all of its statutory obligations as a consumer protection agency. In most case, the measure established new minimum fees, and also capped future fees to increase no more than 30 percent.

AB 1071 was signed by the Governor on October 11, 2009, resulting in Chapter 270, Statutes of 2009. This mandate is effective January 1, 2010.

A copy proposed/draft language is attached, as well as a copy of Chapter 270

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

##### **ATTACHMENT B-1**

#### **Amend 16 CCR §1773 and Adopt § 1773.5 – Establishment of an Ethics Course as an Optional Enforcement Component for Discipline**

***Amendments to 16 CCR §1773 and §1773.5 became effective on September 3, 2009.***

In April 2007, the board established a subcommittee to examine the development of an ethics course for pharmacists as an enforcement option as part of discipline. Based on the work of this subcommittee, the subcommittee recommended to the full the board that it vote to create a program similar to the program used by the Medical Board. This proposal would establish in regulation the minimum requirements for the ethics program. These minimum requirements are designed to better guide the board and licensees when they are finding a course and will ensure that the course will be of high quality. This proposal will provide licensees with the necessary information to assist in their rehabilitation.

The board determined the requirements as necessary, based on testimony received during the October 2007 Board Meeting. During the meeting, the board received testimony from the Institute for Medical Quality (IMQ), the course provider for the Medical Board's ethics course. The board determined that a minimum of 14 direct contact hours is appropriate to allow for case presentations, group discussion and experiential exercises and role-playing to ensure sufficient time to discuss and evaluate situations. In addition, based on the recommendation of IMQ, the board's proposal also incorporates an additional 8 hours of time to allow the pharmacist to complete self-reflection on the decisions made that led to the violations and ultimate referral to the program and post-classroom instruction for up to one year. This self-reflection includes completing questions as part of a background assessment. The two post-course longitudinal studies ensure that the pharmacist has successfully internalized the necessary changes to prevent future violations resulting from unethical behavior.

During the October 2008 board meeting, the board held a regulation hearing on the proposed changes. At the conclusion, the board directed staff to take all steps necessary to complete the rulemaking process, including preparing modified text for an additional 15-day comment period, which includes the following amendments: change the word "medicine" to "pharmacy" at proposed §1773.5(a)(5)(B). Absent adverse comments to the 15-day comment period, the Executive Officer was authorized to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt amendments to §1773 as filed and adopt §1773.5 of the proposed regulations with the modified text.

No comments were received during the 15-day comment period. The rulemaking file was compiled and, following department review, transmitted it to the Office of Administrative Law. The Office of Administrative Law approved the regulatory action on August 4, 2009, and the new regulations became effective on September 3, 2009. A copy of the final text is attached.

**C. FOR INFORMATION. Board Adopted Regulations – Undergoing Review by the Administration**

**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**

**ATTACHMENT C-1**

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 are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

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 2<sup>nd</sup> 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 2<sup>nd</sup> 15-day comment period was noticed on May 4, 2009.

At the July 2009 Board Meeting the board considered the comments received during the 2<sup>nd</sup> 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.

Staff compiled the final regulatory proposal, which is currently being reviewed by the department.

A copy of the final text and Self-Assessment Form 17M-39 is attached.

#### **D. Board Approved Regulations – Awaiting Notice**

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

#### **ATTACHMENT D-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 Amendment to Title 16 CCR Sections 1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination; Confidentiality**

**ATTACHMENT D-2**

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.

A copy of the approved text is attached.

**3. Proposed Adoption of Title 16 CCR §1751.9 – Accreditation Agencies for Pharmacies That Compound Injectable Sterile Drug Products**

**ATTACHMENT D-3**

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.

**E. 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.

# **ATTACHMENT A-1**

## **Discussion and Possible Action to Amend Title 16 Section 1749 – Board Fees**

## Board of Pharmacy Specific Language to Amend Section 1749

**Amend Section 1749 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

### §1749 – Fee Schedule

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with sections 163.5, 4110, 4127.8, 4196, and 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a pharmacy license ~~is~~ shall be four hundred dollars (\$400). The fee for the annual renewal of pharmacy license ~~is~~ shall be two hundred fifty dollars (\$250). The penalty for failure to renew is one hundred ~~and~~ twenty five dollars (\$125).

(b) The fee for the issuance of a temporary pharmacy license ~~is~~ shall be two hundred fifty dollars (\$250).

(c) The fee for the issuance of a pharmacy technician license shall be ~~fifty dollars (\$50)~~ eighty dollars (\$80). The fee for the biennial renewal of a pharmacy technician license shall be ~~fifty dollars (\$50)~~ one hundred dollars (\$100). The penalty for failure to renew a pharmacy technician license is ~~twenty-five dollars (\$25)~~ fifty dollars (\$50).

(d) The fee for application and examination as a pharmacist ~~is one hundred eighty-five dollars (\$185)~~ shall be two hundred dollars (\$200).

(e) The fee for regrading an examination ~~is eighty-five dollars (\$85)~~ shall be ninety dollars (\$90).

(f) The fee for the issuance of an original pharmacist license ~~is~~ shall be one hundred fifty dollars (\$150).

(g) The fee for the biennial renewal of a pharmacist's license ~~is~~ shall be one hundred fifty dollars (\$150). The penalty fee for failure to renew is seventy-five dollars (\$75).

(h) ~~The fee for the issuance or renewal of a nongovernmental wholesaler's license is shall~~ be six hundred dollars (\$600). The fee for the renewal of a nongovernmental wholesaler's license shall be six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations is three hundred dollars (\$300). A temporary license fee is six hundred dollars (\$600). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) ~~The fee for the issuance or renewal of a hypodermic needle and syringe license is shall~~ be one hundred twenty five dollars (\$125). The penalty for failure to renew is sixty-two dollars and fifty cents (\$62.50).

(j) ~~The fee for the issuance of a license as a designated representative pursuant to Section 4053 of the Business and Professions Code shall be two hundred fifty dollars (\$250) two~~ hundred fifty-five dollars (\$255). If the applicant is not issued a license as a designated representative, the board shall refund one hundred ten dollars (\$110) five dollars (\$105) of the fee. The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150). The penalty for failure to renew is seventy-five dollars (\$75).

(k) ~~The application fee for the issuance or renewal of a license as a nonresident wholesaler's license issued pursuant to Section 4161 shall be is six hundred dollars~~ (\$600). For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600). The application fee for any additional location after licensure of the first 20 locations is three hundred dollars (\$300). A temporary license fee is six hundred dollars (\$600). The annual renewal fee for a nonresident wholesaler's license shall be six hundred dollars (\$600). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) ~~The fee for an intern pharmacist license is seventy five dollars (\$75) shall be ninety~~ dollars (\$90). The fee for transfer of intern hours or verification of licensure to another state is twenty dollars (\$20) shall be twenty-five dollars (\$25).

