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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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LEGISLATION & REGULATION COMMITTEE

October 25, 2005
Crowne Plaza Hotel
1177 Airport Blvd, Burlingame, CA 94010
3:30 p.m., or upon recess of the Board Meeting

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 48 hours prior to the meeting.

Opportunities are provided to the public to address the committee on each agenda item. Board members who are not on the committee may attend the meeting as observers.

A. Call to Order — **3:30 p.m., or upon recess of the Board Meeting**

B. Requests for Legislation and Regulatory Proposals for 2006

1. **Proposed Legislation**
   a. Adulterated or Counterfeit Drug or Dangerous Device - B&P 4084
   b. Wholesaler: License Required - B&P 4160(e)

2. **Board Approved Legislative Proposals for 2006**
   a. Licensing of Clinics and Surgical Clinics – B&P 4180-4186, B&P 4190-4196

3. **Proposed Regulations**
   a. Abandonment of Application Files – CCR 1706.2
   b. 1775.4. Contested Citations – CCR 1775.4
   c. Section 100 Changes
      i. Designation of a Pharmacist in Charge – CCR 1709.1
      ii. Self Assessment Forms – CCR 1715
         DEA Phone Numbers • Description of Pill
      iii. Wholesalers (Update USP Standard 2004 edition) – CCR 1780
      iv. Wholesalers ("Exemptees" name change to "Designated Representative") CCR 1780.1 & 1781

C. Public Requests for Future Legislation and Regulatory Proposals
(Please bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct it.)

Adjournment
Committee materials will be available on the board's Web Site by October 18, 2005.

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: October 25, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Legislative and Regulation Proposals for 2006

Over the course of the past year the Legislation and Regulation Committee has collected numerous ideas for legislative and regulatory changes in 2006. The following is a brief summary of each proposed change along with proposed language.

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.

State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: October 25, 2005

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Medical Board of California – Proposed Pain Management Legislation

A taskforce within the Division of Medical Quality (DMQ) of the Medical Board of California is in the process of reviewing California law regarding pain management. The intent of the taskforce is to recommend legislative changes to the law as needed. Some of the proposed changes may include changes in Pharmacy Law. A representative from the DQM pain management taskforce is likely to speak during the public comment period of the Committee's Legislative and Regulation Proposals for 2006 hearing. Attached is a memo that provides background information on the taskforce and proposed legislation.

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Memorandum

To: **Members**
Division of Medical Quality

Date: October 14, 2005

From: **Joan M. Jerzak**
Chief, Enforcement Program
Medical Board of California

Subject: **Pain Management Laws Task Force**

In 2003, the University of Wisconsin-Madison Medical School's Pain and Policy Studies Group ("Group") critiqued the pain management laws in all fifty states. As result, California was given a report card rating of "C." In February 2005, representatives from California were invited to attend a pain management workshop, sponsored by the Federation of State Medical Boards. During this seminar, the report card rating by the Wisconsin Group was referenced. Subsequently, at the February 2005 Medical Board meeting, there was feedback from the representatives who attended the pain seminar. Thereafter, at the August Medical Board meeting there was a presentation about the various laws the Wisconsin Group had critiqued. As a result, the Division of Medical Quality convened a task force to review the California laws. The task force will give recommendations back to the Division of Medical Quality including potential changes in law at the November DMQ meeting.

The task force was asked to review pertinent sections of the Business and Professions and the Health and Safety Codes. The task force met on August 22, 2005, and on September 28, 2005. Participants included representatives from: the California Academy of Pain Medicine, California Society of Addiction Medicine, the California Society of Anesthesiology, the Board of Pharmacy, the Medical Board of California, the Department of Justice, DOJ CURES, the California Medical Association, the Center for Public Interest Law, Purdue Pharma., the Northern California Pain Initiative, Intractable Pain Patients United, the National Foundation for the Treatment of Pain and interested parties.

The attached code sections include current laws relating to pain management and suggested changes which are intended as a starting point for discussion.

I. EXCESSIVE PRESCRIBING CODE SECTIONS

Business and Professions Code section 725:

Pain and Policy Group's Criticism of Section 725:

The Pain and Policy Studies Group criticized this statute for setting limits on prescriptions. They felt the terms "clearly excessive" imply there is a limit, but the limit is not specified in the statute. Thus, they felt this term was ambiguous.

Task Force Discussions:

While many people at the meeting proposed eliminating this section, it was generally believed that law enforcement agencies and DAs would strongly oppose any such action and therefore make it politically unfeasible.

Additionally, there was much sentiment expressed by both physician and patient advocate groups that the section should also reflect the undertreatment of pain and underprescribing of medications and modalities. It was generally agreed by the task force that as this code section was specifically enacted to deal with the issue of underprescribing, a separate code section should be created to address underprescribing if there was to be any such code section created.

