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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
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Legislation and Regulation Committee

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LEGISLATION REPORT

ITEM A: *DISCUSSION AND ACTION ON PENDING LEGISLATION*

1. Board Sponsored Legislation

FOR ACTION:

a. Omnibus Provisions Previously Approved by the Board

The following language was approved by the board to be included in an omnibus bill. Several of these provisions are currently included in SB 1779.

Use of Mobile Pharmacies

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

Pharmacist-in-Charge and Designated Representative in Charge

Amend Sections 4022.5, 4305, 4329, 4330 and Add section 4036.5.
The Board of Pharmacy is proposing changes to several sections of the Business and Professions Code to clarify the reporting requirements to document a change in the Pharmacist-In-Charge (PIC). The PIC is responsible for the overall operations in a pharmacy. There are also similar changes for the Designated Representative-in-Charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would also define the term "pharmacist-in-charge" currently referenced throughout pharmacy law as well as place into statute the approval process currently used by the board when evaluating a pharmacy application for approval of a proposed PIC or DRC.

General Omnibus Provisions

Amend Section 4059.5 - Who May order Dangerous Drugs or Devices, Exceptions.
A technical change to this section clarifies that a designated representative must sign for and receive delivery of drugs by a wholesaler. This is important for accountability of drug purchases and receipt in wholesale operations.

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
This section corrects a drafting error that occurred in Senate Bill 1307 (Chapter 857, statutes of 2004). The term "exemptee-in-charge" was incorrectly updated to "representative-in-charge" and requires correction to the appropriate term "designated representative in charge."

Amend Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section clarifies specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section addresses the need to authorize the board to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation. This authority already exists when a pharmacist fails to certify completion of continuing education as part of the renewal application.

H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to require that a clinic that dispenses schedule III and schedule IV controlled substances must report weekly to CURES, similar to the requirements for pharmacies and prescribers who dispense controlled drugs as specified.

Corrections to Sections Referencing Prior Business and Professions Code §§ 4052

Omnibus changes based on recodification of Business and Professions Code section 4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. The below B&PC and H&SC sections reference 4052 and require update.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

In addition to the above omnibus provisions previously approved by the board, board staff is recommending that the following provision also be pursued by the board.

Amend Section 4161 – Nonresident Wholesaler: When License Required: Application
This section clarifies that any person that sells, brokers or distributes dangerous drugs or devices within California must be licensed.

Because of timing within the legislative cycle, this provision was recently included in the omnibus bill at the request of staff. It was reviewed and approved by the Legislation and Regulation Committee for board approval. Should the board not approve the language, board staff will request that the provision be removed from the proposal.

A copy of the proposed language as presented to Senate Business and Professions is provided in **ATTACHMENT 1.**

COMMITTEE RECOMMENDATION: Approve amendment to section 4161 – Nonresident Wholesaler for inclusion in SB 1779.

b. SB 1307 (Ridley-Thomas) Electronic Pedigree

FOR DISCUSSION:

The bill contains additional provisions to improve implementation issues involving serialization and electronic pedigrees. Specifically, it specifies that the serialization number must be contained in the electronic pedigree, delays the implementation date and staggers the implementation dates for e-pedigree compliance, allows for the grandfathering in of existing drug stock in the supply chain, and allows the board to establish criteria for interference requirements by regulation.

The committee did not discuss this proposal at the July committee meeting.

ATTACHMENT 2 contains a copy of the bill in its current form, a letter from State and Consumer Services Agency (Agency), a copy of proposed amendments offered by Agency and a letter from the National Association of Boards of Pharmacy.

2. Legislation Impacting the Board's Jurisdiction or the Practice of Pharmacy

a. Active Bills

FOR ACTION:

Provided in this packet are copies of bills and analyses of legislation impacting the practice of pharmacy or the board's jurisdiction (**ATTACHMENT 3**). A brief summary of the measure is included below. If the board has a current position on the proposal, that is indicated below as well as any recommended position made by the Legislation and Regulation Committee.

If the board so chooses, it can reconsider positions previously taken as well as take positions on new legislation. The committee made no changes to current positions, however is recommending a "support" position on AB 1574.

AB 501 (Swanson and Hancock) Pharmaceutical Devices

Require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to provide upon request of a consumer, a postage prepaid mail-back sharps container for safe disposal of the used device or a sharps container for storage and transport to a sharps consolidation location.

Board Position: Support
Status: Senate – Third Reading

AB 865 (Davis) State Agencies: Live Customer Service Agents

Require specified state agencies to answer incoming phone calls within 10 rings by either a live customer service agent or automated telephone answering equipment which then must include an option to reach a live customer service agent.

The department recently advised the board, that given the recent amendments to the bill, the board is no longer affected by this proposal. As such a copy of the bill and analysis is not provided.

Board Position: Neutral
Status: Senate - Third Reading

AB 1394 (Krekorian) Counterfeit: Trademarks

Remove the requirement that the sale of counterfeit mark be intentional and also make it a misdemeanor or a felony for a business entity to willfully manufacture, sell or knowingly possess for sale any counterfeit registered trademark.

During the committee meeting, public comment suggested that pharmacist could be held accountable for unknowingly dispensing counterfeit products. Board staff has requested a legal review on this legislation. Counsel will be present to discuss this with board members and to provide clarification as necessary.

Board Position: Support
Status: Senate Appropriations Committee

AB 1436 (Hernandez) Nurse Practitioners

Revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized body approved by the Board of Registered Nursing. Expand the scope of practice to allow a nurse practitioner to perform comprehensive health care services as specified and is authorized to admit and discharge patients from health facilities, change a treatment regimen and initiate an emergency procedure in collaboration with healing arts practitioners.

Board Position: None
Status: Senate Business, Professions and Economic Development Committee

AB 1574 (Plescia) Surgical clinics: licensure

Would expand the board's licensing authority to issue a clinic permit to surgical clinics to such clinics that are Medicare certified or accredited by an recognized agency and require the board to perform periodic inspections and establish a self-assessment requirement.

Recommended Position: Support
Status: Senate – Second Reading

AB 1587 (De La Torre) Personal Information: Pharmacy

Exclude from the definition of marketing a written communication or written message provided to a pharmacy patient by a pharmacist or pharmacy personnel that meets specified conditions.

Board Position: None
Status: Senate Judiciary Committee – Not heard

According to the sponsor, this bill will not be moved this year. As such a copy of the bill and analysis is not provided.

AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency

Specify that for purposes of furnishing dangerous drugs and devices during an emergency, a pharmacist is not required to await a declaration of emergency as long the declaration is reasonably anticipated due to the severity of the emergency or natural disaster.

Board Position: None
Status: Assembly Appropriations Committee

SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review

Replaces the process whereby a sunsetted board becomes a bureau in the Department of Consumer Affairs (DCA) with reconstitution of the board's members, and specifies other reporting requirements. In addition, it subjects all Executive Officer's to approval of the Director of the Department of Consumer Affairs, as well as to Senate Confirmation, requires the standardization of board meeting minutes for all boards within the DCA and requires reporting of all ex parte communications by board members.

Board staff has requested that counsel review this legislation specific to the ex parte communication and will be prepared to advise the board on what constitutes ex parte communication. In addition, staff counsel will be available to discuss with the board the requirements of the Bagley-Keene Open Meetings Act.

Board Position: None
Status: Assembly Appropriations Committee

SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree

Create an Electronic Pedigree Taskforce to provide the board with updates regarding industry readiness on the implementation of the pedigree requirements as well as submit an annual report to the board and specified legislative committees.

Board Position: None
Status: Assembly Appropriations Committee

SB 1441 (Ridley-Thomas) Healing Arts Practitioners: Substance Abuse

Create the Substance Abuse Coordination Committee with the Department of Consumer Affairs to develop uniform and specific standards that each healing arts board would be required to use in dealing with substance-abusing licensees.

Board Position: None
Status: Assembly Appropriations Committee

b. Inactive Bills

FOR INFORMATION:

Below is a list of inactive/dead bills that the board previously discussed. Copies of these bills are not provided in this packet and can be downloaded from www.leginfo.ca.gov.

AB 1947 (Emmerson) Pharmacy Technicians

Would increase the minimum requirements for licensure as a pharmacy technician to include both certification by the Pharmacy Technician Certification Board as well as either completion of a technician training program or a specified associate's degree. In addition, would require pharmacy technicians to complete 20 hours of continuing education each renewal cycle.

Board Position: None
Status: Hearing Cancelled at the request of the author.

AB 2122 (Plescia) Surgical clinics: licensure

Would define the operational, staffing and procedural standards for surgical clinics and would require the board to perform periodic inspections at least once every three years.

Board Position: None
Status: Assembly Appropriations Committee – Suspense File

AB 2516 (Mendoza) Prescriptions: electronic transmission

Would require a prescriber to ensure that any prescription issued shall be electronically transmitted to the patient's pharmacist of choice, except as specified.

Board Position: None
Status: Failed Deadline

AB 2643 (Cook) Drugs and Devices

Would replace references to the United State Pharmacopoeia in relevant sections of the Business and Professions Code, Health and Safety Code, Insurance Code, Penal Code, Public Resources Code and Welfare and Institutions Code.

Board Position: None
Status: Failed Deadline

SB 1096 (Calderon) Medical Information

Would allow a pharmacy under specified conditions, to mail specified written communications to a patient, without the patient's authorization.

Board Position: Oppose
Status: Failed Passage – Assembly Health Committee

SB 1504 (Ridley-Thomas) Antiepileptic drug products: substitution.

Would prohibit a pharmacist from filling a prescription for an antiepileptic drug that is prescribed by its trade, brand or generic name by substituting a drug product without prior notification of the prescriber and a signed consent of the patient or the patient's agent.

Board Position: None
Status: Failed Deadline

SB 1594 (Steinberg) Bleeding Disorders Clotting Products

Imposes requirements on providers of blood clotting products for home use that are used to treat hemophilia and other bleeding disorders.

Board Position: None
Status: Failed Deadline

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c. Other legislation Impacting Pharmacy of the Board's Jurisdiction

FOR INFORMATION:

SB 1702 (Machado) Medi-Cal: Fraud

Summary:

Requires the Department of Health Care Services (DHCS) to review and, if necessary, conduct a field audit of, a Medi-Cal provider who serves in excess of a threshold percentage of out-of-county beneficiaries. Directs DHCS to determine the threshold in conjunction with the Attorney General and exempts specified providers from mandatory review.

The California Retailers Association (CRA) request that the board add SB 1702 to their watch list. CRA is concerned that in its current form, this legislation could result in additional Medi-Cal audits because it is using county lines as the triggering event for such audits. CRA proposes that a "service area" should be used instead.

Board staff was recently advised that this bill is dead.

Attachment 1

Omnibus Language

AMENDED IN ASSEMBLY JUNE 12, 2008

AMENDED IN ASSEMBLY JUNE 5, 2008

AMENDED IN SENATE MAY 5, 2008

AMENDED IN SENATE APRIL 16, 2008

SENATE BILL No. 1779

Introduced by Committee on Business, Professions and Economic Development (Senators Ridley-Thomas (Chair), Aanestad, Calderon, Corbett, Denham, Florez, Harman, Simitian, and Yee)

March 13, 2008

An act to amend Sections 128.5, 149, 683, 733, 800, 801, 803, 2089.5, 2096, 2102, 2107, 2135, *2168.4,* 2175, 2307, 2335, 2486, 2488, 2570.5, *2570.7,* 2570.6, 2760.1, 3503, 3517, 3518, 3625, 3633.1, 3635, 3636, 3685, 3750.5, 3753.5, 3773, 4022.5, 4027, 4040, 4051, 4059.5, 4060, 4062, 4076, 4081, 4110, 4111, 4126.5, *4161,* 4174, 4231, 4301, 4305, 4329, 4330, 4980.03, 4980.30, 4980.43, 4982, 4989.54, 4992.3, 4996.2, 4996.17, 4996.18, and 4996.23 of, to amend and renumber Section 2570.185 of, to add Sections *2169,* 2570.36, 4036.5, 4980.04, and 4990.09 to, and to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, and 4996.21 of, the Business and Professions Code, to amend Section 8659 of the Government Code, and to amend Sections 11150 and 11165 of the Health and Safety Code, relating to healing arts, *and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1779, as amended, Committee on Business, Professions and Economic Development. Healing arts.