(m) The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is shall be one hundred dollars (\$100).

(n) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each course hour of accreditation requested.

(o) The fee for the issuance of a nongovernmental clinic license ~~is shall be~~ four hundred dollars (\$400). The fee for the annual renewal of a nongovernmental clinic license ~~is shall be~~ two hundred fifty dollars (\$250). The penalty for failure to renew is one hundred and twenty five dollars (\$125).

(p) The fee for the issuance of a nongovernmental license, ~~or renewal of a license, to~~ compound sterile drug products ~~shall be is~~ six hundred dollars (\$600). The fee for the renewal of a license to compound sterile drug products shall be six hundred dollars (\$600). The fee for a temporary license is six hundred dollars (\$600). The penalty for failure to renew is one hundred fifty dollars (\$150).

(q) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 ~~shall be two hundred fifty dollars (\$250)~~ two hundred fifty-five dollars (\$255). If the applicant is not issued a license as a designated representative, the board shall refund one hundred ~~fifty-five~~ fifty dollars (\$150) ~~(\$105)~~ of the fee. The fee for the annual renewal of a license as a designated representative shall be ~~one hundred ten dollars (\$110)~~ one hundred fifty dollars (\$150). The penalty for failure to renew is ~~fifty-five dollars (\$55)~~ seventy-five dollars (\$75).

(r) The fee for a veterinary food-animal drug retailer license ~~is four hundred dollars (\$400)~~ shall be four hundred five dollars (\$405). The annual renewal fee for a veterinary food-animal drug retailer ~~is shall be~~ two hundred and fifty dollars (\$250). The fee for the issuance of a temporary license is two hundred and fifty dollars (\$250).

(s) The fee for the issuance of a retired pharmacist license shall be ~~thirty dollars (\$30)~~ thirty-five dollars (\$35).

(t) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35).

**Assembly Bill No. 1071**

**CHAPTER 270**

An act to amend Sections 2001, 2020, 2460, 2701, 2708, 3010.5, 3014.6, 3685, 3710, 4001, 4003, 4110, 4127.8, 4160, 4400, and 5810 of, to add and repeal Section 3686 of, and to repeal Section 4127.5 of, the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

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

**LEGISLATIVE COUNSEL'S DIGEST**

AB 1071, Emmerson. Professions and vocations.

(1) Existing law provides for the licensure and regulation of various healing arts licensees by various boards within the Department of Consumer Affairs, including, but not limited to, the Medical Board of California, the California Board of Podiatric Medicine, the Board of Registered Nursing, the State Board of Optometry, the Respiratory Care Board of California, and the California State Board of Pharmacy. Existing law requires or authorizes these boards, with the exception of the California Board of Podiatric Medicine, to appoint an executive director or officer. Under existing law, these provisions will become inoperative on July 1, 2010, and will be repealed on January 1, 2011.

Under this bill, these provisions would become inoperative and be repealed on January 1, 2013. The bill would also make nonsubstantive changes to similar provisions of the Naturopathic Doctors Act.

(2) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists, pharmacy technicians, wholesalers of dangerous drugs or devices, and others by the California State Board of Pharmacy. Existing law imposes fees on these persons and pharmacies for, among other things, application, examination, licensure, and licensure renewal. Under existing law, these fees are fixed by the board based on a fee schedule that sets forth the minimum and maximum fees.

This bill would increase the minimum and maximum fees in that schedule and would make other conforming changes. Because the bill would increase fees that would be deposited into the Pharmacy Board Contingent Fund, which is continuously appropriated, the bill would make an appropriation.

(3) Existing law provides for the certification of interior designers, and repeals these provisions on January 1, 2010.

This bill would instead repeal these provisions on January 1, 2013.

(4) This bill would incorporate additional changes in Section 4110 of the Business and Professions Code proposed by SB 819, to be operative if

SB 819 and this bill become effective on or before January 1, 2010, and this bill is chaptered last.

(5) This bill would incorporate additional changes in Section 4160 of the Business and Professions Code proposed by SB 821, to be operative if SB 821 and this bill become effective on or before January 1, 2010, and this bill is chaptered last.

Appropriation: yes.

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

SECTION 1. Section 2001 of the Business and Professions Code is amended to read:

2001. (a) There is in the Department of Consumer Affairs a Medical Board of California that consists of 15 members, seven of whom shall be public members.

(b) The Governor shall appoint 13 members to the board, subject to confirmation by the Senate, five of whom shall be public members. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(c) Notwithstanding any other provision of law, to reduce the membership of the board to 15, the following shall occur:

(1) Two positions on the board that are public members having a term that expires on June 1, 2010, shall terminate instead on January 1, 2008.

(2) Two positions on the board that are not public members having a term that expires on June 1, 2008, shall terminate instead on August 1, 2008.

(3) Two positions on the board that are not public members having a term that expires on June 1, 2011, shall terminate instead on January 1, 2008.

(d) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 2. Section 2020 of the Business and Professions Code is amended to read:

2020. (a) The board may employ an executive director exempt from the provisions of the Civil Service Act and may also employ investigators, legal counsel, medical consultants, and other assistance as it may deem necessary to carry into effect this chapter. The board may fix the compensation to be paid for services subject to the provisions of applicable state laws and regulations and may incur other expenses as it may deem necessary. Investigators employed by the board shall be provided special training in investigating medical practice activities.

(b) The Attorney General shall act as legal counsel for the board for any judicial and administrative proceedings and his or her services shall be a charge against it.

(c) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 3. Section 2460 of the Business and Professions Code is amended to read:

2460. (a) There is created within the jurisdiction of the Medical Board of California the California Board of Podiatric Medicine.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the California Board of Podiatric Medicine subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 4. Section 2701 of the Business and Professions Code is amended to read:

2701. (a) There is in the Department of Consumer Affairs the Board of Registered Nursing consisting of nine members.

(b) Within the meaning of this chapter, board, or the board, refers to the Board of Registered Nursing. Any reference in state law to the Board of Nurse Examiners of the State of California or California Board of Nursing Education and Nurse Registration shall be construed to refer to the Board of Registered Nursing.

(c) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 5. Section 2708 of the Business and Professions Code is amended to read:

2708. (a) The board shall appoint an executive officer who shall perform the duties delegated by the board and who shall be responsible to it for the accomplishment of those duties.

