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

Legislation and Regulation Committee

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LEGISLATION REPORT

ITEM A: DISCUSSION AND ACTION ON PENDING LEGISLATION

1. Board Sponsored Legislation

a. SB 1307 (Ridley-Thomas) Electronic Pedigree

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, 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.

A copy of the language in its current form is found in **ATTACHMENT 1**.

b. 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, 4101, 4101, 4160, 4196, 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.

Section 4362 – Entry Into Pharmacists Recovery Program (PRP)

This section specifies the administrative co-pay participants pay as part of their participation in the PRP. The board subsidizes the administrative cost, however requires the participant to also pay a portion of the administrative costs of the program. The current administrative co-pay, \$75.00, is set by contract only. The board has not sought a change in this co-pay in over 10 years, and has continually absorbed the additional monthly administrative fee, currently about \$230/month per participant.

This section allows the board the ability to waive a participant's co-pay for demonstrated financial hardship.

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

A copy of the proposed language as presented to Senate Business and Professions is provided in **ATTACHMENT 2**.

FOR ACTION:

Discussion at the Legislation and Regulation Committee included a request that the board clarify section B&PC section 4110 to allow for the use of a mobile pharmacy when the licensed premises is undergoing a remodel. It is recommended that this language in B&PC 4110 be clarified to allow for the use of a mobile pharmacy as described above.

c. Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices

At the April 2007 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices.

After consideration, it was decided not to move the proposal this year. However, it will be reconsidered for possible sponsorship in 2009.

ITEM G: LEGISLATION INTRODUCED IMPACTING THE PRACTICE OF PHARMACY OR THE BOARD'S JURISDICTION

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. There are no committee recommendations.

a. 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 at no additional charge, a postage prepaid mail-back sharps container for safe disposal of the used device.

Committee Recommendation: No change to current position
Board Position: Support
Status: Senate Health Committee

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

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

Committee Recommendation: No change to current position
Board Position: Neutral
Status: Senate Governmental Organization Committee

c. AB 1394 (Krekorian) Counterfeit: Trademarks

This proposal would strengthen the criminal penalties against counterfeit operations.

Committee Recommendation: No change to current position
Board Position: Support
Status: Senate Judiciary Committee and Public Health Committee

d. 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.

Committee Recommendation: Continue to watch the bill
Board Position: None
Status: Senate Business, Professions and Economic Development Committee

e. 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.

The committee was advised that according to the sponsor, this proposal will not move forward unless amendments are agreed upon by various interested stakeholders. Representatives for the sponsor indicated that they do not believe this proposal will move forward this year.

Board Position: None
Status: Senate Judiciary Committee

f. 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.

The committee was advised that this proposal will not move forward this year. The sponsor of the legislation, CSHP, indicated that they will be creating a stakeholders task force to reach consensus and pursue a proposal next year to change the licensing requirements for pharmacy technicians.

A bill analysis for this proposal is not provided as the matter was withdrawn.

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

g. 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.

Committee Recommendation: Support AB 2122, as amended March 24, 2008
Board Position: None
Status: Assembly Appropriations Committee

h. AB 2425 (Coto) State Department of Public Health: water quality: pharmaceuticals

Would require every pharmaceutical manufacturer that does business in California and whose pharmaceutical products have been detected in the drinking water supplies within California to file a report with the State Public Health Officer as specified.

Committee Recommendation: None
Board Position: None
Status: Assembly Health Committee

i. 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.

Committee Recommendation: None
Board Position: None
Status: Assembly Business and Professions Committee

j. AB 2643 (Cook) Drugs and Devices

Would replace references to the United States 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.

The committee was advised that this proposal will not move forward this year. A bill analysis for this proposal is not provided as the matter was withdrawn.

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

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

Makes a nonsubstantive change to Business and Professions Code section 4062.

The bill's sponsor advised the committee that this bill is currently in spot language. This bill will be amended to clarify that a pharmacy can dispense prescriptions during a natural disaster, before a formal declaration of a federal, state, or local emergency.

The committee did not make a recommendation on this proposal, as the amendments are not yet incorporated into the legislation.

Board Position: None
Status: Assembly Business and Professions Committee

l. SB 963 (Ridley Thomas) Regulatory Boards: Sunset Review

Delete provisions subjecting boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection and instead make each of those boards subject to review by a standing policy committee of the Legislature upon request by a member of the Legislature or the chief of the Office of the Consumer Advocate.

The committee was advised this proposal is intended to redefine the Sunset Review Process. The committee did not make a recommendation on this proposal.

Board Position: None
Status: Assembly Business and Professions Committee

m. 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. This bill was recently amended to specify that the information provided to the patient must be in same language as the prescription label and that the information must instruct the patient when to contact a health care professional.

The sponsor of this proposal presented information to the committee about this proposal. At the request of the committee, the sponsor followed up with a written copy of testimony provided, sample

of the information that would be provided by as part of this proposal as well as two studies. This information is provided after the bill and analysis in your packet.

Board Position: Oppose
Status: Senate Health Committee

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

This bill was recently amended and now would create an Electronic Pedigree Taskforce, consisting of specified representatives from the pharmaceutical industry drug supply chain, to provide the board with updates regarding industry readiness of the implementation on the pedigree requirement and the challenges thereof. It also requires the task force to provide an annual report to the board and the Senate and Assembly policies committees with jurisdiction over the issue.

This bill was amended after the committee met. There is no committee recommendation on this bill.

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

o. AB 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 from substituting a drug product without prior notification of the prescriber and a signed consent of the patient or the patient's agent.

The committee was advised that the author withdrew this proposal. A bill analysis for this proposal is not provided as the matter was withdrawn.

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

p. 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.

The committee discussed this proposal briefly and requested that staff complete some additional research on the matter and proposal.

Board Position: None
Status: Senate Appropriations Committee

ITEM B: OTHER LEGISLATION IMPACTING PHARMACY FOR THE BOARD'S JURISDICTION.

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.

A copy of this bill and analysis are provided in **ATTACHMENT 4**.

AB 2661 (Dymally) Telemedicine

Summary

Adds telephone communication to the definition of telemedicine, requires the practitioner practicing telemedicine by telephone to use an electronic medical record (EMR) and provides that a practitioner may be designated by the patient.

This proposal was withdrawn by the author's office. A bill analysis for this proposal is not provided as the matter was withdrawn.

ITEM C: UPDATE ON THE IMPLEMENTATION OF SB 966 (Simitian, Chapter 542, Statutes of 2007)

Board staff will provide an update on the implementation of SB 966, the Take Back initiative.

ITEM D: FIRST QUARTERLY REPORT ON COMMITTEE GOALS FOR 2007/08

FOR INFORMATION:

The update on the third quarterly report on committee's strategic goals for 2007/08 is included in **ATTACHMENT 5**.

Attachment 1

SB 1307(Ridely-Thomas) Pharmacy: Pedigree

AMENDED IN SENATE MARCH 25, 2008

SENATE BILL

No. 1307

Introduced by Senator Ridley-Thomas

February 20, 2008

An act to amend ~~Section 4034~~ of Sections 4034, 4163, and 4163.5 of, and to add Sections 4163.2 and 4163.3 to, 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 ~~and prohibits a wholesaler or pharmacy~~ 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 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 and would* require a pedigree to also include a specified unique identification number. By changing the definition of a crime, the bill would impose a state-mandated local program.

The bill would instead prohibit a wholesaler, on and after January 1, 2012, or a pharmacy, on and after July 1, 2012, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. The bill would authorize the board to extend these compliance dates by up to one year if certain conditions are met.

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. 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 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 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. 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.

violated a term or condition of board probation to pay the costs for investigation and prosecution. The bill would require an applicant for renewal of a respiratory care practitioner license to cooperate in furnishing additional information to the board, as requested, and would provide that, if a licensee fails to furnish the information within 30 days of a request, his or her license would become inactive until the information is received.

Existing law exempts certain healing arts practitioners from liability for specified services rendered during a state of war, state of emergency, or local emergency.

This bill would also exempt respiratory care practitioners from liability for the provision of specified services rendered during a state of war, state of emergency, or local emergency.

(7) Existing law, the Pharmacy Law, the knowing violation of which is a crime, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs.

Existing law authorizes a pharmacy to furnish dangerous drugs only to specified persons or entities, and subjects certain pharmacies and persons who violate the provision to specified fines.

This bill would provide that any violation of this provision by any person or entity would subject the person to the fine.

Existing law requires a pharmacy or pharmacist who is in charge of or manages a pharmacy to notify the board within 30 days of termination of employment of the pharmacist-in-charge or acting as manager, and provides that a violation of this provision is grounds for disciplinary action.

This bill would instead provide that failure by a pharmacist-in-charge or a pharmacy to notify the board in writing that the pharmacist-in-charge has ceased to act as pharmacist-in-charge within 30 days constitutes grounds for disciplinary action, and would also provide that the operation of the pharmacy for more than 30 days without the supervision or management by a pharmacist-in-charge constitutes grounds for disciplinary action. The bill would revise the definition of a designated representative or designated representative-in-charge, and would define a pharmacist-in-charge.

Existing law makes a nonpharmacist owner of a pharmacy who commits acts that would subvert or tend to subvert the efforts of a pharmacist-in-charge to comply with the Pharmacy Law guilty of a misdemeanor.

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, or pharmacies, until final sale to a
8 pharmacy or other person furnishing, administering, or dispensing
9 the dangerous drug. The pedigree shall be created and maintained
10 in an interoperable electronic system, ensuring compatibility
11 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.

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

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

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

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

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

37 (d) A pedigree shall track each dangerous drug at the smallest
38 package or immediate container distributed by the manufacturer,

1 received and distributed by the wholesaler, and received by the
2 pharmacy or another person furnishing, administering, or
3 dispensing the dangerous drug.

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

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

13 (g) The following transactions are not required to be recorded
14 on a pedigree:

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

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

31 (3) The exemption in paragraph (2) shall expire and be
32 inoperative on January 1, ~~2010~~ 2012, unless prior to that date the
33 board receives, at a public hearing, evidence that entities involved
34 in the distribution of the injectable dangerous drugs subject to that
35 paragraph are not able to provide a pedigree in compliance with
36 all of the provisions of California law, and the board votes to
37 extend the expiration date for the exemption until January 1, ~~2011~~
38 2013. The decision as to whether to extend the expiration date
39 shall be within the sole discretion of the board, and shall not be

1 subject to the requirements of Chapter 3.5 (commencing with
2 Section 11340) of Part 1 of Division 3 of the Government Code.

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

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

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

20 (k) This section shall become operative on January 1, ~~2009~~
21 ~~2011~~. However, the board may extend the date for compliance
22 with this section and Section 4163 ~~until January 1, 2011~~, in
23 accordance with Section 4163.5.

24 *SEC. 2. Section 4163 of the Business and Professions Code is*
25 *amended to read:*

26 4163. (a) A manufacturer or wholesaler may not furnish a
27 dangerous drug or dangerous device to an unauthorized person.

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

35 (c) Except as otherwise provided in Section 4163.5, commencing
36 on January 1, ~~2009~~ 2012, a wholesaler ~~or pharmacy~~ may not sell,
37 trade, or transfer a dangerous drug at wholesale without providing
38 a pedigree.

1 (d) Except as otherwise provided in Section 4163.5, commencing
2 on January 1, ~~2009~~ 2012, a wholesaler ~~or pharmacy~~ may not
3 acquire a dangerous drug without receiving a pedigree.

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

7 (f) *Except as otherwise provided in Section 4163.5, commencing*
8 *on July 1, 2012, a pharmacy may not acquire a dangerous drug*
9 *without receiving a pedigree.*

10 SEC. 3. Section 4163.2 is added to the Business and Professions
11 Code, to read:

12 4163.2. (a) (1) *A manufacturer, wholesaler, or pharmacy*
13 *lawfully possessing or owning dangerous drugs manufactured or*
14 *distributed prior to the operative date of the pedigree requirements,*
15 *specified in Sections 4034 and 4163, may designate these*
16 *dangerous drugs as not subject to the pedigree requirements by*
17 *preparing a written declaration made under penalty of perjury*
18 *that lists those dangerous drugs.*

19 (2) *The written declaration shall include the unique*
20 *identification numbers and the dates of manufacture for each*
21 *dangerous drug designated. The written declaration shall be*
22 *submitted to and received by the board no later than 30 days after*
23 *the operative date of the pedigree requirements. The entity or*
24 *person submitting the written declaration shall also retain for a*
25 *period of three years and make available for inspection by the*
26 *board a copy of each written declaration submitted.*

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

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

36 (2) *Any transfer of a dangerous drug without meeting the*
37 *pedigree requirements shall be accompanied by a written*
38 *declaration made under penalty of perjury by a responsible party*
39 *of the transferring entity or person stating that the dangerous drug,*
40 *identified by its unique identification number and date of*

1 *manufacture, met the requirements of subdivision (a) and the*
2 *written declaration prepared pursuant to subdivision (a) shall be*
3 *attached to this written declaration.*

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

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

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

13 *SEC. 4. Section 4163.3 is added to the Business and Professions*
14 *Code, to read:*

15 *4163.3. (a) It is the intent of the Legislature that participants*
16 *in the distribution chain for dangerous drugs, including*
17 *manufacturers, wholesalers, or pharmacies furnishing,*
18 *administering, or dispensing dangerous drugs, distribute and*
19 *receive electronic pedigrees, and verify and validate the delivery*
20 *and receipt of dangerous drugs against those pedigrees at the unit*
21 *level, in a manner that maintains the integrity of the pedigree*
22 *system without an unacceptable increase in the risk of diversion*
23 *or counterfeiting.*

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

32 *SEC. 5. Section 4163.5 of the Business and Professions Code*
33 *is amended to read:*

34 *4163.5. The board may extend the date for compliance with*
35 *the requirement for a pedigree set forth in Sections 4034 and 4163*
36 *until January 1, 2011, if it determines subject to the following*
37 *conditions. If the board determines that manufacturers—~~or,~~*
38 *wholesalers, or pharmacies require additional time to implement*
39 *electronic technologies to track the distribution of dangerous drugs*
40 *within the state, the board may delay the operative date of Sections*

1 4034 and 4163 by up to one year for any or all of these participants
2 in the distribution chain, to any date up to January 1, 2012, for
3 manufacturers, to any date up to January 1, 2013, for wholesalers,
4 and to any date up to July 1, 2013, for pharmacies. A determination
5 by the board to extend the deadline for providing pedigrees shall
6 not be subject to the requirements of Chapter 3.5 (commencing
7 with Section 11340) of Part 1 of Division 3 of Title 2 of the
8 Government Code.

