Agenda Item B2

Legislative Proposals for 2006

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State of California | Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee | Date: January 19, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Legislative Proposals for 2006

FOR ACTION

Action Item 1: Request from the Medical Board of California to amend B&P section 4301(e) related to "excessive" furnishing.

Discussion: At the October 25, 2005 committee meeting Dave Thornton, Executive Director of the Medical Board of California (MBC) reported on a legislative proposal MBC's Pain Management Taskforce is developing for the 2006 Legislative Session. One of the proposal's amendments would affect Pharmacy Law, specifically Business and Professions Code section 4301(e). The amendment would define the phrase "clearly excessive" in the context of unprofessional conduct in furnishing excessive quantities of controlled substances. At the October 2005 committee meeting, board members and staff questioned the need for the definition. The committee directed board staff to work with the MBC and report back at the next committee meeting on any updates or changes made to the MBC's proposal.

On January 20, 2006 the CMB Pain Management Taskforce will meet in Burbank to discuss the legislative proposal. Board staff is planning on attending this meeting. A report on the legislative proposal will be made at the January 26, 2006 Legislation and Regulation Committee meeting.

The proposed language is in Attachment 1.

Action Item 2: Request from the Department of Justice to align California's Prescription Monitoring Program (CURES) with the National All Schedules Prescription Electronic Reporting Act of 2005.

Discussion: The Department of Justice (DOJ) has submitted a legislative proposal to Senator Torlakson to align California's Prescription Monitoring Program (PMP) with the federal National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER Act). This proposal will ensure state compliance with new federal mandates.

The NASPER Act was signed into law by President Bush on August 11, 2005. The Act requires all states to establish a PMP or enhance their current state PMP.

The NASPER Act imposes several mandates not previously required by DOJ's Controlled Substances Utilization Review and Evaluation System (CURES) program. These mandates include:

1. Capturing Schedule IV controlled substances data.
2. Requiring dispensers to report to states within one week of each dispensing of a controlled substance
3. Requiring specific data, such as patient telephone number, number of refills, and whether the prescription is for a refill or a first-time prescription.
4. Requiring secure prescription forms include a refill notation; under current law this notation is optional at the prescriber request.
5. Requiring dispensers to report information in an electronic format specified by the U.S. Secretary of Health and Human Services, with an exception that the state may waive the required format with respect to individual dispensers.

Proposed language is in Attachment 2.

Action Item 3: Proposal to amend B&P sections 4314 and 4315 to authorize the issuance of citations and fines for violation of law related to the voluntary drug repository and distribution program for prescription drugs in county pharmacies.

Discussion: SB 798 (Chapter 444, Statues of 2005) authorizes a county to establish, by local ordinance, a repository and distribution program for purposes of distributing surplus unused medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. SB 798 placed the provisions of the measure in Health and Safety Code (HSC) sections 150200-150207. The board supplied a number of amendments in late August 2005 to make the measure implementable, however, one group of amendments could not be incorporated without making the bill a two-year bill. The board does not have authority to cite and fine or issue letters of admonishment for violations of SB 798's provisions because the provisions are outside of Pharmacy Law. This legislative proposal would amend B&P sections 4314 and 4315 to allow the board to use these sanctions for violations of HSC sections 150200-150207.

Proposed language is in Attachment 3.

Action Item 4. Amend B&P section 4162, resident wholesalers, to waive the surety bond requirement for government owned and operated wholesalers.

Discussion: Under the current law all wholesalers operating in California are required to submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the bond is to secure payment of any administrative fine imposed by the board and any cost recovery. Government agencies are self-insured and do not purchase surety bonds. Currently there are eight government-owned and operated wholesalers licensed with the board. These entities store drugs for public safety and emergency preparedness. Given that government agencies are self-insured, the board would like to exempt government owned and operated wholesalers from the bond requirement.

Proposed language is in Attachment 4.

NO ACTION

Item 5: At the Legislation and Regulation Committee meeting in October, the Committee approved three Legislative proposals. At the February board meeting, the board needs to approve each of the legislative proposals. These proposals are provided in Attachment 5 for your information.

