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

Legislation and Regulation Committee

Robert Graul, RPh, Chair
Bill Powers, Public Member
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ITEM B: LEGISLATION REPORT

FOR INFORMATION

In an unusual political year, the legislature sent over 1187 bills to the Governor for his action; however, because of the budget stalemate and the Governor's decision to not act on any bills until a budget was signed, the Governor had 10 days to review and act on all legislation enrolled at the end of this legislative cycle. The Governor had issued a statement indicating that because of this reduced review time, only the highest priority bills would be signed. The Governor signed 772 and vetoed 415 bills.

1. DISCUSSION AND ACTION ON ENACTED LEGISLATION

a. Board Sponsored Legislation for 2008

SB 1307 (Ridley-Thomas) Pharmacy: Pedigree: Status: Chaptered 9/30/08

As chaptered, this legislation includes additional provisions to improve implementation issues involving serialization and electronic pedigrees. Specifically, it indicates that the serialization number must be contained in the electronic pedigree, delays the implementation date and staggers the implementation dates for e-pedigree compliance, allows for the grandfathering in of existing drug stock in the supply chain, and allows the board to establish criteria for inference requirements by regulation. In addition, this proposal specifies that, should the federal government enact an electronic pedigree requirement, California requirements will be repealed to conform with the federal requirements.

The board will continue to hold implementation meetings to meet with industry, although perhaps less frequently.

ATTACHMENT 1 contains the chaptered bill.

b. Chaptered Bills Impacting the Board's Jurisdiction or Practice of Pharmacy

During the course of this legislative cycle, the board took positions on a number of bills. Below is a brief summary of bills with board positions that were signed by the Governor. A copy of each bill is provided in **ATTACHMENT 2**.

AB 1394 (Krekorian) Counterfeit: Trademarks

This bill modifies the system of penalties and fines related to criminal counterfeit trademark infringement.

Board Position: Support
Status: Chaptered

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

This bill was significantly amended prior to its final passage and enrollment. As enacted this bill extends the sunset dates for several boards with the Department of Consumer Affairs whose sunset date would have occurred in 2009.

Board Position: None
Status: Chaptered

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

This bill will create the Substance Abuse Coordination Committee with the Department of Consumer Affairs to develop uniform and specific standards that each healing arts board must use in dealing with substance-abusing licensees.

Board Position: None
Status: Chaptered

SB 377 (Aanestad) Highway signs: pharmacies and attractions

This bill requires the Department of Transportation to adopt rules and regulations governing the placement and standards for roadway signs indicating the proximity of 24-hour pharmacy services.

Status: Chaptered

c. Vetoed Bills Impacting the Board's Jurisdiction or Practice of Pharmacy

Below is a brief summary of bills the board either took a formal position on or was monitoring that were vetoed by the Governor. A copy of each bill and the veto message is provided in **ATTACHMENT 3**.

SB 1779 (Committee on Business, Professions and Economic Development) Professions and Vocations:

Status: Vetoed

This bill contained omnibus provisions for the board as well as several other boards within DCA. The board's provisions included four types of changes. First provisions sought would have allowed for the use of mobile pharmacies in the event of a declared natural disaster if certain criteria are met or on a temporary basis when a pharmacy is destroyed or damaged. Second the board sought 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 were also similar changes for the designated representative-in-charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would have defined 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. Also included in this proposal were several corrections to references to section 4052, which was recodified in 2006. Lastly, this bill contained several general omnibus provisions to clarify and make technical changes.

AB 501 (Swanson and Hancock) Pharmaceutical Devices

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

Board Position: Support
Status: Vetoed

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

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

Earlier in the session, the bill was amended and the board would not have been affected by this proposal. As such a copy of this proposal and the veto message is not provided.

Board Position: Neutral
Status: Vetoed

AB 1574 (Plescia) Surgical Clinics: licensure

This bill would have expanded the board's licensing authority to issue a clinic permit to surgical clinics that are Medicare certified or accredited by a recognized agency, require the board to perform periodic inspections and establish a self-assessment requirement.

Recommended Position: Support
Status: Vetoed

d. Bills that Failed Passage by the Legislature

The board took positions or watched several other bills that failed passage by the legislature. Below is a list of these bills.

AB 1436 (Hernandez) Nurse practitioners

AB 1587 (De La Torre) Personal Information: Pharmacy

AB 1947 (Emmerson) Pharmacy Technician

AB 2756 (Duvall) Pharmacists: Furnishing Drugs During an Emergency

SB 1270 (Cedillo) Pharmacy: Dangerous Drug and Devices Pedigree

Attachment 1

SB 1307

(Chapter 713, Statutes of 2008)

Senate Bill No. 1307

CHAPTER 713

An act to amend Sections 4033, 4034, 4162, 4162.5, and 4163 of, to add Sections 4034.1, 4044, 4045, 4163.1, 4163.2, 4163.3, and 4163.4 to, and to repeal and add Section 4163.5 of, the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 30, 2008. Filed with
Secretary of State September 30, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, Ridley-Thomas. Pharmacy: pedigree.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. Under existing law, on and after January 1, 2009, pedigree means an electronic record containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. On and after January 1, 2009, existing law prohibits a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree. Existing law, on and after January 1, 2009, requires that a pedigree include certain information, including, but not limited to, the source of the dangerous drug and the trade or generic name of the drug. Existing law exempts specified transactions from the pedigree requirement, and authorizes the board to extend the January 1, 2009, compliance date to January 1, 2011, in specified circumstances. Existing law makes it a crime to knowingly violate the Pharmacy Law.

This bill would instead, on and after January 1, 2015, define a pedigree, as specified, and would revise the information required to be contained in a pedigree to, among other things, include a specified unique identification number.

The bill would prohibit a wholesaler or repackager, as defined, on and after July 1, 2016, or a pharmacy, on and after July 1, 2017, from selling, trading, or transferring a dangerous drug without a pedigree or from acquiring a dangerous drug without receiving a pedigree, except as specified. The bill would prohibit a pharmacy warehouse, as defined, on and after July 1, 2017, from acquiring a dangerous drug without receiving a pedigree. The bill would delete the board's authority to extend these compliance dates. The bill would also prohibit a repackager or pharmacy from furnishing a

dangerous drug or dangerous device to an unauthorized person. The bill would require a manufacturer of a dangerous drug distributed in California to designate certain percentages of the drugs that it manufactures to comply with the pedigree requirement by specified dates, and to notify the board of the drugs so designated and of the technology to be used to meet that requirement. The bill would also revise certain exemptions from the pedigree requirement and would exempt specified additional transactions from the pedigree requirement.