(1) Under existing law, if, upon investigation, a specified state regulatory agency has probable cause to believe that a person is

(b) The licensee shall cooperate in providing additional information as requested by the board. If a licensee fails to provide the requested information within 30 days, the license shall become inactive until the information is received.

~~SEC. 37.~~

SEC. 40. Section 4022.5 of the Business and Professions Code is amended to read:

4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

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

~~SEC. 38.~~

SEC. 41. Section 4027 of the Business and Professions Code is amended to read:

4027. (a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in Section 4052.1, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in Section 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common

ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

~~SEC. 39.~~

SEC. 42. Section 4036.5 is added to the Business and Professions Code, to read:

4036.5. "Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

~~SEC. 40.~~

SEC. 43. Section 4040 of the Business and Professions Code is amended to read:

4040. (a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either Section 4052.1 or 4052.2.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either Section 4052.1 or 4052.2 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

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

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor,

while acting within the scope of his or her license, may have to prescribe a device.

~~SEC. 41.~~

SEC. 44. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052.1, 4052.2, or 4052.3, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

~~SEC. 42.~~

SEC. 45. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the

pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name

and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

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

~~SEC. 43.~~

SEC. 46. Section 4060 of the Business and Professions Code is amended to read:

4060. No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either Section 4052.1 or 4052.2. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

~~SEC. 44.~~

SEC. 47. Section 4062 of the Business and Professions Code is amended to read:

4062. (a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible.

Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.

(2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The mobile pharmacy is located within the declared emergency area or affected areas.

(6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

~~SEC. 45.~~

SEC. 48. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2

orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

~~SEC. 46.~~

SEC. 49. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be

at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

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

~~SEC. 47.~~

SEC. 50. Section 4110 of the Business and Professions Code is amended to read:

4110. (a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.

(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to conduct a pharmacy.

When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage of the pharmacy and an expected restoration date.

(6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

~~SEC. 48.~~

SEC. 51. Section 4111 of the Business and Professions Code is amended to read:

4111. (a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to Section 4052.1 or 4052.2.

~~SEC. 49.~~

SEC. 52. Section 4126.5 of the Business and Professions Code is amended to read:

4126.5. (a) A pharmacy may furnish dangerous drugs only to the following:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

SEC. 53. Section 4161 of the Business and Professions Code is amended to read:

4161. (a) A person located outside this state that *(1)* ships, *sells,* mails, or delivers dangerous drugs or dangerous devices into this state *or (2) sells, brokers, or distributes dangerous drugs or devices within this state* shall be considered a nonresident wholesaler.

(b) A nonresident wholesaler shall be licensed by the board prior to shipping, *selling,* mailing, or delivering dangerous drugs or dangerous devices to a site located in this state *or selling, brokering, or distributing dangerous drugs or devices within this state.*

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, *sold,* mailed, or delivered to a site located in this state *or sold, brokered,*

or distributed within this state. A license shall be renewed annually and shall not be transferable.

(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:

(1) Its agent for service of process in this state.

(2) Its principal corporate officers, as specified by the board, if any.

(3) Its general partners, as specified by the board, if any.

(4) Its owners if the applicant is not a corporation or partnership.

(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.

(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.

(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state *or within this state*, so that the records are in a readily retrievable form.

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident 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.

(k) 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 five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

(*l*) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

~~SEC. 50.~~

SEC. 54. Section 4174 of the Business and Professions Code is amended to read:

4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, or 4052.3.

~~SEC. 51.~~

SEC. 55. Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

~~SEC. 52.~~

SEC. 56. Section 4301 of the Business and Professions Code is amended to read:

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.

(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, of any other 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

1 involving controlled substances or dangerous drugs, to determine
2 if the conviction is of an offense substantially related to the
3 qualifications, functions, and duties of a licensee under this chapter.
4 A plea or verdict of guilty or a conviction following a plea of nolo
5 contendere is deemed to be a conviction within the meaning of
6 this provision. The board may take action when the time for appeal
7 has elapsed, or the judgment of conviction has been affirmed on
8 appeal or when an order granting probation is made suspending
9 the imposition of sentence, irrespective of a subsequent order under
10 Section 1203.4 of the Penal Code allowing the person to withdraw
11 his or her plea of guilty and to enter a plea of not guilty, or setting
12 aside the verdict of guilty, or dismissing the accusation,
13 information, or indictment.
14 (m) The cash compromise of a charge of violation of Chapter
15 13 (commencing with Section 801) of Title 21 of the United States
16 Code regulating controlled substances or of Chapter 7
17 (commencing with Section 14000) of Part 3 of Division 9 of the
18 Welfare and Institutions Code relating to the Medi-Cal program.
19 The record of the compromise is conclusive evidence of
20 unprofessional conduct.
21 (n) The revocation, suspension, or other discipline by another
22 state of a license to practice pharmacy, operate a pharmacy, or do
23 any other act for which a license is required by this chapter.
24 (o) Violating or attempting to violate, directly or indirectly, or
25 assisting in or abetting the violation of or conspiring to violate any
26 provision or term of this chapter or of the applicable federal and
27 state laws and regulations governing pharmacy, including
28 regulations established by the board or by any other state or federal
29 regulatory agency.
30 (p) Actions or conduct that would have warranted denial of a
31 license.
32 (q) Engaging in any conduct that subverts or attempts to subvert
33 an investigation of the board.
34 (r) The selling, trading, transferring, or furnishing of drugs
35 obtained pursuant to Section 256b of Title 42 of the United States
36 Code to any person a licensee knows or reasonably should have
37 known, not to be a patient of a covered entity, as defined in
38 paragraph (4) of subsection (a) of Section 256b of Title 42 of the
39 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. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

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

~~SEC. 53.~~

SEC. 57. Section 4305 of the Business and Professions Code is amended to read:

4305. (a) Failure by any pharmacist to notify the board in writing that he or she has ceased to act as pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified in Sections 4101 and 4113shall constitute grounds for disciplinary action.

(b) Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action.

(c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board that the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge,

shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

~~SEC. 54.~~

SEC. 58. Section 4329 of the Business and Professions Code is amended to read:

4329. Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

~~SEC. 55~~

SEC. 59. Section 4330 of the Business and Professions Code is amended to read:

4330. (a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) Any pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

~~SEC. 56.~~

SEC. 60. Section 4980.03 of the Business and Professions Code is amended to read:

4980.03. (a) "Board," as used in this chapter, means the Board of Behavioral Sciences.

(b) "Intern," as used in this chapter, means an unlicensed person who has earned his or her master's or doctor's degree qualifying him or her for licensure and is registered with the board.

(c) "Trainee," as used in this chapter, means an unlicensed person who is currently enrolled in a master's or doctor's degree program, as specified in Section 4980.40, that is designed to qualify him or her for licensure under this chapter, and who has completed no less than 12 semester units or 18 quarter units of coursework in any qualifying degree program.

(d) "Applicant," as used in this chapter, means an unlicensed person who has completed a master's or doctoral degree program,

Attachment 2

- ***SB 1307(Ridley-Thomas) Pharmacy: Electronic Pedigree***
- ***Letter from State and Consumer Services Agency***
- ***Proposed Amendments***
- ***Letter from the National Association of Boards of Pharmacy***

AMENDED IN ASSEMBLY JUNE 17, 2008

AMENDED IN SENATE MAY 23, 2008

AMENDED IN SENATE APRIL 29, 2008

AMENDED IN SENATE MARCH 25, 2008

SENATE BILL No. 1307

Introduced by Senator Ridley-Thomas

February 20, 2008

An act to amend Sections 4034 and 4163 of, to add Sections 4034.1, 4163.2, ~~and 4163.3~~ *4163.3, and 4163.4* to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as amended, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous

drug and the trade or generic name of the drug. Existing law exempts specified transactions from the pedigree requirement, and authorizes the board to extend the January 1, 2009, compliance date to January 1, 2011, in specified circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would instead, on and after January 1, 2011, define a pedigree, *as specified,* and would require a pedigree to include a specified unique identification number. The bill would also require the board to immediately require the use of federally required standardized numerical identifiers and standardized data elements of a pedigree record if federal standards in that regard are developed under federal law.

The bill would instead prohibit a wholesaler, on and after January 1, ~~2012~~ *2015*, or a pharmacy, on and after July 1, ~~2012~~ *2015*, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree, except as specified. *The bill would require wholesalers and pharmacies, between January 1, 2011, and December 31, 2014, to initiate steps to accept and pass electronic pedigrees for all dangerous drugs subject to the pedigree requirements to enable full readiness to meet the above requirement.* The bill would delete the board's authority to extend these compliance dates. The bill would require a manufacturer of a dangerous drug distributed in California to designate certain percentages of the drugs that it manufactures to comply with the pedigree requirement by specified dates, and to notify the board of the drugs so designated and of the technology to be used to meet that requirement. The bill would also exempt specified additional transactions from the pedigree requirement.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate these drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury, *which would be considered trade secrets and kept confidential by the board.* The bill would~~, for up to 18 months following the operative date of the pedigree requirements,~~ authorize specified dangerous drugs to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements~~, including a written declaration under penalty of perjury stating that the specified dangerous drug met certain requirements~~. Because a knowing

violation of the bill's provisions would be a crime under the Pharmacy Law and because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

The bill would require the board to promulgate regulations defining the circumstances ~~where the board deems it appropriate for manufacturers, wholesalers, or pharmacies, to~~ *under which participants in the distribution chain may* infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, *if certain standard operating procedures are complied with and made available for the board to review. The bill would require board regulations to specify liability associated with accuracy of product information and pedigree using inference.* The bill would declare the intent of the Legislature in this regard.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4034 of the Business and Professions
2 Code is amended to read:
3 4034. (a) "Pedigree" means a record, in electronic form,
4 containing information regarding each transaction resulting in a
5 change of ownership of a given dangerous drug, from sale by a
6 manufacturer, through acquisition and sale by one or more
7 wholesalers, manufacturers, *repackagers,* or pharmacies, until
8 final sale to a pharmacy or other person furnishing, administering,
9 or dispensing the dangerous drug. The pedigree shall be created
10 and maintained in an interoperable electronic system, ensuring
11 compatibility throughout all stages of distribution.
12 (b) A pedigree shall include all of the following information:
13 (1) The source of the dangerous drug, including the name, the
14 federal manufacturer's registration number or a state license
15 number as determined by the board, and principal address of the
16 source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

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

(5) The unique identification number described in subdivision (i).

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or immediate container" of a dangerous drug shall be the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) (A) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(B) The exemption in this paragraph shall expire and be inoperative on January 1, 2012, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2013. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.

(3) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date for manufacturers set forth in subdivision (k) of Section 4034 or Section 4163.5, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the

date of any such determination, this paragraph shall become inoperative.

(4) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(5) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance *in its gaseous or cryogenic liquid form* that meets medical purity standards and has application in a medical *or homecare* environment, including, but not limited to, oxygen and nitrous oxide.

