California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA

Enforcement Committee
And Work Group On E-Pedigree

Contact Person: Virginia Herold
(916) 574-7911

Date: September 20, 2007
Time: 9:00 a.m. – 4:00 p.m.
Place: Hilton Los Angeles Airport
5711 West Century Boulevard
Los Angeles, CA 90045
310-410-4000

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Karen Abbe at (916) 574-7946, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order — 9:00 a.m.

1. Workgroup on E-Pedigree
   a. Progress of the EPCglobal Workgroup and Standards for Electronic Pedigrees
   b. Presentations and Updates by Manufacturers, Wholesalers and Pharmacies on Implementation of Electronic Pedigrees

Lunch — 1:00 p.m.

2. Enforcement Committee — 1:45 p.m.
   a. Proposal to Develop an Ethics Course for Pharmacists, Modeled After the Experiences of the Medical Board of California In Establishing an Ethics Course for Physicians
   b. 2007 Self Assessment Forms for Veterinary Food Animal Drug Retailer
   c. Enforcement Statistics
   d. Proposed Modified Disciplinary Guidelines for the Board of Pharmacy

Adjournment — 4:00 p.m.

Meeting materials will be on the board's Web site by September 17, 2007

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STATE AND CONSUMERS AFFAIRS AGENCY
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ARNOLD SCHWARZENEGGER, GOVERNOR

September 12, 2007

To: Enforcement Committee

Subject: Meeting Materials for September 20, 2007 Enforcement Meeting

1. **Workgroup on E-Pedigree**

   During the meeting, a progress report from EPCglobal and reports from various manufacturers, retailers and software companies will be presented. We anticipate a larger audience attending this meeting. At this time, I have no presentation materials to share.

   California Prescription Drug Pedigree PowerPoint presentation enclosed as Attachment 1.

2. **Enforcement Committee – estimated start time: 1:45 pm**

   a. Ethics Course: A subcommittee update will be provided at the meeting, Attachment 2.

   b. Veterinary Food-Animal Drug Self-Assessment Form: At the January 2007 board meeting, the board voted to approve the addition of 16 CCR 1785 - Self Assessment of a Veterinary Food-Animal Drug Retailed. At this meeting, the committee will review the draft self-assessment form, Attachment 3.

   c. Enforcement Statistics: Enforcement Committee statistics for July – September 2007/08 Fiscal Year are provided in Attachment 4.

   d. Proposed Modified Disciplinary Guidelines

      After discussion at the last Enforcement Committee Meeting Chariperson Goldenberg requested that the guidelines be reviewed at the next Enforcement Committee Meeting for a more detailed discussion.

Specific items identified by Chairperson Goldenberg for this meeting's discussion are:

- Posting a notice when licensee is on probation
- Requirements for the notice employers must sign
- Whether revocation based on nonpayment of cost recovery fees should be pursued.

When the board is ready, the board will need to adopt these guidelines as an amendment to section 1760.

Attachment 5 contains the modified Disciplinary Guidelines and a memo outlining the proposed revisions. Written comments on the revisions received by Ronald Marks, Esq and a summary of the board's response to those comments are also included in Attachment 5.

ATTACHMENT

1

California Prescription Drug Pedigree

Enforcement Committee Meeting
9/20/07

California Pedigree Legislation

- 1/1/2009 pedigree implementation date
- CA Board of Pharmacy may delay implementation of pedigree until 1/1/11

Pedigree Definition

- "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition(s) and sale(s) by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering or dispensing the dangerous drug.

Addition to Pedigree Definition 2006 Legislation

- Pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution

Interoperable electronic system defined

- For prescription drugs
- Uses unique identification number
- Established at point of manufacture
- Contained within standardized non-proprietary data format and architecture
- Uniformly used by manufacturers, wholesalers and pharmacies

Pedigree tracking

- Pedigree tracks each prescription drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler and received by the pharmacy.