The bill would authorize a manufacturer, wholesaler, or pharmacy in possession of dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements to designate those drugs as not subject to the requirements by preparing a specified written declaration under penalty of perjury, which would be considered trade secrets and kept confidential by the board. The bill would authorize dangerous drugs designated on such a declaration to be purchased, sold, acquired, returned, or otherwise transferred, without meeting the pedigree requirements if the transfer complies with specified requirements. Because a knowing violation of the bill's provisions would be a crime under the Pharmacy Law and because the bill would expand the crime of perjury, the bill would impose a state-mandated local program.

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

The bill would make the pedigree requirements inoperative upon the effective date of federal law addressing pedigree or serialization measures for dangerous drugs, or as otherwise specified in the event of a conflict with federal law.

Existing law requires an applicant for issuance or renewal of a wholesaler or nonresident wholesaler license to submit a surety bond of \$100,000 or an equivalent means of security to secure payment of any administrative fines and costs imposed by the board. Existing law makes this requirement inoperative and repeals it on January 1, 2015.

This bill would delete the date upon which these provisions become inoperative and are repealed.

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.

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

SECTION 1. Section 4033 of the Business and Professions Code is amended to read:

4033. (a) (1) "Manufacturer" means and includes every person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufactures on the immediate premises where the drug or device is sold to the ultimate consumer.

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

(b) Notwithstanding subdivision (a), as used in Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, "manufacturer" means a person who prepares, derives, manufactures, produces, or repackages a dangerous drug, as defined in Section 4022, device, or cosmetic. Manufacturer also means the holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), or a Biologics License Application (BLA), provided that such application has been approved; a manufacturer's third party logistics provider; a private label distributor (including colicensed partners) for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged; or the distributor agent for the manufacturer, contract manufacturer, or private label distributor, whether the establishment is a member of the manufacturer's affiliated group (regardless of whether the member takes title to the drug) or is a contract distributor site.

SEC. 2. Section 4034 of the Business and Professions Code is amended to read:

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

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

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

(2) The trade or generic name of the dangerous drug, the quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number or, if not immediately available, a customer-specific shipping reference number linked to the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

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

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

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

(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number. Dangerous drugs that are repackaged shall be serialized by the repackager and a pedigree shall be provided that references the pedigree of the original package or packages provided by the manufacturer.

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

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

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

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

(1) An intracompany sale or transfer of a dangerous drug. For purposes of this section, "intracompany sale or transfer" means any transaction for any valid business purpose between a division, subsidiary, parent, or affiliated or related company under the common ownership and control of the same corporate or legal entity.

(2) Dangerous drugs received by the state or a local government entity from a department or agency of the federal government or an agent of the federal government specifically authorized to deliver dangerous drugs to the state or local government entity.

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

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

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

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

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

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

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

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

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

(8) Dangerous drugs that are placed in a sealed package with a medical device or medical supplies at the point of first shipment into commerce by the manufacturer and the package remains sealed until the drug and device are used, provided that the package is only used for surgical purposes.

(9) A product that meets either of the following criteria:

(A) A product comprised of two or more regulated components, such as a drug/device, biologic/device, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

(B) Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products or device and biological products.

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

(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture and supplemented by a linked unique identification number in the event that drug is repackaged, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, repackagers, and pharmacies for the pedigree of a dangerous drug. No particular data carrier or other technology is mandated to accomplish the attachment of the unique identification number described in this subdivision.

(j) The application of the pedigree requirement shall be subject to review during the board's evaluation pursuant to Section 473.4.

(k) This section shall become operative on January 1, 2015.

SEC. 3. Section 4034.1 is added to the Business and Professions Code, to read:

4034.1. (a) (1) Upon the effective date of federal legislation or adoption of a federal regulation addressing pedigree or serialization measures for dangerous drugs, Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 shall become inoperative.

(2) Within 90 days of the enactment of federal legislation or adoption of a regulation addressing pedigree or serialization measures for dangerous drugs, the board shall publish a notice that Sections 4034, 4163, 4163.1, 4163.2, 4163.4, and 4163.5 are inoperative.

(3) Within 90 days of the enactment of federal legislation or adoption of a regulation that is inconsistent with any provision of California law governing the application of any pedigree or serialization requirement or standard, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(b) (1) If the Food and Drug Administration (FDA) enacts any rule, standard, or takes any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, that provision of California law shall be inoperative.

(2) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall publish a notice that the provision is inoperative.

(3) Within 90 days of the FDA enacting any rule, standard, or taking any other action that is inconsistent with any provision of California law governing application of a pedigree to a dangerous drug, the board shall adopt emergency regulations necessary to reflect the inoperation of state law.

(c) If the board fails to recognize the inoperation within 90 days pursuant to this section, nothing in this section shall preclude a party from filing an action in state or federal court for declaratory or injunctive relief as an alternative to filing a petition with the board.

SEC. 4. Section 4044 is added to the Business and Professions Code, to read:

4044. "Repackager" means a person or entity that is registered with the federal Food and Drug Administration as a repackager and operates an establishment that packages finished drugs from bulk or that repackages dangerous drugs into different containers, excluding shipping containers.

SEC. 5. Section 4045 is added to the Business and Professions Code, to read:

4045. "Third-party logistics provider" or "reverse third-party logistic provider" means an entity licensed as a wholesaler that contracts with a dangerous drug manufacturer to provide or coordinate warehousing, distribution, or other similar services on behalf of a manufacturer, but for which there is no change of ownership in the dangerous drugs. For purposes of Sections 4034, 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, a third-party logistics provider shall not be responsible for generating or updating pedigree documentation, but shall maintain copies of the pedigree. To be exempt from documentation for pedigrees, a reverse third-party logistic provider may only accept decommissioned drugs from pharmacies or wholesalers.

SEC. 6. Section 4162 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

SEC. 7. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000), or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

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

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

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

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.

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

SEC. 8. Section 4163 of the Business and Professions Code is amended to read:

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

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to

obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(d) Except as otherwise provided in Section 4163.5, commencing on July 1, 2016, a wholesaler or repackager may not acquire a dangerous drug without receiving a pedigree.

(e) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without providing a pedigree.

(f) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy may not acquire a dangerous drug without receiving a pedigree.

