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

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations Awaiting Notice

BOARD APPROVED REGULATIONS – AWAITING PUBLIC NOTICE

1. Proposed Repeal of 16 CCR §§ 1716.1 and 1716.2 and amendment to 16 CCR § 1751-1751.8 and adoption of 16 CCR §§1735-1735.8

At the January 2008 board meeting, the board conducted a regulation hearing to hear testimony about the regulation proposal that establishes requirements for pharmacies that compound medications. As a result of this regulation hearing, the board voted to complete a 15-day notice with revised language to address some of the written comments received and oral testimony provided. Staff anticipates initiating this 15-day comment period in advance of the April 2008 board meeting.

Currently, pharmacy law provides the authority for a pharmacist to compound drug products as well as compound sterile injectable products. As required in Business and Professions Code section 4127, the board adopted regulations to implement the provisions for pharmacies that compound sterile injectable products. There are no similar provisions in regulation to detail the requirements for pharmacies that complete general compounding. This proposal would establish guidelines to provide uniformity in compounding for California consumers.

2. Proposed Addition to 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.

A copy of the draft language and form is included in **ATTACHMENT C2.** Staff anticipate initiating the 45-day comment period in advance of the July Board Meeting to allow for action by the board at the July 2008 Meeting.

3. Proposed Amendment to 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 is seeking input from the pharmacy industry to highlight potential problems with referencing the 2005 edition of the USP Standards Reference Material. At the June 2007 committee meeting, Dr. Schell offered to facilitate a taskforce to review the USP Standards Reference Material.

4. Proposed Adoption of 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.

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

A copy of the language is provided in **ATTACHMENT C4.**

5. Proposed Amendment to 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 C5.**

Attachment – Agenda Item C2

16 CCR 1785 Self-Assessment of a Veterinary Food-Animal Drug Retailer

- Proposed Language
- Draft 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.

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

VETERINARY FOOD-ANIMAL DRUG RETAILER SELF ASSESSMENT

All legal references used throughout this self-assessment form are explained on Page 17
All references to "drugs" throughout this self–assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&P) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf) 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)

☐☐☐ 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])

DRIC Initials _____

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)

DRIC Initials _____

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])

☐☐☐ 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])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

DRIC Initials _____

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])

DRIC Initials _____

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])

☐☐☐ 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?

DRIC Initials _____

Yes No N/A

☐☐☐ All applicable federal regulations regarding the exportation of dangerous drugs?

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

_____

_____

CORRECTIVE ACTION OR ACTION PLAN_____

_____

12. Delivery of Drugs

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN_____

_____

13. Controlled Substances

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN_____

_____

14. Consultant Pharmacist

Yes No N/A

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

DRIC Initials _____

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_____

_____

DRIC Initials _____

17. Policies and Procedures

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

Yes	No	N/A	
☐	☐	☐	Handling of veterinary food animal drugs?
☐	☐	☐	Dispensing of veterinary food animal drug?
☐	☐	☐	Staff training records?
☐	☐	☐	Cleaning of equipment?
☐	☐	☐	Storage and maintenance of veterinary food –animal drugs?
☐	☐	☐	Storage and maintenance of equipment?
☐	☐	☐	Record keeping requirements?
☐	☐	☐	Storage requirements?
☐	☐	☐	Security requirements?
☐	☐	☐	Quality assurance?

CORRECTIVE ACTION OR ACTION PLAN_____

_____

18. Record Keeping Requirements

Purchase and Sales Records

Yes	No	N/A	
☐	☐	☐	Are all records of acquisition and disposition of dangerous drugs, retained on the premises, open for inspection, during regular business hours? (B&P 4081, 4332, CCR 1718)
☐	☐	☐	Are all prescription documents and other disposition records for dangerous drugs or extra label use drugs dispensed by a vet food-animal drug retailer kept on file and maintained on the premises for 3 years? (B&P 4198[b])
☐	☐	☐	Are all records of prescription refills retained by your business on the premises for 3 years? (CCR1780.1[I], B&P 4081[a], 4332)
☐	☐	☐	Are all purchase and sales records retained in a readily retrievable form? (B&P 4105[a])

Yes	No	N/A	
☐	☐	☐	Are records of shipment of labeled dangerous drugs to clients (also known as an expanded invoice) included in the client's shipment? This document includes: (CCR1780.1[i])
☐	☐	☐	Drug name?
☐	☐	☐	Quantity shipped?
☐	☐	☐	Manufacturer's name and lot number?

DRIC Initials _____

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])

DRIC Initials _____

Off-site storage waiver

Yes No N/A

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

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

_____

_____

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN_____

_____

19. Reporting Requirements to the Board

Ownership

Yes No N/A

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

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

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

DRIC Initials _____

Yes No N/A

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

Veterinarian

Yes No N/A

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

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

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

Consultant Pharmacist

Yes No N/A

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

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

Designated Representative in Charge/ Designated Representative

Yes No N/A

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

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

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

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)

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])

_____

_____

_____

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 – Agenda Item C4

16 CCR 1751.8 Accreditation Agencies for Pharmacies and Compound Injectable Sterile Drug Products

- Proposed Language

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 – Agenda Item C5

16 CCR 1721 & 1723.1 – Dishonest Conduct on a Pharmacist Licensure Examination/Confidentiality

- Proposed Language

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.

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

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulation Currently Noticed

Proposed Amendment to 16 CCR 17602 – Disciplinary Guidelines

The above regulation notice was published February 22, 2008 and the 45-day comment period ended April 7, 2008. This regulation was initially noticed without a hearing, as the board has held several information meetings. The board received a request for a hearing and as such, a hearing will be scheduled for the April 23 & 24, 2008 Board Meeting.

This rulemaking will allow the board to use the revised 2007 edition of this publication when deciding on appropriate disciplinary action to take for violations of Pharmacy Law. The proposal replaces the existing disciplinary guidelines with guidelines that are consistent with the requirements of Government Code section 11425.50(e).

