



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Legislation and Regulation Committee

Andrea Zinder, Board Member and Chair
D. Timothy Dazé, Board Member
Robert Graul, RPh, Board Member
Kenneth H. Schell, PharmD, Board Member

REGULATION REPORT

B. Report and Action on Items Discussed at the Legislation and Regulation Committee Meeting of October 24, 2007.

Minutes of the Legislation and Regulation Committee Meeting of October 24, 2007, are provided in **ATTACHMENT B**.

C. Approved Regulations

The Office of Administrative Law approved the following regulations since the October 2007 Board Meeting.

1. Amendment to 16 CCR §1707.2 – Notice to Consumers

FOR INFORMATION:

CCR 1707.2 currently requires every pharmacy to prominently post a "Notice to Consumers" poster as authorized by Business and Professions Code section 4122. Assembly Bill 2583 (Chapter 487, Statutes of 2006) amended sections 733 and 4122 of the Business and Professions Code to require the board to amend the "Notice to Consumers" to include a statement that describes a patient's right to obtain medication from a pharmacy even if a pharmacist has ethical, moral or religious grounds against dispensing a particular drug, in which case protocols for getting the medication is required.

The Office of Administrative Law approved this regulation on October 31, 2007. The revised consumer poster(s) are currently under development. Staff hopes to have the finalized poster(s) mailed to all pharmacies no later than July 2008.

2. Amendment to 16 CCR §1749 – Fee Schedule

FOR INFORMATION:

CCR 1749 established specific application and renewal fees for licensees according to the range set forth in Business and Professions Code. At the April 2007 Board Meeting,

the board voted to approve a recommendation from the board's Organizational Development Committee to increase all board fees to their statutory maximum amounts.

This proposal will raise board fees to their statutory maximum as provided for in the referenced Business and Professions Code sections. This proposal is necessary to ensure sufficient revenue to maintain current board operations.

The Office of Administrative Law approved this regulation on November 19, 2007. Licensees were notified of the fee increase through inserts in with renewal applications and an article will be included in the January 2008 edition of *The Script*.

3. Section 100 Changes

FOR INFORMATION:

The Office of Administrative Law approved the section 100 on December 18, 2007. The amendments are listed below. These changes are without regulatory effect because they merely conform to statutory changes already in effect as well as to remove an outdated regulation.

16 CCR §1707. Waiver Requirements for Off-Site Storage of Records - In 2004 Senate Bill 1307 (Chapter 857, Statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section required an amendment to ensure consistency with the Business and Professions Code.

16 CCR §1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge. - In 2004 Senate Bill 1307 (Chapter 857, Statutes of 2004) replaced the term "exemptee-in-charge" with "designated representative-in-charge" in pharmacy law, effective January 1, 2006. This section required an amendment to ensure consistency with the Business and Professions Code.

16 CCR §1715 – Self Assessment Forms - The self-assessment forms, which is incorporated by reference in the regulation, is a compilation of laws. A Section 100 regulation was necessary to update the self-assessment forms to reflect changes in pharmacy law since the form's last revision date.

16 CCR §1717. Pharmacy Practice – This section currently makes reference to section 1306.26 of the Code of Federal Regulations. This reference required correction to reflect the appropriate CFR section, 1306.25.

16 CCR §1746 Emergency Contraception - This section previously referenced Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference required correction.

16 CCR §1780.1 and §1781 – Replace the term "Exemptee" with "Designated Representative"- In 2004 Senate Bill 1307 (Chapter 857, Statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section required an amendment to ensure consistency with the Business and Professions Code.

Proposed Repeal of 16 CCR §1786 – Return of Exemption Certificates - This section is outdated and needed to be repealed. The provision requires a supplier to immediately return a certificate of exemption to the board if an exemptee leaves the employment of a wholesaler. This regulation is based on prior Pharmacy Law, which linked an exemptee license (designated representative) to a specific licensed wholesaler location.

Proposed Amendment to CCR §1787. Authorization to Distribute Dialysis Drugs and Devices - In 2004 Senate Bill 1307 (Chapter 857, Statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section required an amendment to ensure consistency with the Business and Professions Code.

Proposed Amendment to CCR §1790. Assembling and Packaging - In 2004 Senate Bill 1307 (Chapter 857, Statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section required an amendment to ensure consistency with the Business and Professions Code.