9 ~~SEC. 2.~~

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

Attachment 2

Omnibus Language

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 683, 733, 800, 2089.5, 2096, 2102, 2107, 2135, 2175, 2307, 2335, 2486, 2488, 2570.5, 2760.1, 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, 4174, 4231, 4301, 4305, 4329, and 4330 of, to amend and renumber Section 2570.185 of, to add Sections 2570.35, 2570.36, 4036.5, and 4990.09 to, and to repeal Sections 2172, 2173, and 2174 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.

LEGISLATIVE COUNSEL'S DIGEST

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

(1) Existing law requires specified licensure boards to report to the State Department of Health Care Services the name and license number of a person whose license has been revoked, suspended, surrendered, made inactive, or otherwise restricted, and requires specified licensure boards to create and maintain a central file of the names of all persons who hold a license from the board, and to prescribe and promulgate written complaint forms, as specified.

This bill would also subject the California Board of Occupational Therapy to these requirements, and would subject the Acupuncture

1 enforce the order for repayment in any appropriate court. This
2 right of enforcement shall be in addition to any other rights the
3 board may have as to any practitioner directed to pay costs.

4 (c) In any action for recovery of costs, proof of the board's
5 decision shall be conclusive proof of the validity of the order of
6 payment and the terms for payment.

7 (d) (1) The board shall not renew or reinstate the license of any
8 licensee who has failed to pay all of the costs ordered under this
9 section.

10 (2) Notwithstanding paragraph (1), the board may, in its
11 discretion, conditionally renew, for a maximum of one year, the
12 license of any licensee who demonstrates financial hardship,
13 through documentation satisfactory to the board, and who enters
14 into a formal agreement with the board to reimburse the board
15 within that one-year period for those unpaid costs.

16 ~~SEC. 28.~~

17 *SEC. 29.* Section 3773 of the Business and Professions Code
18 is amended to read:

19 3773. (a) At the time of application for renewal of a respiratory
20 care practitioner license, the licensee shall notify the board of all
21 of the following:

22 (1) Whether he or she has been convicted of any crime
23 subsequent to the licensee's previous renewal.

24 (2) The name and address of the licensee's current employer or
25 employers.

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

30 ~~SEC. 29.~~

31 *SEC. 30.* Section 4022.5 of the Business and Professions Code
32 is amended to read:

33 4022.5. (a) "Designated representative" means an individual
34 to whom a license has been granted pursuant to Section 4053. A
35 pharmacist fulfilling the duties of Section 4053 shall not be
36 required to obtain a license as a designated representative.

37 (b) "Designated representative-in-charge" means a designated
38 representative or a pharmacist proposed by a wholesaler or
39 veterinary food-animal drug retailer and approved by the board as
40 the supervisor or manager responsible for ensuring the wholesaler's

1 or veterinary food-animal drug retailer's compliance with all state
2 and federal laws and regulations pertaining to practice in the
3 applicable license category.

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

5 ~~SEC. 30.~~

6 *SEC. 31.* Section 4027 of the Business and Professions Code
7 is amended to read:

8 4027. (a) As used in this chapter, the terms "skilled nursing
9 facility," "intermediate care facility," and other references to health
10 facilities shall be construed with respect to the definitions contained
11 in Article 1 (commencing with Section 1250) of Chapter 2 of
12 Division 2 of the Health and Safety Code.

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

20 (c) As used in Section 4052.2, "health care facility" means a
21 facility, other than a facility licensed under Division 2
22 (commencing with Section 1200) of the Health and Safety Code,
23 that is owned or operated by a health care service plan licensed
24 pursuant to Chapter 2.2 (commencing with Section 1340) of the
25 Health and Safety Code, or by an organization under common
26 ownership or control of the health care service plan; "licensed
27 home health agency" means a private or public organization
28 licensed by the State Department of Health Services pursuant to
29 Chapter 8 (commencing with Section 1725) of Division 2 of the
30 Health and Safety Code, as further defined in Section 1727 of the
31 Health and Safety Code; and "licensed clinic" means a clinic
32 licensed pursuant to Article 1 (commencing with Section 1200)
33 of Chapter 1 of Division 2 of the Health and Safety Code.

34 (d) "Licensed health care facility" or "facility," as used in
35 Section 4065, means a health facility licensed pursuant to Article
36 1 (commencing with Section 1250) of Chapter 2 of Division 2 of
37 the Health and Safety Code or a facility that is owned or operated
38 by a health care service plan licensed pursuant to Chapter 2.2
39 (commencing with Section 1340) of Division 2 of the Health and

1 Safety Code or by an organization under common ownership or
2 control with the health care service plan.

3 ~~SEC. 31.~~

4 *SEC. 32.* Section 4036.5 is added to the Business and
5 Professions Code, to read:

6 4036.5. "Pharmacist-in-charge" means a pharmacist proposed
7 by a pharmacy and approved by the board as the supervisor or
8 manager responsible for ensuring the pharmacy's compliance with
9 all state and federal laws and regulations pertaining to the practice
10 of pharmacy.

11 ~~SEC. 32.~~

12 *SEC. 33.* Section 4040 of the Business and Professions Code
13 is amended to read:

14 4040. (a) "Prescription" means an oral, written, or electronic
15 transmission order that is both of the following:

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

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

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

21 (C) The date of issue.

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

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

28 (F) If in writing, signed by the prescriber issuing the order, or
29 the certified nurse-midwife, nurse practitioner, physician assistant,
30 or naturopathic doctor who issues a drug order pursuant to Section
31 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist
32 who issues a drug order pursuant to either Section 4052.1 or
33 4052.2.

34 (2) Issued by a physician, dentist, optometrist, podiatrist,
35 veterinarian, or naturopathic doctor pursuant to Section 3640.7 or,
36 if a drug order is issued pursuant to Section 2746.51, 2836.1,
37 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner,
38 physician assistant, or naturopathic doctor licensed in this state,
39 or pursuant to either Section 4052.1 or 4052.2 by a pharmacist
40 licensed in this state.

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

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

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

23 (e) Nothing in the amendments made to this section (formerly
24 Section 4036) at the 1969 Regular Session of the Legislature shall
25 be construed as expanding or limiting the right that a chiropractor,
26 while acting within the scope of his or her license, may have to
27 prescribe a device.

28 ~~SEC. 33.~~

29 *SEC. 34.* Section 4051 of the Business and Professions Code
30 is amended to read:

31 4051. (a) Except as otherwise provided in this chapter, it is
32 unlawful for any person to manufacture, compound, furnish, sell,
33 or dispense any dangerous drug or dangerous device, or to dispense
34 or compound any prescription pursuant to Section 4040 of a
35 prescriber unless he or she is a pharmacist under this chapter.

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

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

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

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

8 ~~SEC. 34.~~

9 *SEC. 35.* Section 4059.5 of the Business and Professions Code
10 is amended to read:

11 4059.5. (a) Except as otherwise provided in this chapter,
12 dangerous drugs or dangerous devices may only be ordered by an
13 entity licensed by the board and shall be delivered to the licensed
14 premises and signed for and received by a pharmacist. Where a
15 licensee is permitted to operate through a designated representative,
16 the designated representative shall sign for and receive the delivery.

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

21 (c) Notwithstanding subdivisions (a) and (b), deliveries to a
22 hospital pharmacy may be made to a central receiving location
23 within the hospital. However, the dangerous drugs or dangerous
24 devices shall be delivered to the licensed pharmacy premises within
25 one working day following receipt by the hospital, and the
26 pharmacist on duty at that time shall immediately inventory the
27 dangerous drugs or dangerous devices.

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

37 (e) A dangerous drug or dangerous device shall not be
38 transferred, sold, or delivered to a person outside this state, whether
39 foreign or domestic, unless the transferor, seller, or deliverer does
40 so in compliance with the laws of this state and of the United States

1 and of the state or country to which the dangerous drugs or
2 dangerous devices are to be transferred, sold, or delivered.
3 Compliance with the laws of this state and the United States and
4 of the state or country to which the dangerous drugs or dangerous
5 devices are to be delivered shall include, but not be limited to,
6 determining that the recipient of the dangerous drugs or dangerous
7 devices is authorized by law to receive the dangerous drugs or
8 dangerous devices.

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

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

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

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

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

24 (5) The agent delivering dangerous drugs and dangerous devices
25 pursuant to this subdivision leaves documents indicating the name
26 and amount of each dangerous drug or dangerous device delivered
27 in the secure storage facility.

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

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

34 ~~SEC. 35.~~

35 *SEC. 36.* Section 4060 of the Business and Professions Code
36 is amended to read:

37 4060. No person shall possess any controlled substance, except
38 that furnished to a person upon the prescription of a physician,
39 dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor
40 pursuant to Section 3640.7, or furnished pursuant to a drug order

1 issued by a certified nurse-midwife pursuant to Section 2746.51,
2 a nurse practitioner pursuant to Section 2836.1, a physician
3 assistant pursuant to Section 3502.1, a naturopathic doctor pursuant
4 to Section 3640.5, or a pharmacist pursuant to either Section 4052.1
5 or 4052.2. This section shall not apply to the possession of any
6 controlled substance by a manufacturer, wholesaler, pharmacy,
7 pharmacist, physician, podiatrist, dentist, optometrist, veterinarian,
8 naturopathic doctor, certified nurse-midwife, nurse practitioner,
9 or physician assistant, when in stock in containers correctly labeled
10 with the name and address of the supplier or producer.

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

14 ~~SEC. 36.~~

15 *SEC. 37.* Section 4062 of the Business and Professions Code
16 is amended to read:

17 4062. (a) Notwithstanding Section 4059 or any other provision
18 of law, a pharmacist may, in good faith, furnish a dangerous drug
19 or dangerous device in reasonable quantities without a prescription
20 during a federal, state, or local emergency, to further the health
21 and safety of the public. A record containing the date, name, and
22 address of the person to whom the drug or device is furnished, and
23 the name, strength, and quantity of the drug or device furnished
24 shall be maintained. The pharmacist shall communicate this
25 information to the patient's attending physician as soon as possible.
26 Notwithstanding Section 4060 or any other provision of law, a
27 person may possess a dangerous drug or dangerous device
28 furnished without prescription pursuant to this section.

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

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

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

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

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

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

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

10 (6) The mobile pharmacy ceases the provision of services within
11 48 hours following the termination of the declared emergency.

12 ~~SEC. 37.~~

13 *SEC. 38.* Section 4076 of the Business and Professions Code
14 is amended to read:

15 4076. (a) A pharmacist shall not dispense any prescription
16 except in a container that meets the requirements of state and
17 federal law and is correctly labeled with all of the following:

18 (1) Except where the prescriber or the certified nurse-midwife
19 who functions pursuant to a standardized procedure or protocol
20 described in Section 2746.51, the nurse practitioner who functions
21 pursuant to a standardized procedure described in Section 2836.1,
22 or protocol, the physician assistant who functions pursuant to
23 Section 3502.1, the naturopathic doctor who functions pursuant
24 to a standardized procedure or protocol described in Section
25 3640.5, or the pharmacist who functions pursuant to a policy,
26 procedure, or protocol pursuant to either Section 4052.1 or 4052.2
27 orders otherwise, either the manufacturer's trade name of the drug
28 or the generic name and the name of the manufacturer. Commonly
29 used abbreviations may be used. Preparations containing two or
30 more active ingredients may be identified by the manufacturer's
31 trade name or the commonly used name or the principal active
32 ingredients.

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

34 (3) The name of the patient or patients.

35 (4) The name of the prescriber or, if applicable, the name of the
36 certified nurse-midwife who functions pursuant to a standardized
37 procedure or protocol described in Section 2746.51, the nurse
38 practitioner who functions pursuant to a standardized procedure
39 described in Section 2836.1, or protocol, the physician assistant
40 who functions pursuant to Section 3502.1, the naturopathic doctor

1 who functions pursuant to a standardized procedure or protocol
2 described in Section 3640.5, or the pharmacist who functions
3 pursuant to a policy, procedure, or protocol pursuant to either
4 Section 4052.1 or 4052.2.

5 (5) The date of issue.

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

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

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

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

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

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

19 (i) Prescriptions dispensed by a veterinarian.

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

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

26 (B) This paragraph applies to outpatient pharmacies only.

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

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

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

39 (c) If a pharmacist dispenses a dangerous drug or device in a
40 facility licensed pursuant to Section 1250 of the Health and Safety

1 Code, it is not necessary to include on individual unit dose
2 containers for a specific patient, the name of the certified
3 nurse-midwife who functions pursuant to a standardized procedure
4 or protocol described in Section 2746.51, the nurse practitioner
5 who functions pursuant to a standardized procedure described in
6 Section 2836.1, or protocol, the physician assistant who functions
7 pursuant to Section 3502.1, the naturopathic doctor who functions
8 pursuant to a standardized procedure or protocol described in
9 Section 3640.5, or the pharmacist who functions pursuant to a
10 policy, procedure, or protocol pursuant to either Section 4052.1
11 or 4052.2.