(b) The executive officer shall be a nurse currently licensed under this chapter and shall possess other qualifications as determined by the board.

(c) The executive officer shall not be a member of the board.

(d) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 6. Section 3010.5 of the Business and Professions Code is amended to read:

3010.5. (a) There is in the Department of Consumer Affairs a State Board of Optometry in which the enforcement of this chapter is vested. The board consists of 11 members, five of whom shall be public members.

Six members of the board shall constitute a quorum.

(b) The board shall, with respect to conducting investigations, inquiries, and disciplinary actions and proceedings, have the authority previously vested in the board as created pursuant to Section 3010. The board may enforce any disciplinary actions undertaken by that board.

(c) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 7. Section 3014.6 of the Business and Professions Code is amended to read:

3014.6. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 8. Section 3685 of the Business and Professions Code, as amended by Section 38 of Chapter 18 of the Fourth Extraordinary Session of the Statutes of 2009, is amended to read:

3685. (a) The repeal of this chapter renders the committee subject to the review required by Division 1.2 (commencing with Section 473).

(b) The committee shall prepare the report required by Section 473.2 no later than September 1, 2010.

SEC. 9. Section 3686 is added to the Business and Professions Code, to read:

3686. This chapter shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 10. Section 3710 of the Business and Professions Code is amended to read:

3710. (a) The Respiratory Care Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 11. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) In accordance with Sections 101.1 and 473.1, this section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 12. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

(e) In accordance with Sections 101.1 and 473.1, this section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless

a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 13. Section 4110 of the Business and Professions Code is amended to read:

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

SEC. 13.5. Section 4110 of the Business and Professions Code is amended to read:

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate

upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction of, or damage to, the pharmacy and an expected restoration date.

(6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

SEC. 14. Section 4127.5 of the Business and Professions Code is repealed.

SEC. 15. Section 4127.8 of the Business and Professions Code is amended to read:

4127.8. The board may, at its discretion, issue a temporary license to compound injectable sterile drug products, when the ownership of a pharmacy that is licensed to compound injectable sterile drug products is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (u) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested at the licenseholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary license nor for purposes of any disciplinary or license denial proceeding before the

board shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

SEC. 16. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.

(e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(g) This section shall become operative on January 1, 2006.

SEC. 16.5. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler.

(e) Every wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(f) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(g) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

SEC. 17. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(c) The fee for the pharmacist application and examination shall be two hundred dollars (\$200) and may be increased to two hundred sixty dollars (\$260).

(d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(f) The fee for a nongovernmental wholesaler license and annual renewal shall be six hundred dollars (\$600), and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(g) The fee for a hypodermic license and renewal shall be one hundred twenty-five dollars (\$125) and may be increased to one hundred sixty-five dollars (\$165).

(h) (1) The fee for application, investigation, and issuance of license as a designated representative pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two hundred fifty-five dollars (\$255) and may be increased to three hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be four hundred dollars (\$400) and may be increased to five hundred twenty dollars (\$520) for each license. The annual fee for renewal of the license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325) for each license.

(r) The fee for the issuance of a pharmacy technician license shall be eighty dollars (\$80) and may be increased to one hundred five dollars (\$105). The fee for renewal of a pharmacy technician license shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred five dollars (\$405) and may be increased to four hundred twenty-five dollars (\$425). The annual renewal fee for a veterinary food-animal drug

retailer license shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(u) The fee for issuance or renewal of a nongovernmental license to compound sterile drug products shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

SEC. 18. Section 5810 of the Business and Professions Code is amended to read:

5810. (a) This chapter shall be subject to the review required by Division 1.2 (commencing with Section 473).

(b) This chapter shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 19. Section 13.5 of this bill incorporates amendments to Section 4110 of the Business and Professions Code proposed by this bill and SB 819. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2010, (2) each bill amends Section 4110 of the Business and Profession Code, and (3) this bill is enacted after SB 819, in which case Section 4110 of the Business and Professions Code, as amended by SB 819, shall remain operative only until the operative date of this bill, at which time Section 13.5 of this bill shall become operative, and Section 13 of this bill shall not become operative.

SEC. 20. Section 16.5 of this bill incorporates amendments to Section 4160 of the Business and Professions Code proposed by both this bill and SB 821. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2010, (2) each bill amends Section 4160 of the Business and Professions Code, and (3) this bill is enacted after SB 821, in which case Section 16 of this bill shall not become operative.

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.

# **ATTACHMENT B-1**

**Board Adopted Regulations – Approved by the Office of  
Administrative Law**

**16 CCR §1773 and § 1773.5 – Establishment of an Ethics Course  
as an Optional Enforcement Component for Discipline  
(Effective 9/3/09)**

**Board of Pharmacy**  
**California Code of Regulations**

**Specific Language to Amend Section 1773 and Add Section 1773.5**

Amend Section 1773 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§ 1773. Disciplinary Conditions of Probation of Pharmacist.**

- (a) Unless otherwise directed by the Board in its sole discretion, any pharmacist who is serving a period of probation shall comply with the following conditions:
- (1) Obey all laws and regulations substantially related to the practice of Pharmacy;
  - (2) Report to the Board or its designee quarterly either in person or in writing as directed; the report shall include the name and address of the probationer's employer. If the final probation report is not made as directed, the period of probation shall be extended until such time as the final report is made;
  - (3) Submit to peer review if deemed necessary by the Board;
  - (4) Provide evidence of efforts to maintain skill and knowledge as a pharmacist as directed by the Board;
  - (5) Inform all present and prospective employers of license restrictions and terms of probation. Probationers employed by placement agencies must inform all permittees in whose premises they work of license restrictions and terms of probation.
  - (6) Not supervise any registered interns nor perform any of the duties of a preceptor;
  - (7) The period of probation shall not run during such time that the probationer is engaged in the practice of pharmacy in a jurisdiction other than California.
- (b) If ordered by the Board in an administrative action or agreed upon in the stipulated settlement of an administrative action, any registered pharmacist who is serving a period of probation shall comply with any or all of the following conditions;
- (1) Take and pass all or any sections of the pharmacist licensure examination and/or attend continuing education courses in excess of the required number in specific areas of practice if directed by the Board;
  - (2) Provide evidence of medical or psychiatric care if the need for such care is indicated by the circumstances leading to the violation and is directed by the Board;
  - (3) Allow the Board to obtain samples of blood or urine (at the pharmacist's option) for analysis at the pharmacist's expense, if the need for such a procedure is indicated by the circumstances leading to the violation and is directed by the Board;
  - (4) If and as directed by the Board, practice only under the supervision of a pharmacist not on probation to the Board. The supervision directed may be continuous supervision, substantial supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for supervision, partial supervision, or supervision by daily review as deemed necessary by the Board for the protection of the public health and safety.
  - (5) Complete an ethics course that meets the requirements of section 1773.5.
- (c) When the circumstances of the case so require, the Board may impose conditions of probation in addition to those enumerated herein by the terms of its decision in an administrative case or by stipulation of the parties.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