Initial Suggestions Regarding Potential Revisions to the Section 725:

(a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, or optometrist. ~~However, pursuant to Section 2241.5, no physician and surgeon in compliance with the California Intractable Pain Treatment Act shall be subject to disciplinary action for lawfully prescribing or administering controlled substances in the course of treatment of a person for intractable pain.~~

(b)Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both the fine and imprisonment.

(c) For purposes of this section "clearly excessive" shall mean an amount or extent that is both (1) without substantial medical basis and (2) substantially greater than the usual amount of prescribing, administration, or use of therapeutic modalities.

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Business and Professions Code section 4301:

Note: this section will be amended effective January 1, 2006. Accordingly, given as it is now the fall of 2005, this memorandum will only contain the version of the section which will become effective January 1, 2006. (The memorandum handed out at the August 22, 2005, meeting contained both the current and future version of this section.)

Pain and Policy Group's Criticism of Section 4301:

Similar to the criticisms of Section 725, the Pain and Policy Studies Group was critical of subsection (d) which they believe implies there is a limit to the number of pills which can be prescribed.

Task Force Discussions:

This section is part of the Pharmacy Law enforced by the Pharmacy Board. A Pharmacy Board representative was at the meeting and reported she did not believe that the Pharmacy Board had any objection to adding a definition of "clearly excessive" to section 4301 paralleling the language proposed for section 725. She said that either someone from the Pharmacy Board would come to the November Medical Board meeting to confirm this or the Pharmacy Board would submit a written statement of its position.

It was felt by the task force that any amendments to subdivision (e) be identical to those changes made to Section 725.

It was also felt that subsection (i) be amended to incorporate the definition of addict that will be added to code section 2241 which is discussed below.

Initial Suggestions Regarding Potential Revisions to Section 4301:

4301. The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

(a) Gross immorality.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code. <u>For purposes of this subdivision and subdivision (e), "clearly excessive" shall mean an amount or extent that is both substantially greater than the usual amount of dispensing of controlled substances and that is without substantial medical or pharmacological basis.</u>

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances

furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering or offering to sell, furnish, give away, or administer any controlled substance to an addict, as defined by Section 2241(d).

(j) The violation of any of the statutes of this state or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program. The record of the compromise is conclusive evidence of unprofessional conduct.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code.

(t) This section shall become operative on January 1, 2006."

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III. PRESCRIBING TO ADDICTS CODE SECTIONS

Business and Professions Code section 2241:

Pain and Policy Group's Criticism of Section 2241:

The Group criticized this statute for creating a separate category of prescribing to addicts. It observed that it was unusual to create a regulatory exception in order to establish new requirements and a standard of care only for excepted patient groups. The group felt the section restricts medical decisions and the restrictions are based on patient characteristics.

Task Force Discussions:

Currently, section 2241 provides that a doctor may not prescribe to an addict. The task force will recommend that it be amended to reflect the current standard of practice which is that a doctor ***may*** prescribe to an addict, even for purposes other than maintenance or detoxification from the substance to which the patient is addicted.

It was decided not to change "addict" to "drug abuser." The term "addict" has been accepted and defined by various addiction societies. Some form of this definition should be added to proposed subdivision (d). A reference to diversion of drugs may also be added to subdivision (d).

Initial Suggestions Regarding Potential Revisions to Section 2241:

2241. ~~Unless otherwise provided by this section, the prescribing, selling, furnishing, giving away, or administering or offering to prescribe, sell, furnish, give away, or administer any of the drugs or compounds mentioned in Section 2239 to an addict or habitue constitutes unprofessional conduct.~~
~~If the drugs or compounds are administered or applied by a licensed physician and surgeon or by a registered nurse acting under his or her instruction and supervision, this section shall not apply to any of the following cases:~~
(a) A physician and surgeon may prescribe, dispense, or administer prescription drugs, including prescription controlled substances, to an addict under the physician and surgeon's treatment for a condition other than maintenance on or detoxification from prescription drugs or controlled substances.
(b) A physician and surgeon may prescribe prescription drugs, including prescription controlled substances, for or administer those drugs or substances to or dispense those drugs or substances for a patient for purposes of maintenance on or detoxification from prescription drugs or controlled substances only as set out below or in [the Health and Safety Code].
(c) Despite subdivision (a), drugs or controlled substances may also be administered or applied by a physician and surgeon or by a registered nurse acting under his or her instruction and supervision for maintenance or detoxification under the following circumstances:

(~~a~~1) Emergency treatment of a patient whose ~~addiction~~ abuse of drugs is complicated by the presence of incurable disease, ~~serious~~ accident, illness, or injury, or the infirmities attendant upon age.

(~~b~~2) Treatment of ~~addicts or habitues~~ a drug abuser in state licensed institutions where the patient is kept under restraint and control, or in city or county jails or state prisons.