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

22 ~~SEC. 38.~~

23 *SEC. 39.* Section 4081 of the Business and Professions Code
24 is amended to read:

25 4081. (a) All records of manufacture and of sale, acquisition,
26 or disposition of dangerous drugs or dangerous devices shall be
27 at all times during business hours open to inspection by authorized
28 officers of the law, and shall be preserved for at least three years
29 from the date of making. A current inventory shall be kept by every
30 manufacturer, wholesaler, pharmacy, veterinary food-animal drug
31 retailer, physician, dentist, podiatrist, veterinarian, laboratory,
32 clinic, hospital, institution, or establishment holding a currently
33 valid and unrevoked certificate, license, permit, registration, or
34 exemption under Division 2 (commencing with Section 1200) of
35 the Health and Safety Code or under Part 4 (commencing with
36 Section 16000) of Division 9 of the Welfare and Institutions Code
37 who maintains a stock of dangerous drugs or dangerous devices.

38 (b) The owner, officer, and partner of a pharmacy, wholesaler,
39 or veterinary food-animal drug retailer shall be jointly responsible,
40 with the pharmacist-in-charge or designated

1 representative-in-charge, for maintaining the records and inventory
2 described in this section.

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

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

10 ~~SEC. 39.~~

11 *SEC. 40.* Section 4110 of the Business and Professions Code
12 is amended to read:

13 4110. (a) No person shall conduct a pharmacy in the State of
14 California unless he or she has obtained a license from the board.
15 A license shall be required for each pharmacy owned or operated
16 by a specific person. A separate license shall be required for each
17 of the premises of any person operating a pharmacy in more than
18 one location. The license shall be renewed annually. The board
19 may, by regulation, determine the circumstances under which a
20 license may be transferred.

21 (b) The board may, at its discretion, issue a temporary permit,
22 when the ownership of a pharmacy is transferred from one person
23 to another, upon the conditions and for any periods of time as the
24 board determines to be in the public interest. A temporary permit
25 fee shall be established by the board at an amount not to exceed
26 the annual fee for renewal of a permit to conduct a pharmacy.
27 When needed to protect public safety, a temporary permit may be
28 issued for a period not to exceed 180 days, and may be issued
29 subject to terms and conditions the board deems necessary. If the
30 board determines a temporary permit was issued by mistake or
31 denies the application for a permanent license or registration, the
32 temporary license or registration shall terminate upon either
33 personal service of the notice of termination upon the permitholder
34 or service by certified mail, return receipt requested, at the
35 permitholder's address of record with the board, whichever comes
36 first. Neither for purposes of retaining a temporary permit nor for
37 purposes of any disciplinary or license denial proceeding before
38 the board shall the temporary permitholder be deemed to have a
39 vested property right or interest in the permit.

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

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

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

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

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

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

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

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

23 ~~SEC. 40.~~

24 *SEC. 41.* Section 4111 of the Business and Professions Code
25 is amended to read:

26 4111. (a) Except as otherwise provided in subdivision (b), (d),
27 or (e), the board shall not issue or renew a license to conduct a
28 pharmacy to any of the following:

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

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

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

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

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

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

12 (e) Subdivision (a) shall not preclude the issuance of a new or
13 renewal license for a pharmacy to be owned or owned and operated
14 by a pharmacist authorized to issue a drug order pursuant to Section
15 4052.1 or 4052.2.

16 ~~SEC. 41.~~

17 *SEC. 42.* Section 4126.5 of the Business and Professions Code
18 is amended to read:

19 4126.5. (a) A pharmacy may furnish dangerous drugs only to
20 the following:

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

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

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

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

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

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

35 (7) To another pharmacy under common control.

36 (b) Notwithstanding any other provision of law, a violation of
37 this section may subject the person or persons who committed the
38 violation to a fine not to exceed the amount specified in Section
39 125.9 for each occurrence pursuant to a citation issued by the
40 board.

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

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

10 ~~SEC. 42.~~

11 *SEC. 43.* Section 4174 of the Business and Professions Code
12 is amended to read:

13 4174. Notwithstanding any other provision of law, a pharmacist
14 may dispense drugs or devices upon the drug order of a nurse
15 practitioner functioning pursuant to Section 2836.1 or a certified
16 nurse-midwife functioning pursuant to Section 2746.51, a drug
17 order of a physician assistant functioning pursuant to Section
18 3502.1 or a naturopathic doctor functioning pursuant to Section
19 3640.5, or the order of a pharmacist acting under Section 4052.1,
20 4052.2, or 4052.3.

21 ~~SEC. 43.~~

22 *SEC. 44.* Section 4231 of the Business and Professions Code
23 is amended to read:

24 4231. (a) The board shall not renew a pharmacist license unless
25 the applicant submits proof satisfactory to the board that he or she
26 has successfully completed 30 hours of approved courses of
27 continuing pharmacy education during the two years preceding
28 the application for renewal.

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

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

1 proof to the board that the licensee has completed 30 hours of
2 continuing pharmacy education.

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

12 ~~SEC. 44.~~

13 *SEC. 45.* Section 4301 of the Business and Professions Code
14 is amended to read:

15 4301. The board shall take action against any holder of a license
16 who is guilty of unprofessional conduct or whose license has been
17 procured by fraud or misrepresentation or issued by mistake.
18 Unprofessional conduct shall include, but is not limited to, any of
19 the following:

20 (a) Gross immorality.

21 (b) Incompetence.

22 (c) Gross negligence.

23 (d) The clearly excessive furnishing of controlled substances
24 in violation of subdivision (a) of Section 11153 of the Health and
25 Safety Code.

26 (e) The clearly excessive furnishing of controlled substances in
27 violation of subdivision (a) of Section 11153.5 of the Health and
28 Safety Code. Factors to be considered in determining whether the
29 furnishing of controlled substances is clearly excessive shall
30 include, but not be limited to, the amount of controlled substances
31 furnished, the previous ordering pattern of the customer (including
32 size and frequency of orders), the type and size of the customer,
33 and where and to whom the customer distributes its product.

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

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

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

8 (i) Except as otherwise authorized by law, knowingly selling,
9 furnishing, giving away, or administering, or offering to sell,
10 furnish, give away, or administer, any controlled substance to an
11 addict.

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

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

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

1 aside the verdict of guilty, or dismissing the accusation,
2 information, or indictment.

3 (m) The cash compromise of a charge of violation of Chapter
4 13 (commencing with Section 801) of Title 21 of the United States
5 Code regulating controlled substances or of Chapter 7
6 (commencing with Section 14000) of Part 3 of Division 9 of the
7 Welfare and Institutions Code relating to the Medi-Cal program.
8 The record of the compromise is conclusive evidence of
9 unprofessional conduct.

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

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

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

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

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

29 (s) The clearly excessive furnishing of dangerous drugs by a
30 wholesaler to a pharmacy that primarily or solely dispenses
31 prescription drugs to patients of long-term care facilities. Factors
32 to be considered in determining whether the furnishing of
33 dangerous drugs is clearly excessive shall include, but not be
34 limited to, the amount of dangerous drugs furnished to a pharmacy
35 that primarily or solely dispenses prescription drugs to patients of
36 long-term care facilities, the previous ordering pattern of the
37 pharmacy, and the general patient population to whom the
38 pharmacy distributes the dangerous drugs. That a wholesaler has
39 established, and employs, a tracking system that complies with
40 the requirements of subdivision (b) of Section 4164 shall be

1 considered in determining whether there has been a violation of
2 this subdivision. This provision shall not be interpreted to require
3 a wholesaler to obtain personal medical information or be
4 authorized to permit a wholesaler to have access to personal
5 medical information except as otherwise authorized by Section 56
6 and following of the Civil Code. For purposes of this section,
7 “long-term care facility” shall have the same meaning given the
8 term in Section 1418 of the Health and Safety Code.

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

10 ~~SEC. 45.~~

11 *SEC. 46.* Section 4305 of the Business and Professions Code
12 is amended to read:

13 4305. (a) Failure by any pharmacist to notify the board in
14 writing that he or she has ceased to act as pharmacist-in-charge of
15 a pharmacy, or by any pharmacy to notify the board in writing that
16 a pharmacist-in-charge is no longer acting in that capacity, within
17 the 30-day period specified in Sections 4101 and 4113 shall
18 constitute grounds for disciplinary action.

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

22 (c) Any person who has obtained a license to conduct a
23 pharmacy, who willfully fails to timely notify the board that the
24 pharmacist-in-charge of the pharmacy has ceased to act in that
25 capacity, and who continues to permit the compounding or
26 dispensing of prescriptions, or the furnishing of drugs or poisons,
27 in his or her pharmacy, except by a pharmacist subject to the
28 supervision and management of a responsible pharmacist-in-charge,
29 shall be subject to summary suspension or revocation of his or her
30 license to conduct a pharmacy.

31 ~~SEC. 46.~~

32 *SEC. 47.* Section 4329 of the Business and Professions Code
33 is amended to read:

34 4329. Any nonpharmacist who takes charge of or acts as
35 supervisor, manager, or pharmacist-in-charge of any pharmacy,
36 or who compounds or dispenses a prescription or furnishes
37 dangerous drugs except as otherwise provided in this chapter, is
38 guilty of a misdemeanor.

1 ~~SEC. 47.~~

2 *SEC. 48.* Section 4330 of the Business and Professions Code
3 is amended to read:

4 4330. (a) Any person who has obtained a license to conduct
5 a pharmacy, who fails to place in charge of the pharmacy a
6 pharmacist, or any person, who by himself or herself, or by any
7 other person, permits the compounding or dispensing of
8 prescriptions, or the furnishing of dangerous drugs, in his or her
9 pharmacy, except by a pharmacist, or as otherwise provided in this
10 chapter, is guilty of a misdemeanor.

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

15 ~~SEC. 48.~~

16 *SEC. 49.* Section 4990.09 is added to the Business and
17 Professions Code, to read:

18 4990.09. The board shall not publish on the Internet the final
19 determination of a citation and fine of one thousand five hundred
20 dollars (\$1,500) or less issued against a licensee or registrant
21 pursuant to Section 125.9 for a period of time in excess of five
22 years from the date of issuance of the citation.

23 ~~SEC. 49.~~

24 *SEC. 50.* Section 8659 of the Government Code is amended
25 to read:

26 8659. Any physician or surgeon (whether licensed in this state
27 or any other state), hospital, pharmacist, respiratory care
28 practitioner, nurse, or dentist who renders services during any state
29 of war emergency, a state of emergency, or a local emergency at
30 the express or implied request of any responsible state or local
31 official or agency shall have no liability for any injury sustained
32 by any person by reason of those services, regardless of how or
33 under what circumstances or by what cause those injuries are
34 sustained; provided, however, that the immunity herein granted
35 shall not apply in the event of a willful act or omission.

36 ~~SEC. 50.~~

37 *SEC. 51.* Section 11150 of the Health and Safety Code is
38 amended to read:

39 11150. No person other than a physician, dentist, podiatrist,
40 or veterinarian, or naturopathic doctor acting pursuant to Section

1 3640.7 of the Business and Professions Code, or pharmacist acting
2 within the scope of a project authorized under Article 1
3 (commencing with Section 128125) of Chapter 3 of Part 3 of
4 Division 107 or within the scope of Section 4052.1 or 4052.2 of
5 the Business and Professions Code, a registered nurse acting within
6 the scope of a project authorized under Article 1 (commencing
7 with Section 128125) of Chapter 3 of Part 3 of Division 107, a
8 certified nurse-midwife acting within the scope of Section 2746.51
9 of the Business and Professions Code, a nurse practitioner acting
10 within the scope of Section 2836.1 of the Business and Professions
11 Code, a physician assistant acting within the scope of a project
12 authorized under Article 1 (commencing with Section 128125) of
13 Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the
14 Business and Professions Code, a naturopathic doctor acting within
15 the scope of Section 3640.5 of the Business and Professions Code,
16 or an optometrist acting within the scope of Section 3041 of the
17 Business and Professions Code, or an out-of-state prescriber acting
18 pursuant to Section 4005 of the Business and Professions Code
19 shall write or issue a prescription.

20 ~~SEC. 51.~~

21 *SEC. 52.* Section 11165 of the Health and Safety Code is
22 amended to read:

23 11165. (a) To assist law enforcement and regulatory agencies
24 in their efforts to control the diversion and resultant abuse of
25 Schedule II, Schedule III, and Schedule IV controlled substances,
26 and for statistical analysis, education, and research, the Department
27 of Justice shall, contingent upon the availability of adequate funds
28 from the Contingent Fund of the Medical Board of California, the
29 Pharmacy Board Contingent Fund, the State Dentistry Fund, the
30 Board of Registered Nursing Fund, and the Osteopathic Medical
31 Board of California Contingent Fund, maintain the Controlled
32 Substance Utilization Review and Evaluation System (CURES)
33 for the electronic monitoring of the prescribing and dispensing of
34 Schedule II, Schedule III, and Schedule IV controlled substances
35 by all practitioners authorized to prescribe or dispense these
36 controlled substances.

37 (b) The reporting of Schedule III and Schedule IV controlled
38 substance prescriptions to CURES shall be contingent upon the
39 availability of adequate funds from the Department of Justice. The
40 Department of Justice may seek and use grant funds to pay the

1 costs incurred from the reporting of controlled substance
2 prescriptions to CURES. Funds shall not be appropriated from the
3 Contingent Fund of the Medical Board of California, the Pharmacy
4 Board Contingent Fund, the State Dentistry Fund, the Board of
5 Registered Nursing Fund, the Naturopathic Doctor's Fund, or the
6 Osteopathic Medical Board of California Contingent Fund to pay
7 the costs of reporting Schedule III and Schedule IV controlled
8 substance prescriptions to CURES.

