MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: OCTOBER 25, 2005
LOCATION: Crowne Plaza San Francisco Airport
1177 Airport Blvd.
Burlingame, CA 94010
4:45 P.M. – 5:30 P.M.

BOARD MEMBERS PRESENT:

JOHN JONES, CHAIR
KENNETH H. SCHELL, MEMBER
DAVE FONG, MEMBER
ANDREA ZINDER, MEMBER

BOARD STAFF PRESENT:

PATRICIA HARRIS
VIRGINIA HEROLD
JAN PEREZ

The meeting was convened at 4:45 p.m.

Legislation

The committee began the meeting by soliciting legislative and regulation proposals from the public.

Dave Thornton, Executive Director of the Medical Board of California reported on proposed legislative changes, regarding pain management that the Medical Board is developing for the 2006 Legislative session. The committee, Josh Room (Deputy Attorney General), and board staff raised concerns about a proposed change to Pharmacy Law, B&P section 4301(e). The proposed amendment would define the phrase "clearly excessive" in the context of unprofessional conduct in furnishing excessive quantities of controlled substances. All questioned the need for the definition. The committee directed board staff to work with the Medical Board and report back at the next committee meeting on any updates or changes made to the Medical Board's proposal.

Maria Serpa, California Society of Health-System Pharmacists (CSHP) representative, presented proposed language for a regulation that would permit general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. The proposed regulation is similar to CSHP's sponsored Senate Bill 592 (Aanestead, 2005); SB 592 is a two-year bill that is currently in Assembly Health Committee. The

committee directed staff to review SB 592 and the proposed regulation, and to bring an analysis of each to the next committee hearing so board members can discuss the issue.

Jan Perez, board staff, presented the committee with proposed regulation and legislative changes for 2006. The committee approved all the proposed changes and directed staff to correct minor drafting errors in the proposed language, prior to the next board meeting.

The following is a brief summary of each proposed change along with language that was approved by the committee.

Proposed Legislation

ITEM 1: Adulterated or Counterfeit Drug or Dangerous Device

The change is proposed to correct a drafting error in law. Board inspectors periodically have need to restrict misbranded drugs as well as counterfeit drugs. (Any drug or device is misbranded if its labeling is false or misleading in any way.)

B&P 4084. (a) When a board inspector finds, or has probable cause to believe, that any dangerous drug or dangerous device is adulterated, misbranded, or counterfeit, the board inspector shall affix a tag or other marking to that dangerous drug or dangerous device. The board inspector shall give notice to the person that the dangerous drug or dangerous device bearing the tag or marking has been embargoed.
(b) When a board inspector has found that an embargoed dangerous drug or dangerous device is not adulterated or counterfeit, a board inspector shall remove the tag or other marking.
(c) A board inspector may secure a sample or specimen of a dangerous drug or dangerous device. If the board inspector obtains a sample prior to leaving the premises, the board inspector shall leave a receipt describing the sample.
(d) For the purposes of this article "counterfeit" shall have the meaning defined in Section 109905 of the Health and Safety Code.
(e) For the purposes of this article "adulterated" shall have the meaning defined in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

ITEM 2: Wholesaler License Required

The change is proposed to correct a drafting error in the law regarding wholesalers and drug manufacturers when SB 1307 was enacted in 2004.

B&P 4160. (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
(c) A separate license shall be required for each place of business owned or operated

by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of that designated representative. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. A wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge. A pharmacist may be identified as the designated representative-in-charge.
(e) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.
(f) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler.
(g) This section shall become operative on January 1, 2006.

Board Approved Legislative Proposals for 2006

The board has approved the following proposals at prior board meetings.

ITEM 3: Nonprofit or Free Clinics

A clinic license issued by the board allows the purchase of drugs at wholesale and allows for a common stock of dangerous drugs and devices that are then dispensed by authorized prescribers. Without a clinic license, each prescriber must maintain a separate drug supply.

In 2005, staff reviewed the licensing requirements for clinics and found inconsistencies between the requirements for nonprofit or free clinics and surgical clinics. The proposed statutory changes will streamline the application process, better define who is accountable for the license, and make consistent the two types of licenses issued by the board. The proposed changes were discussed at the board's Licensing Committee meetings on March 16, 2005 and June 15, 2005. Additionally, the board discussed the changes at the full board meeting on July 20, 2005.

B&P 4180. (a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic:
(A) A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.
(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the clinic sites owned and operated by a single county, tribe or tribal organization, non-profit corporation or public institution of higher education. A clinic that changes location, shall notify the board of the change of address on a form provided by the board.

(c) The addition or deletion of a member of the Board of Directors of a tax-exempt clinic's non-profit corporation shall be reported to the board within 30 days on a form to be furnished by the Board.