Add Section 1773.5 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

## **§ 1773.5 Ethics Course Required as Condition of Probation.**

When directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course that meets the requirements of this section as a condition of probation, license reinstatement or as abatement for a citation and fine. Board approval must be obtained prior to the commencement of an ethics course.

a. The board will consider for approval an ethics course that at minimum satisfies the following requirements:

- (1) Duration. The course shall consist of a minimum of 22 hours, of which at least 14 are contact hours and at least 8 additional hours are credited for preparation, evaluation and assessment.
- (2) Faculty. Every instructor shall either possess a valid unrestricted California professional license or otherwise be qualified, by virtue of prior training, education and experience, to teach an ethics or professionalism course at a university or teaching institution.
- (3) Educational Objectives. There are clearly stated educational objectives that can be realistically accomplished within the framework of the course.
- (4) Methods of Instruction. The course shall describe the teaching methods for each component of the program, e.g., lecture, seminar, role-playing, group discussion, video, etc.
- (5) Content. The course shall contain all of the following components:
  - (A) A background assessment to familiarize the provider and instructors with the factors that led to the prospective candidate's referral to the class.
  - (B) A baseline assessment of knowledge to determine the participant's knowledge/awareness of ethical and legal issues related to the practice of pharmacy in California, including but not limited to those legal and ethical issues related to the specific case(s) for which the participant has been referred to the program.
  - (C) An assessment of the participant's expectations of the program, recognition of need for change, and commitment to change.
  - (D) Didactic presentation of material related to those areas that were problems for the participants based upon the results of the background assessments and baseline assessments of knowledge.
  - (E) Experiential exercises that allow the participants to practice concepts and newly developed skills they have learned during the didactic section of the class.
  - (F) A longitudinal follow-up component that includes (1) a minimum of two contacts at spaced intervals (e.g., 6 months and 12 months) within one year after course completion or prior to completion of the participant's probationary period if probation is less than one year, to assess the participant's status; and (2) a status report submitted to the division within 10 calendar days after the last contact.
- (6) Class Size. A class shall not exceed a maximum of 12 participants.

- (7) Evaluation. The course shall include an evaluation method that documents that educational objectives have been met - e.g. written examination or written evaluation - and that provides for written follow-up evaluation at the conclusion of the longitudinal assessment.
- (8) Records. The course provider shall maintain all records pertaining to the program, including a record of the attendance for each participant, for a minimum of 3 years and shall make those records available for inspection and copying by the board or its designee.
- (9) Course Completion. The provider shall issue a certificate of completion to a participant who has successfully completed the program. The provider shall also notify the board or its designee in writing of its determination that a participant did not successfully complete the program. The provider shall fail a participant who either was not actively involved in the class or demonstrated behavior indicating a lack of insight (e.g., inappropriate comments, projection of blame). This notification shall be made within 10 calendar days of that determination and shall be accompanied by all documents supporting the determination.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4300, Business and Professions Code.

# ATTACHMENT C-1

**Board Adopted Regulations – Undergoing Review by the Administration**

**Pharmacies that Compound**

**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**

**Order of Adoption**  
**Board of Pharmacy**  
**California Code of Regulations**

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.

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.).

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.

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) Pursuant to Business and Professions Code section 4052(a)(1), a "reasonable quantity" of compounded drug product may be furnished to a prescriber for office use upon prescriber order, where "reasonable quantity" is 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 compendia 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 (form 17m-39 rev. 10/07). 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 odd-numbered each 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.

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.

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 1735.4 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.

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.

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.

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.

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.

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 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
  - (2) Walls, ceilings and floors shall be constructed in accordance with Section 490A.3 of Title 24, Part 2, Chapter 4A of the California Code of Regulations.
  - (3) Be ventilated in a manner in accordance with Section 505.12 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 of Title 24, Part 2, Chapter 4A 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.3.4 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.

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 ~~1716.1~~ 1735.2 shall, in addition to those records required by section ~~1716.2~~ 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.

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."

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.

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:

**§1751.01. 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 4-1106(b) of Title 24 of the California Administrative Code, 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.

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.

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.

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.

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.

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.~~

~~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.

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

Re-number 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.

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



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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 4745-1735.2 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 has an area suitable for confidential patient consultation, compounds prescriptions as defined in CCR 1735. (CCR 1764, 1714)

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 is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714) 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 premises, fixtures, and equipment is are maintained in a clean and orderly condition. 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]). (CCR 1714)

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 sink has hot and cold running water. (CCR 1714)

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]) ~~The pharmacy has a readily accessible restroom. (CCR 1714)~~

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

~~Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR 1707.2)~~

~~If applicable, a notice of shared electronic prescription files is posted in public view where it can be clearly read by the purchasing public. (CCR 1717.2)~~

Compounded drug products are given an expiration date representing the date beyond which, in the professional judgment of the pharmacist, it should not be used as defined in CCR 1735.2 (h) and does not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product. (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.
- \_\_\_\_\_ 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 original board issued pharmacy license and the current renewal is are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

- 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])

Does the pharmacy compound sterile injectable drugs?  
(If yes, complete section 23 — “Compounding Sterile Injectable Drugs”.)

- Chemicals, bulk drug substances, drug products, and components used to compound drug products are obtained from reliable suppliers. (CCR 1735.3 [c]) Dangerous drugs and dangerous devices are only delivered to the licensed premise, and signed for and received by a pharmacist. (B&PC 4059.5[a])

- 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]) A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

- \_\_\_\_\_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 are labeled with the name(s) of the active ingredient(s), concentration of strength, volume or weight, and expiration date. (CCR 1735.4[c])

CORRECTIVE ACTION OR ACTION PLAN: \_\_\_\_\_

**5.5. 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])

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[d])

The manual includes procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding and for training on these procedures. (CCR 1735.5[e])

The manual includes documentation on the methodology used to test integrity, potency, quality and labeled strength of compounded drug products. (CCR 1735.5[f])

The manual includes documentation of the methodology used to determine appropriate expiration dates for compounded drug products. (CCR 1735.5[g])

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 used 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 175.8[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

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 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 4-1006(b) of Title 24 of the California Administrative Code 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;

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 \_\_\_\_\_ Date \_\_\_\_\_  
(Pharmacist-in-Charge)

# **ATTACHMENT D-1**

**Board Approved Regulations – Awaiting Notice**

**Proposed Addition to Title 16 CCR Section 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.



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

## VETERINARY FOOD-ANIMAL DRUG RETAILER SELF ASSESSMENT

All legal references used throughout this self-assessment form are explained on Page 17. All references to “drugs” throughout this self–assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&P) section 4022. ([http://www.pharmacy.ca.gov/laws\\_regs/lawbook.pdf](http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf)) Dangerous drug or dangerous device means any drug or device unsafe for self-use in humans or animals.