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

23 (d) For each prescription for a Schedule II, Schedule III, or
24 Schedule IV controlled substance, the dispensing pharmacy or
25 clinic shall provide the following information to the Department
26 of Justice on a weekly basis and in a format specified by the
27 Department of Justice:

28 (1) Full name, address, and the telephone number of the ultimate
29 user or research subject, or contact information as determined by
30 the Secretary of the United States Department of Health and Human
31 Services, and the gender, and date of birth of the ultimate user.

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

37 (3) Pharmacy prescription number, license number, and federal
38 controlled substance registration number.

39 (4) NDC (National Drug Code) number of the controlled
40 substance dispensed.

- 1 (5) Quantity of the controlled substance dispensed.
- 2 (6) ICD-9 (diagnosis code), if available.
- 3 (7) Number of refills ordered.
- 4 (8) Whether the drug was dispensed as a refill of a prescription
- 5 or as a first-time request.
- 6 (9) Date of origin of the prescription.
- 7 (10) Date of dispensing of the prescription.
- 8 (e) This section shall become operative on January 1, 2005.

9 ~~SEC. 52.~~

10 *SEC. 53.* No reimbursement is required by this act pursuant to
11 Section 6 of Article XIII B of the California Constitution because
12 the only costs that may be incurred by a local agency or school
13 district will be incurred because this act creates a new crime or
14 infraction, eliminates a crime or infraction, or changes the penalty
15 for a crime or infraction, within the meaning of Section 17556 of
16 the Government Code, or changes the definition of a crime within
17 the meaning of Section 6 of Article XIII B of the California
18 Constitution.

Attachment 3

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

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, along with concise information on ~~specified disposal~~ *safe disposal alternatives and options for sharps*.

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
- 11 manufacturers for the provision of their product to California
- 12 residents.
- 13 (c) The increased use of prefilled syringes, prefilled pens, and
- 14 other prefilled devices with needles will generate millions of
- 15 home-generated sharps each year. Prefilled pen devices are being
- 16 used for the treatment of some of the most serious health conditions
- 17 such as HIV/AIDS, hepatitis C, and many other diseases. If
- 18 improperly disposed in solid waste and recycling containers these
- 19 needles will result in significant public health risks.
- 20 (d) The Legislature has found that sharps mail-back programs
- 21 utilizing containers and packaging approved by the United States
- 22 Postal Service offer one of the most convenient means for
- 23 collecting and destroying home-generated sharps and that the

1 cooperative efforts of the pharmaceutical industry are needed to
2 develop a safe needle disposal system for California.

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

5 118288. (a) Upon request of a consumer of a prefilled syringe,
6 prefilled pen, or other prefilled injection device administered at
7 home, a pharmaceutical manufacturer shall arrange to provide the
8 consumer with either of the following:

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

12 (2) A sharps container for the safe storage of, and transport to,
13 a sharps consolidation location that is approved by the State
14 Department of Public Health or to a clinic, physician, or pharmacy
15 that accepts home-generated sharps waste. This sharps container
16 shall be provided with concise information on ~~the closest available~~
17 ~~safe sharps disposal sites~~ *safe disposal alternatives and options*
18 *for sharps.*

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

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 501

VERSION: As amended March 13, 2008

AUTHOR: Swanson

**SPONSOR: Alameda County Board of
Supervisors**

POSITION: Support

**SUBJECT: Pharmaceutical devices: hypodermic needle and syringe
disposal**

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 for greenwaste
 - b. Any container used for the commercial collection of solid waste or recyclable materials from a business establishment
 - 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 container approved by the enforcement agency as managed by one 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 through the use of an approved medical waster 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. Require a pharmaceutical manufacturer to arrange to provide a postage prepaid, mail-back sharps container that has been approved by the U.S. Postal Service and the Department of Public Health as requested by a consumer of a prefilled syringe, prefilled pen, or other prefilled injection device administered at home.
4. **As amended 3/13/2008.** Allow a pharmaceutical manufacturer to provide its consumers concise information on ~~convenient locally available safe needle disposal options.~~ safe disposal alternatives and options for sharps.
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.

PRIOR HISTORY/RELATED BILLS

SB 1305 (Figueroa) Chapter 64, Statutes of 2006 – Prohibits, as of January 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.

HISTORY:

Dates	Actions
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.

Revised March 31, 2008

AMENDED IN ASSEMBLY JANUARY 22, 2008

AMENDED IN ASSEMBLY JANUARY 17, 2008

AMENDED IN ASSEMBLY APRIL 23, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 865

Introduced by Assembly Member Davis

February 22, 2007

An act to amend Section 11022 of the Government Code, relating to state agencies.

LEGISLATIVE COUNSEL'S DIGEST

AB 865, as amended, Davis. State agencies: live customer service agents.

Existing law requires each state agency to establish a procedure whereby incoming telephone calls on any public line shall be answered within 10 rings during regular business hours, subject to certain exceptions.

This bill would name these provisions the State Agency Live Customer Service Act. It would require each state agency to answer an incoming call on ~~any~~ *its* main public line with a live customer service agent or automated telephone answering equipment with an automated prompt that allows a caller to select the option to speak with a live customer service agent, subject to certain exceptions.

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 11022 of the Government Code is
2 amended to read:

3 11022. (a) This section shall be known and may be cited as
4 the State Agency Live Customer Service Act.

5 (b) Each state agency shall establish a procedure pursuant to
6 which incoming telephone calls on ~~any~~ *the* main public line shall
7 be answered by a live customer service agent, or automated
8 telephone answering equipment in accordance with subdivision

9 (c), within 10 rings during regular business hours as set forth in
10 Section 11020, except when emergency or illness requires
11 adjustments to normal staffing levels.

12 (c) During regular business hours, as set forth in Section 11020,
13 the headquarters of every state agency that uses automated
14 telephone answering equipment shall have for all incoming
15 telephone calls on ~~a~~ *the* main public line, an automated prompt
16 that allows a caller to select the option to speak with a live
17 customer service agent and shall have a live customer service agent
18 available for this purpose.

19 (d) Subdivision (c) does not apply to ~~the following:~~

20 ~~(1) Field offices.~~

21 ~~(2) Telephone telephone~~ lines dedicated as hotlines for
22 emergency services, telephone lines dedicated exclusively to
23 providing general information, and any system that is designed to
24 permit an individual to conduct a complete transaction with a state
25 agency over the telephone solely by pressing one or more
26 touch-tone telephone keys in response to automated prompts.

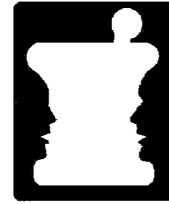
27 (e) For the purposes of this section, the following definitions
28 shall apply:

29 (1) "Headquarters" means the chief executive office of the
30 agency designated by the director or head of the agency as its main
31 office.

32 (2) "Main public line" means ~~_____~~ *the line designated by the*
33 *director or head of the agency as its main public line.*

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 865

VERSION: As amended January 22, 2008

AUTHOR: Davis

SPONSOR: Author

BOARD POSITION: Neutral

SUBJECT: State agencies, live customer service agents

EXISTING LAW:

1. Requires each state agency to establish a procedure to ensure that incoming calls on any public line will be answered within 10 rings during regular business hours.

THIS BILL WOULD:

1. **As amended 1/22/08.** Require the headquarter for each state agency to answer telephone calls on ~~any~~ its main public line by a live customer service agent within 10 rings during regular business hours or an automated answering service. If an automated answering service is used, an option must be available to the caller to speak with a life customer service agent.
2. Provide exemptions to ~~field offices and~~ telephone lines dedicated as hotlines for emergency services or others as specified.
3. Define headquarters as the office or agency located in Sacramento, or where the director or head of the agency is located.
4. Defines "main public line" means the line designated by the director or head of the agency as its main public line.

AUTHOR'S INTENT

This legislation is to address the general frustration some constituents experience trying to access a live agent to speak with. Illinois enacted a similar requirement in 2005.

FISCAL IMPACT

Should this bill be enacted, the board will need to pursue a part-time office assistant to help assist board receptionists during peak calling times, (e.g., Mondays, during renewal cycles etc.).

COMMENTS

The board's main public number is currently automated with the use of a phone tree. Callers are advised at the beginning of the recorded message of the option to zero-out to speak with a board receptionist. This proposal would require the board to eliminate the use of the phone tree resulting in additional staff resources to respond to incoming calls. Because of limitations with the current phone system, staff is not aware of a new incoming call when the line is already in use.

The author's office indicates that there may be room to negotiate a requirement similar to the Illinois legislation.

HISTORY:

02/07/08 Feb. 7 Referred to Com. on G.O.
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 76. Noes 0. Page 3835.)
01/24/08 Jan. 24 From committee: Do pass. (Ayes 16. Noes 0. Page 3814.) (January 24).
Read second time. To third reading.
01/23/08 Jan. 23 Re-referred to Com. on APPR.
01/22/08 Jan. 22 From committee chair, with author's amendments: Amend, and re-refer to Com. on APPR. Read second time and amended.
01/18/08 Jan. 18 Re-referred to Com. on APPR.
01/17/08 Jan. 17 Read second time and amended.
01/16/08 Jan. 16 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 10. Noes 0.) (January 15).
04/24/07 Apr. 24 Re-referred to Com. on B. & P.
04/23/07 Apr. 23 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
04/17/07 Apr. 17 In committee: Set, second hearing. Hearing canceled at the request of author.
04/10/07 Apr. 10 In committee: Set, first hearing. Hearing canceled at the request of author.
03/12/07 Mar. 12 Referred to Com. on B. & P.
02/23/07 Feb. 23 From printer. May be heard in committee March 25.
02/22/07 Feb. 22 Read first time. To print.

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 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, ~~intentional~~ 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.*

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 who willfully manufactures, *intentionally*
4 transports, ~~intentionally~~ sells, offers for sale, *or* distributes, or
5 knowingly possesses for sale any counterfeit of a mark registered
6 with the Secretary of State or registered on the Principal Register
7 of the United States Patent and Trademark Office, shall, upon
8 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 corporation,
16 by a fine of not more than one hundred thousand dollars
17 (\$100,000).

18 (2) When the offense involves 1,000 or more of the articles
19 described in this subdivision, or has a total retail or fair market
20 value equal to or greater than that required for grand theft as
21 defined in Section 487, and if the person is an individual, he or
22 she shall be punished by imprisonment in a county jail not to
23 exceed one year, or in the state prison for 16 months, or two or
24 three years, or by a fine not to exceed the greater of two hundred
25 fifty thousand dollars (\$250,000), or three times the total retail or
26 fair market value of the articles described in this subdivision, or

1 by both that imprisonment and fine; or, if the person is a
2 corporation, by a fine not to exceed the greater of five hundred
3 thousand dollars (\$500,000) or three times the total retail or fair
4 market value of the articles described in this subdivision.

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

14 (c) Any person who has been convicted of a violation of
15 subdivision (a) and who, by virtue of the conduct that was the basis
16 of the conviction, has directly and foreseeably caused death or
17 great bodily injury to another through reliance on the counterfeited
18 item for its intended purpose shall, if the person is an individual,
19 be punished by a fine of not more than fifty thousand dollars
20 (\$50,000), or by imprisonment in the state prison for two, three,
21 or four years, or by both that fine and imprisonment; or, if the
22 person is a corporation, by a fine of not more than two hundred
23 thousand dollars (\$200,000).

24 (d) In any action brought under this section resulting in a
25 conviction or a plea of nolo contendere, the court shall order the
26 forfeiture and destruction of all of those marks and of all goods,
27 articles, or other matter bearing the marks, and the forfeiture and
28 destruction or other disposition of all means of making the marks,
29 and any and all electrical, mechanical, or other devices for
30 manufacturing, reproducing, transporting, or assembling these
31 marks, that were used in connection with, or were part of, any
32 violation of this section, and the forfeiture of all proceeds of the
33 crime. However, no vehicle shall be forfeited under this section
34 that may be lawfully driven on the highway with a class 3 or 4
35 license, as prescribed in Section 12804 of the Vehicle Code, and
36 that is any of the following:

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

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

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

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

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

12 (2) “Counterfeit mark” means a spurious mark that is identical
13 with, or confusingly similar to, a registered mark and is used, or
14 intended to be used, on or in connection with the same type of
15 goods or services for which the genuine mark is registered. It is
16 not necessary for the mark to be displayed on the outside of an
17 article for there to be a violation. For articles containing digitally
18 stored information, it shall be sufficient to constitute a violation
19 if the counterfeit mark appears on a video display when the
20 information is retrieved from the article. The term “spurious mark”
21 includes genuine marks used on or in connection with spurious
22 articles and includes identical articles containing identical marks,
23 where the goods or marks were reproduced without authorization
24 of, or in excess of any authorization granted by, the registrant.
25 When counterfeited but unassembled components of any articles
26 described under subdivision (a) are recovered, including, but not
27 limited to, labels, patches, fabric, stickers, wrappers, badges,
28 emblems, medallions, charms, boxes, containers, cans, cases,
29 hangtags, documentation, or packaging, or any other components
30 of any type or nature that are designed, marketed, or otherwise
31 intended to be used on or in connection with any articles described
32 under subdivision (a), the number of “articles” shall be equivalent
33 to the number of completed articles that could have been made
34 from those components.

35 (3) “Knowingly possess” means that the person possessing an
36 article knew or had reason to believe that it was spurious, or that
37 it was used on or in connection with spurious articles, or that it
38 was reproduced without authorization of, or in excess of any
39 authorization granted by, the registrant.