Electronic Pedigree Requirements

- Prescription Drug Information
- Transaction and Source Information
- Ownership Information
- Certification

Prescription Drug Information

- Drug name – trade or generic
- Quantity
- Dosage form
- Strength
- Container size
- Number of containers
- Expiration dates
- Lot numbers

Transaction and Source Information

- Business name
- FDA manufacturing registration number or state license number as determined by the Board
- Principal address of the source
- Date of transaction
- Sales invoice number

Ownership Information

- For each prior owner of the drug the pedigree must contain:
  - Prescription drug information
  - Source information
  - Transaction information
  - Name & address of each person certifying delivery or receipt of prescription drug

Pedigree Certification

- A certification under penalty of perjury from a responsible party of the source of the dangerous drug that the information contained in the pedigree is true and accurate

Repackaging-a part of original pedigree

Single pedigree includes every change of ownership from initial manufacturer through the final transaction to a pharmacy or other person for furnishing, administering or dispensing the prescription drug, regardless of repackaging or assignment of another National Drug Code (NDC)Directory number

Drug Returns

- Prescription drugs returned to the manufacturer or wholesaler are documented on the same pedigree document as the transaction that resulted in receipt of the drug by the party returning it.

Transactions not requiring a pedigree

- Samples –provision of prescription drug samples by a manufacture's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge

Transactions not requiring a pedigree (cont)

- Injectable prescription drugs delivered directly by manufacturer to an authorized prescriber directly responsible for the administration of the injectable
  - may not be dispensed to a patient or patient's agent for self administration
  - Must be administered to patient by prescriber or other authorized entity receiving drug directly from manuracturer
  - Exemption expires 1/1/10 unless industry requests extension and Board grants to 1/1/11

Reporting requirement

- Manufacturer, wholesaler or pharmacy with reasonable cause to believe a prescription drug in, or having been in, its possession is counterfeit or subject of a fraudulent transaction, the manufacturer, wholesaler or pharmacy shall notify CA Board in writing within 72 hours of obtaining knowledge.
  - Applicable only if drugs sold or distributed in or through the state of California

What do we do to prepare for 1/1/09

- Develop interoperability standards
- Develop unique identifier standards
- Participate in public CA Board of Pharmacy quarterly pedigree workgroup meeting
- Participate at pharmacy, wholesaler and manufacturer levels to assure compliance by 1/1/09

What is the problem , why state legislation?

- Counterfeit drugs entering legitimate pharmaceutical supply chain
- Inability to track source of counterfeits
- Obvious danger to health & safety of public
- Federal legislation implementation delayed

California regulation of prescription drugs

- Prescription drugs from manufacture through all stages of distribution until dispensed or administered to a patient by a pharmacy or prescriber are regulated in CA through required licensing of both the businesses and the individuals working in those businesses

Related Existing Law

- All wholesalers selling into or located in CA must be licensed in CA (effective 1/1/05)
- Surety bond required for all licensed wholesalers
- Restrictions on pharmacy furnishing, manufacturers and wholesalers (effective 1/1/05)
- Wholesaler or pharmacy may not purchase, sell, trade or transfer a prescription drug without receiving or issuing a pedigree (effective 1/1/09)

Pharmacy Furnishing Restrictions

- Pharmacy may only furnish prescription drugs to:
  - Wholesaler/manufacturer from whom the drug acquired
  - Pharmacy/wholesaler of common control – drugs may only be transferred to wholesaler by pharmacy if drugs originally purchased from commonly controlled wholesaler
  - Licensed wholesale reverse distributor
  - Pharmacy or wholesaler in sufficient quantity to alleviate a specific shortage

Pharmacy furnishing restrictions (cont)

- Patient or pharmacy pursuant to a prescription
- Health care provider authorized to purchase prescription drugs
- Pharmacy under common control

Other restrictions

- Manufacturer/wholesaler may only furnish to an authorized person
- Manufacturer/wholesaler/pharmacy may only furnish prescription drugs to a licensed business or prescriber
- Acquire prescription drugs only from a manufacturer or licensed wholesaler
- Effective 1/1/09, a wholesaler or pharmacy may not receive, sell, trade or transfer a dangerous drug without a pedigree