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Legislative Proposals for 2006

Attachment 1

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PAIN MANAGEMENT LAWS TASK FORCE

January 4, 2006

The Division of Medical Quality ("DMQ") convened a task force to review pertinent sections of the Business and Professions and the Health and Safety Codes pertaining to pain management following a critique of those laws by the University of Wisconsin-Madison Medical School's Pain and Policy Studies Group. At the November 2005 Medical Board meeting in San Diego, members of the task force advised the DMQ of the work of the task force to date and its recommendations. The DMQ also entertained public comment. Based upon the DMQ's acceptance of the task force's recommendations, the task force has completed its review of the following code sections: Business and Professions code section 725 (excessive prescribing) and Health and Safety code sections 4301 (excessive prescribing), 124961 (pain patient bill of rights), 11213 (controlled substances research) and 11159.2 (Schedule II /terminal illness). The task force is still reviewing the following code sections: Business and Professions code section 2241 and Health and Safety code section 11156 (prescribing to addicts); Business and Professions Code sections 2241.5 (Intractable Pain) and 2242 (good faith prior examination). This memo highlights the recommendations made to the DMQ at the November 2005 meeting and the remaining issues to be discussed at the January 20, 2006, task force meeting.

I. CODE SECTIONS REQUIRING FURTHER DISCUSSION

A. Prescribing to Addicts Code Sections

1. Business and Professions Code section 2241:

Current Text of Section 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) Emergency treatment of a patient whose addiction is complicated by the presence of incurable disease, serious accident or injury, or the infirmities attendant upon age.

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

"(c) Treatment of addicts as provided for by Section 11217.5 of the Health and Safety Code."

Task Force Discussions and Presentation to Division of Medical Quality:

The task force advised the DMQ this section should define the term "addict" and indicated the American Academy of Pain Medicine, the American Pain Society, and the American Academy of Addictionology, among others, have defined it. Further, as the standard of care does permit prescribing to an addict, the section needs to be re-written so as to comport with the standard of care. The task force also advised the Board about concerns voiced by emergency room physicians who use the code section as currently-worded as a shield against "drug-seeking patients" who use the E.R. as a way to get narcotics.

Issues Remaining to be Discussed:

- Agreeing on a definition of "addict." (CSAM proposed one definition.)

- Conforming language in the section to the standard of care.

- Addressing concerns of E.R. physicians.

<u>Initial Suggestions Regarding Potential Revisions to Section 2241:</u>

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 under the following circumstances:

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

(~~b~~2) Treatment of addicts ~~or habitues~~ 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.]

"An addict is a person whose actions are characterized by impaired control over drug use, compulsive use, continued use despite harm and craving."

2. Health and Safety Code section 11156:

Current Text of Section 11156:

"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."

Task Force Discussions and Presentation to Division of Medical Quality:

The term "addict" should be defined here as in section 2241. The term "habitual user" should be deleted.

Issues Remaining to be Discussed:

Same as for section 2241, above. Section 2241 and 11156 should be compatible.

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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B. Intractable Pain Code Section

Business and Professions Code section 2241.5:

Current Text of Section 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 record keeping 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 Substance 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."

Task Force Discussions and Presentation to Division of Medical Quality:

The task force recommended removing the term "intractable pain" from the section and re-writing the section to more aptly comport with the standard of care. Concerns were voiced that making any changes to the section would both remove defenses physicians believe they currently have to being prosecuted for treating pain patients and also hinder patient access to pain management.

Issues Remaining to be Discussed:

- Consensus on proposed changes to section.

- Addressing concerns of physicians that amendments remove defenses to MBC actions.

- Addressing patient concerns that amendments deter patient access to care.

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.

C. Good Faith Prior Examination Code Section

Business and Professions Code section 2242:

Current 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 and Presentation to Division of Medical Quality:

Disagreement remains among the task force as to how to define "good faith prior examination." One suggested definition is below. There are cases which discuss "good faith" in terms of the prescriber's intent, however concern was expressed that such a definition may lead to physicians claiming they are not subject to prosecution as they did not "intend to do harm." This argument has been made several times in Internet prescribing cases.

Issues Remaining to be Discussed:

- Consensus for defining term "good faith prior examination"

- Allaying concerns of physicians claiming they are not subject to prosecution as they did not "intend to do harm."

Initial Suggestions Regarding Potential Revisions to Section 2242:

add a subsection (c) to the code section which defines "good faith prior examination."

"(c) "good faith prior examination" means [DEFINE TERM HERE]

- OR-

"(c) "Good faith" as used in this section means the honest exercise of medical judgment; "prior examination" means and refers to an examination, including a physical examination of the patient by the prescribing practitioner or an individual who is licensed to perform the examination and is acting at the direction of the prescribing practitioner. The examination shall also include such other and further evaluative techniques, including but not limited to laboratory tests, as are indicated by the patient's condition, suspected ailment or injury, and treatment(s) being considered. The prior examination, if any, required before continuing to prescribe the same dangerous drug or class of drugs or prescribing some other class of drugs or for some other condition shall be based on the practitioner's exercise of prudent medical judgment."