1 (4) "Registrant" means any person to whom the registration of
2 a mark is issued and that person's legal representatives, successors,
3 or assigns.

4 (5) "Sale" includes resale.

5 (6) "Value" has the following meanings:

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

10 (B) When counterfeited but unassembled components of
11 computer software packages or any other articles described under
12 subdivision (a) are recovered, including, but not limited to,
13 counterfeited digital disks, instruction manuals, licensing
14 envelopes, labels, patches, fabric, stickers, wrappers, badges,
15 emblems, medallions, charms, boxes, containers, cans, cases,
16 hangtags, documentation, or packaging, or any other components
17 of any type or nature that are designed, marketed, or otherwise
18 intended to be used on or in connection with any articles described
19 under subdivision (a), the "value" of those components shall be
20 equivalent to the retail price or fair market value of the number of
21 completed computer software packages or other completed articles
22 described under subdivision (a) that could have been made from
23 those components.

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

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

35 (g) An owner, officer, employee, or agent who provides, rents,
36 leases, licenses, or sells real property upon which a violation of
37 subdivision (a) occurs shall not be subject to a criminal penalty
38 pursuant to this section, unless he or she sells, or possesses for
39 sale, articles bearing a counterfeit mark in violation of this section.

1 This subdivision shall not be construed to abrogate or limit any
2 civil rights or remedies for a trademark violation.

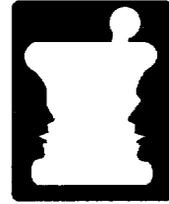
3 *(h) This section shall not be enforced against any party who*
4 *engages in fair uses of a mark, as specified in Section 14247 of*
5 *the Business and Professions Code.*

6 ~~(h)~~

7 *(i) When a person is convicted of an offense under this section,*
8 *the court shall order the person to pay restitution to the trademark*
9 *owner and any other victim of the offense pursuant to Section*
10 *1202.4. In determining the value of the economic loss in a case*
11 *involving an offense against the trademark owner, a court shall*
12 *grant restitution for any and all economic loss, including, but not*
13 *limited to, expenses incurred by the trademark owner in the*
14 *investigation and prosecution of the offense.*

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

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1394 **VERSION: As amended January 9, 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 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 being marks used in connection with, or were part of any violation.
4. Defines counterfeit mark.

THIS BILL WOULD:

1. Also prohibit transport, offers for sale, distribution of counterfeit products. Make it a misdemeanor or a felony for a person to intentionally transport, offer for sale, or distribute any counterfeit registered trademark, as specified.
2. Will enhance the penalties for violation by a person to include a fine not to exceed \$250,000 or three times the total retail or fair market value of the articles described and will enhance the penalties for violation by a corporation to include a fine not to exceed \$500,000 or three times the total retail or fair Market value of the articles described in this subdivision.
3. Require as part of a conviction or a plea of nolo contendere, the forfeiture of all proceeds of the crime.
4. 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.
5. Expand the unassembled components of articles to be included then determining the value that could have been made from the components.
 6. Require the court to order a convicted person of an offense to pay restitution to the trademark owner or other victim of the offense including restitution for any economic loss as well as expenses incurred by the owner in the investigation and prosecution of the offense.
 7. 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. In addition, current state law caps the monetary penalties. This proposal will require consideration of the potential profits of the counterfeit operation.

COMMENT

This proposal would strengthen the criminal penalties against counterfeit operations and meshes with our public protection mandate and e-pedigree requirements.

FISCAL IMPACT

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

HISTORY:

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

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

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, 2725.1, Section 2835.5, and 2836.1 of, and to add Section 2835.7 to, of the Business and Professions Code, relating to the nursing.

LEGISLATIVE COUNSEL'S DIGEST

AB 1436, as amended, Hernandez. Nurse practitioners: scope of practice.

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 service ordered by specified healing arts practitioners, including dispensing of drugs or devices upon their order in a clinic setting, as defined.

This bill would specify that the practice of nursing includes those actions taken pursuant to an order by a nurse practitioner or a nurse-midwife. The bill would provide that a nurse practitioner is authorized to perform comprehensive health care services for which he

~~or she is educationally prepared and competent to perform and to admit and discharge patients from health facilities 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. 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~~

This bill 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.

~~Because this bill would impose additional requirements under the Nursing Practice Act, the violation of which would be a 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-no*.

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

1 SECTION 1. Section 2835.5 of the Business and Professions
2 Code is amended to read:

3 2835.5. (a) A registered nurse who is holding himself or herself
4 out as a nurse practitioner or who desires to hold himself or herself
5 out as a nurse practitioner shall, within the time prescribed by the
6 board and prior to his or her next license renewal or the issuance
7 of an initial license, submit educational, experience, and other
8 credentials and information as the board may require for it to
9 determine that the person qualifies to use the title "nurse
10 practitioner," pursuant to the standards and qualifications
11 established by the board.

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

1 issue to each qualified person a certificate evidencing that the
2 person is qualified to use the title “nurse practitioner.”

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

8 ~~On and after January 1, 2008, an~~ *An* applicant for initial
9 qualification or certification as a nurse practitioner under this article
10 who has not been qualified or certified as a nurse practitioner in
11 California or any other state shall meet the following requirements:

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

14 (2) Possess a master’s degree in nursing, ~~a master’s degree in~~
15 ~~a clinical field related to nursing, or a graduate or doctoral degree~~
16 in nursing.

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

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

21 ~~SECTION 1. Section 2725 of the Business and Professions~~
22 ~~Code is amended to read:~~

23
24
25 **All matter omitted in this version of the bill**
26 **appears in the bill as amended in the**
27 **Assembly 05/30/07. (JR11)**
28

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1436

VERSION: As amended January 7, 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. 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.
2. Require satisfactory completion of a nurse practitioner program approved by the board.
3. Require that the nurse practitioner be certified by a nationally recognized certifying body approved by the board.

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

PRIOR HISTORY/RELATED BILLS:

Prior to amendment, this bill contained several of the provisions found in SB 809. This bill was amended and is requiring annual certification as a nurse practitioner as well as allowing a nurse practitioner to use a doctoral degree in nursing as a qualification method.

FISCAL IMPACT:

The board does not anticipate any fiscal impact.

COMMENTS:

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. As amended, the scope of practice issues has been removed.

HISTORY:

Dates	Actions
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 AUGUST 20, 2007

AMENDED IN SENATE JULY 19, 2007

AMENDED IN SENATE JULY 16, 2007

AMENDED IN SENATE JUNE 27, 2007

AMENDED IN ASSEMBLY MAY 21, 2007

AMENDED IN ASSEMBLY MAY 8, 2007

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 1587

Introduced by Assembly Member De La Torre
(Principal coauthor: Senator Lowenthal)

February 23, 2007

~~An act to relating to recall elections, and declaring the urgency thereof, to take effect immediately. An act to amend Section 56.05 of the Civil Code, relating to personal information.~~

LEGISLATIVE COUNSEL'S DIGEST

AB 1587, as amended, De La Torre. ~~Recall elections: City of Lynwood. Personal information: pharmacy.~~

The Confidentiality of Medical Information Act prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, using for marketing, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, unless a specified exception applies. That law excludes from the definition of marketing communications that are for a specified descriptive purpose, that are tailored to the circumstances of a

particular individual, or for which the communicator does not receive remuneration from a 3rd party, as specified.

This bill would additionally 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.

~~Existing law provides the procedure for the recall of local government officers pursuant to a petition that is circulated for signatures and submitted by the proponents of the recall. It requires that when the city or county elections official is the officer sought to be recalled, the elections official's duties in connection with the recall process be performed by some other person designated by the applicable governing board.~~

~~This bill would state legislative findings that there exists a need for an experienced, objective, impartial, and professional entity to conduct any recall or special election that is held in the City of Lynwood in the County of Los Angeles during calendar years 2007 and 2008, and would state the intent of the Legislature in connection with this bill. It would require any recall or special election held in the City of Lynwood during the 2007 and 2008 calendar years to be administered by the Los Angeles County Registrar-Recorder, subject to approval by the Board of Supervisors.~~

~~This bill would require the City of Lynwood to pay the County of Los Angeles from the city treasury for any expenses authorized and necessarily incurred in conducting any recall or special election held in the City of Lynwood pursuant to this bill. It would provide a procedure under which the Controller would reallocate to the county amounts otherwise scheduled for distribution to the city from unrestricted funds or moneys, as specified.~~

~~The California Constitution provides that a local or special statute is invalid in any case if a general statute can be made applicable.~~

~~This bill would declare that, due to the unique circumstances pertaining to the City of Lynwood that the bill is intended to remedy, a general statute within the meaning of specified provisions of the California Constitution cannot be made applicable and a special statute is necessary.~~

~~This bill would declare that it is to take effect immediately as an urgency statute.~~

~~Vote: $\frac{2}{3}$ -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 56.05 of the Civil Code is amended to
2 read:

3 56.05. For purposes of this part:

4 (a) "Authorization" means permission granted in accordance
5 with Section 56.11 or 56.21 for the disclosure of medical
6 information.

7 (b) "Authorized recipient" means any person who is authorized
8 to receive medical information pursuant to Section 56.10 or 56.20.

9 (c) "Contractor" means any person or entity that is a medical
10 group, independent practice association, pharmaceutical benefits
11 manager, or a medical service organization and is not a health care
12 service plan or provider of health care. "Contractor" does not
13 include insurance institutions as defined in subdivision (k) of
14 Section 791.02 of the Insurance Code or pharmaceutical benefits
15 managers licensed pursuant to the Knox-Keene Health Care Service
16 Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340)
17 of Division 2 of the Health and Safety Code).

18 (d) "Health care service plan" means any entity regulated
19 pursuant to the Knox-Keene Health Care Service Plan Act of 1975
20 (Chapter 2.2 (commencing with Section 1340) of Division 2 of
21 the Health and Safety Code).

22 (e) "Licensed health care professional" means any person
23 licensed or certified pursuant to Division 2 (commencing with
24 Section 500) of the Business and Professions Code, the Osteopathic
25 Initiative Act or the Chiropractic Initiative Act, or Division 2.5
26 (commencing with Section 1797) of the Health and Safety Code.

27 (f) "Marketing" means to make a communication about a
28 product or service that encourages recipients of the communication
29 to purchase or use the product or service.

30 "Marketing" does not include any of the following:

31 (1) Communications made orally or in writing for which the
32 communicator does not receive direct or indirect remuneration,
33 including, but not limited to, gifts, fees, payments, subsidies, or
34 other economic benefits, from a third party for making the
35 communication.

36 (2) Communications made to current enrollees solely for the
37 purpose of describing a provider's participation in an existing
38 health care provider network or health plan network of a

1 Knox-Keene licensed health plan to which the enrollees already
2 subscribe; communications made to current enrollees solely for
3 the purpose of describing if, and the extent to which, a product or
4 service, or payment for a product or service, is provided by a
5 provider, contractor, or plan or included in a plan of benefits of a
6 Knox-Keene licensed health plan to which the enrollees already
7 subscribe; or communications made to plan enrollees describing
8 the availability of more cost-effective pharmaceuticals.

9 (3) Communications that are tailored to the circumstances of a
10 particular individual to educate or advise the individual about
11 treatment options, and otherwise maintain the individual's
12 adherence to a prescribed course of medical treatment, as provided
13 in Section 1399.901 of the Health and Safety Code, for a chronic
14 and seriously debilitating or life-threatening condition as defined
15 in subdivisions (d) and (e) of Section 1367.21 of the Health and
16 Safety Code, if the health care provider, contractor, or health plan
17 receives direct or indirect remuneration, including, but not limited
18 to, gifts, fees, payments, subsidies, or other economic benefits,
19 from a third party for making the communication, if all of the
20 following apply:

21 (A) The individual receiving the communication is notified in
22 the communication in typeface no smaller than 14-point type of
23 the fact that the provider, contractor, or health plan has been
24 remunerated and the source of the remuneration.

25 (B) The individual is provided the opportunity to opt out of
26 receiving future remunerated communications.

27 (C) The communication contains instructions in typeface no
28 smaller than 14-point type describing how the individual can opt
29 out of receiving further communications by calling a toll-free
30 number of the health care provider, contractor, or health plan
31 making the remunerated communications. No further
32 communication may be made to an individual who has opted out
33 after 30 calendar days from the date the individual makes the opt
34 out request.