ATTACHMENT

2

State of California **Department of Consumer Affairs**

Memorandum

To: **Enforcement Committee** **Date: September 5, 2007**

From: **Board of Pharmacy**

Subject: **Ethics Course**

At the January 2007 Board Meeting, the board voted to form an exploratory subcommittee to examine the development of an ethics course for pharmacists as a enforcement option as part of discipline. President Powers appointed Dr. Ravnan and Dr. Swart to this subcommittee.

In June 2007 the subcommittee met with an ethicist that works with the Dental Board. The ethicist provides assessment and individual therapy to respondents referred by the Dental Board. Upon approval by the Dental Board, the respondent must comply with the individual therapy recommended.

In August 2007, Dr. Ravnan, Ms. Herold and Ms. Sodergren met with the representatives from the Institute for Medical Quality, the course provider for the Medical Board's 22-hour course which is authorized by Medical Board regulations.

The course requirements include:

- Pre-program Requirements
  - Background Assessment Application
  - Baseline Assessment of Knowledge Test
  - Reading Assignment
  - Participant Expectation of Program Statement
- Two-Day Ethics Course
  - Case presentations
  - Break out groups
  - Experiential exercises
  - Role-playing
- Longitudinal Follow-Up
  - 6 month
  - 12 month

The subcommittee recommends that the board pursue adoption of a course similar to the one used by the Medical Board.

Initial discussions with a potential course provider indicate that the development of the course would not require significant resources from board staff, a principal duty would be to identify case scenarios that would be discussed during the course.

Sample Language that could be incorporated in the board's Disciplinary Guidelines is as follows:

> Within 60 calendar days of the effective date of this Decision, respondent shall enroll in a course in ethics, at respondent's expense, approved in advance by the Board, or its designee. Failure to successfully complete the course during the first year of probation is a violation of probation.
>
> Respondent shall submit a certificate of completion to the Board or its designee within 5 calendar days after completing the course.

ATTACHMENT

3

State of California Department of Consumer Affairs

Memorandum

To: Enforcement Committee Date: September 12, 2007

From: Board of Pharmacy

Subject: Veterinary Food-Animal Drug Self Assessment Form

At the January 2007 Board Meeting, the board voted to approve the addition of 16 CCR 1785 – Self Assessment of a Veterinary Food-Animal Drug Retailer.

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

Attached for committee review and comment is the draft self-assessment form. Based on the outcome of the committee meeting, the form will be presented at the October Board Meeting with the intent of obtaining board approval to move forward with the formal rulemaking process after the October Board Meeting.

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_____

_____

DRIC Initials _____

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)

Yes No N/A

☐☐☐ 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])

DRIC Initials _____

☐☐☐ 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])

☐☐☐ 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])

DRIC Initials _____

☐☐☐ 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)

CORRECTIVE ACTION OR ACTION PLAN_____

_____

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])

Yes No N/A

☐☐☐ 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])

DRIC Initials _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

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?
Yes	No	N/A	
☐	☐	☐	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_____

_____

DRIC Initials _____

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])

CORRECTIVE ACTION OR ACTION PLAN_____

_____

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])

Yes No N/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)

DRIC Initials _____

_____

_____

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?

☐☐☐ 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])

DRIC Initials _____

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])
☐	☐	☐	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_____

_____

DRIC Initials _____

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?

Yes	No	N/A	
☐	☐	☐	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)

DRIC Initials _____

☐☐☐ 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])

☐☐☐ 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?