(g) Except as otherwise provided in Section 4163.5, commencing on July 1, 2017, a pharmacy warehouse may not acquire a dangerous drug without receiving a pedigree. For purposes of this section and Section 4034, a “pharmacy warehouse” means a physical location licensed as a wholesaler for prescription drugs that acts as a central warehouse and performs intracompany sales or transfers of those drugs to a group of pharmacies under common ownership and control.

SEC. 9. Section 4163.1 is added to the Business and Professions Code, to read:

4163.1. (a) For purposes of Sections 4034 and 4163, “drop shipment” means a sale of a dangerous drug by the manufacturer of the dangerous drug whereby all of the following occur:

(1) The pharmacy, or other person authorized by law to dispense or administer the drug, receives delivery of the dangerous drug directly from the manufacturer.

(2) The wholesale distributor takes ownership of, but not physical possession of, the dangerous drug.

(3) The wholesale distributor invoices the pharmacy or other person authorized by law to dispense or administer the drug in place of the manufacturer.

(b) The board may develop regulations to establish an alternative process to convey the pedigree information required in Section 4034 for dangerous drugs that are sold by drop shipment.

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

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

(2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written

declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

(3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

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

SEC. 11. Section 4163.3 is added to the Business and Professions Code, to read:

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

(b) To meet this goal, and to facilitate efficiency and safety in the distribution chain, the board shall, by regulation, define the circumstances under which participants in the distribution chain may infer the contents of a case, pallet, or other aggregate of individual units, packages, or containers of dangerous drugs, from a unique identifier associated with the case, pallet, or other aggregate, without opening each case, pallet, or other aggregate or otherwise individually validating each unit.

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

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

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

SEC. 12. Section 4163.4 is added to the Business and Professions Code, to read:

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

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

SEC. 13. Section 4163.5 of the Business and Professions Code is repealed.

SEC. 14. Section 4163.5 is added to the Business and Professions Code, to read:

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

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

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

(b) Before January 1, 2015, each manufacturer of a dangerous drug distributed in California shall designate those dangerous drugs representing a minimum of 50 percent of its drugs, generic or single source, distributed in California, for which it is listed as the manufacturer by the federal Food and Drug Administration, which shall be the subject of its initial phase of compliance with the January 1, 2015, deadline of the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

(c) Before January 1, 2016, each manufacturer of a dangerous drug distributed in California shall designate the final 50 percent of its drugs, generic or single source, distributed in California for which it is listed as the manufacturer by the federal Food and Drug Administration that are subject to the state's serialized electronic pedigree requirements set forth in Sections 4034 and 4163, which shall comply with the state's serialized electronic pedigree requirement by January 1, 2016. Each manufacturer shall notify the Board of Pharmacy of the drugs so designated and the measure or measures used in designating its drugs to be serialized, and shall include in the notification the technology to be used to meet the serialized

electronic pedigree requirements. The notification process for these specific actions may be specified by the board.

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

- (1) Unit volume.
- (2) Product package (SKU) type.
- (3) Drug product family.

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

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

Attachment 2

*Chaptered Bills Impacting the Board's
Jurisdiction or Practice of Pharmacy*

Assembly Bill No. 1394

CHAPTER 431

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

[Approved by Governor September 27, 2008. Filed with
Secretary of State September 27, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1394, 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 provides for the punishment for the violation and subsequent violations of these provisions if the person is a corporation. 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 make those punishment provisions relating to corporations instead applicable to business entities and would define "business entity" as including a corporation, limited liability company, or partnership. This bill would specify the procedure for the forfeiture of the counterfeited items. This bill would also expand the definition of a "counterfeit mark" and would apply those provisions to the unassembled components of any counterfeited article, as specified.

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.

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

SECTION 1. Section 350 of the Penal Code is amended to read:

350. (a) Any person who willfully manufactures, intentionally sells, or knowingly possesses for sale any counterfeit mark registered with the Secretary of State or registered on the Principal Register of the United States Patent and Trademark Office, shall, upon conviction, be punishable as follows:

(1) When the offense involves less than 1,000 of the articles described in this subdivision, with a total retail or fair market value less than that required for grand theft as defined in Section 487, and if the person is an individual, he or she shall be punished by a fine of not more than five thousand dollars (\$5,000), or by imprisonment in a county jail for not more than one year, or by both that fine and imprisonment; or, if the person is a business entity, by a fine of not more than one hundred thousand dollars (\$100,000).

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

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

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

(d) In any action brought under this section resulting in a conviction or a plea of nolo contendere, the court shall order the forfeiture and destruction of all of those marks and of all goods, articles, or other matter bearing the marks, and the forfeiture and destruction or other disposition of all means of making the marks, and any and all electrical, mechanical, or other devices for manufacturing, reproducing, transporting, or assembling these marks, that were used in connection with, or were part of, any violation of this section. Forfeiture of the proceeds of the crime shall be subject to Chapter 9 (commencing with Section 186) of Title 7 of Part 1. However, no vehicle shall be forfeited under this section that may be lawfully driven on the highway with a class 3 or 4 license, as prescribed in Section 12804 of the Vehicle Code, and that is any of the following:

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

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

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

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

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

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

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

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

(5) Notwithstanding Section 7, "person" includes, but is not limited to, a business entity.

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

(7) "Sale" includes resale.

(8) "Value" has the following meanings:

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

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

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

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

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

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

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

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

Senate Bill No. 963

CHAPTER 385

An act to amend Sections 2920, 2933, 4928, 4934, 4990, 4990.04, 7000.5, 7011, 7810, 7815.5, 8000, 8030.2, 8030.4, 8030.6, 8030.8, 18602, and 18613 of the Business and Professions Code, and to amend and repeal Section 94801.5 of the Education Code, relating to regulatory boards.

[Approved by Governor September 27, 2008. Filed with
Secretary of State September 27, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 963, Ridley-Thomas. Department of Consumer Affairs: regulatory boards.

(1) Existing law establishes the Board of Psychology, the Acupuncture Board, the Board of Behavioral Sciences, the Contractors' State License Board, the Board for Geologists and Geophysicists, the Court Reporters Board of California, and the State Athletic Commission. Existing law authorizes or requires those boards to appoint an executive officer. Under existing law, excess funds, as specified, generated by the initial certificate fee collected by the Court Reporters Board of California are used to provide shorthand reporting services for indigent persons, as defined, and are transferred from the Court Reporters' Fund into the Transcript Reimbursement Fund for expenditure for that purpose. Existing law provides that these provisions become inoperative on July 1, 2009, and are repealed on January 1, 2010.