35 (4) *A written communication or written message provided to a*
36 *pharmacy patient during a face-to-face interaction with a*
37 *pharmacist or pharmacy personnel, in conjunction with dispensing*
38 *a prescription drug, if all of the following apply:*

39 (A) *The communication does not involve the sale or transfer of*
40 *medical information by the pharmacy to any other entity, or to the*

1 *pharmacy from another entity. Additionally, the communication*
2 *is based only on medical information that has already been*
3 *provided to, and maintained by, the pharmacist as necessary to*
4 *the performance of the pharmacist's duties to fill prescriptions.*

5 *(B) The communication, either in whole or in part, assists the*
6 *pharmacist or pharmacy personnel in meeting the goals of Section*
7 *601 of Public Law 104-180 with respect to the transmittal of useful*
8 *information regarding a prescription drug dispensed to the patient.*

9 *(C) The content of the communication provides information*
10 *regarding any of the following:*

11 *(i) The dispensed drug or a disease or health condition for which*
12 *the dispensed drug is indicated.*

13 *(ii) Another treatment or therapy for a disease or health*
14 *condition for which the dispensed drug is indicated if the content*
15 *of the communication does not include any mention of, or negative*
16 *statements regarding, the dispensed drug by proprietary or brand*
17 *name and the treatment or therapy satisfies one or more of the*
18 *following conditions:*

19 *(I) Is an adjunctive treatment or therapy that augments or assists*
20 *the dispensed drug or therapy.*

21 *(II) Is a generic alternative for the dispensed drug.*

22 *(III) Has demonstrable benefits for the patient as compared to*
23 *the dispensed drug based upon the prescribing information*
24 *approved by the federal Food and Drug Administration (FDA), a*
25 *finding or conclusion contained in the FDA approval package, or*
26 *requirements or policies of the FDA. Any such claim may not be*
27 *inconsistent with applicable requirements or policies of the FDA.*
28 *These demonstrable benefits may include being more effective,*
29 *having fewer or less serious side effects, or offering more*
30 *convenient dosing.*

31 *(iii) A drug dispensed to the patient during the preceding year*
32 *or a disease or health condition for which that drug is indicated.*

33 *(iv) General information about a health condition for which the*
34 *patient's disease or health condition puts the patient at risk and*
35 *that, if left untreated, may result in worsening of the health,*
36 *symptoms, or daily functioning of the patient.*

37 *(v) General information about a health condition for which the*
38 *patient may be at risk given the age or gender of the patient and*
39 *that, if left untreated, may result in worsening of the health,*
40 *symptoms, or daily functioning of the patient.*

1 (vi) *The information described in clauses (iii) to (v), inclusive,*
2 *shall not include any mention, by the proprietary name, brand*
3 *name, or generic name, of a specific drug or other product,*
4 *treatment, therapy, or service, other than the dispensed drug or a*
5 *drug dispensed to the patient during the preceding year.*

6 (D) *The pharmacist is available upon request of the patient to*
7 *answer the questions regarding the communication and the*
8 *communication notifies the patient that he or she should consult*
9 *a health care provider.*

10 (E) *If the communication is paid for, in whole or in part, by a*
11 *manufacturer, distributor, or provider of a health care product or*
12 *service, other than the pharmacy or a business associate of the*
13 *pharmacy, the communication shall comply with all of the*
14 *following:*

15 (i) *The communication shall, in a clear written statement placed*
16 *in a clear and conspicuous location, disclose the source of the*
17 *sponsorship in a typeface no smaller than 14-point type.*

18 (ii) *If the communication is related to information referenced*
19 *in clause (i), (ii), or (iii) of subparagraph (C) and mentions a*
20 *prescription drug or other product, treatment, therapy, or service,*
21 *other than the dispensed prescription drug, by its proprietary*
22 *name, brand name, or generic name, the communication shall also*
23 *contain the words "paid advertisement" in a typeface no smaller*
24 *than 14-point type at the top of each sponsored message.*

25 (iii) *If a sponsored message is printed on more than one page*
26 *of a communication, the statement required by clause (ii) shall*
27 *appear on each page on which the sponsored message appears.*

28 (iv) *If a sponsored message is printed on more than one panel*
29 *of the same page of a communication, the statement required by*
30 *clause (ii) shall appear on each panel on which the sponsored*
31 *message appears.*

32 (v) *If the communication is related to information referenced*
33 *in clause (i), (ii), or (iii) of subparagraph (C) and mentions a*
34 *prescription or other product, treatment, therapy, or service, other*
35 *than the dispensed prescription drug, by its proprietary name,*
36 *brand name, or generic name, the communication shall also*
37 *contain the words "results may vary—consult your doctor."*

38 (F) *The communication contains instructions in a typeface no*
39 *smaller than 14-point type describing how the patient can opt out*
40 *of the portion of a pharmacy's communication that is paid for by*

1 *a manufacturer, distributor, or provider of a health care product*
2 *or service by calling a toll-free number. No further sponsored*
3 *message from the pharmacy may be made to an individual who*
4 *has opted out after 30 calendar days from the date the individual*
5 *makes the opt out request.*

6 (G) *A majority of the printed space of the entire communication*
7 *delivered to the patient in the pharmacy is used for purposes other*
8 *than a sponsored message that is subject to clause (ii) of*
9 *subparagraph (E).*

10 (H) *Compliance with any provision in this paragraph shall not*
11 *necessarily render any communication as truthful, not misleading,*
12 *fairly balanced, or adequately substantiated, within the meaning*
13 *of any applicable federal or state law, if that communication is*
14 *otherwise false, misleading, lacking in fair balance, or not*
15 *adequately substantiated.*

16 (g) “Medical information” means any individually identifiable
17 information, in electronic or physical form, in possession of or
18 derived from a provider of health care, health care service plan,
19 pharmaceutical company, or contractor regarding a patient’s
20 medical history, mental or physical condition, or treatment.
21 “Individually identifiable” means that the medical information
22 includes or contains any element of personal identifying
23 information sufficient to allow identification of the individual,
24 such as the patient’s name, address, electronic mail address,
25 telephone number, or social security number, or other information
26 that, alone or in combination with other publicly available
27 information, reveals the individual’s identity.

28 (h) “Patient” means any natural person, whether or not still
29 living, who received health care services from a provider of health
30 care and to whom medical information pertains.

31 (i) “Pharmaceutical company” means any company or business,
32 or an agent or representative thereof, that manufactures, sells, or
33 distributes pharmaceuticals, medications, or prescription drugs.
34 “Pharmaceutical company” does not include a pharmaceutical
35 benefits manager, as included in subdivision (c), or a provider of
36 health care.

37 (j) “Provider of health care” means any person licensed or
38 certified pursuant to Division 2 (commencing with Section 500)
39 of the Business and Professions Code; any person licensed pursuant
40 to the Osteopathic Initiative Act or the Chiropractic Initiative Act;

1 any person certified pursuant to Division 2.5 (commencing with
2 Section 1797) of the Health and Safety Code; any clinic, health
3 dispensary, or health facility licensed pursuant to Division 2
4 (commencing with Section 1200) of the Health and Safety Code.
5 “Provider of health care” does not include insurance institutions
6 as defined in subdivision (k) of Section 791.02 of the Insurance
7 Code.

8 ~~SECTION 1. The Legislature finds and declares that there~~
9 ~~exists a need for an experienced, objective, impartial, and~~
10 ~~professional entity to conduct any recall or special election that is~~
11 ~~held in the City of Lynwood in the County of Los Angeles during~~
12 ~~the 2007 and 2008 calendar years. It is the intent of the Legislature~~
13 ~~in enacting this statute to ensure the integrity, efficiency, and lawful~~
14 ~~conduct of recall and special elections in the City of Lynwood, to~~
15 ~~avoid real bias or the perception of bias or impropriety, and to~~
16 ~~strengthen the public’s confidence in the fair and free operation~~
17 ~~of the election process and the reporting of election results.~~

18 ~~SEC. 2. Any recall or special election in the City of Lynwood~~
19 ~~held during the 2007 and 2008 calendar years shall be administered,~~
20 ~~for all purposes, by the Los Angeles County Registrar-Recorder~~
21 ~~upon approval by the Board of Supervisors of the County of Los~~
22 ~~Angeles.~~

23 ~~SEC. 3. (a) The City of Lynwood shall pay from its city~~
24 ~~treasury for all expenses authorized and necessarily incurred in~~
25 ~~conducting any special or recall election held during the 2007 and~~
26 ~~2008 calendar years. These expenses shall be paid to the County~~
27 ~~of Los Angeles to reimburse the county for the costs of conducting~~
28 ~~the special or recall election.~~

29 ~~(b) If payment is not made in a timely manner, and after~~
30 ~~sufficient notice to the City of Lynwood, the Board of Supervisors~~
31 ~~of the County of Los Angeles may pass a resolution informing the~~
32 ~~Controller that some or all of the amount due is outstanding.~~

33 ~~(c) Following receipt of the resolution, the Controller shall~~
34 ~~deduct from apportionments scheduled for periodic distribution~~
35 ~~to the City of Lynwood, from any unrestricted funds or moneys,~~
36 ~~the outstanding balance owed and instead pay the amount to the~~
37 ~~County of Los Angeles.~~

38 ~~SEC. 4. The Legislature finds and declares that because of the~~
39 ~~unique circumstances of the City of Lynwood, relating to the~~
40 ~~conduct of elections, a statute of general applicability cannot be~~

1 ~~enacted within the meaning of subdivision (b) of Section 16 of~~
2 ~~Article IV of the California Constitution. Therefore, it is necessary~~
3 ~~to enact a special statute applicable only to the City of Lynwood.~~

4 ~~SEC. 5. This act is an urgency statute necessary for the~~
5 ~~immediate preservation of the public peace, health, or safety within~~
6 ~~the meaning of Article IV of the Constitution and shall go into~~
7 ~~immediate effect. The facts constituting the necessity are:~~

8 ~~In order to ensure that recall elections in the City of Lynwood~~
9 ~~proceed in a timely fashion in accordance with state law, and to~~
10 ~~preserve the public's confidence in the electoral process and the~~
11 ~~voters' reserve power to recall elected officials, it is necessary that~~
12 ~~this act take effect immediately.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1587

VERSION: As Amended August 20, 2007

AUTHOR: De La Torre

SPONSOR: Catalina Health Resource

BOARD POSITION: None

SUBJECT: Personal information: pharmacy.

EXISTING LAW:

1. Defines "marketing" as a communication about a product or service that encourages recipients of the communication to purchase or use the product of service.
2. Details exemptions to the definition to include:
 - Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration
 - Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network.
 - Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about, among other things, treatment options. Such communications may result in direct or indirect remuneration if the individual receiving the communication is notified of such, in a typeface no smaller than 14-point font.

THIS BILL WOULD:

1. Also exempt a written communication or message provided to a pharmacy patient during a face-to-face interaction with a pharmacist or pharmacy personnel, if all of the following apply:
 - The communication does not involve the sale or transfer of individually identifiable patient information
 - The communication assists the pharmacist or pharmacy personnel in the transmittal of use information regarding a prescription drug dispensed to the patient
 - The content of the communication provides information about the dispensed drug, another treatment or therapy for a disease or health condition for which the drug is dispensed or a drug dispensed within the last three years, general information about a health condition for which the patient's disease may put the patient at risk, or general information about a health condition for which the patient may be at risk given the age or gender of the patient.

- The pharmacist is available upon request of the patient to answer questions regarding the communication
- If the communication is paid for, the communication must also include, among other things, the source of the sponsorship in typeface no smaller than 14-point type.
- The communication contains instruction in typeface no smaller than 14-point font, describing how the patient can opt out of the portion of the communication that is an advertisement paid for.
- The communication does not involve the sale or transfer to medical information by or to the pharmacy by another entity and the communication is based only on medical information that has already been provided to and maintained by the pharmacist.

AUTHOR'S INTENT

This bill is intended to clarify the existing statute and would exempt drug information from the definition of "marketing communications."

FISCAL IMPACT:

The board does not anticipate any major fiscal impact to the board. Any minor impact could most likely be absorbed with existing resources.

SUPPORT and OPPOSITION:

Support

National Association of Chain Drug Stores
 National Council on Patient Information and Education
 National Consumers League
 CA Retailers Association
 Coalition for Healthcare Communication
 Embracing Wellness
 AIDS Legal Referral Panel
 STOP AIDS Project
 Marin AIDS Project
 Pacific Center for Human Growth
 Greenlining Institute
 AIDS Emergency Fund & Breast Cancer Emergency Fund
 Mission Neighborhood Health Center

Opposition

Consumers Union
 Southern CA HIV Advocacy Coalition
 Pfizer, Inc.
 World Privacy Forum

COMMENTS:

The intent of this legislation is to provide additional information to consumers. However the board may want to consider if is appropriate for a pharmacist to provide a patient with drug information on a medication that is not being dispensed by the pharmacist and if this undermines the value of patient consultation. Also, it is unclear who is responsible for the enforcement of these provisions.

This bill is inactive.

HISTORY:

Dates	Actions
01/31/08	Jan. 31 Re-referred to Com. on JUD.
11/28/07	Nov. 28 Withdrawn from committee. Re-referred to Com. on RLS.
08/20/07	Aug. 20 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on E., R. & C.A.
07/20/07	July 20 In committee: Hearing postponed by committee. Joint Rule 62(a), file notice waived. (Page 1917.)
07/19/07	July 19 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on E., R. & C.A. In committee: Hearing postponed by committee.
07/17/07	July 17 Withdrawn from committee. Re-referred to Com. on RLS. Re-referred to Com. on E., R. & C.A.
07/16/07	July 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. Failed passage. Reconsideration granted.
06/27/07	June 27 Read second time, amended, and re-referred to Com. on JUD.

06/26/07	June 26 From committee: Amend, do pass as amended, and re-refer to Com. on JUD. (Ayes 6. Noes 2.)
06/07/07	June 7 Referred to Coms. on HEALTH and JUD.
05/24/07	May 24 In Senate. Read first time. To Com. on RLS. for assignment.
05/24/07	May 24 Read third time, passed, and to Senate. (Ayes 70. Noes 6. Page 1615.)
05/21/07	May 21 Read third time, amended, and returned to third reading. (Page 1565.).
05/09/07	May 9 Read second time. To third reading.
05/08/07	May 8 Read second time and amended. Ordered returned to second reading.
05/07/07	May 7 From committee: Amend, and do pass as amended. (Ayes 15. Noes 0.) (May 1).
03/29/07	Mar. 29 Referred to Com. on HEALTH.
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 ASSEMBLY MARCH 24, 2008

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 1947

Introduced by Assembly Member Emmerson

February 13, 2008

An act to amend ~~Section 4202~~ *Sections 4202 and 4231* of, and to add ~~Section 4231.5~~ *Sections 4230, 4230.5, and 4410* to, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1947, as amended, Emmerson. Pharmacy technicians.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacy technicians by the California State Board of Pharmacy. Existing law authorizes the board to adopt rules and regulations necessary for the protection of the public. Existing law authorizes the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate equivalent and has either obtained a specified associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board. Existing law prohibits the board from renewing a pharmacist license, after the first renewal, unless the applicant submits satisfactory proof that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the 2 years preceding the application for renewal.