☐☐☐ 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])

DRIC Initials _____

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_____

_____

DRIC Initials _____

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])

☐☐☐ 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

DRIC Initials _____

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])

DRIC Initials _____

Discontinuation of Business

Yes No N/A

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

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

Controlled substances (if applicable)

Yes No N/A

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

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

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

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

_____

_____

_____

DRIC Initials _____

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

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

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

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

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.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

4

Board of Pharmacy Enforcement Committee Statistics
Fiscal Year 2007/2008

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 07/08
Complaints/Investigations					
Initiated	257				257
Closed	286				286
Pending (at the end of quarter)	923				923
Application Investigations					
Initiated	47				47
Closed					
Approved	24				24
Denied	13				13
Total*	37				37
Pending (at the end of quarter)	197				197
Citation & Fine					
Issued	134				134
Citations Closed	89				89
Total Fines Collected	$89,970.00				$89,970.00

* This figure includes withdrawn applications.

** Fines collected and reports in previous fiscal year.

Inspections Completed					
Administrative Cases (by effective date of decision)					
Referred to AG's Office**	10				10
Pleadings Filed	17				17
Pending					
Pre-accusation	55				55
Post Accusation	61				61
Total***	135				135
Closed	13				13
Cost Recovery Collected	$37,519.00				$37,519.00

* This figure includes cases withdrawn

** This figure includes Citation Appeals

*** This figure includes Citation Appeals at he Attorney General's Office

As of September 1, 2007.

ATTACHMENT

5

State of California **Department of Consumer Affairs**

Memorandum

To: **ENFORCEMENT COMMITTEE** **Date: June 15, 2007**
Reissued: September 12, 2007

From: **SUSAN CAPPELLO**
Enforcement Coordinator
Board of Pharmacy

Subject: **Proposed Revisions to the Disciplinary Guidelines**

Enclosed with your enforcement committee packet is the suggested revision to the Disciplinary Guidelines for your review.

These guidelines are being revised to clarify language, ensure that terms and conditions are consistent for all license types (where appropriate), to define consequences for non-compliances and to include new terms of probation. Strikeouts indicate deleted language and underlines indicate new language.

Pharmacist/Intern Conditions; pages 34-56

Significant changes made to standard conditions are as follows:

- No Supervision of Interns, Serving as Pharmacist-in-Charge (PIC) or Designated Representative-in-Charge (DRIC), or Serving as a Consultant (pg 36) – better defines the language for this provision. Restricts the pharmacist from serving as DRIC in a wholesaler or veterinary food-animal drug retailer. *(NOTE: This term has not yet been updated to reflect the DRIC language)*
- Tolling of Probation (pg 38) -

Significant changes made to optional conditions:

- Pharmacist Examination (pg 40) – changed to reflect the new exam structure (CPJE & NAPLEX).
- Mental Health Examination (pg 41) – changes made to broaden the definition of the licensed health practitioner who can complete the mental health exam. Additionally, this term now better defines the condition under which the ongoing therapy must occur, if recommended.
- Psychotherapy (pg 43) - changes made to broaden the definition of the licensed health practitioner who can complete the mental health exam. Additionally, this term now better defines the condition under which the ongoing therapy must occur if recommended.
- Medical Evaluation (pg 44) – details more specifically the procedures to carry out this term.

- Pharmacists Recovery Program (pg 47) – this term now includes the automatic suspension for any confirmed positive test for drugs or alcohol under certain conditions and details the suspension provisions.
- Random Drug Screening (pg 49) - details more specifically the procedures to carry out this term.
- Abstain from Drugs and Alcohol Use (pg 49) – expands the definition of this term to include the prohibition of physical proximity to persons using illicit substances.
- Tolling of Suspension (pg 55) – details more specifically the procedures to carry out this term.

New optional terms and conditions of probation:

- Prescription Coordination and Monitoring of Prescription Use (pg 50) – this term will be recommended for individuals whose violations indicate chemical dependencies or psychiatric disorders. Designates a single health care practitioner to coordinate and monitor prescriptions. Also defines the procedures to carry out this term.
- Pharmacy Self-Assessment Mechanism (PSAM) (pg 52) – this term will be recommended to provide a self-assessment mechanism to aide the pharmacist in identifying deficient areas of practice.
- Surrender of DEA Permit (pg 56) – this term will be recommended for pharmacists to prevent him or her from prescribing.