Proposed Amendment to CCR §1793.8. – Pharmacy Technicians in Hospitals - This section previously referenced Business and Professions Code section 4052, however because of recodification of this section included in Assembly Bill 2408 (Chapter 777, Statutes of 2006) this reference required correction.

4. Board Approved Regulations Awaiting Conformance with California Building Standards Rulemaking Process

FOR INFORMATION:

At the April 2006 Board Meeting, the board voted to amend language in the California Building Code, Title 24, California Code of Regulations, section 490A.3 and 505.12 with respect to the building standards for pharmacies that compound parenteral solutions. Thereafter, the Building Standards Commission advised the board of a new process to submit items into the California Building Code. These changes were approved by the Building Standards Commission.

D. BOARD APPROVED REGULATIONS – AWAITING PUBLIC NOTICE

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

FOR INFORMATION:

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.

A copy of the draft language and form is included in **ATTACHMENT D-1**. Staff anticipate initiating the 45-day comment period in advance of the July Board Meeting to allow for action by the board at the July 2008 Meeting.

2. Proposed Amendment to 16 CCR §1760 – Disciplinary Guidelines

FOR INFORMATION:

The board also approved amendment to 16 CCR §1760 – Disciplinary Guidelines.

This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. The Guidelines were finalized in November and staff anticipates that the proposal will be noticed in advance of the April 2008 Board Meeting for final adoption.

A copy of the draft language is included in **ATTACHMENT D-2**.

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

FOR INFORMATION:

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 standards. The USP Standards is updated and published annually. Consequently, this section requires an amendment to amend Section 1780(b) to reflect the 2005 version of the publication and to hold wholesalers accountable to the latest standards.

At the April 2007 Legislation and Regulation Committee Meeting the committee was advised to review the updates made in the USP Standards Reference Material referenced in the proposed language to ensure that the board was fully aware of and in support of the USP changes. Given this, board staff did not include this proposed regulation change, but rather is seeking input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material. At the June 2007 committee meeting, Dr. Schell offered to facilitate a taskforce to review the USP Standards Reference Material.

4. Proposed Regulation 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

FOR INFORMATION:

Business and Professions Code section 4127.1 requires a separate license to compound injectable sterile 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.

This proposed regulation would specify the criteria the board uses to evaluate these agencies.

At the July 2007 Board Meeting, the board voted to move this proposal. Staff anticipates initiating the rulemaking process in for final adoption by the July 2008 board meeting.

A copy of the language is provided in **ATTACHMENT D-4**.

5. Proposed Amendment to 16 CCR §§1721 and 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality.

FOR INFORMATION:

At the October 2007 Board Meeting, the board voted to approve proposed amendments to 16 CCR 1721 and 1723.1 that would 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 the licensing examination.

This recommendation was generated from the board's competency committee, which is responsible for the development of the CPJE examination. According to the board's current exam psychometrician, the cost to generate a new test item is \$2000/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 language is provided in **ATTACHMENT D-5**.

E. Board-Approved – Language to be Developed

At the October 2007 Board Meeting, the board voted to pursue a regulation proposal to develop an ethics course for pharmacists, modeled after the program used by the Medical Board of California. Staff is working with the Institute for Medical Quality to define the scope of the proposal.

Draft language will be developed in concert with staff counsel for consideration at the Enforcement Committee Meeting scheduled for January 23, 2008.

Attachment B

*Meeting Summary Legislation and Regulation
Committee Meeting of October 24, 2007*



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LEGISLATION AND REGULATION COMMITTEE
MINUTES**

DATE: October 24, 2007

LOCATION: San Jose Doubletree Hotel
2050 Gateway Place
San Jose, CA 95110

**BOARD MEMBERS
PRESENT:** Andrea Zinder, Public Member, Chairperson
D. Timothy Dazé, Esq., Public Member

**BOARD MEMBERS
NOT PRESENT:** Kenneth H. Schell, PharmD
Robert Graul, RPh

STAFF PRESENT: Virginia Herold, Executive Officer
Karen Cates, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Spencer Walker, DCA Staff Counsel
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

**BOARD MEMBERS
IN AUDIENCE:** Stanley Goldenberg, RPh
Robert Swart, PharmD
Ruth Conroy, PharmD

CALL TO ORDER

Chairperson Zinder called the meeting to order at 5:10 p.m. Ms. Zinder advised that only two members of the Legislation and Regulation Committee were present, so there would not be a quorum for voting.