This bill would instead authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or possesses a general educational development certificate

equivalent, is certified by the Pharmacy Technician Certification Board or passes a ~~specified board-approved~~ *pharmacy technician examination approved by the board*, and has either obtained a specified associate's degree, completed a specified course of training, or graduated from a specified school of pharmacy. *The bill would specify that these requirements shall only apply to pharmacy technicians issued on initial license on and after January 1, 2009.* The bill would also prohibit the board from renewing a pharmacist technician license, after the first renewal, unless the applicant submits satisfactory proof that he or she has successfully completed 20 hours of approved courses of continuing pharmacy education during the 2 years preceding the application for renewal. ~~The bill would require the board to adopt regulations with respect to this continuing education requirement.~~ *The bill would specify the form and subject matter content for these courses. The bill would provide that a pharmacy technician license that is not renewed within 3 years after expiration may not be renewed and shall be canceled at the end of the 3-year period. The bill would make conforming changes.*

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 4202 of the Business and Professions
2 Code is amended to read:
3 4202. (a) The board may issue a pharmacy technician license
4 to an individual if he or she is a high school graduate or possesses
5 a general educational development certificate equivalent, is
6 certified by the Pharmacy Technician Certification Board or passes
7 ~~a board-approved examination that is based on psychometrically~~
8 ~~sound principles~~ *a pharmacy technician examination approved by*
9 *the board*, and meets any one of the following requirements:
10 (1) Has obtained an associate's degree in pharmacy technology.
11 (2) Has completed a course of training specified by the board.
12 (3) Has graduated from a school of pharmacy recognized by
13 the board.
14 (b) The board shall adopt regulations pursuant to this section
15 for the licensure of pharmacy technicians and for the specification
16 of training courses as set out in paragraph (2) of subdivision (a).
17 Proof of the qualifications of any applicant for licensure as a

1 pharmacy technician shall be made to the satisfaction of the board
2 and shall be substantiated by any evidence required by the board.

3 (c) The board shall conduct a criminal background check of an
4 applicant to determine if the applicant has committed acts that
5 would constitute grounds for denial of licensure, pursuant to this
6 chapter or Chapter 2 (commencing with Section 480) of Division
7 1.5.

8 (d) The board may suspend or revoke a license issued pursuant
9 to this section on any ground specified in Section 4301.

10 (e) Once licensed as a pharmacist, the pharmacy technician
11 registration is no longer valid and the pharmacy technician license
12 shall be returned to the board within 15 days.

13 (f) *An examination for certification of a pharmacy technician*
14 *or a pharmacy technician examination approved by the board*
15 *shall be subject to Section 139.*

16 (g) *The requirement in subdivision (a) of certification by the*
17 *Pharmacy Technician Certification Board or passing a pharmacy*
18 *technician examination approved by the board shall only apply to*
19 *pharmacy technicians issued an initial license on and after January*
20 *1, 2009.*

21 SEC. 2. Section ~~4231.5~~ 4230 is added to the Business and
22 Professions Code, to read:

23 ~~4231.5.~~

24 4230. (a) The board shall not renew a pharmacy technician
25 license unless the applicant submits proof satisfactory to the board
26 that he or she has successfully completed 20 hours of approved
27 courses of continuing pharmacy *technician* education *as described*
28 *in Section 4230.5* during the two years preceding the application
29 for renewal.

30 (b) Notwithstanding subdivision (a), the board shall not require
31 completion of continuing education for the first renewal of a
32 pharmacy technician license.

33 (c) If an applicant for renewal of a pharmacy technician license
34 submits the renewal application and payment of the renewal fee
35 but does not submit proof satisfactory to the board that the licensee
36 has completed 20 hours of continuing pharmacy education, the
37 board shall not renew the license and shall issue the applicant an
38 inactive pharmacy technician license. A licensee with an inactive
39 pharmacy technician license issued pursuant to this section may
40 obtain an active pharmacy technician license by paying the renewal

1 fees due and submitting satisfactory proof to the board that the
2 licensee has completed 20 hours of continuing pharmacy education.

3 ~~(d) The board shall adopt regulations to implement this section.~~

4 SEC. 3. Section 4230.5 is added to the Business and Professions
5 Code, to read:

6 4230.5. (a) The courses shall be in the form of studies,
7 institutes, seminars, lectures, conferences, workshops, extension
8 studies, correspondence courses, and other similar methods of
9 conveying continuing professional pharmacy technician education.

10 (b) The subject matter may be pertinent to the socioeconomic
11 and legal aspects of health care, the properties and actions of
12 drugs and dosage forms, and the etiology, characteristics, and
13 therapeutics of the disease state.

14 (c) The subject matter of the courses may also include, but shall
15 not be limited to, the following: pharmacology, biochemistry,
16 physiology, pharmaceutical chemistry, pharmacy administration,
17 pharmacy jurisprudence, public health and communicable diseases,
18 professional practice management, anatomy, and histology.

19 SEC. 4. Section 4231 of the Business and Professions Code is
20 amended to read:

21 4231. (a) The board shall not renew a pharmacist license unless
22 the applicant submits proof satisfactory to the board that he or she
23 has successfully completed 30 hours of approved courses of
24 continuing pharmacy education as described in Section 4232 during
25 the two years preceding the application for renewal.

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

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

39 SEC. 5. Section 4410 is added to the Business and Professions
40 Code, to read:

1 4410. *Any pharmacy technician license that is not renewed*
2 *within three years following its expiration may not be renewed*
3 *and shall be canceled by operation of law at the end of the*
4 *three-year period.*

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1947

VERSION: As Amended March 24, 2008

AUTHOR: Emmerson

**SPONSOR: California Society of Health-
System Pharmacists**

RECOMMENDED POSITION:

SUBJECT: Pharmacy technicians

EXISTING LAW:

1. Provides for the licensure and regulation of pharmacy technicians by the Board of Pharmacy.
2. Authorizes the board to issue a pharmacy technician license to an individual who is a high school graduate or who possesses a GED and has either obtained a specified associate's degree, completed a specified course of training, graduated from a specified school of pharmacy, or is certified by the Pharmacy Technician Certification Board.

THIS BILL WOULD:

1. Authorize the board to issue a pharmacy technician license to an individual if that individual is a high school graduate or who possesses a GED, is certified by the Pharmacy Technician Certification Board or passes a pharmacy technician examination approved by the board, and has either a obtained a specified associate's degree, completed a specified courses of training, or graduated from a specified school of pharmacy.
2. The bill specifies that these requirements shall only apply to pharmacy technicians issued an initial license on and after January 1, 2009.
3. Require a pharmacy technician to successfully complete 20 hours of approved courses of continuing pharmacy education during the 2-years preceding an application for renewal.
4. Specify the form and subject matter content for these continuing education courses.
5. Provide that a pharmacy technician license that is not renewed within 3-years after expiration may not be renewed and shall be canceled at the end of a 3-year period.

AUTHOR'S INTENT

This bill is intended to amend section 4202 and 4231 of the Business and Professions Code and add sections 4230, 4230.5 and 4410 to the Business and Professions Code as it relates the licensure requirements for pharmacy technicians and conditions for renewal and cancellation of a pharmacy technician license.

FISCAL IMPACT:

The board anticipates the addition of one staff person to audit continuing education and issue citations and fines for violations.

SUPPORT and OPPOSITION:

COMMENTS:

At this time, the sponsor, CSHP is not moving the bill.

HISTORY:

Dates Actions

03/25/08	Mar. 25	Re-referred to Com. on B. & P.
03/24/08	Mar. 24	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
02/28/08	Feb. 28	Referred to Com. on B. & P.
02/14/08	Feb. 14	From printer. May be heard in committee March 15.
02/13/08	Feb. 13	Read first time. To print.

AMENDED IN ASSEMBLY MARCH 24, 2008

CALIFORNIA LEGISLATURE—2007—08 REGULAR SESSION

ASSEMBLY BILL

No. 2122

Introduced by Assembly Member Plescia
(Principal coauthor: Assembly Member Jones)

February 20, 2008

An act to amend Section 4190 of the Business and Professions Code, and to add Section 1212.5 to the Health and Safety Code, relating to clinics.

LEGISLATIVE COUNSEL'S DIGEST

AB 2122, 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. A violation of these provisions is a crime.

This bill would enact the California Outpatient Surgery Patient Safety and Improvement Act, which would require, on or after January 1, 2009, any person, firm, association, partnership, or corporation desiring a license for a surgical clinic, except specified surgical clinics, in addition to other prescribed licensing requirements, to meet prescribed operational, staffing, and procedural standards. The bill would require the department to perform *initial periodic* inspections of a surgical clinic within 45 calendar days of an application approval, and to perform periodic inspections *clinics* at least once every 3 years thereafter.

The bill would require the department, until January 1, 2016, if sufficient funds are made available for this purpose, as determined by

~~the department, pursuant to an appropriation in the annual Budget Act or other statute, to establish a program for the training of ambulatory surgical center inspection personnel, and would require the department to prepare a comprehensive report on the training program, as provided.~~
By

By imposing new licensure requirements on surgical clinics, a violation of which would be a crime, the bill would impose a state-mandated local program.

Existing law 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 by an accreditation agency, or certified to participate in the Medicare program is not entitled to the above-described benefits without a license issued by the board. It would also specify board inspection requirements for the accredited or certified surgical clinics, and would require self-assessments by any clinic licensed by the board.

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 Patient Safety and Improvement
- 3 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 and Section 1212.5 of the Health and Safety
- 9 Code, accredited by an accreditation agency, as defined in
- 10 subdivision (d) of Section 1248 of the Health and Safety Code, or
- 11 certified to participate in the Medicare program under Title XVIII

1 of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.),
2 may purchase drugs at wholesale for administration or dispensing,
3 under the direction of a physician, to patients registered for care
4 at the clinic, as provided in subdivision (b). The clinic shall keep
5 records of the kind and amounts of drugs purchased, administered,
6 and dispensed, and the records shall be available and maintained
7 for a minimum of three years for inspection by all properly
8 authorized personnel.

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

18 (c) No surgical clinic shall be entitled to the benefits of this
19 section until it has obtained a license from the board. A separate
20 license shall be required for each clinic location. A clinic shall
21 notify the board of any change in the clinic's address on a form
22 furnished by the board.

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

29 (e) The board shall inspect a surgical clinic that is accredited
30 by an accreditation agency or is certified to participate in the
31 Medicare program, as specified in subdivision (a), but is not
32 licensed pursuant to Sections 1204 and 1212.5 of the Health and
33 Safety Code, within 120 days of the issuance of a clinic licensed
34 pursuant to this article, and at least annually thereafter.

35 (f) Every surgical clinic issued a license pursuant to this article
36 shall complete a self-assessment within 30 days of opening and at
37 least 30 days before each license renewal pursuant to this article.
38 The completed self-assessment form shall be retained at the
39 licensed premises for a period of three years.

1 SEC. 3. Section 1212.5 is added to the Health and Safety Code,
2 to read:

3 1212.5. (a) In addition to other licensing requirements of this
4 chapter, any person, firm, association, partnership, or corporation
5 desiring a license for a surgical clinic shall meet the following
6 standards:

7 (1) Comply with the Medicare conditions of coverage for
8 ambulatory surgical centers, as set forth in Subpart C (commencing
9 with Section 416.40) of Part 416 of Title 42 of the Code of Federal
10 Regulations, including interpretive guidelines issued by the Centers
11 for Medicare and Medicaid Services as those guidelines pertain
12 to that subpart.

13 (2) Limit surgical procedures to those that:

14 (A) Do not result in extensive blood loss.

15 (B) Do not require major or prolonged invasion of body cavities.

16 (C) Do not directly involve major blood vessels.

17 (D) Do not constitute an emergency or are not life threatening
18 in nature.

19 (3) Establish and implement policies and procedures consistent
20 with the Medicare conditions of coverage set forth in Subpart C
21 (commencing with Section 416.40) of Part 416 of Title 42 of the
22 Code of Federal Regulations, including interpretive guidelines
23 issued by the Centers for Medicare and Medicaid Services as those
24 guidelines pertain to that subpart, including, but not limited to:

25 (A) Physician services, policies, and procedures, including
26 surgical and anesthesia services.

27 (B) Nursing services, policies, and procedures.

28 (C) Infection control policies and procedures.

29 (D) Pharmaceutical services, policies, and procedures.

30 (E) Housekeeping services, policies, and procedures that include
31 provisions for maintenance of a safe and clean environment.

32 (F) Laboratory and radiology services.

33 (G) Patient health records policies and procedures, which shall
34 be developed with the assistance of a person skilled in records
35 maintenance and preservation.

36 (H) Personnel policies and procedures.

37 (b) Notwithstanding subdivision (c) of Section 1228, the
38 department shall perform ~~initial inspections of a surgical clinic~~
39 ~~within 45 calendar days of the date the completed application is~~
40 ~~received and approved by the department. Periodic inspections~~

1 ~~shall occur at least once every three years thereafter. *periodic*~~
2 ~~*inspections of surgical clinics at least once every three years.*~~

3 (c) The department may contract with licensed physicians and
4 surgeons to serve as surveyors to perform inspections of surgical
5 clinics for compliance with the licensure requirements of this
6 chapter and in a manner that is consistent with department
7 inspections pursuant to Section 1279.