(6) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

(k) This section shall become operative on January 1, 2011. However, the board may extend the date for compliance with this section and Section 4163 in accordance with Section 4163.5.

SEC. 2. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. Notwithstanding anything to the contrary in Section 4034 or 4163, if federal standards are developed pursuant to Section 505D of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355e) regarding the identification, validation, authentication, tracking, and tracing of prescription drugs, and with respect to a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing and repacking at the package or pallet level, the board shall immediately issue emergency regulations or take other action within 30 days to require use of the federally identified standardized numerical identifier as the unique identification number otherwise required by subdivision (i) of Section 4034. In addition, if the federal standards developed pursuant to the above-referenced section of the federal act include a specification of standardized data elements of a pedigree record, those data elements shall be automatically substituted by the board for those otherwise required by subdivision (b) of Section 4034. Notwithstanding subdivision (k) of Section 4034, the requirements of this section with respect to the use of standardized numerical identifiers and specification of standarized data elements shall be in effect immediately upon the board's action to implement this section.

SEC. 3. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) From January 1, 2011, to December 31, 2014, inclusive, wholesalers and pharmacies shall initiate steps to accept and pass electronic pedigrees for all dangerous drugs subject to the

requirements of Section 4034, in order to enable full readiness to comply with subdivisions (d) to (g), inclusive.

~~(c)~~

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2012~~ *2015*, a wholesaler may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

~~(d)~~

(e) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~2012~~ *2015*, a wholesaler may not acquire a dangerous drug without receiving a pedigree.

~~(e)~~

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, ~~2012~~ *2015*, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

~~(f)~~

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, ~~2012~~ *2015*, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

SEC. 4. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory ~~number and batch number and the dates of manufacture~~ *lot number* for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. *Information contained in these*

declarations shall be considered trade secrets and kept confidential by the board.

~~(b) (1) For up to 18 months following the operative date of the pedigree requirements, any~~

(b) Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

~~(2) Any transfer of a dangerous drug without meeting the pedigree requirements shall be accompanied by a written declaration made under penalty of perjury by a responsible party of the transferring entity or person stating that the dangerous drug, identified by its National Drug Code Directory number and batch number and date of manufacture, met the requirements of subdivision (a) and the written declaration prepared pursuant to subdivision (a) shall be attached to this written declaration.~~

~~(3) Both the transferring and receiving parties shall retain for a period of three years and make available for inspection by the board a copy of each written declaration.~~

~~(4) The board may, by regulation, further specify the requirements and procedures for these transfers and the necessary documentation.~~

~~(5) The board may, by regulation, further extend beyond 18 months the period for transfers of nonpedigreed drugs, either for all drugs or for specified categories or subcategories of drugs.~~

SEC. 5. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, *and to facilitate efficiency and safety in the distribution chain,* the board shall, by regulation, define the circumstances under which ~~the board deems it appropriate for~~

participants in the distribution chain ~~to~~ *may* infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

(c) Manufacturers, wholesalers, and pharmacies opting to employ the use of inference as authorized by the board to comply with the pedigree requirements shall document their processes and procedures in their standard operating procedures (SOPs) and shall make those SOPs available for board review.

(d) SOPs regarding inference shall include a process for statistically sampling the accuracy of information sent with inbound product.

(e) Liability associated with accuracy of product information and pedigree using inference shall be specified in the board's regulations.

SEC. 6. Section 4163.4 is added to the Business and Professions Code, to read:

4163.4. (a) All units of dangerous drug in the possession of a wholesaler or pharmacy, for which the manufacturer does not hold legal title on the effective date of the pedigree requirement set forth in Section 4163.5, shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163. However, if any units of those drugs are subsequently returned to the manufacturer, they shall be subject to the pedigree requirements if the manufacturer distributes those units in California.

(b) All units of dangerous drug manufactured in California but distributed outside the state for dispensing outside the state shall not be subject to the pedigree requirements set forth in Sections 4034 and 4163 at either the time of initial distribution or in the event that any of those units are subsequently returned to the manufacturer.

~~SEC. 6.~~

SEC. 7. Section 4163.5 of the Business and Professions Code is repealed.

~~SEC. 7.~~

SEC. 8. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1) The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. Those benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.

(2) At the same time, it is recognized that the process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, pharmacies, and other supply chain participants. The Legislature seeks to ensure continued availability of prescription drugs in California while drug manufacturers implement these requirements.

(b) ~~On or before January 1, 2010~~ *Before January 1, 2011*, each manufacturer of a dangerous drug to be distributed in California shall designate drugs representing a minimum of 20 percent of the drugs, generic or single source, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with *the January 1, 2011, deadline of* the state's serialized pedigree requirement set forth in Sections 4034 and 4163. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

(c) ~~On or before January 1, 2011~~ *Before January 1, 2013*, each manufacturer shall designate a minimum of an additional 30 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, ~~2012~~ *2013*. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

(d) ~~On or before January 1, 2012~~ *Before January 1, 2015*, each manufacturer shall designate a minimum of an additional 50 percent of the drugs for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, ~~2013~~ *2015*. The manufacturer shall notify the Board of Pharmacy of the drugs so designated and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirement.

~~(e) All new dangerous drugs that are approved for sale on or after January 1, 2011, shall be subject to the serialized electronic pedigree requirements set forth in Sections 4034 and 4163 when introduced on the market, and shall not be included in a manufacturer's yearly implementation quota.~~

(e) For purposes of designating drugs to be serialized as required by subdivisions (b), (c), and (d), manufacturers shall select from any of the following measures:

(1) Unit volume.

(2) Product package (SKU) type.

(3) Drug product family.

(f) Drugs not subject to compliance with the pedigree requirements set forth in Sections 4034 and 4163 under this section shall not be subject to the provisions of subdivisions (c), (d), (e), and (f) of Section 4163.

~~SEC. 8.~~

SEC. 9. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

ARNOLD SCHWARZENEGGER
GOVERNOR

State and Consumer Services Agency

915 CAPITOL MALL, SUITE 200
SACRAMENTO, CA 95814

African American Museum
Building Standards Commission
Consumer Affairs
Fair Employment & Housing
Fair Employment & Housing Commission
Franchise Tax Board
General Services
Information Security and Privacy Protection
Insurance Advisor
Science Center
Seismic Safety Commission
Personnel Board
Public Employees' Retirement System
Teachers' Retirement System
Technology Services
Victim Compensation & Government Claims Board

June 20, 2008

The Honorable Mark Ridley-Thomas
California State Senate
State Capitol, Room 4061
Sacramento, CA 95814

RE: SB 1307 (Ridley-Thomas) – Oppose Unless Amended

Dear Senator Ridley-Thomas:

The State and Consumer Services Agency has reviewed the June 17, 2008 version of SB 1307 and has taken an oppose unless amended position. We continue to look forward to an opportunity to meet with you and discuss the amendments we provided to your office on June 13, 2008.

These amendments will ensure consumer protections by establishing a mandatory accreditation process for those in the distribution chain that do not utilize an e-pedigree and generates fines of up to $5,000 per saleable unit for those that violate either method of distribution. The accreditation process will protect the security of drug distribution in California and will reduce the cost pressure on drug prices. This will allow us to work together to build upon Governor Schwarzenegger's additional healthcare priorities, including e-prescribing, personal health records and healthcare access. These are priorities that you clearly share given your past support of healthcare reform efforts.

As you know, the existing law presents significant costs to state and local governments and non-profits including pharmacies, hospitals, clinics, prisons and mental health facilities. Each receiving entity will be required to acquire the hardware deployed by each manufacturer and existing resources will need to be redirected to provide the necessary training for staff and system maintenance. At a time of increased budget pressures it is important that we evaluate every opportunity to reduce or avoid costs that will not harm public safety or reduce services to

Californians. The existing law would likely require tens of millions of dollars annually in additional General Fund allocations if it is determined to be a local mandate.

I look forward to working with you.

Sincerely,

Greg Hurner
Deputy Secretary, Legislation

cc: Members, Assembly Business & Professions Committee
Jennifer Kent, Deputy Legislative Secretary, Office of the Governor

BILL NUMBER: SB 1307 AS PROPOSED TO BE AMENDED

AMENDED IN SENATE MAY 23, 2008
AMENDED IN SENATE APRIL 29, 2008
AMENDED IN SENATE MARCH 25, 2008

INTRODUCED BY Senator Ridley-Thomas

FEBRUARY 20, 2008

An act to amend Sections 4034, ~~and~~ 4163 ***and 4314*** of, to add Sections 4034.1, 4163.2, and 4163.3 to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

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SECTION 1. Section 4034 of the Business and Professions Code is amended to read:

4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug ***from the point it leaves the accredited distribution chain,*** ~~from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies,~~ until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system~~, ensuring compatibility throughout all stages of distribution~~.

(b) A pedigree shall include all of the following information:

(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.

(2) The trade or generic name of the drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

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

(5) The unique identification number described in subdivision ~~(i)~~ *(j)*.

(c) A single pedigree shall include every change of ownership of a given dangerous drug from ***the point it leaves the accredited distribution chain*** ~~its initial manufacture~~ through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.

(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug. For purposes of this section, the "smallest package or

immediate container" of a dangerous drug shall be the smallest unit made by the manufacturer for sale to the pharmacy or other person furnishing, administering, or dispensing the drug.

(e) Any return of a dangerous drug, ***that has left the accredited distribution chain,*** to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.

(f) If a licensed health care service plan, hospital organization, and one or more physician organizations have exclusive contractual relationships to provide health care services, drugs distributed between these persons shall be deemed not to have changed ownership.

(g) The following transactions are exempt from the pedigree requirement created by this section:

(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.

(2) (A) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.

(B) The exemption in this paragraph shall expire and be inoperative on January 1, 2012, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2013. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 113[illegible] Division 3 of the Government Code.

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(3) (A) A sale, trade, or transfer of a radioactive drug, as defined in Section 1708.3 of Title 16 of the California Code of Regulations, between any two entities licensed by the Radiologic Health Branch of the State Department of Public Health, the federal Nuclear Regulatory Commission, or an Agreement state.

(B) The exemption in this paragraph shall remain in effect unless the board, no earlier than the date that is two years after the compliance date ~~for manufacturers~~ set forth in subdivision ~~(k)~~ *(1)* of Section 4034 ~~or Section 4163.5~~, determines after consultation with the Radiologic Health Branch of the State Department of Public Health that the risk of counterfeiting or diversion of a radioactive drug is sufficient to require a pedigree. Two years following the date of any such determination, this paragraph shall become inoperative.

(4) The sale, trade, or transfer of a dangerous drug that is labeled by the manufacturer as "for veterinary use only."

(5) The sale, trade, or transfer of compressed medical gas. For purposes of this section, "compressed medical gas" means any substance that meets medical purity standards and has application in a medical environment, including, but not limited to, oxygen and nitrous oxide.

(6) The sale, trade, or transfer of solutions. For purposes of this section, "solutions" means any of the following:

(A) Those intravenous products that, by their formulation, are intended for the replenishment of fluids and electrolytes, such as sodium, chloride, and potassium, calories, such as dextrose and amino acids, or both.

(B) Those intravenous products used to maintain the equilibrium of water and minerals in the body, such as dialysis solutions.

(C) Products that are intended for irrigation or reconstitution, as well as sterile water, whether intended for those purposes or for injection.