REQUESTS FOR LEGISLATIVE AND REGULATORY PROPOSALS FOR 2008

- **Previously Discussed Proposed Legislation**

- a. Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – Amendment to B&PC Section 4052 and Addition of Section 4052.8

Chairperson Zinder noted that this agenda item was considered during the Licensing Committee section of the board meeting. The board took action to support the proposed legislation to allow pharmacists to administer immunizations.

- b. Furnishing Dangerous Drugs During an Emergency – B&PC Section 4062

Ms. Sodergren noted that this agenda item was considered during the Licensing Committee portion of the meeting. This is a proposed amendment to B&PC Section 4062. The board voted to support the legislative proposal.

- c. Temporary Permit for Damaged Pharmacies – B&PC Section 4110

Ms. Sodergren noted that this agenda item also was considered during the Licensing Committee portion of the meeting. This is a proposed amendment to B&PC Section 4110. The board voted to support the legislative proposal at the meeting.

- **Proposed Legislation**

Ms. Sodergren noted that omnibus changes were recommended for technical changes as well as refining the definitions of pharmacist-in-charge (PIC) and designated representative-in-charge (DRIC), and to clarify reporting requirements when a change of PIC or DRIC occurs. Proposed language of the recommended changes was provided in the meeting materials.

Chairperson Zinder noted that because the committee lacked a quorum, these items would be brought to the January 2008 Board Meeting for a vote without a committee recommendation for action.

Section 4022.5 – Designated Representative; Designated Representative-in-Charge
This section requires amendment to clarify the definition of “designated representative-in-charge” as well as the responsibilities of a licensee serving as such.

Section 4036.5 – Pharmacist-in-Charge

A new section is needed to refine the term “pharmacist-in-charge” as well as the responsibilities of a pharmacist serving as such.

Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.

This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he/she ceased to serve in such a capacity.

Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications

This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has occurred. In addition, this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

Section 4160 – Wholesaler Licenses

This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

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

This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.

Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action

This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.

Section 4329 – Nonpharmacists; Prohibited Acts

This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.

Section 4330 – Proprietors; Prohibited Acts

This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

Additional Proposals for the Omnibus Bill:

In addition to the changes listed above, all of the following proposals are also recommended omnibus provisions for 2008.

Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.

A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.

Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy

This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee

This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal fails to provide proof either as part of an audit or investigation.

Section 4362 – Entry Into Pharmacists Recovery Program

This section requires amendment to specify the administrative co-pay participants pay.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature

This section requires amendment to require that a clinic that dispenses Schedule III and Schedule IV controlled substances must report to CURES weekly.

Business and Professions Code section 4052 was recodified into four sections in 2006. The B&PC and H&SC sections below reference 4052 and require update. The proposed language was provided in the committee materials.

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

- **Proposed Regulations**

- a. Graduate of Foreign Pharmacy Schools (technical change) – 16 CCR Section 1720.1

This regulation defines the certification requirement for graduates of foreign pharmacy schools. This section requires amendment to correct the name of the certification. Specifically, the correct language shall refer to the Foreign Pharmacy Graduate Examination Committee. This should be a "section 100 change."

- b. Implementation of Electronic Monitoring of Schedule II Prescriptions – 16 CCR Section 1715.5

This regulation defines the information that must be reported to CURES. This section currently references schedule II controlled substances and requires updating to reflect the expansion of CURES reporting requirements to include Schedule III and IV controlled substances.

PUBLIC REQUESTS FOR FUTURE LEGISLATION AND REGULATORY PROPOSALS

Philip Swanger, Director of Government Affairs for the California Society of Health-System Pharmacists (CSHP) presented a letter to the board dated October 23, 2007. The letter referred to a Task Force that is developing recommendations for the minimum levels of education, training, and testing for licensure of pharmacy technicians. Information from this task force will be provided to the board in the future.

ADJOURNMENT

Ms. Zinder adjourned the meeting at 5:34 p.m.