This bill would change the dates on which these provisions are to become inoperative and repealed to January 1, 2011.

(2) Senate Bill 823 of the 2007–08 Regular Session would, among other things, establish the Bureau for Private Postsecondary Education in the Department of Consumer Affairs as a successor agency to the former Bureau for Private Postsecondary and Vocational Education in the Department of Consumer Affairs.

This bill would make the bureau inoperative and repealed on January 1, 2013. The bill would provide that this provision shall become operative only if SB 823 of the 2007–08 Regular Session is also enacted and becomes operative.

(3) This bill would incorporate additional changes to Section 4990 of the Business and Professions Code made by this bill and AB 239 to take effect if both bills are chaptered and this bill is chaptered last.

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

SECTION 1. Section 2920 of the Business and Professions Code is amended to read:

2920. The Board of Psychology shall enforce and administer this chapter. The board shall consist of nine members, four of whom shall be public members.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 2. Section 2933 of the Business and Professions Code is amended to read:

2933. Except as provided by Section 159.5, the board shall employ and shall make available to the board within the limits of the funds received by the board all personnel necessary to carry out this chapter. The board may employ, exempt from the State Civil Service Act, an executive officer to the Board of Psychology. The board shall make all expenditures to carry out this chapter. The board may accept contributions to effectuate the purposes of this chapter.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 3. Section 4928 of the Business and Professions Code is amended to read:

4928. The Acupuncture Board, which consists of seven members, shall enforce and administer this chapter. The appointing powers, as described in Section 4929, may appoint to the board a person who was a member of the prior board prior to the repeal of that board on January 1, 2006.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 4. Section 4934 of the Business and Professions Code is amended to read:

4934. (a) The board, by and with the approval of the director, may employ personnel necessary for the administration of this chapter, and the board, by and with the approval of the director, may appoint an executive officer who is exempt from the provisions of the Civil Service Act.

(b) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 5. Section 4990 of the Business and Professions Code is amended to read:

4990. (a) There is in the Department of Consumer Affairs, a Board of Behavioral Sciences that consists of 11 members composed as follows:

- (1) Two state licensed clinical social workers.

- (2) One state licensed educational psychologist.
- (3) Two state licensed marriage and family therapists.
- (4) Six public members.

(b) Each member, except the six public members, shall have at least two years of experience in his or her profession.

(c) Each member shall reside in the State of California.

(d) The Governor shall appoint four of the public members and the five licensed members with the advice and consent of the Senate. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(e) Each member of the board shall be appointed for a term of four years. A member appointed by the Speaker of the Assembly or the Senate Committee on Rules shall hold office until the appointment and qualification of his or her successor or until one year from the expiration date of the term for which he or she was appointed, whichever first occurs. Pursuant to Section 1774 of the Government Code, a member appointed by the Governor shall hold office until the appointment and qualification of his or her successor or until 60 days from the expiration date of the term for which he or she was appointed, whichever first occurs.

(f) A vacancy on the board shall be filled by appointment for the unexpired term by the authority who appointed the member whose membership was vacated.

(g) Not later than the first of June of each calendar year, the board shall elect a chairperson and a vice chairperson from its membership.

(h) Each member of the board shall receive a per diem and reimbursement of expenses as provided in Section 103.

(i) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 5.5. Section 4990 of the Business and Professions Code is amended to read:

4990. (a) There is in the Department of Consumer Affairs, a Board of Behavioral Sciences that consists of the following members:

- (1) Two state-licensed clinical social workers.
- (2) One state-licensed educational psychologist.
- (3) Two state-licensed marriage and family therapists.

(4) After January 1, 2011, one state-licensed alcoholism and drug abuse counselor.

(5) Seven public members.

(b) Each member, except the seven public members, shall have at least two years of experience in his or her profession.

(c) Each member shall reside in the State of California.

(d) The Governor shall appoint five of the public members and the six licensed members with the advice and consent of the Senate. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(e) Each member of the board shall be appointed for a term of four years. A member appointed by the Speaker of the Assembly or the Senate Committee on Rules shall hold office until the appointment and qualification of his or her successor or until one year from the expiration date of the term for which he or she was appointed, whichever first occurs. Pursuant to Section 1774 of the Government Code, a member appointed by the Governor shall hold office until the appointment and qualification of his or her successor or until 60 days from the expiration date of the term for which he or she was appointed, whichever first occurs.

(f) A vacancy on the board shall be filled by appointment for the unexpired term by the authority who appointed the member whose membership was vacated.

(g) Not later than the first of June of each calendar year, the board shall elect a chairperson and a vice chairperson from its membership.

(h) Each member of the board shall receive a per diem and reimbursement of expenses as provided in Section 103.

(i) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 6. Section 4990.04 of the Business and Professions Code is amended to read:

4990.04. (a) The board shall appoint an executive officer. This position is designated as a confidential position and is exempt from civil service under subdivision (e) of Section 4 of Article VII of the California Constitution.

(b) The executive officer serves at the pleasure of the board.

(c) The executive officer shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

(d) With the approval of the director, the board shall fix the salary of the executive officer.

(e) The chairperson and executive officer may call meetings of the board and any duly appointed committee at a specified time and place. For purposes of this section, "call meetings" means setting the agenda, time, date, or place for any meeting of the board or any committee.

(f) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 7. Section 7000.5 of the Business and Professions Code is amended to read:

7000.5. (a) There is in the Department of Consumer Affairs a Contractors' State License Board, which consists of 15 members.

(b) The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473). However, the review of this board by the department shall be limited to only those unresolved issues identified by the Joint Committee on Boards, Commissions, and Consumer Protection.

(c) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 8. Section 7011 of the Business and Professions Code is amended to read:

7011. The board, by and with the approval of the director, shall appoint a registrar of contractors and fix his or her compensation.

The registrar shall be the executive officer and secretary of the board and shall carry out all of the administrative duties as provided in this chapter and as delegated to him or her by the board.

For the purpose of administration of this chapter, there may be appointed a deputy registrar, a chief reviewing and hearing officer, and, subject to Section 159.5, other assistants and subordinates as may be necessary.

Appointments shall be made in accordance with the provisions of civil service laws.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 9. Section 7810 of the Business and Professions Code is amended to read:

7810. The Board for Geologists and Geophysicists is within the department and is subject to the jurisdiction of the department. Except as provided in this section, the board shall consist of eight members, five of whom shall be public members, two of whom shall be geologists, and one of whom shall be a geophysicist.