(7) The sale, transfer or trade of a dangerous drug through the accredited distribution chain. For purposes of this section, "accredited distribution chain" means a chain of custody for a dangerous drug that goes by drop shipment or is directly sold, traded or transferred from either: (a) a manufacturer of the dangerous drug; (b) a manufacturer's co-licensee; (c) a manufacturer's wholesaler; (d) a manufacturer's exclusive distributor to: a chain pharmacy wholesaler, pharmacy, hospital, clinic or other designated persons authorized by law to dispense or administer the drug to a patient; or either (e)(1) a distributor or wholesaler that is accredited by the National Association of Board of Pharmacy's Verified-Accredited Wholesale Distributors program or (2) other standards adopted by the Board developed pursuant to subdivision (h). For purposes of this section "chain pharmacy wholesaler" means a physical location for drugs that acts as a central warehouse and performs intracompany sales or transfers of drugs to a group of chain pharmacies that have the same common ownership and control.

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(h) ***The board shall develop guidelines for the purpose of accrediting distributors and wholesalers who are not accredited by the National Board of Pharmacy. These guidelines shall include provisions that provide assurance of security to the supply chain and patient protection. The guidelines shall be developed by regulation on or before January 1, 2010. The Board shall consult with the Healthcare Distribution Management Association and representatives from the secondary wholesalers.***

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(i) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has ~~been sold or~~ distributed in or through this state.

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~~(i)~~ ***(j)*** "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point ~~of manufacture~~ ***the drug leaves the accredited distribution chain,*** contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.

~~(j)~~ ***(k)*** The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

~~(k)~~ ***(l)*** This section shall become operative on January 1, 2011.

However, the board may extend the date for compliance with this section and Section 4163 in accordance with Section 4163.5.

(m) The Board shall adopt regulations no later than January 1, 2010, setting forth the manner and means by which the prescription drugs, subject to the pedigree requirements are to be identified, validated and authenticated. The method of tracking and tracing the dangerous drugs shall utilize a standardized numerical identifier to be applied to the drug container at the point drug leaves the accredited distribution chain.

(n) The board shall establish by regulation the structure for an audit system that provides periodic auditing of the distribution of dangerous drugs within the state.

(1) All invoices and packing slips in the Accredited Chain of Distribution shall be by lot number corresponding to lot received.

(2) If (a) is not met, then the Board may impose penalties pursuant to Section 4314.

SEC. 2. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. Notwithstanding anything to the contrary in Section 4034 or 4163, if federal standards are developed pursuant to Section 505D of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355e) regarding the identification, validation, authentication, tracking, and tracing of prescription drugs, and with respect to a standardized numerical identifier to be applied to a prescription drug at the point of manufacturing and repacking at the package or pallet level, ***sections 4034 and 4163 shall be deemed preempted by the federal standard upon the effective date of the federal standard, and*** the board shall immediately issue emergency regulations or take other action within 30 days to require use of the federally identified standardized numerical identifier as the unique identification number otherwise required by subdivision ~~(i)~~ ***(j)*** of Section 4034. In addition, if the federal standards developed pursuant to the above-referenced section of the federal act include a specification of standardized data elements of a pedigree record, those data elements shall be automatically substituted by the board for those otherwise required by subdivision~~s~~ (b)~~-~~ ***(h)*** of Section 4034. Notwithstanding subdivision ~~(k)~~ ***(l)*** of Section 4034, the requirements of this section with respect to the use of standardized numerical identifiers and specification of standarized data elements shall be in effect immediately upon the board's action to implement this section.

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SEC. 3. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) A manufacturer or wholesaler may not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section ~~4163.5~~ ***4034***, commencing on January 1, 2012, a wholesaler may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree ***to a non-accredited person.***

(d) Except as otherwise provided in Section ~~4163.5~~ *4034*, commencing on January 1, 2012, a wholesaler may not acquire a dangerous drug without receiving a pedigree ***from a non-accredited person.***

(e) Except as otherwise provided in Section ~~4163.5~~ *4034*, commencing on July 1, 2012, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree ***to a non-accredited person.***

(f) Except as otherwise provided in Section ~~4163.5~~ *4034*, commencing on July 1, 2012, a pharmacy may not acquire a dangerous drug without receiving a pedigree ***from a non-accredited person.***

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SEC. 4. Section 4163.2 is added to the Business and Professions Code, to read:

4163.2. (a) (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

(2) The written declaration shall include the National Drug Code Directory number and batch number and the dates of manufacture for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations.

(b) (1) For up to 18 months following the operative date of the pedigree requirements, any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.

(2) Any transfer of a dangerous drug without meeting the pedigree requirements shall be accompanied by a written declaration made under penalty of perjury by a responsible party of the transferring entity or person stating that the dangerous drug, identified by its National Drug Code Directory number and batch number and date of manufacture, met the requirements of subdivision (a) and the written declaration prepared pursuant to subdivision (a) shall be attached to this written declaration.

(3) Both the transferring and receiving parties shall retain for a period of three years and make available for inspection by the board a copy of each written declaration.

(4) The board may, by regulation, further specify the requirements and procedures for these transfers and the necessary documentation.

(5) The board may, by regulation, further extend beyond 18 months the period for transfers of nonpedigreed drugs, either for all drugs or for specified categories or subcategories of drugs.

SEC. 5. Section 4163.3 is added to the Business and Professions Code, to read:

4163.3. (a) It is the intent of the Legislature that participants in the ***non-accredited*** distribution chain for dangerous drugs, including manufacturers, wholesalers, or pharmacies furnishing, administering, or dispensing dangerous drugs, distribute and receive electronic

pedigrees, and verify and validate the delivery and receipt of dangerous drugs against those pedigrees at the unit level, in a manner that maintains the integrity of the pedigree system without an unacceptable increase in the risk of diversion or counterfeiting.

(b) To meet this goal, the board shall, by regulation, define the circumstances under which the board deems it appropriate for participants in the ***non-accredited*** distribution chain to infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

SEC. 6. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 7. Section 4163.5 is added to the Business and Professions Code , to read:

4163.5. (a) The Legislature hereby finds and declares that:

(1) ***Technological innovations have the potential to provide significant benefits for consumers by improving communications between doctors and pharmacists; allowing accurate transfer of prescriptions between providers; and increasing the portability of personal health records for diagnosis and treatment.***

(2) ***The State Board of Pharmacy, in conjunction with the relevant stakeholder community including, but not limited to, consumer protection advocates, pharmaceutical manufacturers, health care providers, distributors, health facilities and pharmacists, shall work to assist the state in implementing electronic prescribing authority by 2012.***

(3) Public access to a safe, effective and reliable supply of beneficial drugs at reasonable costs help to extend and improve the quality of life of our state's citizens. ~~The electronic pedigree system required by Sections 4034 and 4163 will provide tremendous benefits to the public and to all participants in the distribution chain. These benefits should be made available as quickly as possible through the full cooperation of prescription drug supply chain participants. To this end, all drug manufacturers and repackagers are strongly encouraged to serialize drug products and initiate electronic pedigrees as soon as possible, and all participants in the supply chain are encouraged to immediately ready themselves to receive and pass electronic pedigrees.~~

(3) ~~At the same time, it is recognized that the~~ ***The*** process of implementing serialized electronic pedigree for all prescription drugs in the entire chain of distribution is a complicated technological and logistical undertaking for manufacturers, wholesalers, pharmacies, and other supply chain participants~~. The Legislature seeks to ensure continued availability of prescription drugs in California while drug manufacturers implement these requirements.~~ ***and its effectiveness will be compromised without a national standard.***

(4) The federal government is strongly encouraged to develop a national standard for the tracking and tracing of drugs that will target any deficiencies in the supply chain without needlessly increasing the costs or limiting access of drugs to the public.

(b) ***The Board shall annually post on their website a report on:***

(1) Any case of counterfeit drugs in California confirmed by a state or federal agency.

(2) The source of the counterfeit drug.

(3) The location the counterfeit drug entered the supply chain.

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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) ***Notwithstanding any other provision of law, for any knowing or intentional violation of Section 4034, the board may issue a citation containing a fine not to exceed $10,000 for each event.***

(e) Any entity that knowingly or intentionally fails to produce sufficient records required to demonstrate compliance with Section 4034 (n) shall be subject to a fine of up to $5,000 per saleable unit.

(f) Any entity that knowingly or intentionally provides the board with a fraudulent pedigree shall be subject to a fine of up to $5,000 per saleable unit.

(g) 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.

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nabp

National Association of Boards of Pharmacy

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July 9, 2008

Honorable Senator Ridley-Thomas
California State Senate
Capitol Building #4061
Sacramento, CA 95814

Senator Ridley-Thomas:

I am writing today on behalf of the Executive Committee of the National Association of Boards of Pharmacy (NABP). We recently learned that amendments to SB 1307 have been presented that reference our Verified-Accredited Wholesale Distributors (VAWD) program. Our understanding is that these proposed amendments would create an "accredited distribution channel" that would ultimately replace California's existing law and exempt accredited wholesalers from California's pedigree requirements. To that end, we would like to provide background information on our VAWD program and our involvement in the effort to prevent counterfeit drugs from entering the legitimate supply chain.

VAWD Program

In 2005, NABP's VAWD program launched, with the goal of serving as a *licensure* tool to assist the Boards of Pharmacy in effectively regulating wholesale distributors. Our program comprises of an in-depth policy and procedure review, criminal background checks, verification of a surety bond, an on-site inspection and a criteria compliance review (based on our Model Rules). To date, we have accredited 275 wholesale distributors. From a Board of Pharmacy perspective, 2 Boards require VAWD for all wholesale distributors that ship drugs into their state and 21 others recognize VAWD-accredited wholesaler distributors as meeting their licensure requirements.

Model Rules for Licensure of Wholesale Distributors

Since the inception of the Prescription Drug Marketing Act, NABP has worked with the Boards of Pharmacy to develop uniform standards for the licensure and regulation of wholesale distributors. In our Model Rules, NABP has long advocated for a pedigree system like what California presently has in law, that would track and trace a prescription drug throughout the distribution system. In 2005, to address concerns from industry about their ability to comply with such a track and trace pedigree system, NABP chose to endorse the "normal distribution concept" as an interim solution—a band-aid—with the understanding that industry would continue to work toward compliance with a full pedigree system—similar to what is currently in California law. Our current Model Rules still advocate for such a pedigree system.

SB 1307
While NABP appreciates the authors of the proposed amendments for recognizing the same value that the Boards of Pharmacy have found with our accreditation program, we cannot support the proposed amendments. While the "accredited distribution channel" concept would be "good for business", we cannot support a proposal that would take California a step backward with their pedigree system and do away with an end-to-end system that is sorely needed to protect the drug distribution system—not just in California, but across the country.

NABP remains committed to assisting the state of California in working toward a solution that will protect their citizens from the threat of counterfeit drugs. Please do not hesitate to contact us if we can be of additional assistance on this matter.

Respectfully Submitted,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Carmen A. Catizone, MS, RPh, DPh
Executive Directory/Secretary

cc: NABP Executive Committee
Virginia Herold, Executive Director, CA Board of Pharmacy

Attachment 3

- ***Bills***
- ***Bill Analysis***

AMENDED IN SENATE JUNE 19, 2008

AMENDED IN SENATE JUNE 11, 2008

AMENDED IN SENATE MAY 6, 2008

AMENDED IN SENATE MARCH 13, 2008

AMENDED IN ASSEMBLY JANUARY 29, 2008

AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY JUNE 21, 2007

AMENDED IN ASSEMBLY APRIL 30, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 501

Introduced by Assembly Members Swanson and Hancock (Coauthor: Assembly Member Dymally)

February 20, 2007

An act to add Section 118288 to the Health and Safety Code, relating to pharmaceutical devices.