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II. TASK FORCE RECOMMENDATIONS OF CODE SECTIONS REVIEWED

The following code sections are those which, based upon the Division's acceptance of the task force's recommendations, the task force has completed its review.

A. Excessive Prescribing Code Sections

1. Business and Professions Code section725:

Current Text of Section 725:

"Repeated acts of clearly excessive prescribing 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.

"Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shal1 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."

Task Force Discussions and Presentation to Division of Medical Quality:

Despite strong sentiment that the section be repealed, it was believed law enforcement agencies and DAs would strongly oppose any such action. The DMQ was also advised of sentiment expressed by both physician and patient advocate groups that the section be amended to reflect the under-treatment of pain and under-prescribing of medications and modalities. Section 725 was specifically enacted to deal with the issue of over-prescribing, therefore a separate code section could be created to address under-prescribing. It was generally agreed by the task force that a definition of "clearly excessive" should be added.

Task Force Recommended 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.

2. Business and Professions Code section 4301:

Note: this section was amended effective January 1, 2006. Accordingly, only that versions was presented at the November 2005 Division meeting.

Text of Section 4301 (effective January 1, 2006):

"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.

(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.

(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."

Task Force Recommended Revisions to the 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. 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.

(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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B. Pain Patient Bill of Rights

Health and Safety Code section 124961:

Task Force Recommended Revisions:

It was generally conceded that the section has appeal to both pain patients and physicians although it offers no rights to patients that are not already provided elsewhere. Thus, the task force recommended making no changes to the section.

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C. Controlled Substances Research Code Section

Health and Safety Code section 11213:

Task Force Recommended Revisions:

The task force recommended making no changes to this section.

****

D. Schedule II / Terminal Illness Code Section:

Health and Safety Code section 11159.2:

Task Force Recommended Revisions:

While it was initially discussed that this section could be repealed given SB 151, representatives from the Pharmacy Board indicated there are provisions in this section they still implement and so the task force recommended making no changes to this section.

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Legislative Proposals for 2006

Attachment 2

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DOJ PROPOSAL TO CONFORM CURES TO NASPER

Amend Health and Safety Code section 11162.1 as follows:

11162.1 Form and Content of Prescription Blanks for Controlled Substances

11162.1. (a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermo-chromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity checkoff boxes shall be printed on the form and the following quantities shall appear:

1-24
25-49
50-74
75-100
101-150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall either (A) contain a statement printed on the bottom of the prescription blank that the "Prescription is void if more than one controlled substance prescription is written per blank" or (B) contain a space for the prescriber to specify the number of drugs prescribed on the prescription and a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, and federal controlled substance registration number of the prescribing practitioner.

(10) The telephone number of the ultimate user or research subject, or contact information as determined by the U.S. Secretary of Health and Human Services

(11) Check boxes shall be printed on the form and the shall indicate whether it is a

first-time request or shall indicate the number of refills ordered since the first prescription.

(12) the date of origin of the prescription

~~(10)~~ *(13)* A check box indicating the prescriber's order not to substitute.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a).

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility preprinted on the form.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom controlled substance prescription forms are issued, which record shall include the name, category of licensure, license number, federal controlled substance registration number, and the quantity of controlled substance prescription forms issued to each prescriber and shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) This section shall become operative on July 1, 2004.

11164 Completion of Prescription for Schedule II, III, IV and V Controlled Substance

11164. Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b),

shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the telephone number of the ultimate user or research subject, or contact information as determined by the U.S. Secretary of Health and Human Services, refill information such as the number of refills ordered, whether the prescription is a first-time request or a refill, and the date of origin of the prescription; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

(2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.

(b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.

(2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.

(3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.

(c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(d) Notwithstanding any provision of subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical

need.

(e) This section shall become operative on January 1, 2005.