Each member shall hold office until the appointment and qualification of the member's successor or until one year has elapsed from the expiration of the term for which the member was appointed, whichever occurs first. Vacancies occurring prior to the expiration of the term shall be filled by appointment for the remainder of the unexpired term.

Each appointment shall be for a four-year term expiring June 1 of the fourth year following the year in which the previous term expired. No person shall serve as a member of the board for more than two consecutive terms.

The Governor shall appoint three of the public members and the three members qualified as provided in Section 7811. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member, and their initial appointment shall be made to fill, respectively, the first and second public member vacancies that occurred on or after January 1, 1983.

At the time the first vacancy is created by the expiration of the term of a public member appointed by the Governor, the board shall be reduced to consist of seven members, four of whom shall be public members, two of whom shall be geologists, and one of whom shall be a geophysicist. Notwithstanding any other provision of law, the term of that member shall not be extended for any reason, except as provided in this section.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 10. Section 7815.5 of the Business and Professions Code is amended to read:

7815.5. The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 11. Section 8000 of the Business and Professions Code is amended to read:

8000. There is in the Department of Consumer Affairs a Court Reporters Board of California, which consists of five members, three of whom shall be public members and two of whom shall be holders of certificates issued under this chapter who have been actively engaged as shorthand reporters within this state for at least five years immediately preceding their appointment.

This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 12. Section 8030.2 of the Business and Professions Code is amended to read:

8030.2. (a) To provide shorthand reporting services to low-income litigants in civil cases, who are unable to otherwise afford those services, funds generated by fees received by the board pursuant to subdivision (c) of Section 8031 in excess of funds needed to support the board's operating budget for the fiscal year in which a transfer described below is made shall be used by the board for the purpose of establishing and maintaining a Transcript Reimbursement Fund. The Transcript Reimbursement Fund shall be established by a transfer of funds from the Court Reporters' Fund in the amount of three hundred thousand dollars (\$300,000) at the beginning of each fiscal year. Notwithstanding any other provision of this article, a transfer to the Transcript Reimbursement Fund in excess of the fund balance established at the beginning of each fiscal year shall not be made by the board if the transfer will result in the reduction of the balance of the Court Reporters' Fund to an amount less than six months' operating budget.

(b) All moneys held in the Court Reporters' Fund on the effective date of this section in excess of the board's operating budget for the 1996-97 fiscal year shall be used as provided in subdivision (a).

(c) Refunds and unexpended funds that are anticipated to remain in the Transcript Reimbursement Fund at the end of the fiscal year shall be considered by the board in establishing the fee assessment pursuant to

Section 8031 so that the assessment shall maintain the level of funding for the Transcript Reimbursement Fund, as specified in subdivision (a), in the following fiscal year.

(d) The Transcript Reimbursement Fund is hereby created in the State Treasury. Notwithstanding Section 13340 of the Government Code, moneys in the Transcript Reimbursement Fund are continuously appropriated for the purposes of this chapter.

(e) Applicants who have been reimbursed pursuant to this chapter for services provided to litigants and who are awarded court costs or attorneys' fees by judgment or by settlement agreement shall refund the full amount of that reimbursement to the fund within 90 days of receipt of the award or settlement.

(f) Subject to the limitations of this chapter, the board shall maintain the fund at a level that is sufficient to pay all qualified claims. To accomplish this objective, the board shall utilize all refunds, unexpended funds, fees, and any other moneys received by the board.

(g) Notwithstanding Section 16346 of the Government Code, all unencumbered funds remaining in the Transcript Reimbursement Fund as of June 29, 2009, shall be transferred to the Court Reporters' Fund.

(h) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 13. Section 8030.4 of the Business and Professions Code is amended to read:

8030.4. As used in this chapter:

(a) "Qualified legal services project" means a nonprofit project incorporated and operated exclusively in California that provides as its primary purpose and function legal services without charge to indigent persons, has a board of directors or advisory board composed of both attorneys and consumers of legal services, and provides for community participation in legal services programming. Legal services projects funded either in whole or in part by the Legal Services Corporation or with Older Americans Act funds are presumed to be qualified legal services projects for the purposes of this chapter.

(b) "Qualified support center" means an incorporated nonprofit legal services center, having an office or offices in California, which office or offices provide legal services or technical assistance without charge to qualified legal services projects and their clients on a multicounty basis in California. Support centers funded either in whole or in part by the Legal Services Corporation or with Older Americans Act funds are presumed to be qualified legal services projects for the purposes of this chapter.

(c) "Other qualified project" means a nonprofit organization formed for charitable or other public purposes, not receiving funds from the Legal Services Corporation or pursuant to the Older Americans Act, which organization or association provides free legal services to indigent persons.

(d) "Pro bono attorney" means any attorney, law firm, or legal corporation, licensed to practice law in this state, that undertakes without

charge to the party, the representation of an indigent person, referred by a qualified legal services project, qualified support center, or other qualified project, in a case not considered to be fee generating as defined in this chapter.

(e) "Applicant" means a qualified legal services project, qualified support center, other qualified project, or pro bono attorney applying to receive funds from the Transcript Reimbursement Fund established by this chapter. The term "applicant" shall not include persons appearing pro se to represent themselves at any stage of the case.

(f) (1) "Indigent person" means any of the following:

(A) A person whose income is 125 percent or less of the current poverty threshold established by the Office of Management and Budget of the United States.

(B) A person who is eligible for supplemental security income.

(C) A person who is eligible for, or receiving, free services under the Older Americans Act or the Developmentally Disabled Assistance Act.

(D) A person whose income is 75 percent or less of the maximum level of income for lower income households as defined in Section 50079.5 of the Health and Safety Code, for purposes of a program that provides legal assistance by an attorney in private practice on a pro bono basis.

(2) For the purposes of this subdivision, the income of a person who is disabled shall be determined after deducting the costs of medical and other disability-related special expenses.

(g) "Fee-generating case" means any case or matter that, if undertaken on behalf of an eligible client by an attorney in private practice, reasonably may be expected to result in payment of a fee for legal services from an award to a client, from public funds, or from an opposing party. A reasonable expectation as to payment of a legal fee exists wherever a client enters into a contingent fee agreement with his or her lawyer. If there is no contingent fee agreement, a case is not considered fee generating if adequate representation is deemed to be unavailable because of the occurrence of any of the following circumstances:

(1) If the applicant has determined that referral is not possible because of any of the following:

(A) The case has been rejected by the local lawyer referral service, or if there is no such service, by two private attorneys who have experience in the subject matter of the case.