Pharmacy Technician Conditions; pages 63-72

Significant changes made to standard conditions are as follows:

- Obey All Laws (pg 63) – this term will be recommended to make consistent with other license types.
- License Surrender While on Probation/Suspension (pg 66) - this term was relocated within the standard terms to be consistent with the other license types.

Significant changes made to optional conditions:

- Random Drug Screening (pg 69) - details more specifically the procedures to carry out this term.
- Abstain from Drugs and Alcohol Use (pg 70) – expands the definition of this term to include the prohibition of physical proximity to persons using illicit substances.
- Tolling of Suspension (pg 72) – details more specifically the procedures to carry out this term.
- Restitution (pg 72) – this term will be recommended for those cases where drug diversion, theft fraudulent billing or patient harm resulting from negligence or incompetence occurred.

Designated Representative Conditions; pages 80-91

Significant changes made to standard conditions are as follows:

- Reexamination Prior to Resuming Work – this term was deleted because an exam is no longer a requirement for licensure.
- Obey All Laws (pg 80) – this term will be recommended to make consistent with other license types.
- No Being Designated Representative-in-Charge (pg 83) – this term is similar to the No Being PIC and will be recommended to prohibit a designated representative from serving as a designated representative-in-charge in a wholesaler or veterinary food-animal drug retailer.
- License Surrender While on Probation/Suspension (pg 84) - this term was relocated within the standard terms to be consistent with the other license types.

Significant changes made to optional conditions:

- Random Drug Screening (pg 89) - details more specifically the procedures to carry out this term.
- Abstain from Drugs and Alcohol Use (pg 90) – expands the definition of this term to include the prohibition of physical proximity to persons using illicit substances.
- Tolling of Suspension (pg 91) – details more specifically the procedures to carry out this term.
- Restitution (pg 91) – this term will be recommended for those cases where drug diversion, theft fraudulent billing or patient harm resulting from negligence or incompetence occurred.

Premises Conditions; pages 115-120

Significant changes made to standard conditions are as follows:

- Posted Notice of Probation (pg 118) – this term will be recommended for all premises to post to alert the consumer of the discipline imposed by the board.

Summary of Written Comments Received from Ron Marks:

1. Posted Notice of Probation for Premises, page 118.

   "…. serves little public benefit for a pharmacy to post a notice of probation for the entire time of probation and would …..alarm customers resulting in the failure to the business or significant financial loss…..to check out a business customer can go to board's website."

   Response

   This term is recommended in order to provide another avenue in which to alert the consumer of the probationary status imposed by the board. The board currently requires a premise to post a notice of suspension, page 120.

2. Automatic Revocation of License for Missing Cost Recovery, pages 36-37.

   "….concerned about the optional condition of automatic revocation for missing a cost payment deadline."

   Response

   This is optional language that may be imposed either by the administrative law judge as part of a decision or by the board in cases of a settlement. The optional language is appropriate for this term, as compliance does not require judgment; probationer either is or is not making payments. Also, this option does not preclude the probationer from making a presentation of hardship or mitigating circumstances to the board's probation monitor or to the executive officer.

3. Automatic Suspension for Confirmed Positive test, page 47.

   "…concerned about a failed drug test. There should be some provision for having a drug sample re-tested. .."

   Response

   A confirmed positive test for alcohol or any drug does mean that the "failed" drug test had been retested and may have been retested more than once through an appropriate and reliable process as directed by the Board's Pharmacist Recovery Program (PRP). The board's statutory mandate is the protection of the public, this term allows that protection to occur by the automatic suspension of the license and allows the PRP the time needed to confirm when a licensee may safely resume the practice of pharmacy.

4. Notification of the Resumption of Practice After Suspension, page 28

...."Don't know why a licensee who is on suspension cannot resume working until notified by the Board. "

Response

The language on page 28 currently reads "As part of probation, respondent is suspended from the practice of pharmacy for _____, beginning the effective date of this decision. Respondent shall not resume the practice of pharmacy until notified by the board."