**Definitions:**

“Veterinary Food-Animal Drug Retailer” (vet retailer) is an area, place or premises, other than a pharmacy that holds a valid license from the California State Board of Pharmacy as a wholesaler and, in and from which veterinary drugs for food-producing animals are dispensed pursuant to a prescription from a licensed Veterinarian. It is a separate and additional license from a wholesaler license. Veterinary food–animal drug retailer includes but is not limited to any area, place or premises described in a permit issued by the board wherein veterinary food-animal drugs (as defined in Business & Professions Code section 4042) are stored, possessed, or repackaged, and from which veterinary drugs are furnished, sold, or dispensed at retail pursuant to a prescription from a licensed veterinarian.

“Veterinary Food–Animal Drugs” include any drug to be used in food-producing animals bearing the legend “Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian” or words of similar import. Also included is any drug as defined in section 14206 of the Food and Agriculture Code that is used in a manner that would require a veterinary prescription.

Veterinary Food-Animal Drug Retailer Name \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

E-mail address (optional) \_\_\_\_\_

Ownership: Please mark one

- Sole owner     
  Partnership     
  Corporation     
  LLC  
 Non-licensed owner     
  other (please specify) \_\_\_\_\_

CA Veterinary Food-Animal Drug Retailer Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_

CA Wholesaler Permit # \_\_\_\_\_ Expiration Date \_\_\_\_\_

DEA Registration # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Date of most recent DEA Inventory \_\_\_\_\_

Hours: Daily \_\_\_\_\_ Sat \_\_\_\_\_ Sun \_\_\_\_\_ 24 hours \_\_\_\_\_

Designated representative-in charge (DRIC) /pharmacist (RPH) \_\_\_\_\_

DRIC License # / RPH License # \_\_\_\_\_ Expiration Date \_\_\_\_\_

Licensed Veterinary Food-Animal Drug Retailer Staff (designated representative (DRep, pharmacist):

1. \_\_\_\_\_ DRep/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_

2. \_\_\_\_\_ DRep/RPH# \_\_\_\_\_ Exp. Date \_\_\_\_\_

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

### 1. Ownership/Location

Yes No N/A

Review the current veterinary food-animal drug retailer permit for this business. Are the listed owners correct and is the listed address correct? If either is incorrect, notify the board in writing. (B&PC 4196 [a] [d])

**Attach a copy of the notification letter to the board to this document.**

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

### 2. Facility

Yes No N/A

Are only pharmacists, intern pharmacists, designated representatives, and authorized officers of the law, or a person authorized to prescribe, permitted in the area place or premises described in the permit as a veterinary food-animal drug retailer without supervision? (B&P 4196[c])

Is a pharmacist or designated representative responsible for any person who enters the premises for clerical, inventory control, housekeeping, delivery, maintenance, or similar functions related to the business of a veterinary food animal drug retailer? (B&P 4196[c])

Are all veterinary food-animal drugs stored in a secure, lockable area? (B&P 4197[a][1])

Premises, Fixtures and equipment: (B&P 4197[a][2])

Fixtures and equipment - Clean and orderly

Premises - dry

Premises - well ventilated

Premises - Adequately lighting

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

### 3. Designated Representative-in-Charge/Owner Responsibilities

Yes No N/A

Are the owner and the designated representative-in-charge both equally responsible for maintenance of the records and inventory? (B&P 4081[b])

Is the designated representative-in-charge responsible for the veterinary food-animal drug retailer's compliance with all state and federal laws related to practice as a veterinary food-animal drug retailer? (B&P 4196[d]).

Has the owner notified the board within 30 days of the termination of the designated representative-in-charge or pharmacist? (B&P 4305.5[a])

Has the owner identified and notified the board of the appointment of a new designated representative-in-charge within 30 days of the termination of the former designated representative-in-charge? (B & P 4196[d], 4331[b]. The appropriate form for this notification is a "Change of Designated Representative-in-Charge", which is available on the board's web site.

Has any designated representative-in-charge who ends his or her employment at a wholesaler, notified the board within 30 days? (B & P 4305.5[c], 4101[b]. This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_  
\_\_\_\_\_

### 4. Designated Representative/Pharmacist

Yes No N/A

Does your veterinary food-animal drug retailer operate only when a pharmacist or veterinary designated representative is on the premises? (4053[c])

Is the address of the veterinary designated representative(s) current on their printed permit? (B&P4100,1704)

If a veterinary designated representative or pharmacist changes his/her name or personal address of record, he/she will notify the board in writing within 30 days? (B&P 4100, CCR 1704)

A pharmacist or veterinary retailer designated representative only dispenses drugs for use on food-producing animals on the basis of a written, electronically transmitted or oral order received from a licensed veterinarian? (CCR 1780.1[d])

Only a pharmacist or the veterinary designated representative receives an oral order for a veterinary food-animal drug from the veterinarian? (CCR 1780.1[d])

Yes No N/A

A written copy of any oral prescription is sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**5. Ordering Drugs by this Business for Future Sale/Transfer or Trade**

Yes No N/A

Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&P 4163[b], 4169)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**6. Receipt of Drugs by this Business**

Yes No N/A

When drugs are received by your business, are they delivered to the licensed wholesale premises, and received by and signed for only by a designated representative or a pharmacist? (B&P 4059.5[a])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**7. Drug Stock**

Yes No N/A

Is all drug stock open for inspection during regular business hours? (B&P 4081[a])

Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&P 4342[a])

If dangerous drugs, legend drugs or extra label use drugs are returned to the veterinary food-animal drug retailer from a client are they treated as damaged or outdated prescription drugs and stored in the quarantine area specified in California Code of Regulations section 1780(3)(1) and are not returned to stock, or dispensed, distributed or resold? (CCR 1780.1)

**8. Prescription Dispensing**

Yes No N/A

Are dangerous drugs and extra label use drugs for use on food producing animals dispensed to clients pursuant to a prescription written by a veterinarian? (CCR 1780.1[a][d])

Are dangerous drugs, and extra label use drugs prepared and labeled by a pharmacist or designated representative only? (CCR 1781.1[d])

A veterinarian's prescription for a food-producing animal can only be refilled if the initial prescription issued indicated a specific number of refills. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead a new prescription must be obtained from the veterinarian? (CCR 1780.1[g][1])

No veterinary food-animal drug prescriptions are refilled over six months from the date of issuance of the initial order? (CCR 1780.1[g][2])

Are prescriptions partially filled? If unable to fill the full quantity of drugs prescribed, fill and ship a portion of the order, so long as the full quantity is shipped within 30 days? (CCR 1780.1[j])

When partially filling a prescription, does the pharmacist or veterinary designated representative note the following information on the written prescription for each date the drugs are shipped: (CCR 1780.1[j])

Quantity shipped?