(B) Neither the referral service nor any lawyer will consider the case without payment of a consultation fee.

(C) The case is of the type that private attorneys in the area ordinarily do not accept or do not accept without prepayment of a fee.

(D) Emergency circumstances compel immediate action before referral can be made, but the client is advised that, if appropriate and consistent with professional responsibility, referral will be attempted at a later time.

(2) If recovery of damages is not the principal object of the case and a request for damages is merely ancillary to an action for equitable or other nonpecuniary relief or inclusion of a counterclaim requesting damages is

necessary for effective defense or because of applicable rules governing joinder of counterclaims.

(3) If a court appoints an applicant or an employee of an applicant pursuant to a statute or a court rule or practice of equal applicability to all attorneys in the jurisdiction.

(4) In any case involving the rights of a claimant under a public supported benefit program for which entitlement to benefit is based on need.

(h) "Legal Services Corporation" means the Legal Services Corporation established under the Legal Services Corporation Act of 1974, Public Law 93-355, as amended.

(i) "Supplemental security income recipient" means an individual receiving or eligible to receive payments under Title XVI of the Social Security Act, Public Law 92-603, as amended, or payment under Chapter 3 (commencing with Section 12000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(j) "Lawyer referral service" means a lawyer referral program authorized by the State Bar of California pursuant to the rules of professional conduct.

(k) "Older Americans Act" means the Older Americans Act of 1965, Public Law 89-73, as amended.

(l) "Rules of professional conduct" means those rules adopted by the State Bar pursuant to Sections 6076 and 6077.

(m) "Certified shorthand reporter" means a shorthand reporter certified pursuant to Article 3 (commencing with Section 8020) performing shorthand reporting services pursuant to Section 8017.

(n) "Case" means a single legal proceeding from its inception, through all levels of hearing, trial, and appeal, until its ultimate conclusion and disposition.

(o) "Developmentally Disabled Assistance Act" means the Developmentally Disabled Assistance and Bill of Rights Act of 1975, (42 U.S.C. Sec. 6001 et seq.) as amended.

(p) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 14. Section 8030.6 of the Business and Professions Code is amended to read:

8030.6. The board shall disburse funds from the Transcript Reimbursement Fund for the costs, exclusive of per diem charges by official reporters, of preparing either an original transcript and one copy thereof, or where appropriate, a copy of the transcript, of court or deposition proceedings, or both, incurred as a contractual obligation between the shorthand reporter and the applicant, for litigation conducted in California. If there is no deposition transcript, the board may reimburse the applicant or the certified shorthand reporter designated in the application for per diem costs. The rate of per diem for depositions shall not exceed seventy-five dollars (\$75) for a half day, or one hundred twenty-five dollars (\$125) for a full day. If a transcript is ordered within one year of the date of the deposition, but subsequent to the per diem having been reimbursed by the

Transcript Reimbursement Fund, the amount of the per diem shall be deducted from the regular customary charges for a transcript. Reimbursement may be obtained through the following procedures:

(a) The applicant or certified shorthand reporter shall promptly submit to the board the certified shorthand reporter's invoice for transcripts together with the appropriate documentation as is required by this chapter.

(b) Except as provided in subdivision (c), the board shall promptly determine if the applicant or the certified shorthand reporter is entitled to reimbursement under this chapter and shall make payment as follows:

(1) Regular customary charges for preparation of original deposition transcripts and one copy thereof, or a copy of the transcripts.

(2) Regular customary charges for expedited deposition transcripts up to a maximum of two thousand five hundred dollars (\$2,500) per case.

(3) Regular customary charges for the preparation of original transcripts and one copy thereof, or a copy of transcripts of court proceedings.

(4) Regular customary charges for expedited or daily charges for preparation of original transcripts and one copy thereof or a copy of transcripts of court proceedings.

(5) The charges may not include notary or handling fees. The charges may include actual shipping costs and exhibits, except that the cost of exhibits may not exceed thirty-five cents (\$0.35) each or a total of thirty-five dollars (\$35) per transcript.

(c) The maximum amount reimbursable by the fund under subdivision (b) may not exceed twenty thousand dollars (\$20,000) per case per year.

(d) If entitled, and funds are available, the board shall forthwith disburse the appropriate sum to the applicant or the certified shorthand reporter when documentation as provided in subdivision (d) of Section 8030.8 accompanies the application. A notice shall be sent to the recipient requiring the recipient to file a notice with the court in which the action is pending stating the sum of reimbursement paid pursuant to this section. The notice filed with the court shall also state that if the sum is subsequently included in any award of costs made in the action, that the sum is to be ordered refunded by the applicant to the Transcript Reimbursement Fund whenever the sum is actually recovered as costs. The court may not consider whether payment has been made from the Transcript Reimbursement Fund in determining the appropriateness of any award of costs to the parties. The board shall also forthwith notify the applicant that the reimbursed sum has been paid to the certified shorthand reporter and shall likewise notify the applicant of the duty to refund any of the sum actually recovered as costs in the action.

(e) If not entitled, the board shall forthwith return a copy of the invoice to the applicant and the designated certified shorthand reporter together with a notice stating the grounds for denial.

(f) The board shall complete its actions under this section within 30 days of receipt of the invoice and all required documentation, including a completed application.

(g) Applications for reimbursements from the fund shall be filled on a first-come basis.

(h) Applications for reimbursement that cannot be paid from the fund due to insufficiency of the fund for that fiscal year shall be held over until the next fiscal year to be paid out of the renewed fund. Applications held over shall be given a priority standing in the next fiscal year.

(i) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 15. Section 8030.8 of the Business and Professions Code is amended to read:

8030.8. (a) For purposes of this chapter, documentation accompanying an invoice is sufficient to establish entitlement for reimbursement from the Transcript Reimbursement Fund if it is filed with the executive officer on an application form prescribed by the board that is complete in all respects, and that establishes all of the following:

(1) The case name and number and that the litigant or litigants requesting the reimbursement are indigent persons.

(2) The applicant is qualified under the provisions of this chapter.

(3) The case is not a fee-generating case, as defined in Section 8030.4.