LEGISLATIVE COUNSEL'S DIGEST

AB 501, as amended, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act prohibits, on or

after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

This bill would require a pharmaceutical manufacturer whose product is administered for home use through a prefilled syringe, prefilled pen, or other prefilled injection device to arrange to provide, upon request from a consumer, a postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the department or a sharps container for the safe storage and transport of sharps to a sharps consolidation location approved by the department or a clinic, physician, or pharmacy that accepts home-generated sharps waste, as defined, along with concise information on safe disposal alternatives and options for sharps *and notice of the act's above described prohibition, that commences September 1, 2008.* As ~~an alternative~~ *a means of meeting these above described requirements*, the manufacturer may provide the consumer with a coupon that can be exchanged for, or a toll-free telephone number or Web site that can direct the patient to a supplier of, a qualified sharps container. This bill would also prohibit the manufacturer, or any person or agent with whom the manufacturer contracts, from using information collected for this purpose for any other purpose.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. The Legislature finds and declares all of the
2 following:
3 (a) An estimated 1 million Californians must self-inject
4 prescription medications annually to treat a broad range of serious
5 health problems.
6 (b) The use of prefilled syringes, prefilled pens, and other
7 prefilled devices with needles is an effective method of prescription
8 drug delivery and is expected to increase significantly in the future.
9 Prefilled syringes, prefilled pens, and other prefilled devices with
10 needles are clearly identified and linked to specific pharmaceutical

manufacturers for the provision of their product to California residents.

(c) The increased use of prefilled syringes, prefilled pens, and other prefilled devices with needles will generate millions of home-generated sharps each year. Prefilled pen devices are being used for the treatment of some of the most serious health conditions such as HIV/AIDS, hepatitis C, and many other diseases. If improperly disposed in solid waste and recycling containers these needles will result in significant public health risks.

(d) The Legislature has found that sharps mail-back programs utilizing containers and packaging approved by the United States Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that the cooperative efforts of the pharmaceutical industry are needed to develop a safe needle disposal system for California.

SEC. 2. Section 118288 is added to the Health and Safety Code, to read:

118288. (a) Upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device for administration at home ~~that meets the definition of home-generated sharps waste in Section 117671,~~, a pharmaceutical manufacturer shall arrange to provide the consumer with either of the following:

(1) A postage prepaid, mail-back sharps container that has been approved by the United States Postal Service and the State Department of Public Health.

(2) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by the State Department of Public Health or to a clinic, physician, or pharmacy that accepts home-generated sharps waste.

(3) In addition to providing an appropriate sharps container, the manufacturer shall provide information on safe disposal alternatives and options for sharps *and notice to the consumer that effective September 1, 2008, California law prohibits a person from knowingly disposing of home-generated sharps in any container used for the collection of solid waste, recyclable materials, or green waste or for the commercial collection of solid waste or recyclable materials from business establishments.*

(b) For purposes of this section, "sharps container" has the same meaning as in Section 117750.

(c) As ~~an alternative to~~ *a means of* meeting the requirements of subdivision (a), a manufacturer may do either of the following:

(1) Supply a coupon, either to be delivered to the patient or with the device when it is dispensed, that may be exchanged for a sharps container that meets the requirements of paragraph (1) or (2) of subdivision (a).

(2) Provide a toll-free telephone number or Web site, noted on the packaging containing the device, that directs the patient to a supplier of sharps containers that meets the requirements of paragraph (1) or (2) of subdivision (a).

(d) A manufacturer shall not use or disclose information that it receives in the course of complying with this section for any other purpose, including, but not limited to, marketing, without the written consent of the consumer. This prohibition shall apply to any person or agent with whom the manufacturer contracts or otherwise makes arrangements to carry out the requirements of this section.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 501 **VERSION: As amended June 19, 2008**

AUTHOR: Swanson **SPONSOR: Alameda County Board of Supervisors**

POSITION: Support

SUBJECT: Pharmaceutical devices: hypodermic needle and syringe disposal

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EXISTING LAW:

1. Prohibits the disposal of a hypodermic needle or syringe on the grounds of a playground, beach, park, or any public or private elementary school, vocational, junior high or high school.
2. States that a person who knowingly violates this section is guilty of a misdemeanor.
3. Requires that on or after September 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers:
   a. Any container used for collection of solid waste or recyclable materials, or greenwaste
   b. Any container used for the commercial collection of solid waste or recyclable materials from business establishments
   c. Any roll-off container used for collectables of solid waste, construction, and demolition debris, greenwaste or other recyclable materials
4. Requires that on or after September 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency and shall only be managed at any of the following:
   a. A household hazardous waste facility
   b. A "home generated sharps consolidation point"
   c. A medical waste generator's facility
   d. A facility though the use of an approved medical waste mail-back container

THIS BILL WOULD:

1. Make a number of findings and declarations about the medical need and use of prefilled self-injection prescription medications.
2. State that the Legislature has found that sharps mail-back programs approved by the U.S. Postal Service offer one of the most convenient means for collecting and destroying home-generated sharps and that cooperative efforts of the pharmaceutical industry is necessary to develop a safe needle disposal system.
3. Requires that upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device administered at home, the manufacturer must arrange to provide either of the following:
   - A postage prepaid, mail-back sharps container that has been approved by the U.S. Postal Service and the Department of Public Health (DPH)
   - A sharps container for the safe storage and delivery to a sharps consolidation location approved by the DPH or to a clinic, physician or pharmacy that accepts home-generated sharps waste.
4. Requires that the pharmaceutical manufacturer provide information on safe disposal alternatives and options for sharps as well as a notice to consumers that effective September 1, 2008, California law prohibits a person from disposing of such items in any container used for collection of solid waste, recycle, green waste or commercial collection of solid waste or recyclable materials from business establishments.
5. Defines "sharps container" consistent with the definition in Health and Safety Code Section 117750.

AUTHOR'S INTENT

This bill is intended as a continuation of the legislation regarding the safe needle program - - and to further that purpose. Consumers currently do not have a safe way to dispose of used needles and syringes. According to the author, at least two billion lawful injections of medications occur yearly outside of health care settings in California and that most of these used needles end up in household trash, posing a signification risk or injury and/or infection.

COMMENTS

As initially introduced, this bill would have required a pharmaceutical company whose product is dispensed in the form of a prefilled syringe, prefilled pen, or other prefilled injection device to make available, at no cost and through an annually renewable program, postage pre-paid, mail-back sharps containers. This bill has been amended several times.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 – Prohibits, as of September 1, 2008, a person from placing home-generated sharps waste in specified commercial and residential solid waste collection containers, including containers used for recyclable materials or greenwaste as well as roll-off containers used for construction and demolition debris. It also requires that home-generated sharps waste be transported in an approved sharps container with an approved facility approved by the Department of Toxics and removes home-generated sharps waste as among those items subject to the state's medical waste control laws. The board had no position on this legislation.

FISCAL IMPACT

The board does not anticipate any substantial fiscal impact on its operations. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION

Support

Alameda County Board of Supervisors (Sponsor)
California Association of Environmental Health Administrators (if amended)
California Association of Sanitation Agencies
California Conference of Machinists
California Labor Federation
California Nurses Association
California Refuse Removal Council
County of Santa Clara Board of Supervisors
Engineers and Scientists of California
Los Angeles County Solid Waste Management Committee
National Multiple Sclerosis Society-California Action Network

Planning and Conservation League
Regional Council of Rural Counties (Support if amended)
San Mateo County Central Labor Council
Solid Waste Association of North America
United Food and Commercial Workers Union, Western States Council

Oppose
Amgen
California Healthcare Institute
Del Norte Solid Waste Management Authroity (Oppose unless amended)
Sanofi-aventis

HISTORY:

Date	Action
06/26/08	June 26 From committee: Do pass. (Ayes 6. Noes 3.)
06/19/08	June 19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
06/11/08	June 11 In committee: Set, first hearing. Hearing canceled at the request of author. From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
05/06/08	May 6 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
03/13/08	Mar. 13 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
02/07/08	Feb. 7 Referred to Com. on HEALTH.
01/30/08	Jan. 30 In Senate. Read first time. To Com. on RLS. for assignment.
01/29/08	Jan. 29 Read third time, amended, and returned to third reading. (Page 3855.). Assembly Rule 69(d) suspended. Read third time, passed, and to Senate. (Ayes 45. Noes 27. Page 3871.)
01/17/08	Jan. 17 Read second time. To third reading.
01/16/08	Jan. 16 From committee: Do pass. (Ayes 9. Noes 6.) (January 15).
01/10/08	Jan. 10 Re-referred to Com. on HEALTH.
01/09/08	Jan. 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
01/08/08	Jan. 8 Re-referred to Com. on HEALTH.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
06/25/07	June 25 Re-referred to Com. on HEALTH.
06/21/07	June 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
05/08/07	May 8 In committee: Set, second hearing. Hearing canceled at the request of author.
05/01/07	May 1 In committee: Set, first hearing. Hearing canceled at the request of author.
05/01/07	May 1 Re-referred to Com. on HEALTH.
04/30/07	Apr. 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

03/22/07 Mar. 22 Referred to Com. on HEALTH.
02/21/07 Feb. 21 From printer. May be heard in committee March 23.
02/20/07 Feb. 20 Read first time. To print.

AMENDED IN SENATE JUNE 24, 2008

AMENDED IN SENATE JUNE 2, 2008

AMENDED IN ASSEMBLY JANUARY 9, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1394

Introduced by Assembly Member Krekorian

February 23, 2007

An act to amend Section 350 of the Penal Code, relating to counterfeiting.

LEGISLATIVE COUNSEL'S DIGEST

AB 1394, as amended, Krekorian. Counterfeit: trademarks.

Existing law makes it a misdemeanor or a felony for a person to willfully manufacture, intentionally sell, or knowingly possess for sale any counterfeit registered trademark, as specified. Existing law also provides, upon conviction, for the forfeiture and destruction of all the counterfeit trademarks and related articles, as specified. Existing law regarding counterfeited trademarks also applies to unassembled components of computer software packages. Under existing law, a court is required to order restitution, as specified, to a victim of a crime.

~~This bill would, in addition, make it a misdemeanor or a felony for a person or business entity, as specified, to intentionally transport, offer for sale, or distribute any counterfeit registered trademark, as specified. This bill would also increase the maximum fine allowed to be imposed upon conviction. This bill would require the forfeiture of all proceeds from the willful manufacture, intentional transport, sale, offering for~~

~~sale, distribution, or knowing possession for sale of any counterfeit registered trademark. This bill would also apply provisions related to counterfeited trademarks to unassembled components, as specified, and would require restitution to be paid to the victim of a trademark offense.~~

This bill would remove the requirement that the sale of the counterfeit mark be intentional. This bill would, in addition, make it a misdemeanor or a felony for a business entity, as defined, to willfully manufacture, sell, or knowingly possess for sale any counterfeit registered trademark, as specified. This bill would specify the procedure for the forfeiture of the counterfeited items. This bill would also expand the definition of a "counterfeit mark."

Because this bill would expand the definition of an existing crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 350 of the Penal Code is amended to
2 read:
3 350. (a) Any person or business entity who willfully
4 manufactures, ~~intentionally transports,~~ sells, ~~offers for sale, or~~
5 ~~distributes;~~ or knowingly possesses for sale any counterfeit mark
6 registered with the Secretary of State or registered on the Principal
7 Register of the United States Patent and Trademark Office, shall,
8 upon conviction, be punishable as follows:
9 (1) When the offense involves less than 1,000 of the articles
10 described in this subdivision, with a total retail or fair market value
11 less than that required for grand theft as defined in Section 487,
12 and if the person is an individual, he or she shall be punished by
13 a fine of not more than five thousand dollars ($5,000), or by
14 imprisonment in a county jail for not more than one year, or by
15 both that fine and imprisonment; or, if the person is a business
16 entity, by a fine of not more than one hundred thousand dollars
17 ($100,000).