Attachment D-1

*Proposed Addition to CCR §1785 – Self-
Assessment of a Veterinary Food-Animal Drug
Retailer*

Board of Pharmacy
Specific Language to Add Section 1785

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

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

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

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

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

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

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

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

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

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

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



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) 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])

CORRECTIVE ACTION OR ACTION PLAN _____

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 _____

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 _____

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 _____

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 3years? (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])

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 _____

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[I]).

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[I])

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)

Yes No N/A

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? (CFR1301.52[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 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 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.

California Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento CA 95834
(916) 574-7900
fax: (916) 574-8618
www.pharmacy.ca.gov

Bureau of Narcotic Enforcement
Security Prescription and CURES Programs
1102 Q Street, 6th Fl.
Sacramento, CA 95817
(916) 319-9062
Fax: (916) 319-9448
<http://www.ag.ca.gov/bne>

California Pharmacy Law may be obtained by contacting:
Law Tech
1060 Calle Cordillera, Suite 105
San Clements CA 92673
(800) 498-0911 Ext. 5
www.lawtech-pub.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
1426 Howe Avenue, Suite 54
Sacramento CA 95825
(800) 633-2322
(916) 263-2499
Fax: (916) 263-2387
<http://www.mbc.ca.gov>

Atlantic Associates, Inc. (CURES)
Prescription Collection
8030 S. Willow Street, Bldg. III, Unit 3
Manchester NH 03103
Phone: (888) 539-3370
Fax: 877-508-6704

Dental Board of California

1432 Howe Ave. #85
Sacramento, CA 95825
(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
(916) 322-3350
fax: (916) 574-8637
<http://www.rn.ca.gov/>

Board of Optometry

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

Osteopathic Medical Board of California

2720 Gateway Oaks Drive, #350
Sacramento, CA 95833
(916) 263-3100
fax: (916) 263-3117
<http://www.ombc.ca.gov>

Physician Assistant Committee

1424 Howe Avenue, #35
Sacramento, CA 95825
(916) 561-8780
fax: (916) 263-2671
<http://www.physicianassistant.ca.gov>

Board of Podiatric Medicine

1420 Howe Avenue, #8
Sacramento, CA 95825
(800) 633-2322
(916) 263-2647
fax: (916) 263-2651
<http://www.bpm.ca.gov>

Veterinary Medical Board

1420 Howe Avenue, #6
Sacramento, CA 95825
(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.deadiversion.usdoj.gov>

Online Registration – New Applicants:

http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm

Online Registration - Renewal:

www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm

Registration Changes (Forms):

http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html

DEA Registration Support (all of CA):

(800) 882-9539

Online DEA 106 Theft/Loss Reporting:

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

Online DEA 222 Controlled Substance Ordering System (CSOS):

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

DEA - Fresno

2444 Main Street, Suite 240
Fresno, CA 93721
Registration: (888) 304-3251 or
(415) 436-7900
Diversion or Investigation: (559) 487-5402

DEA - Los Angeles

255 East Temple Street, 20th Floor
Los Angeles CA 90012
(888) 415-9822 or (213) 621-6960 (Registration)
(213) 621-6942 or 6952
(Diversion or Investigation)

DEA – Oakland

1301 Clay Street, Suite 460N
Oakland, CA 94612
Registration: (888) 304-3251 or
(415) 436-7900
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: (909) 328-6000 or
(909) 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

Attachment D-2

*Proposed Amendment to 16 CCR §1760 –
Disciplinary Guidelines*

**Board of Pharmacy
Specific Language**

Amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. 4/2004 10/2007), which are hereby incorporated by reference.

Deviation from these guidelines and orders, including the standard terms of probation, is appropriate where the board, in its sole discretion, determines that the facts of the particular case warrant such a deviation--the presence of mitigating factors; the age of the case; evidentiary problems.

Authority cited: Section 4005, Business and Professions Code; and Section 11400.20, Government Code. Reference: Sections 4300 and 4301, Business and Professions Code; and Sections 11400.20 and 11425.50(e), Government Code.

Attachment D-4

*Proposed Addition to 16 CCR §1751.8 –
Accreditation Agencies for Pharmacies that
Compound Injectable Sterile Drug Products*

1751.8 – 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, 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 standard-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 will submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months.
- (f) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.
- (g) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Attachment D-5

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

**Board of Pharmacy
Specific Language**

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.