Date shipped?

Number of containers shipped?

If multiple containers, each container must be sequentially numbered?

If unable to fill the full quantity of a prescription within 30 days, has a new veterinarian's prescription been written to fill the remainder of the drugs originally prescribed? (CCR 1780.1[j])

**9. Prescription Labeling**

Yes No N/A

Does only a pharmacist or veterinary designated representative prepare and affix the label to a veterinary food-animal drug product?

Pursuant to a veterinarian's prescription, are prescription labels affixed to all drug containers that include: (CCR 1780.1[h][1-14])

Active ingredients or the generic name(s) of the drug?

Manufacturer of the drug?

Strength of the drug dispensed?

Quantity of the drug dispensed?

Name of the client?

Species of food-producing animal for which the drug is described?

Condition for which the drug is prescribed?

Directions for use?

Withdrawal time?

Cautionary statements, if any?

Name of the veterinarian prescriber?

Date dispensed?

Name and address of the veterinary food-animal drug retailer?

Prescription number or another means of identifying the prescription?

If an order is filled in multiple containers, a sequential numbering system to provide a means to identify multiple units if shipped to the same client from the same prescription? (container 1 of 6, container 2 of 6)

Manufacture's expiration date?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**10. Repackaging**

**Definition** - Repackaging within the meaning of B&P 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a) or extra label use drugs, so long as the seals on the individual containers are not broken.

Yes No N/A

Are only sealed original manufacturer's containers labeled for distribution to clients? Veterinary retailers or wholesalers cannot open a container and count out or measure out any quantity of a dangerous legend or extra label use drug. (CCR 1780.1[b])

**11. Sale or Transfer of Drugs by this Business**

Yes No N/A

Are all dangerous drugs and extra label drugs that are sold, only sold pursuant to a prescription issued by a veterinarian to a veterinarian's client for use on food-producing animals? (CCR 1780.1[a])

No dangerous drugs or extra label drugs are sold, traded or transferred at wholesale by the veterinary retailers? (B&P 4041)

Are practices in place to prevent dangerous drugs from being sold, traded or transferred if the vet retailer or wholesaler knew or reasonably should have known the drugs were adulterated as defined by CA Health & Safety Code section 111250, misbranded as defined by CA Health & Safety Code section 111335, or beyond the use date on the label? (B&P 4169[a])

List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

Do your advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&P 4341, 4651, CCR 1766)

Do you offer any rebates, refunds, commissions or preferences, discounts, or other considerations for referring clients? If your business has any of these arrangements, please list with whom? (B&P 650)

If your business sells, transfers or delivers dangerous drugs outside of California, either to another state within the United States or a foreign country, do you comply with:

All CA pharmacy and veterinary laws related to the distribution of drugs?

The pharmacy law and veterinary laws of the receiving state within the United States?

The statutes and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration?

All laws of the receiving foreign country related to drugs for food producing animals?

Yes No N/A

All applicable federal regulations regarding the exportation of dangerous drugs?

Describe how you determine a client in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&P 4059.5[e])

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CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**12. Delivery of Drugs**

Yes No N/A

Upon delivery of appropriately labeled prescription drugs or extra label drugs to a client, pursuant to a veterinarian's prescription, do you obtain the signature of the client, or the client's agent, on the invoice with notations of any discrepancies, corrections or damage? (CCR 1780.1[k])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**13. Controlled Substances**

Yes No N/A

If a controlled substance is dispensed, are the labels on the containers countersigned by the prescribing veterinarian before being provided to the client? (CCR1780.1[e])

**Note:** Please refer to "Controlled Substances" section of the Wholesaler Self Assessment for additional controlled substance statutes, regulations, and requirements your business must follow

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**14. Consultant Pharmacist**

Yes No N/A

Does your consulting pharmacist assure compliance with all statutes and regulations governing veterinary food-animal drug retailers? (B&P 4198[e])

Yes No N/A

Does your consultant pharmacist visit routinely, but at least quarterly?  
(B&P 4198[e])

Does your consultant pharmacist: (B&P 4198[e])

Review and revise policies and procedures?

Assure compliance with state and federal statutes and regulations for labeling, storage and dispensing of veterinary food-animal drugs?

Provide a written report twice yearly certifying whether or not the veterinary food-animal drug retailer is operating in compliance with the requirements of this chapter?

Are these written reports readily available for inspection upon request?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**15. Designated Representative Training.**

Yes No N/A

Does your business prepare and maintain records of training and demonstrated competence for each individual employed or retained by you? (B&P 4198[b])

Are records of training and demonstrated competence for each employee maintained for 3 years after the last date of employment? (B&P 4198[b])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**16. Quality Assurance Program**

Does your business have an ongoing, documented quality assurance program, which includes but is not limited to: (B&P 4198 [c])

Yes No N/A

Monitoring personnel performance?

Storage of veterinary food-animal drugs?

Maintenance of equipment?

Dispensing of veterinary food-animal drugs?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**17. Policies and Procedures**

Does your business maintain and adhere to policies and procedures for:  
(B&P 4198)

Yes No N/A

Handling of veterinary food animal drugs?

Dispensing of veterinary food animal drug?

Staff training records?

Cleaning of equipment?

Storage and maintenance of veterinary food –animal drugs?

Storage and maintenance of equipment?

Record keeping requirements?

Storage requirements?

Security requirements?

Quality assurance?