(2) When the offense involves 1,000 or more of the articles described in this subdivision, or has a total retail or fair market value equal to or greater than that required for grand theft as defined in Section 487, and if the person is an individual, he or she shall be punished by imprisonment in a county jail not to exceed one year, or in the state prison for 16 months, or two or three years, or by a fine not to exceed ~~the greater of~~ two hundred fifty thousand dollars ($250,000), or ~~three times the total retail or fair market value of the articles described in this subdivision, or~~ by both that imprisonment and fine; or, if the offender is a business entity, by a fine not to exceed ~~the greater of~~ five hundred thousand dollars ($500,000) ~~or three times the total retail or fair market value of the articles described in this subdivision.~~.

(b) Any offender who has been convicted of a violation of either paragraph (1) or (2) of subdivision (a) shall, upon a subsequent conviction of paragraph (1) of subdivision (a), if the offender is an individual, be punished by a fine of not more than fifty thousand dollars ($50,000), or by imprisonment in a county jail for not more than one year, or in the state prison for 16 months, or two or three years, or by both that fine and imprisonment; or, if the offender is a business entity, by a fine of not more than two hundred thousand dollars ($200,000).

(c) Any offender who has been convicted of a violation of subdivision (a) and who, by virtue of the conduct that was the basis of the conviction, has directly and foreseeably caused death or great bodily injury to another through reliance on the counterfeited item for its intended purpose shall, if the person is an individual, be punished by a fine of not more than fifty thousand dollars ($50,000), or by imprisonment in the state prison for two, three, or four years, or by both that fine and imprisonment; or, if the offender is a business entity, by a fine of not more than two hundred thousand dollars ($200,000).

(d) In any action brought under this section resulting in a conviction or a plea of nolo contendere, the court shall order the forfeiture and destruction of all of those marks and of all goods, articles, or other matter bearing the marks, and the forfeiture and destruction or other disposition of all means of making the marks, and any and all electrical, mechanical, or other devices for manufacturing, reproducing, transporting, or assembling these marks, that were used in connection with, or were part of, any

violation of this ~~section, and the forfeiture of all proceeds of the crime.~~ *section. Forfeiture of the proceeds of the crime shall be subject to Chapter 9 (commencing with Section 186) of Title 7 of Part 1.* However, no vehicle shall be forfeited under this section that may be lawfully driven on the highway with a class 3 or 4 license, as prescribed in Section 12804 of the Vehicle Code, and that is any of the following:

(1) A community property asset of a person other than the defendant.

(2) The sole class 3 or 4 vehicle available to the immediate family of that person or of the defendant.

(3) Reasonably necessary to be retained by the defendant for the purpose of lawfully earning a living, or for any other reasonable and lawful purpose.

(e) For the purposes of this section, the following definitions shall apply:

(1) When counterfeited but unassembled components of computer software packages are recovered, including, but not limited to, counterfeited computer diskettes, instruction manuals, or licensing envelopes, the number of "articles" shall be equivalent to the number of completed computer software packages that could have been made from those components.

(2) "Business entity" includes, but is not limited to, a corporation~~,~~ *or a* limited liability ~~company, or sole proprietorship.~~ *company. "Business entity" does not include a sole proprietorship.*

(3) "Counterfeit mark" means a spurious mark that is identical with, or confusingly similar to, a registered mark and is used, or intended to be used, on or in connection with the same type of goods or services for which the genuine mark is registered. It is not necessary for the mark to be displayed on the outside of an article for there to be a violation. For articles containing digitally stored information, it shall be sufficient to constitute a violation if the counterfeit mark appears on a video display when the information is retrieved from the article. The term "spurious mark" includes genuine marks used on or in connection with spurious articles and includes identical articles containing identical marks, where the goods or marks were reproduced without authorization of, or in excess of any authorization granted by, the registrant. When counterfeited but unassembled components of any articles described under subdivision (a) are recovered, including, but not

limited to, labels, patches, fabric, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging, or any other components of any type or nature that are designed, marketed, or otherwise intended to be used on or in connection with any articles described under subdivision (a), the number of "articles" shall be equivalent to the number of completed articles that could have been made from those components.

~~(4) "Intentionally transports," "intentionally offers for sale," or "intentionally distributes" requires knowing possession, custody, or control.~~

~~(5)~~

(4) "Knowingly possess" means that the person or business entity possessing an article knew or had reason to believe that it was spurious, or that it was used on or in connection with spurious articles, or that it was reproduced without authorization of, or in excess of any authorization granted by, the registrant.

~~(6)~~

(5) "Registrant" means any person or business entity to whom the registration of a mark is issued and that person's or business entity's legal representatives, successors, or assigns.

~~(7)~~

(6) "Sale" includes resale.

~~(8)~~

(7) "Value" has the following meanings:

(A) When counterfeit items of computer software are manufactured or possessed for sale, the "value" of those items shall be equivalent to the retail price or fair market price of the true items that are counterfeited.

(B) When counterfeited but unassembled components of computer software packages or any other articles described under subdivision (a) are recovered, including, but not limited to, counterfeited digital disks, instruction manuals, licensing envelopes, labels, patches, fabric, stickers, wrappers, badges, emblems, medallions, charms, boxes, containers, cans, cases, hangtags, documentation, or packaging, or any other components of any type or nature that are designed, marketed, or otherwise intended to be used on or in connection with any articles described under subdivision (a), the "value" of those components shall be equivalent to the retail price or fair market value of the number of

completed computer software packages or other completed articles described under subdivision (a) that could have been made from those components.

(C) "Retail or fair market value" of a counterfeit article means a value equivalent to the retail price or fair market value, as of the last day of the charged crime, of a completed similar genuine article containing a genuine mark.

(f) This section shall not be enforced against any party who has adopted and lawfully used the same or confusingly similar mark in the rendition of like services or the manufacture or sale of like goods in this state from a date prior to the earliest effective date of registration of the service mark or trademark either with the Secretary of State or on the Principle Register of the United States Patent and Trademark Office.

(g) An owner, officer, employee, or agent who provides, rents, leases, licenses, or sells real property upon which a violation of subdivision (a) occurs shall not be subject to a criminal penalty pursuant to this section, unless he or she sells, or possesses for sale, articles bearing a counterfeit mark in violation of this section. This subdivision shall not be construed to abrogate or limit any civil rights or remedies for a trademark violation.

(h) This section shall not be enforced against any party who engages in fair uses of a mark, as specified in Section 14247 of the Business and Professions Code.

(i) When a person or business entity is convicted of an offense under this section, the court shall order the person to pay restitution to the trademark owner and any other victim of the offense pursuant to Section 1202.4.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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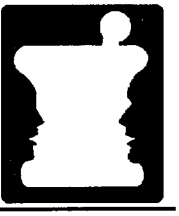
CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1394 **VERSION: As amended June 24, 2008**

AUTHOR: Krekorian **SPONSOR: California Chamber of Commerce**

BOARD POSITION: Support

SUBJECT: Counterfeit Trademarks

EXISTING LAW

1. Prohibits the manufacture, sale and possession for sale of counterfeit products as specified in Penal Code §350.
2. Establishes the penalties for an offense and sets fine amounts of $250,000 for individuals and $500,000 for corporations for an offense that involves 1,000 or more articles.
3. Requires as part of a conviction or a plea of nolo contendere, the forfeiture and destruction of all of those marks and of all goods, articles and other matter bearing marks used in connection with, or were part of any violation.
4. Defines counterfeit mark.

THIS BILL WOULD

1. Make it a misdemeanor or a felony for a person or a "business entity", as defined, to willfully manufacture, sell or knowingly possess for sale any counterfeit mark.
2. Remove from current law the requirement that the sale of a counterfeit mark be intentionally to be punishable as a criminal offense.
3. Require as part of a conviction or a plea of nolo contendere, that forfeiture of all proceeds of the crime shall be subject to Chapter 9 (commencing with Section 186) of Title 7 of Part 1.
4. Add a new definition for the new term "business entity" that specifies that a business entity includes a corporation, or limited liability company, and does not include a sole proprietorship.

5. Expand the definition of a counterfeit mark to also include not only those marks used, but also those intended to be used. Clarify that when counterfeited but unassembled components of any articles are recovered, the number of articles shall be equivalent to the number of completed articles that could have been made from those components.
6. Expand the unassembled components of articles to be included when determining the value that could have been made from the components.
7. Require the court to order a convicted person of an offense to pay restitution to the trademark owner or other victim of the offense.
8. Shall not be enforced against any party who engages in fair uses of a mark, as specified in Section 14247 of the Business and Professions Code.

AUTHOR'S INTENT

According to the Sponsor, current law is unclear and lacks consistency with federal law. Several unclear provisions create loopholes that undermine enforcement efforts.

COMMENT

This bill has been amended several times. As amended in January 2008, this proposal would have strengthened the criminal penalties against counterfeit operations and mesh with our public protection mandate and e-pedigree requirements. Several of these provisions were subsequently amended out of the proposal.

FISCAL IMPACT

The board does not anticipate any substantial fiscal impact on its operations. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION

Support
California Alliance for Consumer Protection
California Grocers Association

California Retailers Association
International AntiCounterfeiting Coalition
United States Chamber of Commerce
Valley Industry and Commerce Association

Oppose
None on file

HISTORY

Dates	Actions
06/24/08	June 24 Read second time, amended, and re-referred to Com. on APPR.
06/23/08	June 23 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 4. Noes 0.) .
06/04/08	June 4 In committee: Set, first hearing. Hearing canceled at the request of author.
06/02/08	June 2 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on PUB. S.
05/23/08	May 23 Withdrawn from committee. Re-referred to Com. on PUB. S.
02/07/08	Feb. 7 Referred to Coms. on JUD. and PUB. S.
01/28/08	Jan. 28 In Senate. Read first time. To Com. on RLS. for assignment.
01/28/08	Jan. 28 Read third time, passed, and to Senate. (Ayes 75. Noes 0. Page 3840.)
01/24/08	Jan. 24 In committee: Set, first hearing. Referred to APPR. suspense file. From committee: Do pass. (Ayes 16. Noes 0. Page 3814.) (January 24). Read second time. To third reading.
01/16/08	Jan. 16 From committee: Do pass, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. Re-referred. (Ayes 7. Noes 0.) (January 15).
01/10/08	Jan. 10 Re-referred to Com. on PUB. S.
01/09/08	Jan. 9 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
01/08/08	Jan. 8 Re-referred to Com. on PUB. S.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
03/22/07	Mar. 22 Referred to Com. on PUB. S.
02/26/07	Feb. 26 Read first time.
02/25/07	Feb. 25 From printer. May be heard in committee March 27.
02/23/07	Feb. 23 Introduced. To print.

AMENDED IN SENATE JUNE 10, 2008

AMENDED IN SENATE MAY 23, 2008

AMENDED IN ASSEMBLY JANUARY 7, 2008

AMENDED IN ASSEMBLY MAY 30, 2007

AMENDED IN ASSEMBLY APRIL 17, 2007

AMENDED IN ASSEMBLY APRIL 9, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1436

Introduced by Assembly Member Hernandez
(Coauthor: Assembly Member Niello)

February 23, 2007

An act to amend Sections 2725.5 and 2835.5 of, and to add Section 2835.7 to, the Business and Professions Code, relating to nursing.

LEGISLATIVE COUNSEL'S DIGEST

AB 1436, as amended, Hernandez. Nurse practitioners.