The proposed changes to the Disciplinary Guidelines are necessary to incorporate changes that have occurred in pharmacy law since the last revision, 1/2001. These changes will ensure the consistent use of titles and terms between the Disciplinary Guidelines and the Pharmacy Law Book, remove outdated and unnecessary terms and conditions of probation and incorporate new changes as necessary to ensure rehabilitation of the licensees on probation to ensure the board's ability to meet its consumer protection mandate.

A copy of the language, notice and Initial Statement of Reasons is provided in **ATTACHMENT D**.

Board of Pharmacy
Specific Language

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

§1760. Disciplinary Guidelines.

In reaching a decision on a disciplinary action under the Administrative Procedure Act (Government Code section 11400 et seq.) the board shall consider the disciplinary guidelines entitled "Disciplinary Guidelines" (Rev. ~~1/2001~~ 10/2007), which are hereby incorporated by reference.

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

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

TITLE 16. Board of Pharmacy

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 7, 2008.

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office not later than 5 p.m. on March 24, 2008.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by section 4005 of the Business and Professions Code and section 11420 et seq. of the Government Code and to implement, interpret, and make specific sections 4300 and 4301 of the Business and Professions Code, and sections 11420.20 and 11425.50(e) of the Government Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined.

Government Code section 11420.20 authorizes the board to adopt regulations to govern an adjudicative proceeding.

Government Code section 11425.50(e) prohibits a penalty from being based upon a guideline unless the guideline has been adopted as a regulation.

16 California Code of Regulations Section 1760 incorporates by reference the Disciplinary Guidelines. Board staff, Deputy Attorneys General, Administrative Law Judges, licensees, and attorneys use these guidelines to assist in determining penalties

in the disciplinary case against board licensees. The board is proposing to update the "Disciplinary Guidelines" to conform with changes to the pharmacy law, to clarify some existing terms and conditions of probation that appear ambiguous, establish new terms and conditions necessary to ensure rehabilitation of licensees and remove terms no longer utilized or necessary in the interest of public protection.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states as it only affects licensees that have been disciplined by the board.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur unless that individual is licensed by the board and subject to disciplinary action by the board.

Effect on Housing Costs: None.

EFFECT ON SMALL BUSINESS

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business as it will only effect businesses licensed by the board that are subject to disciplinary action.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed or would be as effective

and less burdensome to affected private persons than the proposed action.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd. N219, Sacramento, California 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulation is based is contained in the rulemaking file, which is available for public inspection by contacting the person, named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the website listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Virginia Herold
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7911
Fax No.:	(916) 574-8618
E-Mail Address:	virginia_herold@dca.ca.gov

The backup contact person is:

Name:	Karen Cates
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7914
Fax No.:	(916) 574-8618

E-Mail Address: karen_cates@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.

Board of Pharmacy

Initial Statement of Reasons

Subject Matter of Proposed Regulation: Disciplinary Guidelines

Sections Affected: Amend 1760

Specific Purpose of the Proposed Changes:

The Board of Pharmacy proposes to amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to update the Disciplinary Guidelines that are incorporated by reference in section 1760.

The board uses disciplinary guidelines when taking action to suspend, revoke or place a license on probation. The proposal would replace the existing disciplinary guidelines with guidelines that are consistent with the requirements of Government Code section 11425.50(e).

The proposed changes to the Disciplinary Guidelines are necessary to incorporate changes that have occurred in pharmacy law since the last revision, 1/2001, to ensure the consistent use of titles and terms between the Disciplinary Guidelines and the Pharmacy Law Book, to remove outdated and unnecessary terms and conditions of probation and to incorporate new changes necessary to ensure rehabilitation of the licensees on probation to ensure the board's ability to meet its consumer protection mandate.

A summary of the proposed changes is below.

Title Page

Update the contact information for the board.

Table of Contents

Replace the term "exemptee" with designated representative. In 2004, Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. In addition the page numbers to be updated to reflect the new location of items.

Introduction

Changes are proposed to provide clarification and allow for easier reading and consistency.

Factors to be Considered in Determining Penalties

Changes are proposed to incorporate the various levels of previous action the board may have taken against a licensee and now will require the board to also consider aggravating evidence, as well as compliance with parole or probation, when determining whether the minimum, maximum or an intermediate penalty should be imposed.

Mitigating Evidence

Changes are proposed to this section to further define and clarify examples of appropriate evidence a respondent may submit to demonstrate rehabilitative efforts and competency.

Terms of Probation – Pharmacist/Intern Pharmacist

Categories of Violations and Recommended Penalties

The proposed changes to better define the grounds for discipline as well as to explain the structure under each category as well as how the board should use the information provided. This will assist users in following the format of the Disciplinary Guidelines and serve as a tool to assist in the penalties imposed as part of a disciplinary action.

Category 1

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user in the use of the Disciplinary Guidelines.

B&PC 4052.1, 4052.5 and 4052.7 are added to category 1 violations as a result of recodification of section 4052 included in Assembly Bill 2408 (Chapter 777, Statutes of 2006).

B&PC 4055 was not included in the previous revision of the Disciplinary Guidelines, rev. 1/2001.

B&P 4068 was added to statute in Section Bill 1913 (Chapter 695, Statutes of 2004) and is now being included.

B&PC 4102 was repealed in Assembly Bill 586 (Chapter 501, Statutes of 2001) and therefore is being removed.

B&PC 4146 was repealed in Senate Bill 1159 (Chapter 608, Statutes of 2004) and therefore is being removed.

CCR 1712 was added to regulation effective 10/2005 and is being added.

CCR 1727 was repealed effective 10/2005 and therefore is being removed.

CCR 1746 was added to regulation effective 12/2004 and is being added.

CCR 1751 – 1751.12 was added to regulation effective 10/2004 and is being added.

H&SC 11124 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 111225 – 111655 are being moved from the "Miscellaneous – Health and Safety Code, Title 22" to be consolidated with all other Health and Safety Code references.