4181. (a) Prior to the issuance of a clinic license authorized under Section 4180, the clinic shall comply with all applicable laws and regulations of the State Department of Health Services relating to the drug distribution service to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation occur in a manner that is consistent with the promotion and protection of the health and safety of the public. The policies and procedures to implement the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and the clinic administrator.

~~(b) These policies and procedures shall include a written description of the method used in developing and approving them and any revision thereof.~~

(c) The dispensing of drugs in a clinic shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4182. (a) Each clinic that makes an application for a license under Section 4180 shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing ~~least twice a year~~ quarterly that the clinic is, or is not, operating in compliance with the requirements of this article, ~~and the most recent of those written certifications shall be submitted with the annual application for the renewal of a clinic license~~. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended if appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director on a form provided by the board.

Surgical Clinics

B&P 4190. (a) Notwithstanding any provision of this chapter, a surgical clinic, as defined in paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of ~~seven~~ three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient' s needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall operate without a license issued by the board nor shall it be entitled to the benefits of this section until it has obtained a license from the board. ~~Each license shall be issued to a specific clinic and for a specific location.~~ A separate license shall be required for each of the premises of any person operating a clinic in more than one location.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 calendar days prior to (i) execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest, or (ii) any transfer of ownership or beneficial interest, whichever occurs earlier.

4191. (a) Prior to the issuance of a clinic license authorized under this article the clinic shall comply with all applicable laws and regulations of the State Department of Health Services and the board relating to drug distribution to insure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. ~~These policies and procedures shall include a written description of the method used to develop, approve, and revise those policies and procedures.~~ The policies and procedures to implement

the laws and regulations shall be developed and approved by the consulting pharmacist, the professional director, and clinic administrator.

(b) The dispensing of drugs in a clinic that has received a license under this article shall be performed only by a physician, a pharmacist, or other person lawfully authorized to dispense drugs, and only in compliance with all applicable laws and regulations.

4192. Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing least quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each written certification shall be kept on file in the clinic for three years after it is performed and shall include corrective actions recommended in appropriate.

(c) For the purposes of this article, "professional director" means a physician acting in his or her capacity as medical director or dentist or podiatrist acting in his or her capacity as a professional director in a clinic where only dental or podiatric services are provided.

(d) Any person who has obtained a license to conduct a clinic shall notify the board within 30 days of a change in professional director.

Proposed Regulations

ITEM 4: Abandonment of Application Files

For years, the board has had a regulation that establishes provisions defining when an applicant has abandoned an application. However, applications for veterinary food-animal drug retailer, hypodermic needle and syringes, or designated representatives are not included. This proposal would make consistent the board's provisions for when an application has been abandoned.

CCR 1706.2. (a) An applicant for a license to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy~~,~~ wholesaler, out-of-state distributor, ~~or~~ clinic, veterinary food-animal drug retailer, or to sell hypodermic needle and syringes who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have

abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
(c) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
(d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4029, 4037, 4043, 4110, 4112, 4115, 4120~~,~~ 4127.1, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4203, 4204, and 4205, Business and Professions Code.

ITEM 5: Contested Citations
In 2003, the board revised its system for issuing citations to make its procedures more consistent with the procedures used by other boards within the Department of Consumer Affairs. During the revision process, a provision in CCR 1775(a) that allows a person or entity to only reschedule an informal office conference one time was left out of the revised regulations. This proposal would restore the provision to CCR 1775.4.

CCR 1775.4. (a) Any person or entity served with a citation may contest the citation by appealing to the board in writing within 30 days of the issuance of the citation. Appeals shall be conducted pursuant to the adjudication provisions of the Administrative Procedure Act. (Government Code Section 11500 et seq.)
(b) In addition to requesting a hearing, as provided for in subdivision (a), the person or entity cited may, within 14 calendar days after service of a citation, submit a written request for an informal office conference. The person or entity cited may contest any or all aspects of the citation. The informal office conference will be conducted by the executive officer or his/her designee within 30 calendars days of receiving the request. Persons or entities may reschedule an informal office conference once.
(c) The executive officer or his/her designee shall hold an informal office conference upon request as provided for in subdivision (b) with the person or entity cited and their legal counsel or authorized representative if they desire representation at the informal office conference. At the conclusion of the informal office conference, the executive officer or his/her designee may affirm, modify or dismiss the citation, including any administrative fine levied or order of abatement issued. The executive officer or his/her designee shall state in writing the reasons for their action and serve or send by certified mail, a copy of their findings and decision to the person or entity cited within 14 calendar days from the date of the informal office conference. This decision shall be deemed to be a final order with regard to the citation issued, including the administrative fine levied and/or an order of abatement.
(d) The person or entity cited does not waive their request for a hearing to contest a citation by requesting an informal office conference after which the citation is affirmed by the executive officer or his/her designee. If the citation is dismissed after the informal office conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any administrative fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn

and a new citation issued. If a hearing is requested for the subsequent citation, it shall be requested within 30 days of the issuance of the subsequent citation.