11165. Controlled Substance Utilization Review and Evaluation System (CURES)

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II ~~and ,~~ Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, ~~and~~ Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) ~~The reporting of Schedule III controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice.~~ The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. ~~Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III controlled substance prescriptions to CURES.~~

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, ~~or~~ Schedule III, *or Schedule IV* controlled substance, the dispensing pharmacy shall provide the following information to the Department of Justice in a frequency and

format specified by the Department of Justice:
(1) Full name, address, telephone number of the ultimate user or research subject, or such contact information as determined by the U.S. Secretary of Health and Human Services, gender, and date of birth of the patient.
(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
(3) Pharmacy prescription number, license number, and federal controlled substance registration number.
(4) NDC (National Drug Code) number of the controlled substance dispensed.
(5) Quantity of the controlled substance dispensed.
(6) ICD-9 (diagnosis code), if available.
(7) Number of refills ordered
(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
(~~7~~) (9) Date of ~~issue~~ origin of the prescription.
(~~8~~) (10) Date of dispensing of the prescription.
(e) This section shall become operative on January 1, 2005.

11165.1 History of Controlled Substances
11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II ~~or~~, Schedule III, and Schedule IV controlled substances or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.
(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.
(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II ~~or~~, Schedule III, and Schedule IV controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

11190. (a) Every practitioner, other than a pharmacist, who prescribes or administers a controlled substance classified in Schedule II shall make a record that, as to the transaction, shows all of the following:

(1) The name and address of the patient.

(2) The date.

(3) The character, including the name and strength, and quantity of controlled substances involved.

(b) The prescriber's record shall show the pathology and purpose for which the controlled substance was administered or prescribed.

(c) (1) For each prescription for a Schedule II or Schedule III controlled substance that is dispensed by a prescriber pursuant to Section 4170 of the Business and Professions Code, the prescriber shall record and maintain the following information:

(A) Full name, address, telephone of the ultimate user or research subject, or such contact information as determined by the U.S. Secretary of Health and Human Services,
gender, and date of birth of the patient.

(B) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(C) NDC (National Drug Code) number of the controlled substance dispensed.

(D) Quantity of the controlled substance dispensed.

(E) ICD-9 (diagnosis code), if available.

(F) Number of refills ordered

(G) Whether the drug was dispensed as a refill of a prescription or as a first-time request

(~~F~~) (H) Date of ~~dispensing~~ origin of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a weekly ~~monthly~~ basis in either hard copy or electronic form.

(d) This section shall become operative on January 1, 2005.

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Legislative Proposals for 2006

Attachment 3

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Proposed Legislation in response to SB 798(Chapter 444, Statutes of 2005)

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections, and Health and Safety Code Sections 150200 through 150206.
(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, or Health and Safety Code Sections 150200 through 150206, directing the licensee to come into compliance.
(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.
(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

(1) Submit a written request for an office conference to the executive officer of the board to contest the letter of admonishment.

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.
(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.
(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

(E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the letter of admonishment.

(2) Comply with the letter of admonishment and submit a written corrective action plan to the executive officer documenting compliance. If an office conference is not requested pursuant to this section, compliance with the letter of admonishment shall not constitute an admission of the violation noted in the letter of admonishment.

(d) The letter of admonishment shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.

(e) The licensee shall maintain and have readily available a copy of the letter of admonishment and corrective action plan, if any, for at least three years from the date of issuance of the letter of admonishment.

(f) Nothing in this section shall in any way limit the board's authority or ability to do either of the following:

(1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775 of Title 16 of the California Code of Regulations.

(2) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).

Legislative Proposals for 2006

Attachment 4

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Proposed Legislation to Exempt Publicly Owned Wholesalers from the Bonding Requirements in B&P section4162

Wholesaler License Surety Bond Requirements

4162. (a) (1) An applicant, that is not a government owned and operated wholesaler, for the issuance or renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) or other equivalent means of security acceptable to the board payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(2) For purposes of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars ($100,000) if the annual gross receipts of the previous tax year for the wholesaler is ten million dollars ($10,000,000) or less, in which case the surety bond shall be twenty-five thousand dollars ($25,000).

(3) A person to whom an approved new drug application has been issued by the United States Food and Drug Administration who engages in the wholesale distribution of only the dangerous drug specified in the new drug application, and is licensed or applies for licensure as a wholesaler, shall not be required to post a surety bond as provided in paragraph (1).

(4) For licensees subject to paragraph (2), or (3), the board may require a bond up to one hundred thousand dollars ($100,000) for any licensee who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days after the order imposing the fine, or costs become final.

(c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

(d) This section shall become operative on January 1, 2006, and shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

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Legislative Proposals for 2006

Attachment 5

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Legislative Proposals Approved by the Committee on October 25, 2005

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.

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.

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