CFR 1304.11 was inadvertently not included in previous versions of the Disciplinary Guidelines

CFR 1304.18 was renumbered to CFR 1304.21.

CFR 1305.03 – 1305.16 are changing as a result of renumbering that occurred in 2005 to include allowing electronic orders on controlled substances. Changes to relevant sections of the CFR are necessary to reflect the renumbering that occurred as part of this process.

16 CFR 1700.1 to 1707.15 is being moved from "Miscellaneous – Federal Regulations" to be consolidated with all other Code of Federal Regulations references.

Category II

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one the published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

B&PC 650, 650.1 and 651 were not included in the previous version of the

"Disciplinary Guidelines rev 1/2001."

Section 4125 was added to statute in Senate Bill 1399 (Chapter 677, Statutes of 2000) and is now being included.

B&PC 4169(a)(1) was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

CCR 1717.2 was repealed effective March 2007.

CCR 1793.1 – 1793.7 are now being listed as individual references.

CCR 1793.8 allows for a specially trained pharmacy technician to check the work of another technician in the acute care pharmacy setting and was added to regulation effective January 2007.

H&SC 11123, 11124, 11125, 11128, 11129, 11130 & 11131 were repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and are being removed.

H&SC 150205 was added to statute in SB 798 (Chapter 444, Statues of 2005) to authorize a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

Category III

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

B&PC 4034 establishes the pedigree requirement and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4085 makes it unlawful to remove, sell, or dispose of embargoed drugs and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4059.5 establishes requirements for the acquisition and disposition of dangerous drugs and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4169(a)(2) to 4169(a)(5) defines prohibited acts and was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4380 prohibits the resale of preferentially priced drugs and provides some exceptions. This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

CCR 1707 establishes the waiver requirements to allow for off-site storage of records and became effective in October 2000.

CCR 1771 – 1774 are now being listed as individual references.

H&SC 11122 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 11167.5 allows for an oral or electronic prescription for Schedule II controlled substances for specified patients and was not included in the previous version of the "Disciplinary Guidelines, rev. 1/2001."

H&SC 111295 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111300 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111305 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111440 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111445 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111450 was inadvertently not included in the previous version of the Disciplinary Guidelines.

Category IV

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as

the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

Model Disciplinary Language – Pharmacist/Intern Pharmacist

Revocation: This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same.

Suspension: This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation.

Standard Stay/Probation Order: This section is clarifying that a license is revoked, but the revocation stayed.

Issuance of Probationary License: The changes in this section are for clarification only and do not establish new requirements.

Surrender: The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to correct the reference to the Office of the Attorney General.

Standard Conditions Listing: Changes to titles to ensure consistency and clarification.

Optional Conditions Listing: Changes to titles to ensure consistency and clarification and include new terms that will be incorporated.

Standard Conditions: To Be Included in All Probations

1. Obey all Laws: Specifies that failure to comply with the suspension will be considered a violation of probation.
2. Reporting to the Board: Clarifies the reporting requirement.
3. Interview with the Board: Clarifies the language and specifies that failure to appear at two or more scheduled interviews will be considered a violation of probation.
4. Cooperate with board Staff: Grammatical changes only.
5. Continuing Education: Specifies that the respondent must provide proof to the board or now its designee.

6. Notice to Employers: Clarifies who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the probationer to ensure that appropriate documentation is submitted to the board confirming compliance with requirement. In addition, changes specify that failure to comply will be considered a violation of probation.
7. No Supervision of Interns, Pharmacist-in-Charge (PIC), Serving as Designated Representative-in-Charge or Serving as a Consultant: The proposed changes will now also prohibit a respondent from serving as a designated representative-in-charge or a consultant. In addition, changes specify that failure to comply will be considered a violation of probation.
8. Reimbursement of Board Costs: Clarifies that costs must be paid prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
9. Probation Monitoring Costs: Clarifies the requirements and changes it from an annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
10. Status of License: Specifies that failure to comply will be considered a violation of probation and clarifies the intent of the term of probation.
11. License Surrender While of Probation: Specifies that surrender under this term would constitute a record of discipline and will become a part of the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication.
12. Notification of a Change in Name, Residence Address. Mailing Address or Employment Changes: Changes the title of the term, clarifies the requirement and specify that failure to comply will be considered a violation of probation.
13. Tolling of Probation: The changes proposed are designed to clarify the intent of this term. Specifically, a key component during a probationary term is monitoring of the respondent to ensure that necessary changes in his or her practice are occurring to eliminate subsequent violations. This monitoring can only occur if the board has the ability to monitor the respondent while working in pharmacy. The revised term strikes a balance between the needs of the respondent to meet individual employment needs, e.g. part-time work, while allowing the board sufficient opportunity to monitor the respondent at the worksite. An additional option is suggested to allow further flexibility with this term. In addition, changes specify that failure to comply will be considered a violation of probation.
14. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
15. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

Optional Conditions of Probation
All of the Optional Conditions are renumbered.