8 ~~(d) If sufficient funds are made available for this purpose,~~
9 ~~pursuant to an appropriation in the annual Budget Act or other~~
10 ~~statute, the department shall, until January 1, 2016, establish a~~
11 ~~program for training of surgical clinic inspection personnel. The~~
12 ~~goal of this program shall be to provide a sufficient number of~~
13 ~~qualified persons to facilitate the timely performance of the~~
14 ~~department's duties and responsibilities relating to initial and~~
15 ~~periodic licensing inspections of surgical clinics, in order to ensure~~
16 ~~compliance with this chapter.~~

17 ~~(c) (1) The department shall prepare a comprehensive report~~
18 ~~on the training program setting forth its goals, objectives, and~~
19 ~~structure. The report shall assess processing time for initial and~~
20 ~~periodic licensing inspections of surgical clinics and include~~
21 ~~information on all of the following:~~

22 ~~(A) The number of surgical clinic inspection personnel to be~~
23 ~~trained annually.~~

24 ~~(B) A timeline for completion of training.~~

25 ~~(C) A process for gathering information to evaluate the training~~
26 ~~program's efficiency that includes dropout and retention rates.~~

27 ~~(D) A mechanism to annually assess the need for the training~~
28 ~~program to continue.~~

29 ~~(2) The report required by paragraph (1) shall be submitted to~~
30 ~~the Joint Legislative Budget Committee no later than July 1, 2009,~~
31 ~~and no later than July 1 of each year thereafter, through July 1,~~
32 ~~2014.~~

33 ~~(f)~~

34 ~~(d) (1) This section shall not apply to any surgical clinic that~~
35 ~~is any of the following:~~

36 ~~(A) Accredited by an accreditation agency as defined in Section~~
37 ~~1248.~~

38 ~~(B) Certified to participate in the Medicare program under Title~~
39 ~~XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et~~
40 ~~seq.).~~

1 (C) Exempt from licensure pursuant to Section 1206.

2 (2) An entity exempt from the requirements of this section
3 pursuant to paragraph (1) may, at its option, apply for licensure as
4 a surgical clinic.

5 SEC. 4. No reimbursement is required by this act pursuant to
6 Section 6 of Article XIII B of the California Constitution because
7 the only costs that may be incurred by a local agency or school
8 district will be incurred because this act creates a new crime or
9 infraction, eliminates a crime or infraction, or changes the penalty
10 for a crime or infraction, within the meaning of Section 17556 of
11 the Government Code, or changes the definition of a crime within
12 the meaning of Section 6 of Article XIII B of the California
13 Constitution.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 2122

VERSION: As Amended March 24, 2008

AUTHOR: Plescia

SPONSOR: CA Ambulatory Surgery Assoc.

RECOMMENDED POSITION:

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.
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 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.
4. Specify standard operating requirements for surgical clinics licensed by the Department of Public Health (DPH) to include:
 - Compliance with Medicare conditions of coverage for ambulatory surgical centers as required in the Code of Federal Regulations

- Limit surgical procedures to those that do not result in extensive blood loss, do not require major or prolonged invasion of body cavities, do not directly involve major blood vessels, and are not emergency or life threatening in nature.
 - Establishing and implementing policies and procedures consistent with Medicare conditions as set forth in the Code of Federal Regulations.
5. Require the DPH to perform periodic inspections of a surgical clinic at least once every three years.
 6. Exempts accredited surgical clinics, those certified to participate in the Medicare Program, as those exempt from state licensure pursuant to 1206 of the Health and Safety Code from the provisions listed in 4 and 5.

AUTHOR'S INTENT

The sponsor states that this bill is intended to define operation staffing and procedural standards for surgical clinics licensed by the Department of Public Health.

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.

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 license specified.

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)
Advanced Pain Management
Ambulatory Surgery Center of Stockton
Apple Surgery Center Inc.
Arthroscopic Surgery Associates
Aspen Surgery Center
Brentwood Surgery Center
California Society of Anesthesiologists
Center for Endoscopy
Center for Surgery of Encinitas
Compliance Doctor
Cypress Surgery Center
Endo Center of Santa Rosa
Endoscopy Center of Sonoma County
Foot Ankle Center
Foothill Ranch Surgery and Medical Center
Foothill Surgery Center
Indio Surgery Center
Langston Healthcare Services
McGann Orthopaedics

Monterey Peninsula Surgery Center
Mount Diablo Surgery Center
Pacific Endoscopy & Surgery Center
Pacific Endo-Surgical Center
Pacific Gastroenterology Endoscopy Center
Pediatric Dental Initiative
Peninsula Eye Surgery Center
Peninsula Interventional Pain Management Center
Redwood Empire Surgery Center, Inc.
San Diego Center for Reproductive Surgery, Inc.
Sequoia Surgical Pavillion
Service Employees International Union
Sierra Pacific Orthopaedic & Spine Center Medical Group
Sierra Pacific Orthopaedic Center Medical Group
South Bay Orthopedic Specialists
Summit Surgical
Surgecenter of Palo Alto
Torrance Surgery Center
United Medical Endoscopy Center
United Surgical Partners International
Valley Endoscopy Center
West Torrance Podiatrists Group, Inc.
Numerous Individuals (Identified as Physicians)

Oppose

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

HISTORY:

Date	Action
04/02/08	Apr. 2 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 13. Noes 0. Page 4424.) (April 1).
03/25/08	Mar. 25 Re-referred to Com. on HEALTH.
03/24/08	Mar. 24 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
03/05/08	Mar. 5 Referred to Com. on HEALTH.
02/21/08	Feb. 21 From printer. May be heard in committee March 22.
02/20/08	Feb. 20 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 1, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL

No. 2425

Introduced by Assembly Member Coto

February 21, 2008

~~An act relating to health.~~ *An act to add and repeal Chapter 6.62 (commencing with Section 25255) of Division 20 of the Health and Safety Code, relating to water quality.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2425, as amended, Coto. State Department of Public Health: ~~study: water quality: pharmaceuticals.~~

Existing law prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, except as specified.

This bill would, by July 1, 2009, require every pharmaceutical manufacturer that does business with the state and whose pharmaceutical products have been detected in the drinking water supplies within the state to file a specified report with the State Public Health Officer. The bill would repeal this reporting requirement on January 1, 2014.

~~Existing law provides for the administration of various programs addressing public health by the State Department of Public Health.~~

~~This bill would require the department to conduct a study of the use of pharmaceuticals by vulnerable segments of the California population and the consequential adverse health effects, including the effects of~~

unintentional misuse of prescription drugs, and to report the results of the study to the appropriate committees of the Legislature:

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. *The Legislature hereby finds and declares all of*
2 *the following:*

3 (a) *In the course of a major study conducted and reported by*
4 *the Associated Press, pharmaceutical drugs have been detected*
5 *in the drinking water supplies of 24 major metropolitan areas of*
6 *the country, including southern California.*

7 (b) *The federal government does not require safety testing of*
8 *pharmaceutical products in drinking water. Some local water*
9 *providers screen only for one or two pharmaceutical products,*
10 *but not other pharmaceutical products that can cause harm.*

11 (c) *An official of the United States Environmental Protection*
12 *Agency has acknowledged that pharmaceutical "contamination*
13 *in water supplies is a growing concern and that government has*
14 *some catching up to do."*

15 (d) *In California, prescription drug spending totaled over \$188*
16 *billion in 2004, a \$14 billion dollar per year spending increase*
17 *from 1984.*

18 (e) *It is the purpose of this act to address the issue of*
19 *prescription drugs in public drinking water systems.*

20 SEC. 2. *Chapter 6.62 (commencing with Section 25255) is*
21 *added to Division 20 of the Health and Safety Code, to read:*

22
23 CHAPTER 6.62. WATER CONTAMINATION FROM
24 PHARMACEUTICALS

25
26 25255. *For purposes of this chapter, the following definitions*
27 *shall apply:*

28 (a) *"Pharmaceuticals" means any drug that is sold over the*
29 *counter and any drug that is required to bear the legend, "Caution:*
30 *Federal law prohibits dispensing without a prescription," "RX*
31 *only," or words of similar import.*

32 (b) *"Pharmaceutical manufacturer" means a drug manufacturer*
33 *as defined in Section 4033 of the Business and Professions Code.*

1 25256. *On or before July 1, 2009, every pharmaceutical*
2 *manufacturer that does business with the state, and whose*
3 *pharmaceutical products have been detected by their chemical*
4 *signatures in the drinking water supplies within the state, shall*
5 *file with the State Public Health Officer a report that includes the*
6 *following:*

7 (a) *An analysis of how these pharmaceuticals entered the*
8 *drinking water supply of the state.*

9 (b) *Identification of the methods of preventing and removing*
10 *pharmaceutical contaminants from the drinking water supplies of*
11 *the state.*

12 25257. *This chapter shall remain in effect only until January*
13 *1, 2014, and as of that date is repealed, unless a later enacted*
14 *statute, that is enacted before January 1, 2014, deletes or extends*
15 *that date.*

16 ~~SECTION 1. The State Department of Public Health shall~~
17 ~~conduct a study of the use of pharmaceuticals by vulnerable~~
18 ~~segments of the California population and their consequential~~
19 ~~adverse health effects, including the effects of unintentional misuse~~
20 ~~of prescription drugs, and to report the results of the study to the~~
21 ~~appropriate committees of the Legislature.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 2425

VERSION: As Amended April 1, 2008

AUTHOR: Coto

SPONSOR: Member sponsored

RECOMMENDED POSITION:

SUBJECT: State Department of Public Health: Water Quality: Purity

EXISTING LAW:

Prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or into land where the chemical would or possible could pass into any source of drinking water.

THIS BILL WOULD:

1. Effective by July 1, 2009, would require every pharmaceutical manufacturer that does business in California and whose pharmaceutical products have been detected in the drinking water to file a report with the State Public Health Officer as specified.
2. The reporting requirements would be repealed on January 1, 2014.

AUTHOR'S INTENT

The purpose of this bill is to identify how pharmaceutical drugs have entered the drinking water supplies and to identify the methods of preventing and removing these products from drinking water.

FISCAL IMPACT:

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

HISTORY:

Dates Actions

04/03/08 Apr. 3 Re-referred to Com. on HEALTH.

04/01/08 Apr. 1 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

03/06/08 Mar. 6 Referred to Com. on HEALTH.

02/22/08 Feb. 22 From printer. May be heard in committee March 23.

02/21/08 Feb. 21 Read first time. To print.

ASSEMBLY BILL

No. 2516

Introduced by Assembly Member Mendoza

February 21, 2008

An act to add Section 4072.5 to the Business and Professions Code, relating to prescriptions.

LEGISLATIVE COUNSEL'S DIGEST

AB 2516, as introduced, Mendoza. Prescriptions: electronic transmission.

The Pharmacy Law regulates, among other matters, the dispensing by prescription of dangerous drugs and dangerous devices, and sets forth specified requirements for prescriptions. Existing law authorizes a prescriber or his or her authorized agent to electronically transmit a prescription to a pharmacist, subject to certain exceptions. A knowing violation of the Pharmacy Law is a crime.

This bill would, commencing January 1, 2010, require a prescriber to ensure that any prescription issued or made by him or her be electronically transmitted to the patient's pharmacy of choice, except as specified. The bill would provide that a violation of these provisions is not a crime.

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 4072.5 is added to the Business and
- 2 Professions Code, to read:

- 1 4072.5. (a) A prescriber shall ensure that any prescription
2 issued or made by him or her be electronically transmitted to the
3 patient's pharmacy of choice, except for any of the following:
- 4 (1) A prescription required by federal law to be transmitted in
5 another manner.
 - 6 (2) A prescription that is prevented from being transmitted
7 electronically at the time of issuance by an emergency or
8 unexpected technical problem.
 - 9 (3) An order meeting the requirements of Section 4019 if the
10 prescribed drug is to be administered at the hospital.
- 11 (b) Notwithstanding any other provisions of law, a violation of
12 this section shall not be a crime.
- 13 (c) This section shall become operative on January 1, 2010.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 2516

VERSION: Introduced February 21, 2008

AUTHOR: Mendoza

SPONSOR: California Senior Legislature

RECOMMENDED POSITION: None

SUBJECT: Prescriptions: electronic Transmission

EXISTING LAW:

1. Regulates the dispensing by prescription of dangerous drugs and dangerous devices.
2. Authorizes a prescriber or his or her authorized agent to electronically transmit a prescription to a pharmacy, subject to certain exceptions.

THIS BILL WOULD:

1. Commencing January 1, 2010, requires a prescriber to ensure that any prescription issued or made by him or her be electronically transmitted to the patient's pharmacy of choice, except as specified.
2. Provide that a violation of these provisions is not a crime.

AUTHOR'S INTENT

According to the author's office, electronic prescriptions will give patients the exact medication their doctor prescribes without any error or hassle. The prescriptions will be processed in a safe and timely fashion and bypass confusion between doctor's and pharmacies.

FISCAL IMPACT:

Board staff needs to seek clarification from legal counsel about the enforcement of these provisions. Based on the results of this discussion we can estimate fiscal impact to the board, if any.

COMMENTS:

During the committee meeting, comments from the public included concern over whether the liability would lie with the prescriber or the pharmacy when a prescription is not prescribed electronically and that there is potential concern over the effective date for implementation and the lack of technology in place for some pharmacies that receive prescriptions from Kaiser. In addition

discussion included concern over the poor legibility on faxed handwritten transmissions.

According to the author's office, they are considering amending the bill to require that faxed prescriptions be typewritten.

HISTORY:

Dates	Actions
03/06/08	Mar. 6 Referred to Com. on B. & P.
02/23/08	Feb. 23 From printer. May be heard in committee March 24.
02/21/08	Feb. 21 Read first time. To print.