Existing law, the Nursing Practice Act, provides for the certification and regulation of nurse practitioners and nurse-midwives by the Board of Registered Nursing and specifies requirements for qualification or certification as a nurse practitioner. Under the act, the practice of nursing is defined, in part, as providing direct and indirect patient care services, as specified, including dispensing of drugs or devices upon their order in a clinic setting, as defined.

This bill would provide that a nurse practitioner is authorized to perform comprehensive health care services, *as specified,* for which he or she is educationally prepared and competent to perform, and *is*

authorized to admit and discharge patients from health facilities, *change a treatment regimen, or initiate an emergency procedure,* in collaboration, as defined, with specified healing arts practitioners. The bill would ~~deem specified authorizations by a physician and surgeon to include authorizations provided by a certified nurse practitioner~~ *make a nurse practitioner independently responsible for the performance of these services*. The bill would require a certified nurse practitioner to consult or refer a patient to another health care provider if a situation or condition occurs beyond the nurse practitioner's knowledge and experience. The bill also would revise the educational requirements for qualification or certification as a nurse practitioner and would require a nurse practitioner to be certified by a nationally recognized certifying body approved by the board. The bill would require the board to adopt specified regulations.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 2725.5 of the Business and Professions
2 Code is amended to read:
3 2725.5. (a) "Advanced practice registered nurse" means those
4 licensed registered nurses who have met the requirements of Article
5 2.5 (commencing with Section 2746), Article 7 (commencing with
6 Section 2825), Article 8 (commencing with Section 2834), or
7 Article 9 (commencing with Section 2838).
8 (b) Advanced practice registered nursing is based on knowledge
9 and skills acquired in basic nursing education, licensure as a
10 registered nurse, graduation from a graduate level advanced
11 practice registered nursing program approved by the board, and
12 current certification by a national certifying body in the appropriate
13 advanced practice registered nursing role and specialty.
14 SEC. 2. Section 2835.5 of the Business and Professions Code
15 is amended to read:
16 2835.5. (a) A registered nurse who is holding himself or herself
17 out as a nurse practitioner or who desires to hold himself or herself
18 out as a nurse practitioner shall, within the time prescribed by the
19 board and prior to his or her next license renewal or the issuance
20 of an initial license, submit educational, experience, and other
21 credentials and information as the board may require for it to

determine that the person qualifies to use the title "nurse practitioner," pursuant to the standards and qualifications established by the board.

(b) Upon finding that a person is qualified to hold himself or herself out as a nurse practitioner, the board shall appropriately indicate on the license issued or renewed, that the person is qualified to use the title "nurse practitioner." The board shall also issue to each qualified person a certificate evidencing that the person is qualified to use the title "nurse practitioner."

(c) A person who has been found to be qualified by the board to use the title "nurse practitioner" prior to the effective date of this section shall not be required to submit any further qualifications or information to the board and shall be deemed to have met the requirements of this section.

(d) An applicant for initial qualification or certification as a nurse practitioner under this article who has not been qualified or certified as a nurse practitioner in California or any other state shall meet the following requirements:

(1) Hold a valid and active registered nursing license issued under this chapter.

(2) Possess a master's degree or doctoral degree in nursing.

(3) Satisfactorily complete a nurse practitioner program approved by the board.

(4) Be certified as a nurse practitioner by a nationally recognized certifying body approved by the board.

SEC. 3. Section 2835.7 is added to the Business and Professions Code, to read:

2835.7. (a) A certificate to practice as a nurse practitioner authorizes the holder to provide comprehensive health care ~~services, including, but not limited to, advanced assessment,~~ *services through psychosocial assessment, physical* diagnosis, and management of health and illness needs for which the nurse practitioner has been educationally prepared and is clinically competent to perform.

(b) Notwithstanding any other provision of law, a nurse practitioner, in collaboration with a physician and surgeon or doctor of osteopathy, may admit patients to and discharge patients from hospitals, skilled nursing facilities, nursing facilities, home health care, hospice facilities, and other inpatient facilities, subject to medical staff privileges. ~~"Collaboration," for the purposes of this~~

~~section, is defined as a relationship between a nurse practitioner and a physician and surgeon that includes both autonomous and cooperative decisionmaking, with the nurse practitioner and the physician and surgeon contributing their respective expertise.~~

~~(c) Notwithstanding any other provision of law, whenever any law or regulation requires a signature, certification, stamp, verification, affidavit, or endorsement by a physician and surgeon, it shall be deemed to include a signature, certification, stamp, verification, affidavit, or endorsement by a nurse practitioner.~~ *In addition, a nurse practitioner may, in collaboration with a physician and surgeon or doctor of osteopathy, change any treatment regimen ordered by a physician and surgeon or doctor of osteopathy, or initiate an emergency procedure. "Collaboration" means, for purposes of this section, consultation with a physician and surgeon or doctor of osteopathy in person, telephonically, or electronically.*

~~(d)~~

(c) A nurse practitioner shall consult or refer a patient to a physician and surgeon or other health care provider if the referral will protect the health and welfare of the patient and a situation or condition occurs in a patient that is beyond the nurse practitioner's knowledge and experience.

(d) A nurse practitioner shall be independently responsible for the performance of services authorized by this section.

(e) Nothing in this article shall be construed to limit, revise, or expand the current scope of practice of a registered nurse, as defined in Section ~~2527~~ *2725*.

(f) The board shall adopt regulations necessary to effectuate the purposes of this chapter relating to nurse practitioners, and has sole authority to interpret the practice of nurse practitioners.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1436 **VERSION: As amended June 10, 2008**

AUTHOR: Hernandez **SPONSOR: CA Association for Nurse Practitioners**

BOARD POSITION: None

SUBJECT: Nurse practitioners: scope of practice.

EXISTING LAW

1. Defines the scope of practice for nurse practitioners.
2. Allows a nurse practitioner to dispense drugs pursuant to a protocol and specifies the conditions under which this can be done.
3. Details the requirements for a certificate evidencing that a person is qualified as a nurse practitioner.
4. Specifies the information required on a written order for a prescriber.

THIS BILL WOULD

1. Specify that advanced practice registered nursing is based on knowledge and skills acquired in basic nursing education, licensure as a registered nurse, graduation from a graduate level advanced practice registered nursing program approved by the Board of Registered Nursing (board) and current certification.
2. Revise the education requirement for an initial qualification or certification as a nurse practitioner to include either a master's degree or a doctoral degree in nursing.
3. Require satisfactory completion of a nurse practitioner program approved by the board.
4. Require that the nurse practitioner be certified by a nationally recognized certifying body approved by the board.
5. Allow a certified nurse practitioner to provide comprehensive health care services through psychosocial assessment, physical diagnosis and management of health and illness needs for which the nurse practitioner has been educationally prepared and is clinically competent to perform.
6. Allow a nurse practitioner, in collaboration with a physician, surgeon or doctor of osteopathy, to admit patients and discharge patients from specified healthcare settings.
7. Allow a nurse practitioner, in collaboration with a physician, surgeon or doctor of osteopathy, to change any treatment regimen ordered or initiate an emergency procedure.

8. Require a nurse practitioner to consult or refer a patient to another health care provider if the referral protects the health and welfare of the patient and it situation or condition in the patient is beyond the nurse practitioner's knowledge and experience
9. Specify that a nurse practitioner is independently responsible for the performance of services authorized by this bill.
10. Require the Board of Registered Nursing to promulgate regulations as necessary.

AUTHOR'S INTENT

According to the sponsor, this bill strengthens requirements for licensure as a nurse practitioner, defines the standards for Advanced Practice Registered Nursing, and defines the scope of practice for nurse practitioners. The sponsor indicates that requiring certification will align California with other states that require similar certification and maintain a high level of quality care delivered by nurse practitioners. In addition, the sponsor states that the bill is necessary to define the scope of practice of nurse practitioners and eliminate confusion among stakeholders.

PRIOR HISTORY/RELATED BILLS

SB 809 (Ashburn) defined the scope of practice of nurse practitioners and authorized nurse practitioners to perform specified acts. This bill was never heard and died in committee.

FISCAL IMPACT

The board does not anticipate any fiscal impact. Any minor impact could be absorbed within existing resources.

COMMENTS

This proposal was significantly amended on several occasions. The board did not take a position on this legislation previously; however, earlier discussions by the board about this legislation included concern about the potential increase in prescription errors by nurse practitioners. The provisions to allow for a nurse practitioner to independently prescribe dangerous drugs and devices was amended out of the bill in April 2007.

SUPPORT/OPPOSITION

Support
California Association of Nurse Practitioners (Sponsor)

American Federation of State, County and Municipal Employees
Association of California Health Care Districts
California Family Health Council, Inc.
California Nurses Association (Support if Amended)
United Nurses Association of California/Union of Health Care Professionals
Numerous individuals, including nurse practitioners

Oppose
American College of Obstetricians and Gynecologists District IX
American Society for Dermatologic Surgery Association
California Academy of Eye Physicians and Surgeons
California Academy of Family Physicians
California Academy of Physician Assistants
California Medical Association
California Society of Health Systems Pharmacists
California Society of Plastic Surgeons
Medical Board of California

HISTORY:

Dates	Actions
06/10/08	June 10 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
06/04/08	June 4 In committee: Set, first hearing. Hearing canceled at the request of author.
05/23/08	May 23 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
02/07/08	Feb. 7 Referred to Com. on B., P. & E.D.
01/30/08	Jan. 30 In Senate. Read first time. To Com. on RLS. for assignment.
01/29/08	Jan. 29 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 3883.)
01/24/08	Jan. 24 From committee: Do pass. To Consent Calendar. (January 24). Read second time. To Consent Calendar.
01/15/08	Jan. 15 From committee: Do pass, and re-refer to Com. on APPR. with recommendation: To Consent Calendar. Re-referred. (Ayes 10. Noes 0.) (January 15).
01/08/08	Jan. 8 Re-referred to Com. on B. & P.
01/07/08	Jan. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
05/31/07	May 31 Re-referred to Com. on B. & P.
05/30/07	May 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/24/07	Apr. 24 In committee: Set, first hearing. Hearing canceled at the request of author.
04/23/07	Apr. 23 Joint Rule 62(a), file notice waived. (Page 1106.)
04/18/07	Apr. 18 Re-referred to Com. on B. & P.
04/17/07	Apr. 17 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/10/07	Apr. 10 Re-referred to Com. on B. & P.

04/09/07 Apr. 9 Referred to Coms. on B. & P. and HEALTH. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be heard in committee March 27.

02/23/07 Feb. 23 Introduced. To print.

AMENDED IN SENATE JULY 2, 2008

AMENDED IN SENATE JUNE 16, 2008

AMENDED IN SENATE JULY 5, 2007

AMENDED IN SENATE JUNE 19, 2007

AMENDED IN ASSEMBLY MAY 15, 2007

AMENDED IN ASSEMBLY MAY 3, 2007

AMENDED IN ASSEMBLY APRIL 23, 2007

AMENDED IN ASSEMBLY MARCH 29, 2007

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 1574

Introduced by Assembly Members Plescia and Jones (Coauthor: Assembly Member Villines)

February 23, 2007

An act to amend Section 4190 of the Business and Professions Code, relating to clinics.

LEGISLATIVE COUNSEL'S DIGEST

AB 1574, as amended, Plescia. Surgical clinics: licensure.

Existing law, with certain exceptions, provides for the licensure and regulation of clinics, including specialty clinics, by the State Department of Public Health. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. The Pharmacy Law, the knowing violation of which is as misdemeanor, provides that a surgical clinic may not operate and is not entitled to the benefits of

specified provisions of the Pharmacy Law without a license issued by the California State Board of Pharmacy. Existing law authorizes the board to inspect a clinic at any time.