Before the effective date of the penalty, the board does notify the respondent in writing when their suspension begins and ends. Board staff feels that this initial notification is sufficient. It is planned to eliminate this sentence from the proposed suspension language.

5. No Supervision of Technicians, page 53.

..."concerns about the condition of probation that prohibits the supervision of pharmacy technicians. If a probationer cannot be a PIC or supervise technicians...he or she is precluded from about 99% of the jobs in California."

Response

Currently the standard term and condition for pharmacist-in-charge restrictions (page 36) states that respondent shall not supervise any intern pharmacist, be the pharmacist-in-charge..." The standard term does allow the respondent to supervise technicians.

The optional terms for pharmacist-in-charge, page 53, allows a respondent to be a PIC with a consultant. This term also allows the respondent to supervise technicians.

Optional term #31, page 53, does not allow a respondent to supervise ancillary personnel, including, but not limited to pharmacy technicians or designated representatives. This is an optional term, not a standard, and is employed by an ALJ or by the board in appropriate circumstances.

RONALD S. MARKS

A Professional Law Corporation

21900 Burbank Boulevard, Suite 300
Woodland Hills, California 91367
Telephone: (818) 347-8112
Facsimile: (818) 347-3834

June 15, 2007

Susan Cappello
State Board of Pharmacy
1625 North Market Blvd., Suite N 219
Sacramento, CA 95834

RE: PROPOSED DISCIPLINARY GUIDELINES

Dear Susan:

I'm not able to make the Enforcement Committee meeting on June 20th in Sacramento but I have some concerns about the Proposed Disciplinary Guidelines that I hope you can pass on.

I believe it serves little public benefit for a pharmacy to have to post a notice of probation for the entire time of probation which is typically three years. It might tend to unduly alarm customers resulting in the failure of the business or significant financial loss. If a customer is concerned enough to check out a pharmacy, they can go to the Board's website.

I am concerned about the optional condition of automatic revocation for missing a cost payment deadline. Aside from raising due process issues that will no doubt be litigated, it is too draconian. There is no ability to present mitigating circumstances. Another issue that concerns me is that there are no factors to consider in when to impose that optional condition. In other words, under what circumstances should an ALJ or the Board decide that a particular licensee should be subject to an automatic revocation? Should it be based on the underlying violation, the amount of the costs, the financial ability of the licensee to pay costs? How can there be any uniformity between ALJ's when there are no guidelines or factors to base the optional condition on?

I am similarly concerned about a failed drug test. There should be some provision for having a drug sample re-tested. I have been apprised of so many instances of false positive drug tests. A more sophisticated (and, of course, costly) test which would be recognized as more reliable should be utilized to confirm or dispute a failed sample. And, of course, any type of automatic action would be subject to due process challenges.

I don't know why a licensee who is on a suspension cannot resume working until notified by the Board. Suspensions are usually weeks or months and waiting for formal notification will just serve to extend suspensions in a random fashion. This may also involve a due process issue if the Board declines to notify the licensee that the suspension is over because of a suspected violation. The licensee could be subjected to an unwarranted lengthy suspension without notice and opportunity to be heard in violation of his due process rights.

I have had concerns for some time now about the condition of probation that prohibits the supervision of pharmacy technicians. If a probationer cannot be a PIC or supervise technicians, coupled with the fact that he or she is on probation, he or she is precluded from about 99% of jobs in California. With such a condition, probation is tantamount to a revocation. Since a probationer is usually prohibited from being a PIC, then there would be a PIC in a supervisory role. Technicians also have there own license to protect and therefore can act as informal monitors of the pharmacist on probation. There is little public protection to be gained and the condition makes it almost impossible for a probationer to find employment.

Thank you for allowing me to offer my thoughts on the proposed guidelines. I have more but I think these are my main concerns that the committee might want to consider.

Sincerely,

RONALD S. MARKS