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

## **Legislation and Regulation Committee**

**Robert Graul, RPh, Chair**  
**Bill Powers, Public Member**  
**Robert Swart, PharmD**  
**Shirley Wheat, Public Member**  
**Andrea Zinder, Public Member**

### ***ITEM A: REGULATION REPORT AND ACTION***

The committee did not hold a public meeting in advance of the October Board Meeting.

#### **1. Board Approved Regulations – Undergoing Administrative Review**

FOR INFORMATION:

##### Proposed Amendment to Title 16 CCR §1760 – Disciplinary Guidelines.

At the April 2008 Board Meeting, the board voted to adopt a regulation change to amend Title 16 CCR §1760 – Disciplinary Guidelines. During discussion at this Board Meeting, counsel recommended that the board add several responses to comments submitted during the written comment period.

Staff has since received these comments from our counsel and the compiled rulemaking was submitted to the department on September 12, 2008. The Department has 30 days to complete its review of the rulemaking and then it will be forwarded to the Office of Administrative Law for final review.

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

FOR INFORMATION:

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

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 will be recommending to the Legislation and Regulation Committee that this rulemaking be placed on hold until the conclusion of program review to ensure any recommendations made and implemented are incorporated into this rulemaking.

A copy of the draft language and form is included in **ATTACHMENT 1**.

b. 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 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 sought input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material.

At the July 2008 Legislation and Regulation Committee Meeting, staff requested guidance from the board on pursuing this regulation change, as no additional information was submitted. The committee was advised that comments are forthcoming detailing the possible consequences of incorporating the 2005 version of the USP Standards Reference Materials. Upon receipt, the committee will review the concerns and make a recommendation to the board as warranted.

Also, during the July 2008 Board Meeting, the board heard testimony about the complexity of review the four volumes of USP Standards Reference Materials. It was suggested that the board contact wholesalers to determine what requirements are currently in place and how they satisfy USP requirements currently. Unfortunately because of staff shortages, board staff has been unable to complete this review and survey.

c. Proposed Adoption of Title 16 CCR §1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

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.

A copy of the language is provided in **ATTACHMENT 2**.

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

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 3**.

### **3. Proposed Regulation Language for Board Discussion and Possible Action**

a. Proposed Amendment to Title 16 CCR §1715 – Self-Assessment Forms for Community and Inpatient Pharmacies.

This section establishes requirements for the pharmacist-in-charge (PIC) of a licensed pharmacy to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, this form makes the pharmacy inspection process more meaningful and provides relevant information to pharmacies and their PIC.

Board staff is working on updates to the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in section 1715, the board must pursue a regulation change to require use of the new form.

The Legislation and Regulation Committee will review changes and if appropriate make a recommendation to the full board for consideration and action.

b. Proposed Amendment to Title 16 CCR §1784 – Self-Assessment Forms for Wholesalers

This section establishes the requirement for the designated representative-in-charge of a licensed wholesaler to complete a self-assessment form to ensure compliance with pharmacy law. This self-assessment form is to assist wholesalers in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. Additionally, the this form makes the pharmacy inspection process more meaningful and provide relevant information to wholesalers and their DRC.

Board staff is working on updates to the Self-Assessment forms to incorporate changes made in pharmacy law since its last revision in 2007. As these forms are incorporated by reference in section 1715, the board must pursue a regulation change to require use of the new form.

The Legislation and Regulation Committee will review changes and if appropriate make a recommendation to the full board for consideration and action.

# Attachment 1

- *Proposed Adoption of 16 CCR §1785  
– Self-Assessment of a Veterinary  
Food-Animal Drug Retailer*
- *Self-Assessment Form*

**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](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 \_\_\_\_\_

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### 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 \_\_\_\_\_

### 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 \_\_\_\_\_

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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 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])

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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)

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](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  
(916) 574-7900  
fax: (916) 574-8618  
[www.pharmacy.ca.gov](http://www.pharmacy.ca.gov)

*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](http://www.lawtech-pub.com)

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

**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

17M-40  
16 of 18

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

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

### **PRESCRIBER BOARDS:**

**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>

**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.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.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 2

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

**Board of Pharmacy**  
**Specific Language to Add Section 1751.8**

Add Section 1751.8 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§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 3

*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.