(~~c~~3) Treatment of ~~addicts~~ a drug abuser as provided for by Section 11217.5 of the Health and Safety Code.

(d) For purposes of this section and Section 2241.5, "addict" means [INSERT A DEFINITION OF ADDICT HERE]

Health and Safety Code section 11156:

Pain and Policy Group's Criticism of Section 11156:

The Pain and Policy Studies Group criticized the statute for limiting ability to prescribe to an addict.

Task Force Discussions:

As with Section 2241, a definition of "addict" should be added to the code section. Also, the archaic term 'habitual user' should be eliminated."

Initial Suggestions Regarding Potential Revisions to Section 11156:

(a) No person shall prescribe for or administer, or dispense a controlled substance to an addict ~~or habitual user~~, or to any person representing himself as such, except as permitted by this division.

(b) "Addict" means [INSERT A DEFINITION OF ADDICT HERE]

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IV. INTRACTABLE PAIN CODE SECTION

Business and Professions Code section 2241.5 :

Pain and Policy Group's Criticism of Section 2241.5:

The Pain and Policy Studies Group had several criticisms of this section. They felt that the language of subsection (b) implies that opioids are a treatment of last resort and are not part of professional practice. (However, they were complimentary of subsection (a) as they felt it implied that opioids are part of professional practice.) They were also critical of subsection (b)'s requirement of an evaluation by a specialist as they felt this restricted medical decisions. They were critical of subsection (e)'s prohibition form prescribing to addicts as they felt it restricted medical decisions.

Task Force Discussions:

It was felt that this section had outlived its usefulness. Pain management and Medical Board enforcement (as reflected in both the Board's Pain Management Guidelines and manner in which pain cases are investigated and prosecuted) has progressed beyond this section. Thus, there were thoughts that this section should be repealed. However, at this juncture, since many pain management groups and physicians believe this section affords them a level of protection, it was decided to amend the section, as opposed to repealing it. There was also the idea espoused that the section should be broadened to apply to pain patients in general, not just patients in "intractable pain."

Initial Suggestions Regarding Potential Revisions to Section 2241.5:

2241.5. ~~(a) Notwithstanding any other provision of law, a physician and surgeon may prescribe or administer controlled substances to a person in the course of the physician and surgeon's treatment of that person for a diagnosed condition causing intractable pain.~~

~~(b) "Intractable pain," as used in this section, means a pain state in which the cause of the pain cannot be removed or otherwise treated and which in the generally accepted course of medical practice no relief or cure of the cause of the pain is possible or none has been found after reasonable efforts, including, but not limited to, evaluation by the attending physician and surgeon and one or more physicians and surgeons specializing in the treatment of the area, system, or organ of the body perceived as the source of the pain.~~

~~(c) No physician and surgeon shall be subject to disciplinary action by the board for prescribing or administering controlled substances in the course of treatment of a person for intractable pain.~~

~~(d) This section shall not apply to those persons being treated by the physician and surgeon for chemical dependency because of their use of drugs or controlled substances.~~

~~(e) This section shall not authorize a physician and surgeon to prescribe or administer controlled substances to a person the physician and surgeon knows to be using drugs or substances for nontherapeutic purposes.~~

~~(f) This section shall not affect the power of the board to deny, revoke, or suspend the license of any physician and surgeon who does any of the following:~~

~~(1) Prescribes or administers a controlled substance or treatment that is nontherapeutic in nature or nontherapeutic in the manner the controlled substance or treatment is administered or prescribed or is for a nontherapeutic purpose in a nontherapeutic manner.~~

~~(2) Fails to keep complete and accurate records of purchases and disposals of substances listed in the California Controlled Substances Act, or of controlled substances scheduled in, or pursuant to, the federal Comprehensive Drug Abuse Prevention and Control Act of 1970. A physician and surgeon shall keep records of his or her purchases and disposals of these drugs, including the date of purchase, the date and records of the sale or disposal of the drugs by the physician and surgeon, the name and address of the person receiving the drugs, and the reason for the disposal of or the dispensing of the drugs to the person and shall otherwise comply with all state recordkeeping requirements for controlled substances.~~

~~(3) Writes false or fictitious prescriptions for controlled substances listed in the California Controlled Substances Act or scheduled in the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.~~

~~(4) Prescribes, administers, or dispenses in a manner not consistent with public health and welfare controlled substances listed in the California Controlled Substances Act or scheduled in~~

~~the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.~~

~~(5) Prescribes, administers, or dispenses in violation of either Chapter 4 (commencing with Section 11150) or Chapter 5 (commencing with Section 11210) of Division 10 of the Health and Safety Code or this chapter.~~

~~(g) Nothing in this section shall be construed to prohibit the governing body of a hospital from taking disciplinary actions against a physician and surgeon, as authorized pursuant to Sections 809.05, 809.4, and 809.5.~~

a) A physician and surgeon may prescribe for or dispense or administer to a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain.