Authority cited: Sections 125.9, 148 and 4005, Business and Professions Code. Reference: Sections 125.9 and 148, Business and Professions Code.

Section 100 Changes

Section 100 changes are technical corrections made to existing regulations to make the regulation consistent with new laws or correct obvious errors (and nonsubstantive errors). This is a streamline rulemaking process.

ITEM 6: Designation of Pharmacist in Charge

Replaces the term "exemptee-in-charge" with "designated representative-in-charge," a term added to the statutes in 2004.

CCR 1709.1. (a) The pharmacist-in-charge of a pharmacy shall be employed at that location and shall have responsibility for the daily operation of the pharmacy.
(b) The pharmacy owner shall vest the pharmacist-in-charge with adequate authority to assure compliance with the laws governing the operation of a pharmacy.
(c) No pharmacist shall be the pharmacist-in-charge of more than two pharmacies. If a pharmacist serves as pharmacist-in-charge at two pharmacies, those pharmacies shall not be separated by a driving distance of more than 50 miles.
(d) No pharmacist shall be the pharmacist-in-charge of a pharmacy while concurrently serving as the ~~exemptee-in-charge~~ designated representative-in-charge for a wholesaler or a veterinary food-animal drug retailer.
(e) Notwithstanding subdivision (a), a pharmacy may designate any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis as the pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with documentation of the involvement of a pharmacist-in-charge designated pursuant to this subdivision with the pharmacy and efforts to obtain and designate a permanent pharmacist-in-charge.
(f) A pharmacist may refuse to act as a pharmacist-in-charge at a second pharmacy if the pharmacist determines, in the exercise of his or her professional judgment, that assuming responsibility for a second pharmacy would interfere with the effective performance of the pharmacist' s responsibilities under the Pharmacy Law. A pharmacist who refuses to become pharmacist-in-charge at a second pharmacy shall notify the pharmacy owner in writing of his or her determination, specifying the circumstances of concern that have led to that determination.
(g) A person employing a pharmacist may not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this section.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4113, 4305, and 4330, Business and Professions Code.

ITEM 7: Minimum Standards for Wholesalers.

Updates the USP standards to require the 2005 USP Revision.

CCR 1780. The following minimum standards shall apply to all wholesale establishments for which permits have been issued by the Board:

(a) A wholesaler shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.

(1) All facilities shall be equipped with an alarm system to detect entry after hours.

(2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(3) The outside perimeter of the wholesaler premises shall be well-lighted.

(d) All materials must be examined upon receipt or before shipment.

(1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.

(1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.

(2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets appropriate United States Pharmacopeia Standards (~~1990, 22nd~~ 2005, 28th Revision).

(f) Policies and procedures must be written and made available upon request by the board.

(1) Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Wholesale drug distributors shall establish and maintain lists of officers, directors, managers and other persons in charge of wholesale drug distribution,

storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4043, 4051, 4053, 4054, 4059, 4120, 4160, 4161 and 4304, Business and Professions Code.

ITEM 8: Minimum Standards for Veterinary Food-Animal Drug Retailers.
Replaces the term "exemptee" with "designated representative," a term added to the statutes in 2004.

CCR 1780.1. In addition to the minimum standards required of wholesalers by section 1780, the following standards shall apply to veterinary food-animal drug retailers.

a. Drugs dispensed by a veterinary food-animal drug retailer pursuant to a veterinarian's prescription to a veterinarian's client are for use on food-producing animals.

b. Repackaged within the meaning of Business and Professions Code section 4041 means that a veterinary food-animal drug retailer may break down case lots of dangerous drugs as described in 4022(a), legend drugs or extra label use drugs, so long as the seals on the individual containers are not broken. Veterinary food-animal drug retailers shall not open a container and count out or measure out any quantity of a dangerous, legend or extra label use drug.

e. When a vet retailer ~~exemptee~~ designated representative dispenses a prescription for controlled substances, the labels of the containers shall be countersigned by the prescribing veterinarian before being provided to the client.

f. Whenever a vet retailer ~~exemptee~~ designated representative dispenses to the same client for use on the same production class of food-animals, dangerous drugs, legend drugs or extra label use drugs prescribed by multiple veterinarians, the vet retailer ~~exemptee~~ designated representative shall contact the prescribing veterinarians for authorization before dispensing any drugs.

g. Refilling A Veterinarian's Prescription

(1) A veterinary food-animal drug retailer may refill a prescription only if the initial prescription is issued indicating that a specific number of refills are authorized. If no refills are indicated on the initial prescription, no refills may be dispensed. Instead, a new prescription is needed from the veterinarian.