16. Restricted Practice: Provides an option to prohibit the preparation of sterile injectable products during a specified period of probation and states that failure to comply will be considered a violation of probation. This option is necessary for violations that are specific to the preparation of sterile injectable products, especially when the violations are competency based. These products pose an additional, considerable risk to consumers.
17. Pharmacist Examination: In 2004, the board changed the licensing examination for pharmacist. These changes were added into statute in Senate Bill 361 (Chapter 539, Statutes of 2003). This term requires updating to reflect the changes in these requirements and clarify the timeframes to comply with the requirement. For licensing purposes, these exams are used by the board to assess the minimum competence of an applicant prior to issuance of a license. Pharmacy law requires that an applicant who fails to pass the examinations as specified is required to complete 16 units of remedial pharmacy education prior to being requalified for the exam. This term now places a similar requirement on certain respondents and specifies that a failure to take and pass the exam within four attempts will require the respondent to complete additional pharmacy education. In addition, changes specify that failure to comply will be considered a violation of probation.
18. Mental Health Examination: Replaces "psychiatrist or psychotherapist" with "licensed mental health practitioner." Clarifies the intent of the term, which is to require a mental health examination by a licensed mental health practitioner and require compliance with any recommendations for treatment made by the mental health practitioner. The term now specifies the timeframes for compliance as well as the frequency of treatment but allows the board's designee flexibility to modify the frequency as necessary. In addition, the respondent will now be required to provide a copy of the accusation or petition to revoke probation and the decision to the licensed mental health practitioner in advance of an examination, as well as prior to beginning or resuming therapy with a practitioner. The term also clarifies that a respondent will be automatically suspended from practice if the mental health practitioner deems the respondent unable to practice safely as a pharmacist or intern pharmacist. In addition, changes specify that failure to comply will be considered a violation of probation.
19. Psychotherapy: Clarifies the process to comply with this term as well as the documentation required to confirm compliance. The term also clarifies that a respondent will be automatically suspended from practice if the mental health practitioner deems the respondent unable to practice safely as a pharmacist or intern pharmacist and defines the parameters of the suspension. In addition, changes specify that failure to comply will be considered a violation of probation.
20. Medical Evaluation: Requires the respondent to provide a copy of the accusation or petition to revoke probation and the decision to the approved physician and details the process to comply with this term. The term also

clarifies that a respondent will be automatically suspended from practice if the physician deems the respondent is unable to practice safely as a pharmacist or intern pharmacist and defines the parameters of the suspension. In addition, changes specify that failure to comply will be considered a violation of probation.

21. Pharmacists Recovery Program (PRP): The title is changed to reflect the name of the rehabilitation program required and established in pharmacy law. In addition, the term now specifies that failure to comply will be considered a violation of probation and states that any confirmed positive test for alcohol or drugs will result in the automatic suspension of practice. This change is necessary to provide the board with the ability to immediate remove a respondent from practice and is essential for consumer protection. The term specifies the parameters for suspension and requires that a respondent pay administrative fees as invoiced by the PRP and that failure to do so will be considered a violation of probation.
22. Random Drug Screening: Clarifies the intent of the requirement, which is to require the respondent to submit to random drug screenings, a tool used to confirm an individual's sobriety. In addition, the term now specifies that the respondent will need to submit timely documentation of prescription drugs that are legitimately prescribed as part of treatment and that failure to provide such documentation will be considered a violation of probation. The term currently allows for the automatic suspension for a positive drug screen. The proposed language clarifies the conditions under which a suspension would occur and now specifies the parameters for suspension.
23. Abstain from Drugs and Alcohol Use: Clarifies that a board designee may request documentation of medical treatment on behalf of the board and also states that failure to provide such documentation as requested will be considered a violation of probation. Additionally, the term specifies that a respondent shall not be in the same physical location as individuals who are using illicit substances and that any physical proximity to persons using illicit substances will also be considered a violation of probation.
24. Prescription Coordination and Monitoring of Prescription Use: This is a new term that should be considered for inclusion in a probationary order when the violations indicate chemical dependency or psychiatric disorders may be a cause for the discipline. This term requires that the respondent provide the board with the name of a single practitioner, as defined, who will be familiar with the respondent's history and will coordinate and monitor any prescriptions for the respondent. The term establishes a reporting requirement and details the procedures for compliance with this section. In addition, should the practitioner at any time determine that the respondent is unable to practice safely or independently; the respondent will be automatically suspended. The parameters for the suspension are also set forth and failure to comply with the suspension will be considered a violation of probation.
25. Community Service: Clarifies the process by which this term is implemented and specifies that failure to comply will be considered a violation of probation.
26. Restitution: Specifies that failure to comply will be considered a violation of

probation.

27. Remedial Education: Specifies that a respondent may be required to take an approved examination at the direction of the board or its designee and clarifies that if the respondent does not achieve a passing score, it will be considered a violation of probation. In addition, the term now requires that any failed examination will result in the respondent taking another course approved by the board in the same subject area.
28. Pharmacy Self-Assessment Mechanism: Creates an optional term that requires the respondent to complete the Pharmacist Self-Assessment Mechanism (PSAM) and to submit a record of the completion. Specifies that failure to complete the PSAM and submit documentation will be considered a violation of probation. In addition, two options are also provided; one to allow the board or its designee access to the examination results, and the second to require the respondent to provide the examination results and to allow the board to determine appropriate courses in remedial education to address areas of competency deficiency.
29. Intern Pharmacist Experience: Changes the title to conform to pharmacy law. In addition, nonsubstantive changes are made to define the process and now specifies that failure to comply with be considered a violation of probation.
30. Supervised Practice: Clarifying changes are made to better define the implementation and process used to carry out this term and to specify that a respondent's license will be automatically suspended until the board or its designee approves a supervisor. The term now specifies that it is the respondent's responsibility to ensure that employer(s), pharmacist(s)-in-charge and/or supervisor(s) provide necessary acknowledgements to the board and specifies that failure to comply with the terms shall be considered a violation of probation. The term specifies the parameters for suspension.
31. No Supervision of Ancillary Personnel: Rewords term to ensure consistent use of terms between pharmacy law and the guidelines as well as specifies that failure to comply will be considered a violation of probation.
32. No Ownership of Licensed Premises: Adds trustee to the list of prohibited roles the respondent make assume while on probation. In addition, specifies that failure to comply will be considered a violation of probation.
33. Separate File of Records: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
34. Report of Controlled Substances: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
35. No Access to Controlled Substances: Clarifies that the optional term applies during the period of probation as directed by the board or its designee, replaces the term "triplicate" with "security" in conformance with changes in pharmacy law, and specifies that failure to comply will be considered a violation of probation.