(4) The invoice or other documentation shall evidence that the certified shorthand reporter to be reimbursed was, at the time the services were rendered, a duly licensed certified shorthand reporter.

(5) The invoice shall be accompanied by a statement, signed by the applicant, stating that the charges are for transcripts actually provided as indicated on the invoice.

(6) The applicant has acknowledged, in writing, that as a condition of entitlement for reimbursement that the applicant agrees to refund the entire amount disbursed from the Transcript Reimbursement Fund from any costs or attorneys' fees awarded to the applicant by the court or provided for in any settlement agreement in the case.

(7) The certified shorthand reporter's invoice for transcripts shall include separate itemizations of charges claimed, as follows:

(A) Total charges and rates for customary services in preparation of an original transcript and one copy or a copy of the transcript of depositions.

(B) Total charges and rates for expedited deposition transcripts.

(C) Total charges and rates in connection with transcription of court proceedings.

(b) For an applicant claiming to be eligible pursuant to subdivision (a), (b), or (c) of Section 8030.4, a letter from the director of the project or center, certifying that the project or center meets the standards set forth in one of those subdivisions and that the litigant or litigants are indigent persons, is sufficient documentation to establish eligibility.

(c) For an applicant claiming to be eligible pursuant to subdivision (d) of Section 8030.4, a letter certifying that the applicant meets the requirements of that subdivision, that the case is not a fee-generating case, as defined in subdivision (g) of Section 8030.4, and that the litigant or litigants are indigent persons, together with a letter from the director of a project or center defined in subdivision (a), (b), or (c) of Section 8030.4 certifying that the litigant

or litigants had been referred by that project or center to the applicant, is sufficient documentation to establish eligibility.

(d) The applicant may receive reimbursement directly from the board when the applicant has previously paid the certified shorthand reporter for transcripts as provided in Section 8030.6. To receive payment directly, the applicant shall submit, in addition to all other required documentation, an itemized statement signed by the certified shorthand reporter performing the services that describes payment for transcripts in accordance with the requirements of Section 8030.6.

(e) The board may prescribe appropriate forms to be used by applicants and certified shorthand reporters to facilitate these requirements.

(f) This chapter does not restrict the contractual obligation or payment for services, including, but not limited to, billing the applicant directly, during the pendency of the claim.

(g) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 16. Section 18602 of the Business and Professions Code is amended to read:

18602. (a) Except as provided in this section, there is in the Department of Consumer Affairs the State Athletic Commission, which consists of seven members. Five members shall be appointed by the Governor, one member shall be appointed by the Senate Rules Committee, and one member shall be appointed by the Speaker of the Assembly.

The members of the commission appointed by the Governor are subject to confirmation by the Senate pursuant to Section 1322 of the Government Code.

No person who is currently licensed, or who was licensed within the last two years, under this chapter may be appointed or reappointed to, or serve on, the commission.

(b) In appointing commissioners under this section, the Governor, the Senate Rules Committee, and the Speaker of the Assembly shall make every effort to ensure that at least four of the members of the commission shall have experience and demonstrate expertise in one of the following areas:

(1) A licensed physician or surgeon having expertise or specializing in neurology, neurosurgery, head trauma, or sports medicine. Sports medicine includes, but is not limited to, physiology, kinesiology, or other aspects of sports medicine.

(2) Financial management.

(3) Public safety.

(4) Past experience in the activity regulated by this chapter, either as a contestant, a referee or official, a promoter, or a venue operator.

(c) Each member of the commission shall be appointed for a term of four years. All terms shall end on January 1. Vacancies occurring prior to the expiration of the term shall be filled by appointment for the unexpired term. No commission member may serve more than two consecutive terms.

(d) Notwithstanding any other provision of this chapter, members first appointed shall be subject to the following terms:

(1) The Governor shall appoint two members for two years, two members for three years, and one member for four years.

(2) The Senate Committee on Rules shall appoint one member for four years.

(3) The Speaker of the Assembly shall appoint one member for four years.

(4) The appointing powers, as described in subdivision (a), may appoint to the commission a person who was a member of the prior commission prior to the repeal of that commission on July 1, 2006.

(e) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

The repeal of this section renders the commission subject to the review required by Division 1.2 (commencing with Section 473).

SEC. 17. Section 18613 of the Business and Professions Code is amended to read:

18613. (a) (1) To assure the continuity and stable transition as the commission is reformed on January 1, 2007, the person serving as the bureau chief on December 31, 2006, shall serve as the executive officer beginning January 1, 2007, for a term through June 30, 2007. On or before June 30, 2007, but not earlier than June 1, 2007, the commission shall determine whether to retain the services of the person who was serving as the bureau chief on December 31, 2006, or to follow the procedure set forth in paragraph (2) of this subdivision to appoint a new executive officer. During the period between January 1, 2007, and June 30, 2007, any inconsistent provisions of this section notwithstanding, the executive officer may be terminated for cause upon the affirmative vote of a majority of the members of the commission.

(2) The commission shall appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the commission and vested in him or her by this chapter. The appointment of the executive officer is subject to the approval of the Director of Consumer Affairs.

(3) The commission may employ in accordance with Section 154 other personnel as may be necessary for the administration of this chapter.

(b) This section shall remain in effect only until January 1, 2011, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.

SEC. 18. Section 94801.5 of the Education Code, as added by Senate Bill 823 of the 2007–08 Regular Session, is amended to read:

94801.5. (a) There is a Bureau for Private Postsecondary Education in the Department of Consumer Affairs. The bureau has the responsibility for approving and regulating private postsecondary educational institutions and programs.

(b) This section shall remain in effect only until January 1, 2013, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2013, deletes or extends that date.

SEC. 19. Section 5.5 of this bill incorporates amendments to Section 4990 of the Business and Professions Code proposed by both this bill and AB 239. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2009, (2) each bill amends Section 4990 of the Business and Professions Code, and (3) this bill is enacted after AB 239, in which case Section 5 of this bill shall not become operative.

SEC. 20. Section 18 of this bill shall become operative only if Senate Bill 823 of the 2007–08 Regular Session is also enacted, becomes operative, and adds Section 94801.5 to the Education Code.

Senate Bill No. 1441

CHAPTER 548

An act to amend Sections 1695.1, 1695.5, 1695.6, 1697, 1698, 2361, 2365, 2366, 2367, 2369, 2663, 2665, 2666, 2770.1, 2770.7, 2770.8, 2770.11, 2770.12, 3501, 3534.1, 3534.3, 3534.4, 3534.9, and 4371 of, and to add Article 3.6 (commencing with Section 315) to Chapter 4 of Division 1 of, the Business and Professions Code, relating to health care.