(b) A physician and surgeon's authority under this section shall be subject to the provisions of Sections 2234, 2241 and 2242, and Sections 11152, 11153, and 11154 of the Health and Safety Code. Nothing in this section shall authorize a physician and surgeon to prescribe, administer or dispense dangerous drugs or controlled substances to a person he or she knows is using or will use the drugs or substances for a non-medical purpose.

(c) Any physician and surgeon has the legal authority to treat a patient for pain using dangerous drugs or prescription controlled substances but the prescribing, administering, or dispensing physician and surgeon shall exercise reasonable care in determining whether a particular patient or condition, or complexity of the patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with or referral to a more qualified specialist.

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V. PAIN PATIENT BILL OF RIGHTS

Health and Safety Code section 124961:

Pain and Policy Group's Criticism of Section 124961:

The Pain and Policy Studies Group was critical of the phrase "severe chronic intractable pain" used throughout the section because they felt "the intended result of such elaborate and unconventional medical terminology is unclear, but appears to limit the patient population which should be given access to 'proper treatment' of pain, including the use of opioids." The Group questioned the effect this law had on patients with pain that was not "severe," "chronic" or "intractable," and wondered if doctors faced greater discipline in those cases. The Group criticized subsection (b) as being ambiguous because it conflicted with Section 124960(g) which states that patients qualify for opiate treatment after "other means of treatment" but this section does not require patients to "submit" to certain treatments. The Group further criticized subsection (b) as being ambiguous in that it appears to require all opiate treatment to be according to the Intractable Pain Treatment Act [Business and Professions Code section 2241.5, above] which would require a second medical evaluation and would also calls into question whether or not it is legal for physicians to prescribe medically necessary dosages of opioids for patients with "severe chronic pain" who do not qualify under the Intractable Pain Treatment Act.

Task Force Discussions:

It was generally conceded that, while it offers no rights not already accorded elsewhere, the section has such appeal to both pain patients and physicians it will most likely be impossible to eliminate it. The Board's legislative representative recommended against making any changes to this section at this point in time. She agreed with the task force that there would be too much opposition to the Board trying to change the section.

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VI. CONTROLLED SUBSTANCES RESEARCH CODE SECTION

Health and Safety Code section 11213:

Pain and Policy Group's Criticism of Section 11213:

The Pain and Policy Studies Group was critical of the fact this statute places an additional requirement on the use of controlled substances for research by requiring the approval of the Research Advisory Panel.

Task Force Discussions:

The task force agreed to defer any discussion of this section as it is rarely referenced in Board cases.

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VII. SCHEDULE II / TERMINAL ILLNESS CODE SECTION:

Health and Safety Code section 11159.2:

Text of Section 11159.2:

"(a) Notwithstanding any other provision of law, a prescription for a Schedule II controlled substance for use by a patient who has a terminalllness shall not be subject to Section 11164.

(b) (1) The prescription mall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use, The signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) The prescription mall also contain the address of the person for whom the controlled substance is prescribed, as provided in paragraph (3) of subdivision (b) of Section 11164, and shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber, as provided in paragraph (2) of subdivision (b) of Section 11164.

(3) The prescription shall also indicate that the prescriber has certified that the patient is terminally in by the words "11159.2 exemption."

(c) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (3) of subdivision (b), provided that he or she has personal knowledge of the patient's terminal illness, and

subsequently returns the prescription to the prescriber for correction within 72hours,

(d) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:

(1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.

(2) In the reasonable medical judgment of the prescribing physician, the patient's illness wi11, if the illness takes its normal course, bring about the death of the patient within a period of one year.

(3) The patient's treatment by the physician prescribing a Schedule II controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness."

Task Force Discussions:

While it was initially discussed that this section could be repealed based on changes via SB 151, representatives from the Pharmacy Board indicated there are provisions in this section which they still implement and so it was agreed the task force not recommend making any changes to this section at the current time.

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VII. ADDITIONAL CODE SECTIONS THE TASK FORCE WILL REVIEW

Business and Professions Code section 2242 (GOOD FAITH EXAMINATION):

Text of Section 2242:

(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without a good faith prior examination and medical indication therefor, constitutes unprofessional conduct.

(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of his or her practitioner, but in any case no longer than 72 hours.

(2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:

(A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.

(B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be.

(3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or

amount or for more than one refilling.

(4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code.

Task Force Discussions:

At the first meeting, it was suggested that changes be made to Section 2242, the good faith prescribing section because there is no definition of a "good faith exam" in the section. Currently there are competing thoughts as to whether or not a good faith exam includes the physician's "honest intent."

Initial Suggestion Re: Potential Revisions to the Section 2242, add subsection (c):

(c) "Good faith" means [DEFINE IT HERE]