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**18. Record Keeping Requirements**

*Purchase and Sales Records*

Yes No N/A

Are all records of acquisition and disposition of dangerous drugs, retained on the premises, open for inspection, during regular business hours? (B&P 4081, 4332, CCR 1718)

Are all prescription documents and other disposition records for dangerous drugs or extra label use drugs dispensed by a vet food-animal drug retailer kept on file and maintained on the premises for 3 years? (B&P 4198[b])

Are all records of prescription refills retained by your business on the premises for 3 years? (CCR1780.1[i], B&P 4081[a], 4332)

Are all purchase and sales records retained in a readily retrievable form? (B&P 4105[a])

Yes No N/A

Are records of shipment of labeled dangerous drugs to clients (also known as an expanded invoice) included in the client's shipment? This document includes: (CCR1780.1[i])

Drug name?

Quantity shipped?

Manufacturer's name and lot number?

Yes No N/A

Date of shipment?

Name of the pharmacist or vet retailer exemptee who is responsible for the distribution?

Are copies of the records of shipment (also known as the expanded invoice) distributed to the prescribing veterinarian? (CCR 1780.1 [i])

Are copies of the records of shipment (also known as the expanded invoice) of labeled dangerous drugs retained by your business for 3 years? (CCR 1780.1[I])

***Inventory***

Yes No N/A

Is a current, accurate inventory maintained for all dangerous drugs (B&P 4081[a], CCR 1718)

***Consultant Pharmacist***

Yes No N/A

Are consultant pharmacist semi-annual reports retained by your business for 3 years from the making? (B&P 4198 [e])

***Quality Assurance***

Yes No N/A

Is quality assurance documentation retained for 3 years from the making? (B&P 4198[d])

***Policies and Procedures***

Yes No N/A

Are all policies and procedures specified in section 4198(a) maintained for 3 years from the making? (B&P 4198(b))

Are all policies and procedures, documents related to the quality assurance program, and all records of employee training and demonstrated competency open for inspection by authorized officers of the law? (B&P 4198[b])

***Temporary removal of records***

Yes No N/A

If you temporarily remove purchase or sales records from your business, does your business retain, on your licensed premises at all times, a photocopy of each record temporarily removed? (B&P 4105[b])

**Off-site storage waiver**

Yes No N/A

Are required records stored off-site only if a board issued written waiver has been granted? (CCR 1707[a])

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below: (CCR 1707[a])

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Yes No N/A

If an off-site written waiver is in place, is the storage area secure from unauthorized access? (CCR 1707[b][1])

If an off-site waiver is in place, are the records stored off-site retrievable within 2 business days? (1707[b][1])

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

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**19. Reporting Requirements to the Board**

**Ownership**

Yes No N/A

I understand this veterinary retailer license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted, in addition to an application for a permanent new permit, to the board, if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval. (B&P 4201[h][I], 4196[b], CCR 1709[b])

Are transfers, in a single transaction or a series of transactions, of 10% or more of the beneficial interest in a business licensed by the board to a person who did not hold beneficial ownership interest at the time of the initial permit was issued, reported in writing to the board within 30 days of the transaction? (CCR 1709[b])

Any transfer of a beneficial interest in a business licensed by the board, in a single transaction or series of transactions, to a person or entity, which results in the transferee holding 50% or more shall constitute of change of ownership and an application must be submitted to the board for a change of ownership. (CCR 1709 [c])

Yes No N/A

When called upon by an inspector, can the business owner or manager, produce information indicating the names of the business owners, managers and employees and a brief statement of the capacity for each person employed by the business? (B&P 4082)

***Veterinarian***

Yes No N/A

Whenever a veterinary designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, or extra label use drugs prescribed by multiple veterinarians, does the veterinary designated representative contact the prescribing veterinarians for authorization before dispensing any drugs? (CCR 1780.1[f])

Are copies of expanded invoices, documenting sales of dangerous drugs, distributed to the prescribing veterinarian within 72 hours of dispensing? (CCR 1780.1[l]).

Is a written copy of any oral prescription received by either a pharmacist or designated representative of the veterinary food-animal drug retailer sent or electronically transmitted to the prescribing veterinarian within 72 hours? (CCR 1780.1[d])

***Consultant Pharmacist***

Yes No N/A

Does the consultant pharmacist provide written certification every 6 months that your business is or is not in compliance with all applicable statutes and regulation? (B&P 4198[e])

Does your business submit the most recent consultant pharmacist report with the annual application to renew the veterinary food-animal drug retailer license with this board? (B&P 4198[e])

***Designated Representative in Charge/ Designated Representative***

Yes No N/A

If a designated representative-in-charge terminates employment at this business, does the business notify the board within 30 days of the termination? (B&P 4101[b], 4305.5[c])

When a veterinary designated representative leaves the employ of a veterinary food-animal drug retailer, would the business owner immediately return the exemptee license to the Board of Pharmacy? (CCR 1780.1[l])

When a designated representative in charge terminates employment at this business, does the designated representative in charge notify the board within 30 days of the termination.? This requirement is in addition to the requirement for the owner to notify this board. (B&P 4101[c])

***Discontinuation of Business***

Yes No N/A

I understand if this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business? (CCR 1708.2)

I understand the owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs? (CCR 1705)

***Controlled substances (if applicable)***

Yes No N/A

Does the owner report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs? (CCR 1715.6)

Does the owner notify the DEA, on a DEA form 106, of any theft or significant loss of controlled substances upon discovery? (CFR 1301.74[c])

Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

If the business holds a DEA registration, does the owner understand the requirement to notify the DEA promptly of the discontinuation of the business and all unused DEA 222 order forms must be returned to the DEA? (CFR 1301.52[a], 1305.14)

CORRECTIVE ACTION OR ACTION PLAN \_\_\_\_\_

**20. Additional Licenses/Permits Required**

List all licenses and permits required to conduct this business, including local business licenses, wholesaler licenses held in other states, permits or licenses required by foreign countries or other entities (B&P 4107, 4059[a], CFR 1305.11[a])

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Designated Representative-in-Charge/Pharmacist Certification:**

**DESIGNATED REPRESENTATIVE-IN-CHARGE CERTIFICATION:**

I, (Please print) \_\_\_\_\_, RPH # \_\_\_\_\_ hereby certify that I have completed the self-assessment of this veterinary food-animal drug retailer of which I am the designated representative-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 \_\_\_\_\_ Date \_\_\_\_\_  
(Designated Representative-in-Charge)

**Legal References** used in the self-assessment forms (California Code of Regulations [CCR], Title 16 and Title 24, and Business and Professions Code [B&P], Chapter 9, Division 2) can be found in the *California Pharmacy Law* (below) or visit the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) under *California Pharmacy Law and Index*.

The Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act is also in the *California Pharmacy Law* (below) or you can visit the Board of Pharmacy Web site at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov) under *California Pharmacy Law and Index*.

California Code of Regulations (CCR), Chapter 1, Division 5, Title 22, and other references can be found in the California State Law Library or county law libraries.

Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration, may be found at [www.dea.gov](http://www.dea.gov).

**California Board of Pharmacy**  
1625 N. Market Blvd., Suite N219  
Sacramento, CA 95834  
Phone: (916) 574-7900  
Fax: (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

**CURES**  
4949 Broadway  
Sacramento, CA 95820  
Phone: (916) 319-9062  
Fax: (916) 319-9448  
<http://www.ag.ca.gov/bne>

*California Pharmacy Law* may be obtained by contacting:  
LawTech Publishing  
1060 Calle Cordillera, Suite 105  
San Clemente, CA 92673  
(800) 498-0911 Ext. 5  
[www.lawtechpublishing.com](http://www.lawtechpublishing.com)

CURES Patient Activity Report Request Forms:  
<http://www.ag.ca.gov/bne/trips.php>

**PRESCRIBER BOARDS:**

**Pharmacist Recovery Program**  
(800) 522-9198 (24 hours a day)

**Medical Board of California**  
2005 Evergreen St., Suite 1200  
Sacramento, CA 95815  
(800) 633-2322  
(916) 263-2382  
Fax: (916) 263-2944  
<http://www.mbc.ca.gov>

**Atlantic Associates, Inc. (CURES)**  
Prescription Collection  
8030 S. Willow Street  
Manchester, NH 03103  
Phone: (888) 492-7341  
Fax: 877-508-6704

**Dental Board of California**

2005 Evergreen St., Suite 1550  
Sacramento, CA 95815  
Phone: (916) 263-2300  
Fax: (916) 263-2140  
<http://www.dbc.ca.gov>

**Board of Registered Nursing**

1625 N. Market Blvd., Suite N217  
Sacramento, CA 95834  
Phone: (916) 322-3350  
Fax: (916) 574-7697  
<http://www.rn.ca.gov/>

**Board of Optometry**

2420 Del Paso Road, Suite 255  
Sacramento, CA 95834  
Phone: (916) 575-7170  
Fax: (916) 575-7292  
<http://www.optometry.ca.gov/>

**Osteopathic Medical Board of California**

1300 National Drive, Suite 150  
Sacramento, CA 95834  
Phone: (916) 928-8390  
Fax: (916) 928-8392  
<http://www.ombc.ca.gov/>

**Physician Assistant Committee**

2500 Evergreen St., Suite 1100  
Sacramento, CA 95815  
Phone: (916) 561-8780  
Fax: (916) 263-2671  
<http://www.pac.ca.gov/>

**Board of Podiatric Medicine**

2005 Evergreen St., Suite 1300  
Sacramento, CA 95815  
Phone: (916) 263-2647  
Fax: (916) 263-2651  
<http://www.bpm.ca.gov/>

**Veterinary Medical Board**

2005 Evergreen St., Suite 2250  
Sacramento, CA 95815  
Phone: (916) 263-2610  
Fax: (916) 263-2621  
<http://www.vmb.ca.gov/>

**FEDERAL AGENCIES:****Food and Drug Administration****– Industry Compliance**

<http://www.fda.gov/oc/industry/centerlinks.html#drugs>

The **Drug Enforcement Administration** may be contacted at:

**DEA Website:**

<http://www.dea diversion.usdoj.gov>

**Online Registration – New Applicants:**

[http://www.dea diversion.usdoj.gov/drugreg/reg\\_apps/onlineforms\\_new.htm](http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm)

**Online Registration - Renewal:**

[www.dea diversion.usdoj.gov/drugreg/reg\\_apps/onlineforms.htm](http://www.dea diversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm)

**Registration Changes (Forms):**

[http://www.dea diversion.usdoj.gov/drugreg/change\\_requests/index.html](http://www.dea diversion.usdoj.gov/drugreg/change_requests/index.html)

**DEA Registration Support (all of CA):**

(800) 882-9539

**Online DEA 106 Theft/Loss Reporting:**

<https://www.dea diversion.usdoj.gov/webforms/app106Login.jsp>

**Online DEA 222 Controlled Substance Ordering System (CSOS):**

<http://www.deacom.gov/>

**DEA - Fresno**

2444 Main Street, Suite 240  
Fresno, CA 93721

Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (559) 487-5406

**DEA - Los Angeles**

255 East Temple Street, 20th Floor  
Los Angeles, CA 90012

Registration: (888) 415-9822 or (213) 621-6960  
Diversion or Investigation: (213) 621-6942

**DEA – Oakland**

1301 Clay Street, Suite 460N  
Oakland, CA 94612

Registration: (888) 304-3251  
Diversion or Investigation: (510) 637-5600

**DEA – Redding**

310 Hensted Drive, Suite 310  
Redding, CA 96002  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (530) 246-5043

**DEA - Riverside**

4470 Olivewood Avenue  
Riverside, CA 92501-6210  
Registration: (888) 415-9822 or (213) 621-6960  
Diversion or Investigation: (951) 328-6200

**DEA - Sacramento**

4328 Watt Avenue  
Sacramento CA 95821  
Registration: (888) 304-3251 or (415) 436-7900  
Diversion or Investigation: (916) 480-7100 or  
(916) 480-7250

**DEA – San Diego and Imperial Counties**

4560 Viewridge Avenue  
San Diego, CA 92123-1637  
Registration: (800) 284-1152  
Diversion or Investigation: (858) 616-4100

**DEA – San Francisco**

450 Golden Gate Ave., 14<sup>th</sup> Floor  
San Francisco, CA 94102  
Registration: (888) 304-3251  
Theft Reports or Diversion: (415) 436-7900

**DEA – San Jose**

One North First St., Suite 405  
San Jose, CA 95113  
Registration: (888) 304-3251  
Diversion or Investigation: (408) 291-2631

## **ATTACHMENT D-2**

**Board Approved Regulations – Awaiting Notice**

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

**Board of Pharmacy  
Specific Language To  
Amend 16 Cal.Code Reg §1721 and Amend 16 Cal.Code Reg §1723.1**

**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~~ 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.

# **ATTACHMENT D-3**

**Board Approved Regulations – Awaiting Notice**

**Proposed Adoption of Title 16 CCR §1751.9  
Accreditation Agencies for Pharmacies That Compound  
Injectable Sterile Drug Products**

**Board of Pharmacy**  
**Specific Language to Add Section 1751.9**

Add Section 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§1751.9 – 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.