36. Criminal Probation/Parole Reports: Specifies that failure to comply will be considered a violation of probation.
37. Consultant for Owner or Pharmacist-in-Charge: Clarifies when option 1 and option 2 apply and specifies that the term applies during the period of probation, includes the use of a board designee and specifies that failure to comply will be considered a violation of probation.
38. Tolling of Suspension: Rewords the term to better define the provision and the parameters used to implement.
39. Surrender of DEA Permit: Creates a term that requires the respondent to surrender his or her federal DEA permit for cancellation and requires that the respondent provide documentation substantiating the surrender. It further prohibits the respondent from seeking a DEA registration number without prior consent of the board or its designee. In addition two options are created. The first allows for a respondent to obtain a DEA permit that is restricted to specified schedule(s) of controlled substances. The second option prohibits the respondent from ordering, receiving or retailing any federal order forms for controlled substances.
40. Ethics Course: Creates a new term that requires the respondent to enroll in a course of ethics that is approved by the board or its designee. In addition the term specifies that failure to initiate the course during the first year or probation and complete it within the second year is considered a violation of probation.

Model Disciplinary Language Pharmacy Technician

Revocation: This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same. In addition, the Option language is being clarified and the certification requirement is now referencing the appropriate Business and Professions Code section.

Suspension: This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation. In addition it consolidates language from the previous version's "Optional Conditions of Probation."

Standard Stay/Probation Order: This section is clarifying that a license is revoked, but the revocation stayed.

Issuance of Probationary License: This term is being added to the Model Disciplinary Language for Pharmacy Technicians and mirrors the language for a similar term used for pharmacist and intern pharmacist.

Surrender: The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to correct the reference to the Office of the Attorney General.

Standard Conditions: To Be Included in All Probations

1. Certification Prior to Resuming Work: This existing term requires the respondent to be certified as specified prior to resuming work as a pharmacy technician. The changes not reference the legal citation, which specify the certification requirements. Additionally, the term now specifies that failure to comply with the term is considered a violation of probation.
2. Obey All Laws: Specifies the reporting timeframes and process for complying with this term and states that failure to comply will be considered a violation of probation.
3. Report to the Board: Specifies that the reports to the board are to be submitted based on a scheduled directed by the board or its designee and states that failure to submit reports as directed will be considered a violation of probation. The term also states that any period of delinquency in submitting the reports may be added to the total period of probation.
4. Interview with the Board: Clarifies the language and specifies that failure to appear at two or more scheduled interviews will be considered a violation of probation.
5. Cooperate with Board Staff: Cooperate with board Staff: Grammatical changes only.
6. Notice to Employers: Clarifies who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the respondent to ensure that appropriate documentation is submitted to the board confirming compliance with requirement. In addition, changes specify that failure to comply will be considered a violation of probation.
7. Reimbursement of Board Costs: Clarifies that costs must be paid prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
8. Probation Monitoring Costs: Clarifies the requirements and changes it from an annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
9. Status of License: Specifies that failure to comply will be considered a violation of probation and clarifies the intent of the term of probation.
10. License Surrender While on Probation/Suspension: Specifies that surrender under this term would constitute a record of discipline and will become a part of

the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication.

11. Notification of a Change in Name, Residence Address, Mailing Address or Employment: Changes the title of the term, clarifies the requirement and specify that failure to comply will be considered a violation of probation.
12. Tolling of Probation: The changes proposed are designed to clarify the intent of this term. Specifically, a key component during a probationary term is monitoring of the respondent to ensure that necessary changes in his or her practice are occurring to eliminate subsequent violations. This monitoring can only occur if the board has the ability to monitor the respondent while working in pharmacy. The revised term strikes a balance between the needs of the respondent to meet individual employment needs, e.g. part-time work, while allowing the board sufficient opportunity to monitor the respondent at the worksite. An additional option is suggested to allow further flexibility with this term. In addition, changes specify that failure to comply will be considered a violation of probation.
13. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
14. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

Option Conditions of Probation
All of the Optional Conditions are renumbered.

Actual Suspension: This term was consolidated under the Model Disciplinary Language – Pharmacy Technician

15. No Ownership of Licensed Premises: Adds trustee to the list of prohibited roles the respondent make assume while on probation. In addition, specifies that failure to comply will be considered a violation of probation.
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups: Offers a monitoring and recovery model for technicians when the case involves chemical dependency (alcohol,drugs) and clarifies that failure to attend or submit documentation of compliance with this term will be considered a violation of probation. This requirement is necessary as pharmacy technicians do not qualify for participation in the Pharmacist Recovery Program.
17. Random Drug Screening: Clarifies the intent of the requirement, which is to require the respondent to submit to random drug screenings, a tool used to confirm an individual's sobriety. In addition, the term now specifies that the respondent will need to submit timely documentation of prescription drugs that are legitimately prescribed as part of treatment and that failure to provide such documentation will be considered a violation of probation. The term currently allows for the automatic suspension for a positive drug screen. The proposed language clarifies the conditions under which a suspension would

occur and now specifies the parameters for suspension.

18. Work Site Monitor: Clarifies that the respondent is responsible to ensure that required reports are submitted and specifies that failure to identify an acceptable initial or replacement worksite monitor, or to ensure that quarterly reports are submitted will be considered a violation of probation.
19. Notification of Departure: Clarifies that such notification much occur prior to leaving a geographic area as defined by the board or its designee and states that failure to comply with the provision will be considered a violation of probation.
20. Abstain from Drugs and Alcohol: Clarifies that a board designee may request documentation of medical treatment on behalf of the board and also states that failure to provide such documentation as requested will be considered a violation of probation. Additionally, the term specifies that a respondent shall not be in the same physical location as individuals who are using illicit substances and that any physical proximity to persons using illicit substances will also be considered a violation of probation.
21. Tolling of Suspension: Rewords the term to better define the provision and the parameters used to implement.
22. Restitution: Creates a term that requires the respondent to pay restitution within a specified time frame for a specified amount and states that failure to comply will be considered a violation of probation.

Model Disciplinary Language Designated Representative

Throughout this section the term "exemptee" is replaced with the term "designated representative." In 2004 Senate Bill 1307 (Chapter 857, statutes of 2004) replaced the term "exemptee" with "designated representative" in pharmacy law, effective January 1, 2006. This section requires an amendment to ensure consistency with the Business and Professions Code.