(2) A veterinary food-animal drug retailer may not refill a veterinarian's prescription order six months after the issuance date of the initial order. Records of any refills shall be retained by the veterinary food-animal drug retailer for three years.

h. Labels affixed to a veterinary food-animal drug dispensed pursuant to Business and Professions Code section 4041 shall contain the:

(1) Active ingredients or the generic names(s) of the drug
(2) Manufacturer of the drug
(3) Strength of the drug dispensed
(4) Quantity of the drug dispensed
(5) Name of the client
(6) Species of food-producing animals for which the drug is prescribed
(7) Condition for which the drug is prescribed
(8) Directions for use

(9) Withdrawal time
(10) Cautionary statements, if any
(11) Name of the veterinarian prescriber
(12) Date dispensed
(13) Name and address of the veterinary food-animal drug retailer
(14) Prescription number or another means of identifying the prescription, and 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, etc.)
(15) Manufacturer's expiration date

i. A record of shipment or an expanded invoice shall be included in the client's shipment, and shall include the names of the drugs, quantity shipped, manufacturer's name and lot number, date of shipment and the name of the pharmacist or vet retailer ~~exemptee~~ designated representative who is responsible for the distribution. Copies of the records shall be distributed to the prescribing veterinarian and retained by the veterinary food-animal drug retailer for three years.

j. If a retailer is unable at any one time to fill the full quantity of drugs prescribed, the retailer may partially ship a portion so long as the full quantity is shipped within 30 days. When partially filling a veterinarian's prescription, a pharmacist or vet retailer ~~exemptee~~ designated representative must note on the written prescription for each date the drugs are shipped: the quantity shipped, the date shipped, and number of containers shipped, and if multiple containers are dispensed at one time, each container must be sequentially numbered (e.g., 1 of 6 containers), If a retailer is unable to dispense the full quantity prescribed within 30 days, a new veterinarian's prescription is required to dispense the remainder of the drugs originally prescribed.

k. Upon delivery of the drugs, the supplier or his or her agent shall obtain the signature of the client or the client's agent on the invoice with notations of any discrepancies, corrections or damage.

l. If a person, on the basis of whose qualifications a certificate of exemption has been granted under Business and Professions Code Section 4053 (the vet retailer ~~exemptee~~ designated representative), leaves the employ of a veterinary food-animal drug retailer, the retailer shall immediately return the certificate of exemption to the board.

m. Training of Vet Retailer ~~Exemptee~~ Designated Representative:

(1) A course of training that meets the requirements of section 4053(b)(4) shall include at least 240 hours of theoretical and practical instruction, provided that at least 40 hours are theoretical instruction stressing:
(A) Knowledge and understanding of the importance and obligations relative to drug use on food-animals and residue hazards to consumers.
(B) Knowledge and understanding of state and federal law regarding dispensing of drugs, including those prescribed by a veterinarian.
(C) Knowledge and understanding of prescription terminology, abbreviations, dosages and format, particularly for drugs prescribed by a veterinarian.
(D) Understanding of cautionary statements and withdrawal times.
(E) Knowledge and understanding of information contained in package inserts.

(2) As an alternative to the training program specified in paragraph (1), other training programs that satisfy the training requirements of 4053 include fulfillment of one of the following:
(A) Possessing a registration as a registered veterinary technician with the California Veterinary Medical Board.
(B) Being eligible to take the State Board of Pharmacy's pharmacist licensure exam or the Veterinary Medical Board's veterinarian licensure examination.

(C) Having worked at least 1,500 hours within the last three years at a veterinary food-animal drug retailer's premises working under the direct supervision of a vet retailer ~~exemptee~~ designated representative. The specific knowledge, skills and abilities listed in sections 1780.1(m)(1)(A-E) shall be learned as part of the 1500 hours of work experience. A vet retailer ~~exemptee~~ designated representative who vouches for the qualifying experience earned by an applicant for registration must do so under penalty of perjury.

Authority cited: Sections 4005 and 4197, Business and Professions Code. Reference: Sections 4040, 4041, 4053, 4059, 4063, 4070, 4081, 4196, 4197, 4198 and 4199, Business and Professions Code.

1781. Exemption Certificate.
A registered pharmacist, or a~~n exemptee~~ designated representative certified in accordance with Section 4053 or 4054 of the Business and Professions Code shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4053 or 4054, Business and Professions Code.

Adjournment

The committee adjourned at 5:30 p.m..