This bill would, instead, provide that a surgical clinic that is licensed by the State Department of Public Health, ~~accredited as~~ an *accredited* outpatient setting, or ~~certified as~~ an ambulatory surgical center *certified* to participate in the Medicare Program, as specified, is not entitled to the above-described benefits without a license issued by the board. It would also specify board inspection requirements and would require self-assessments by any clinic licensed by the board. Because this bill would impose new requirements under the Pharmacy Law, the knowing violation of which would be a misdemeanor, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. This act shall be known, and may be cited, as the
2 California Outpatient ~~Surgery~~ *Pharmacy* Patient Safety and
3 Improvement Act.
4 SEC. 2. Section 4190 of the Business and Professions Code is
5 amended to read:
6 ~~4190. (a) Notwithstanding any provision of this chapter, a~~
7 ~~surgical clinic, licensed pursuant to paragraph (1) of subdivision~~
8 ~~(b) of Section 1204 of the Health and Safety Code, accredited as~~
9 ~~an outpatient setting by an accreditation agency, as defined in~~
10 ~~Section 1248 of the Health and Safety Code, or certified as an~~
11 ~~ambulatory surgical center to participate in the Medicare Program~~
12 ~~under Title XVIII of the federal Social Security Act (42 U.S.C.~~
13 ~~Sec. 1395 et seq.),~~
14 *4190. (a) For the purposes of this section, "clinic" means a*
15 *surgical clinic licensed pursuant to paragraph (1) of subdivision*
16 *(b) of Section 1204 of the Health and Safety Code, an outpatient*
17 *setting accredited by an accreditation agency, as defined in Section*

1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) Notwithstanding any other provision of this chapter, a clinic may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the ~~facility~~ *clinic*, as provided in subdivision ~~(b). The facility~~ *(c). 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 three years for inspection by all properly authorized personnel.

~~(b)~~

The drug distribution service of a ~~surgical clinic, outpatient setting, or ambulatory surgical center~~ *clinic* shall be limited to the use of drugs for administration to the patients of the ~~surgical~~ clinic, ~~outpatient setting, or ambulatory surgical center and to the~~ *and to the* dispensing of drugs for the control of pain and nausea for patients of the ~~facility~~ *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, outpatient setting, or ambulatory surgical center shall~~

(d) No clinic shall be entitled to the benefits of this section until it has obtained a *clinic* license from the board. A separate license shall be required for each ~~facility location. A facility~~ *clinic location. A clinic* shall notify the board of any change in the ~~facility's~~ *clinic's* address on a form furnished by the board.

~~(d)~~

(e) 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 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

~~(e)~~

(f) (1) The board shall inspect an outpatient setting or ambulatory surgical center within 120 days of the issuance of a

clinic license pursuant to this article, and at least annually thereafter.

(2) The board may inspect a surgical clinic within 120 days of the issuance of a *clinic* license pursuant to this article, and ~~at least~~ *may inspect the surgical clinic* annually thereafter.

~~(3) Every surgical clinic, outpatient setting, or ambulatory surgical center issued a license pursuant to this article shall~~

(3) Every clinic licensed pursuant to this article shall complete a self-assessment within 30 days of ~~opening~~ *licensure* and at least 30 days before each license renewal pursuant to this article. The completed self-assessment form shall be retained at the licensed premises for a period of three years.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1574 **VERSION: As Amended July 2, 2008**

AUTHOR: Plescia **SPONSOR: CA Ambulatory Surgery Assoc.**

RECOMMENDED POSITION: Support

SUBJECT: Surgical centers: licensure

EXISTING LAW

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours.
2. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale unless licensed by the California State Board of Pharmacy (board).
3. Defines the licensing requirements for the board to issue a clinic license to an ambulatory surgery center.

THIS BILL WOULD

1. Modify the licensing requirements for a board-issued clinic license for a surgical clinic to include:
   - licensure by the Department of Public Health (DPH) under 1204 and 1212.5 of the Health and Safety Code
   - accreditation by an approved agency or
   - certification to participate in the Medicare Program.

   (This board-issued license would allow the clinic to purchase drugs at wholesale for administration or dispensing as well as commingle medications.)
2. Require the board to inspect a board-licensed surgical clinic that is accredited by an agency or certified to participate in the Medicare Program within 120 days of the issuance of the license and at least on an annual basis thereafter.
3. Require a board licensed surgical clinic to complete a self-assessment within 30 days of issuance of the license and at least 30 days before each license renewal.

AUTHOR'S INTENT

According to the author, a recent court ruling, Capen v. Shewry, prohibits the Department of Public Health from issuing state licenses to ambulatory surgical centers, which are partially or wholly owned by physicians. As a result, such surgical centers do not qualify for a clinic license from the board. The board-issued clinic license allows the facility to maintain a commingled drug supply as well as purchase drugs at wholesale. The author argues that without this proposal, individual physicians will be required to maintain a myriad of medication to dispense at the point of care, as opposed to medication being centralized.

PRIOR HISTORY/RELATED BILLS

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated, "While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner."

The board had no position on this bill.

AB 543 (Plescia) of 2007 – This bill was vetoed by the governor. The veto message stated, "I am returning Assembly Bill 543 without my signature. While I support the intent of this legislation, I am unable to sign it as it lacks critical patient safety protections. This bill doesn't establish appropriate time limits for performing surgery under general anesthesia. Further, it inappropriately restricts administrative flexibility and creates state fiscal pressure during ongoing budget challenges. I am directing the Department of Public Health to pursue legislation that establishes licensure standards for these facilities that are consistent with federal requirements and protect the health and safety of patients. For these reasons, I am returning AB 543 without my signature."

The board had a support position on this bill.

AB 2122 (Plescia) of 2008 – This bill died in the assembly appropriations committee. The board had a support position on this bill.

FISCAL IMPACT

The sponsor believes that 400 or more additional locations would qualify under the new criteria for licensure as a drug clinic by the board. The board anticipates the need for a part-time office technician to process new applications, should all eligible facilities choose to pursue licensure with the board. In addition, the board would require an additional inspector to complete initial and annual inspections of those surgical licenses specified.

Board staff anticipates additional revenue from additional businesses seeking licensure. This revenue would offset a significant portion of the impact incurred with the additional staff required to implement the provision.

COMMENTS

Current law allows the board to issue a clinic license only to an entity licensed by H&S Code section 1204. However there is no requirement that a surgical center must be licensed by the DPH to operate. The unintended consequence is that approximately 400–500 ambulatory surgical centers do not qualify for licensure as a clinic by the board, but would under this bill.

There are currently four approved accreditation agencies:

- American Association for Accreditation of Ambulatory Surgery Facilities Inc. (AAAASF)
- Accreditation Association for Ambulatory Health Care (AAAHC)
- Joint Commission of Accreditation of Healthcare Organizations (JCAHO)
- The Institute for Medical Quality (IMQ)

SUPPORT/OPPOSITION

Support

California Ambulatory Surgery Association (sponsor)

Oppose

California Society of Plastic Surgeons (CSPS) is opposed unless amended to this bill.

HISTORY

Date	Action
06/19/08	June 19 Re-referred to Com. on HEALTH.

06/17/08 June 17 Withdrawn from committee. Re-referred to Com. on RLS.

06/16/08 June 16 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on JUD.

07/10/07 July 10 In committee: Set, first hearing. Hearing canceled at the request of author.

07/05/07 July 5 Read second time, amended, and re-referred to Com. on JUD.

07/03/07 July 3 From committee: Amend, do pass as amended, and re-refer to Com. on JUD. (Ayes 7. Noes 3.) .

06/19/07 June 19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on T. & H.

06/07/07 June 7 Referred to Coms. on T. & H. and JUD.

05/21/07 May 21 In Senate. Read first time. To Com. on RLS. for assignment.

05/21/07 May 21 Read third time, passed, and to Senate. (Ayes 51. Noes 6. Page 1572.)

05/16/07 May 16 Read second time. To third reading.

05/15/07 May 15 Read second time and amended. Ordered returned to second reading.

05/14/07 May 14 From committee: Amend, and do pass as amended. (Ayes 6. Noes 0.) (May 9).

05/07/07 May 7 Re-referred to Com. on H. & C.D.

05/03/07 May 3 Read second time and amended.

05/02/07 May 2 From committee: Amend, do pass as amended, and re-refer to Com. on H. & C.D. (Ayes 10. Noes 0.) (May 1).

04/24/07 Apr. 24 In committee: Hearing postponed by committee.

04/24/07 Apr. 24 Re-referred to Com. on JUD.

04/23/07 Apr. 23 From committee chair, with author's amendments: Amend, and re-refer to Com. on JUD. Read second time and amended.

04/09/07 Apr. 9 Re-referred to Com. on JUD.

03/29/07 Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com. on JUD. Read second time and amended.

03/26/07 Mar. 26 Referred to Coms. on JUD. and H. & C.D.

02/26/07 Feb. 26 Read first time.

02/25/07 Feb. 25 From printer. May be heard in committee March 27.

02/23/07 Feb. 23 Introduced. To print.

AMENDED IN SENATE JUNE 23, 2008

AMENDED IN SENATE JUNE 12, 2008

AMENDED IN ASSEMBLY APRIL 21, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 2756

Introduced by Assembly Member Duvall

February 22, 2008

An act to amend Section 4062 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2756, as amended, Duvall. Pharmacists: furnishing drugs during emergency.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Existing law authorizes a pharmacist to furnish dangerous drugs or devices in reasonable quantities without a prescription during a federal, state, or local emergency to further the health and safety of the public, as specified. Existing law authorizes the board, during a declared federal, state, or local emergency, to waive application of any provisions of the Pharmacy Law or the regulations adopted thereunder if the waiver will aid in the protection of the public health or the provision of patient care.

This bill would define a federal, state, or local emergency for purposes of these provisions, as specified. The bill would also specify that, for purposes of furnishing dangerous drugs or devices during a federal, state, or local emergency, a pharmacist is not required to await a declaration of emergency so long as the declaration is reasonably

anticipated due to the severity of the ~~conditions believed to constitute an~~ emergency *or natural disaster*.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

1 SECTION 1. Section 4062 of the Business and Professions
2 Code is amended to read:
3 4062. (a) Notwithstanding Section 4059 or any other provision
4 of law, a pharmacist may, in good faith, furnish a dangerous drug
5 or dangerous device in reasonable quantities without a prescription
6 during a federal, state, or local emergency, to further the health
7 and safety of the public. A record containing the date, name, and
8 address of the person to whom the drug or device is furnished, and
9 the name, strength, and quantity of the drug or device furnished
10 shall be maintained. The pharmacist shall communicate this
11 information to the patient's attending physician as soon as possible.
12 Notwithstanding Section 4060 or any other provision of law, a
13 person may possess a dangerous drug or dangerous device
14 furnished without prescription pursuant to this section.
15 (b) During a declared federal, state, or local emergency, the
16 board may waive application of any provisions of this chapter or
17 the regulations adopted pursuant to this chapter if, in the board's
18 opinion, the waiver will aid in the protection of public health or
19 the provision of patient care.
20 (c) For the purposes of subdivision (a), "federal, state, or local
21 emergency" shall mean and include those conditions or degrees
22 of emergency identified in Section 8558 of the Government Code
23 and those forms of disaster identified in Section 8680.3 of the
24 Government Code. For the purposes of subdivision (a), a
25 pharmacist is not required to await a declaration of emergency by
26 federal, state, or local authorities as a prerequisite to acting in good
27 faith to furnish dangerous drugs or dangerous devices in reasonable
28 quantities without a prescription during such emergency, so long
29 as such a declaration is reasonably anticipated due to the severity
30 of the ~~conditions believed to constitute an~~ emergency or *natural*
31 disaster.

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