Revocation: This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same. In addition, the Option language is being clarified and the certification requirement is now referencing the appropriate Business and Professions Code section.

Suspension: This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation. In addition it consolidates language from the previous version's "Optional Conditions of Probation."

Standard Stay/Probation Order: This section is clarifying that a license is revoked, but the revocation stayed.

Issuance of Probationary License: This term is being added to the Model Disciplinary Language for Pharmacy Technicians and mirrors the language for a similar term used for pharmacist and intern pharmacist.

Surrender: The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to correct the reference to the Office of the Attorney General.

Standard Conditions: To Be Included in All Probations
Because of the deletion and creation of new terms, standard conditions are being renumbered.

Certification Prior to Resuming Work: This term is being deleted

1. Obey All Laws: Specifies the reporting requirements, timeframes and process for complying with this term and states that failure to comply will be considered a violation of probation.
2. Report to the Board: Specifies that the reports to the board are to be submitted based on a scheduled directed by the board or its designee and states that failure to submit reports as directed will be considered a violation of probation. The term also states that any period of delinquency in submitting the reports may be added to the total period of probation.
3. Interview with the Board: Clarifies the language and specifies that failure to appear at two or more scheduled interviews will be considered a violation of probation.
4. Cooperate with Board Staff: Grammatical changes only.
5. Notice to Employers: Clarifies who the respondent must notify of the terms and conditions of probation imposed as well as the responsibility of the respondent to ensure that appropriate documentation is submitted to the board confirming compliance with requirement. In addition, changes specify that failure to comply will be considered a violation of probation.
6. No Being Designated Representative-in-Charge: Creates a term that prohibits the respondent from serving as the designated representative-in-charge unless otherwise specified in the order and that failure to comply will be considered a violation of probation.
7. Reimbursement of Board Costs: Clarifies that costs must be paid prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
8. Probation Monitoring Costs: Clarifies the requirements and changes it from an

annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.

9. Status of License: Specifies that failure to comply will be considered a violation of probation and clarifies the intent of the term of probation.
10. License Surrender While on Probation/Suspension: Moves this term and rewords to specify that surrender of the respondent's license under this term would constitute a record of discipline and will become a part of the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication.
11. Notification of a Change in Name, Residence Address, Mailing Address or Employment: Changes the title of the term, clarifies the requirement and specify that failure to comply will be considered a violation of probation.
12. Tolling of Probation: The changes proposed are designed to clarify the intent of this term. Specifically, a key component during a probationary term is monitoring of the respondent to ensure that necessary changes in his or her practice are occurring to eliminate subsequent violations. This monitoring can only occur if the board has the ability to monitor the respondent while working in pharmacy. The revised term strikes a balance between the needs of the respondent to meet individual employment needs, e.g. part-time work, while allowing the board sufficient opportunity to monitor the respondent at the worksite. An additional option is suggested to allow further flexibility with this term. In addition, changes specify that failure to comply will be considered a violation of probation.
13. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
14. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

Option Conditions of Probation

All of the Optional Conditions are renumbered.

Actual Suspension: This term was consolidated under the Model Disciplinary Language – Pharmacy Technician

15. No Ownership of Licensed Premises: Adds trustee to the list of prohibited roles the respondent make assume while on probation. In addition, specifies that failure to comply will be considered a violation of probation.
16. Attend Substance Abuse Recovery Relapse Prevention and Support Groups: Offers a monitoring and recovery model for technicians when the case involves chemical dependency (alcohol,drugs) and clarifies that failure to attend or submit documentation of compliance with this term will be considered a violation of probation. This requirement is necessary as pharmacy technicians do not qualify for participation in the Pharmacist Recovery Program.
17. Random Drug Screening: Clarifies the intent of the requirement, which is to require the respondent to submit to random drug screenings, a tool used to

confirm an individual's sobriety. In addition, the term now specifies that the respondent will need to submit timely documentation of prescription drugs that are legitimately prescribed as part of treatment and that failure to provide such documentation will be considered a violation of probation. The term currently allows for the automatic suspension for a positive drug screen. The proposed language clarifies the conditions under which a suspension would occur and now specifies the parameters for suspension.

18. Work Site Monitor: Clarifies that the respondent is responsible to ensure that required reports are submitted and specifies that failure to identify an acceptable initial or replacement worksite monitor, or to ensure that quarterly reports are submitted will be considered a violation of probation.
19. Notification of Departure: Clarifies that such notification much occur prior to leaving a geographic area as defined by the board or its designee and states that failure to comply with the provision will be considered a violation of probation.
20. Abstain from Drugs and Alcohol: Clarifies that a board designee may request documentation of medical treatment on behalf of the board and also states that failure to provide such documentation as requested will be considered a violation of probation. Additionally, the term specifies that a respondent shall not be in the same physical location as individuals who are using illicit substances and that any physical proximity to persons using illicit substances will also be considered a violation of probation.
21. Tolling of Suspension: Rewords the term to better define the provision and the parameters used to implement.
22. Restitution: Creates a term that requires the respondent to pay restitution within a specified time frame for a specified amount and states that failure to comply will be considered a violation of probation.

Terms of Probation for Premises

Changes are proposed to provide clarification and allow for easier reading and consistency.

Categories of Violations and Recommended Penalties

The proposed changes to better define the grounds for discipline as well as to explain the structure under each category as well as how the board should use the information provided. This will assist users in following the format of the Disciplinary Guidelines and serve as a tool to assist in the penalties imposed as part of a disciplinary action.

Category 1

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into

the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user in the use of the Disciplinary Guidelines. Changes in the titles only are not listed below.

B&PC 4102 was repealed in Assembly Bill 586 (Chapter 501, Statutes of 2001) and therefore is being removed.

B&PC 4120 was incorrectly referenced in the previous version of the document and the correct reference was inadvertently not included.

B&PC 4146 was repealed in Senate Bill 1159 (Chapter 608, Statutes of 2004) and therefore is being removed.

B&PC 4180 - This section currently makes reference to B&PC 4182. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4180.

B&PC 4181 - This section currently makes reference to B&PC 4183. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4180.

B&PC 4231 - This section currently makes reference to B&PC 4233. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4231.

B&PC 4232 - This section currently makes reference to B&PC 4234. This reference is incorrect and needs to be changed to the appropriate reference, B&PC 4232.

CCR 1727 was repealed in October 2005.

CCR 1751 – 1751.12 was added to regulation effective 10/2004 and is being included into this version of the document.

H&SC 11124 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 111225 – 111655 are being moved from the "Miscellaneous – Health and Safety Code, Title 22" to be consolidated with all other Health and Safety Code references.

CFR 1301.78 was repealed and therefore is no longer required.

CFR 1304.11 was inadvertently not included in previous versions of the Disciplinary Guidelines

CFR 1304.18 was renumbered to CFR 1304.21.

CFR 1305.03 – 1305.16 are changing as a result of renumbering that occurred in 2005 to include allowing electronic orders on controlled substances. Changes to relevant sections of the CFR are necessary to reflect the renumbering that occurred as part of this process.

CFR 1306.25 This section currently makes reference to Section 1306.26 of the Code of Federal Regulations. This reference is incorrect and needs to be changed to the appropriate CFR section, 1306.25.

16 CFR 1700.1 to 1707.15 is being moved from "Miscellaneous – Federal Regulations" to be consolidated with all other Code of Federal Regulations references.

Category II

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines. Changes in the titles only are not listed below.

B&PC 650, 650.1 and 651 were not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4104 - This section currently makes reference to B&PC 4106. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4104.

B&PC 4105 - This section currently makes reference to B&PC 4107. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4105.

B&PC 4112 - This section currently makes reference to B&PC 4113. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4113.

B&PC 4115 - This section currently makes reference to B&PC 4116. This reference is incorrect and needs to be changed to the appropriate B&PC section,

4115.

B&PC 4125 was added to statute in Senate Bill 1399 (Chapter 677, Statutes of 2000) and is now being included.

B&PC 4169 was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4305 - This section currently makes reference to B&PC 307 This reference is incorrect and needs to be changed to the appropriate B&PC section, 4305.

B&PC 4306 This section currently makes reference to B&PC 4308. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4306.

B&PC 4381 is being removed as a violation of this section is not grounds for discipline.

16 CCR 1715 corrects an incorrect reference to made to 16CCR 1716 in the previous version of the disciplinary guidelines

16 CCR 1775.3 corrects an incorrect reference to made to 16CCR 1775.4 in the previous version of the disciplinary guidelines

16 CCR 1782 corrects an incorrect reference to made to 16CCR 1784 in the previous version of the disciplinary guidelines

16 CCR 1783 corrects an incorrect reference to made to 16CCR 1785 in the previous version of the disciplinary guidelines

CCR 1793.1 – 1793.7 are now being listed as individual references.

CCR 1793.8 allows for a specially trained pharmacy technician to check the work of another technician in the acute care pharmacy setting and was added to regulation effective January 2007.

H&SC 11123, 11124, 11125, 11128, 11129, 11130 & 11131 were repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and are being removed.

H&SC 11123, 11124, 11125, 11128, 11129, 11130 & 11131 were repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and are being removed.

21 CFR 1306.08 was repealed.

Category III

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines. Changes in the titles only are not listed below.

B&PC 4059 - This section currently makes reference to B&PC 4060. This reference is incorrect and needs to be changed to the appropriate B&PC section, 4113.

B&PC 4085 makes it unlawful to remove, sell, or dispose of embargoed drugs and was added into statute in Senate Bill 1307 (Chapter 857, Statutes of 2004).

B&PC 4169 was amended in Senate Bill 1476 (Chapter 658, Statutes of 2006). This reference was not included in the previous version of the "Disciplinary Guidelines rev 1/2001."

B&PC 4335 was inadvertently not included in the previous version of the disciplinary guidelines

B&PC 4336 was inadvertently not included in the previous version of the disciplinary guidelines.

B&PC 4380 was inadvertently not included in the previous version of the disciplinary guidelines.

CCR 1771 – 1774 are now being listed as individual references.

H&SC 11122 was repealed in Senate Bill 2026 (Chapter 1013, Statutes of 2002) and is being removed.

H&SC 11167.5 allows for an oral or electronic prescription for Schedule II controlled substances for specified patients and was not included in the previous version of the "Disciplinary Guidelines, rev. 1/2001."

H&SC 111295 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111300 was inadvertently not included in the previous version of the

Disciplinary Guidelines.

H&SC 111305 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111440 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111445 was inadvertently not included in the previous version of the Disciplinary Guidelines.

H&SC 111450 was inadvertently not included in the previous version of the Disciplinary Guidelines.

Category IV

The majority of the changes reflected in this section are to titles associated with each section of law. These titles are designed to allow the reader brief insight into the requirements detailed in the specific sections. These titles have no force of law. However, at least one published version of the pharmacy law book, as well as the compilation of pharmacy laws provided on the board's Web site, contains brief titles to assist users. These changes are necessary to aid the user of the Disciplinary Guidelines.

Model Disciplinary Language – Premises

Revocation: This section is being consolidated to include revocations for single and multiple causes under a single term, as the penalty is the same. In addition, the Option language is being clarified and the certification requirement is now referencing the appropriate Business and Professions Code section.

Suspension: This section is being expanded to better define the parameters of the suspension and specifies that failure to comply with the suspension will be considered a violation of probation. In addition it consolidates language from the previous version's "Optional Conditions of Probation."

Standard Stay/Probation Order: This section is clarifying that a license is revoked, but the revocation stayed.

Issuance of Probationary License: This term is being added to the Model Disciplinary Language for Pharmacy Technicians and mirrors the language for a similar term used for pharmacist and intern pharmacist.

Surrender: The changes specify that surrender of the license constitutes the imposition of discipline and specifies general criteria for reinstatement and makes other clarifying

changes.

Public Reprimand: The proposed language now specifies that the respondent is required to report the reprimand as a disciplinary action.

Adoption of Stipulation: Change is to specify that the respondent owner understands the provisions of adoption of a stipulation

Standard Conditions: To Be Included in All Probations
Because of the deletion and creation of new terms, standard conditions are being renumbered.

1. Obey All Laws: Specifies the reporting requirements, timeframes and process for complying with this term and states that failure on the part of the owner to comply will be considered a violation of probation.
2. Report to the Board: Specifies that the owner must report to the board are to be submitted based on a scheduled directed by the board or its designee and states that failure to submit reports as directed will be considered a violation of probation. The term also states that any period of delinquency in submitting the reports may be added to the total period of probation.
3. Interview with the Board: Clarifies the language and specifies that failure of the owner to appear at two or more scheduled interviews will be considered a violation of probation.
4. Cooperate with Board Staff: Clarifies that the owner is responsible to comply with this requirement and makes grammatical changes.
5. Reimbursement of Board Costs: Clarifies that the owner must pay costs prior to successful completion of probation and prior board approval must be obtained to deviate from the cost recovery payment schedule established. In addition, changes specify that failure to comply will be considered a violation of probation. An optional component to allow for the automatic revocation of the license of an individual who fails to comply with any directed payment will also be included for board consideration when imposing terms and conditions.
6. Probation Monitoring Costs: Clarifies that the owner is responsible for costs and clarifies the requirements and changes it from an annual basis to a schedule as directed by the board. In addition, changes specify that failure to comply will be considered a violation of probation.
7. Status of License: Specifies that failure on the part of the owner to comply will be considered a violation of probation and clarifies the intent of the term of probation.
8. License Surrender While of Probation: Specifies that surrender of the license by the owner under this term would constitute a record of discipline and will become a part of the respondent's license history with the board. In addition, it clarifies general requirements of surrender and reapplication
9. Notice to Employees: Clarifies that the owner is responsible for compliance with

this term and clarifies the reporting requirement. In addition it specifies that failure to comply will be considered a violation of probation.

10. Owners and Officers: Knowledge of the Law: Specifies that failure to comply will be considered a violation of probation.
11. Posted Notice of Probation: A new term that requires the owner to post notice of probation, in a place readable to the public, during the entire period of probation. In addition, the term prohibits the owner from engaging in any conduct which is intended to mislead a patient, customer or member of the public and specifies that failure to post the notice will be considered a violation of probation.
12. Violation of Probation: Clarifies that a notice and opportunity to be heard are not required for those provisions that may lead to automatic termination of the stay. In addition the term is reformatted.
13. Completion of Probation: Clarifies that written notice by the board or its designee is required to fully restore a license upon successful completion.

Actual Suspension: This term was consolidated under the Model Disciplinary Language – Pharmacy Technician

14. Community Service: Clarifies the process by which this term is implemented and specifies that failure to comply will be considered a violation of probation.
15. Restitution: Specifies that failure to comply will be considered a violation of probation.
16. Separate File of Records: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
17. Report of Controlled Substances: Clarifies that the optional term is only appropriate for pharmacist owners and pharmacists in charge. Specifies that the records must be made available for inspection and that failure to comply will be considered a violation of probation.
18. Surrender of DEA Permit: Creates a term that requires the respondent to surrender his or her federal DEA permit for cancellation and requires that the respondent provide documentation substantiating the surrender. It further prohibits the respondent from seeking a DEA registration number without prior consent of the board or its designee. In addition two options are created. The first allows for a respondent to obtain a DEA permit that is restricted to specified schedule(s) of controlled substances. The second option prohibits the respondent from ordering, receiving or retailing any federal order forms for controlled substances.
19. Posted Notice of Suspension: Clarifies that the owner is responsible for compliance with this term.

Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy and the administration of Chapter 9, Division 2.

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined.

Government Code section 114200.20 authorizes the board to adopt regulations to govern an adjudicative proceeding.

Government Code section 11425.50(e) prohibits a penalty from being based upon a guideline unless the guideline has been adopted as a regulation.

California Code of Regulations section 1760 incorporates by reference the Disciplinary Guidelines.

The Board regulates the practice of pharmacy and the movement of prescription-required drugs and devices from the time the drugs leave the manufacturing site to the time a drug or device is dispensed to the patient. To achieve this mission, the Board has 12 major licensing classifications with separate requirements that must be satisfied prior to the issuance of a license, as well as an impressive enforcement unit. The Board conducts its own inspections and investigations of licensees and applicants.

The Board currently has over 99,000 licensees and received almost 12,000 applications in FY 2004/05. The Board initiated 1,480 complaint investigations and completed 1,985 investigations in FY 2004/2005. As a result of these investigations, 113 cases were referred to the Office of the Attorney General (AG). In addition to AG referrals, the Board issued 754 citations and fines.

The Disciplinary Guidelines are necessary to assist the board, deputy attorney generals and administrative law judges to identify and impose appropriate disciplinary action against a licensee or applicant who violates the laws governing the practice of pharmacy.

The board has held a series of information hearings on the proposed changes and has either considered and or incorporated changes based on the testimony provided as part of these informational hearings.

Underlying Data

Enforcement and licensing statistics.

Business Impact

The board does not believe that this regulation will have a significant adverse economic impact on businesses as it only affects individuals and those businesses that are disciplined for serious violations of pharmacy law.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

The only alterative to this proposal is to continue to use the existing Disciplinary Guidelines. This alternative is not reasonable given the changes that have occurred in pharmacy law over the passed six years. In addition, it would be contrary to the board's public protection mandate to not include proposed changes designed to allow the board better monitoring of licensees on probation with the board.

No reasonable alternative to amending the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the repeal of the regulation.

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

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

To: Legislation and Regulation Committee

From: Staff

Subject: Board Approved Regulations – Proposed Language to be Developed

Ethics Course for Pharmacists

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

Draft language will be developed in concert with staff counsel for consideration at a future Enforcement Committee Meeting.