[Approved by Governor September 28, 2008. Filed with
Secretary of State September 28, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1441, Ridley-Thomas. Healing arts practitioners: substance abuse.

Existing law requires various healing arts licensing boards, including the Dental Board of California, the Board of Registered Nursing, the Physical Therapy Board of California, the Physician Assistant Committee, the Osteopathic Medical Board of California, and the California State Board of Pharmacy to establish and administer diversion or recovery programs or diversion evaluation committees for the rehabilitation of healing arts practitioners whose competency is impaired due to the abuse of drugs or alcohol, and gives the diversion evaluation committees certain duties related to termination of a licensee from the diversion program and reporting termination, designing treatment programs, denying participation in the program, reviewing activities and performance of contractors, determining completion of the program, and purging and destroying records, as specified. Existing law requires the California State Board of Pharmacy to contract with one or more qualified contractors to administer the pharmacists recovery program and requires the board to review the pharmacists recovery program on a quarterly basis, as specified.

This bill would establish in the Department of Consumer Affairs the Substance Abuse Coordination Committee, which would be comprised of the executive officers of the department's healing arts licensing boards, as specified, and a designee of the State Department of Alcohol Drug Programs. The bill would require the committee to formulate, by January 1, 2010, uniform and specific standards in specified areas that each healing arts board would be required to use in dealing with substance-abusing licensees. The bill would specify that the program managers of the diversion programs for the Dental Board of California, the Board of Registered Nursing, the Physical Therapy Board of California, the Physician Assistant Committee, and the Osteopathic Medical Board of California, as designated by the executive officers of those entities, are responsible for certain duties, including, as specified, duties related to termination of a licensee from the diversion program, the review and evaluation of recommendations of the committee,

approving the designs of treatment programs, denying participation in the program, reviewing activities and performance of contractors, and determining completion of the program. The bill would also provide that diversion evaluation committees created by any of the specified boards or committees operate under the direction of the program manager of the diversion program, and would require those diversion evaluation committees to make certain recommendations. The bill would require the executive officer of the California State Board of Pharmacy to designate a program manager of the pharmacists recovery program, and would require the program manager to review the pharmacists recovery program quarterly and to work with the contractors, as specified. The bill would set forth provisions regarding entry of a registered nurse into the diversion program and the investigation and discipline of registered nurses who are in, or have been in, the diversion program, and would require registered nurses in the diversion program to sign an agreement of understanding regarding withdrawal or termination from the program, as specified.

The bill would specify that the diversion program responsibilities imposed on licensing boards under these provisions shall be considered current operating expenses of those boards.

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

SECTION 1. The Legislature hereby finds and declares all of the following:

(a) Substance abuse is an increasing problem in the health care professions, where the impairment of a health care practitioner for even one moment can mean irreparable harm to a patient.

(b) Several health care licensing boards have “diversion programs” designed to identify substance-abusing licensees, direct them to treatment and monitoring, and return them to practice in a manner that will not endanger the public health and safety.

(c) Substance abuse monitoring programs, particularly for health care professionals, must operate with the highest level of integrity and consistency. Patient protection is paramount.

(d) The diversion program of the Medical Board of California, created in 1981, has been subject to five external performance audits in its 27-year history and has failed all five audits, which uniformly concluded that the program has inadequately monitored substance-abusing physicians and has failed to promptly terminate from the program, and appropriately refer for discipline, physicians who do not comply with the terms and conditions of the program, thus placing patients at risk of harm.

(e) The medical board’s diversion program has failed to protect patients from substance-abusing physicians, and the medical board has properly decided to cease administering the program effective June 30, 2008.

(f) The administration of diversion programs created at other health care boards has been contracted to a series of private vendors, and none of those

vendors has ever been subject to a performance audit, such that it is not possible to determine whether those programs are effective in monitoring substance-abusing licensees and assisting them to recover from their addiction in the long term.

(g) Various health care licensing boards have inconsistent or nonexistent standards that guide the way they deal with substance-abusing licensees.

(h) Patients would be better protected from substance-abusing licensees if their regulatory boards agreed to and enforced consistent and uniform standards and best practices in dealing with substance-abusing licensees.

SEC. 2. It is the intent of the Legislature that:

(a) Pursuant to Section 156.1 of the Business and Professions Code and Section 8546.7 of the Government Code, that the Department of Consumer Affairs conduct a thorough audit of the effectiveness, efficiency, and overall performance of the vendor chosen by the department to manage diversion programs for substance-abusing licensees of health care licensing boards created in the Business and Professions Code, and make recommendations regarding the continuation of the programs and any changes or reforms required to ensure that individuals participating in the programs are appropriately monitored, and the public is protected from health care practitioners who are impaired due to alcohol or drug abuse or mental or physical illness.

(b) The audit shall identify, by type of board licensee, the percentage of self-referred participants, board-referred participants, and board-ordered participants. The audit shall describe in detail the diversion services provided by the vendor, including all aspects of bodily fluids testing, including, but not limited to, frequency of testing, randomness, method of notice to participants, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, such as whether the collection process is observed by the collector, location of testing, and average timeframe from the date of the test to the date the result of the test becomes available; group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by program participants; standards used in determining whether inpatient or outpatient treatment is necessary; and, if applicable, worksite monitoring requirements and standards. The audit shall review the timeliness of diversion services provided by the vendor; the thoroughness of documentation of treatment, aftercare, and monitoring services received by participants; and the thoroughness of documentation of the effectiveness of the treatment and aftercare services received by participants. In determining the effectiveness and efficiency of the vendor, the audit shall evaluate the vendor's approval process for providers or contractors that provide diversion services, including specimen collectors, group meeting facilitators, and worksite monitors; the vendor's disapproval of providers or contractors that fail to provide effective or timely diversion services; and the vendor's promptness in notifying the boards when a participant fails to comply with the terms of his or her

diversion contract or the rules of the board's program. The audit shall also recommend whether the vendor should be more closely monitored by the department, including whether the vendor should provide the department with periodic reports demonstrating the timeliness and thoroughness of documentation of noncompliance with diversion program contracts and regarding its approval and disapproval of providers and contractors that provide diversion services.

(c) The vendor and its staff shall cooperate with the department and shall provide data, information, and case files as requested by the department to perform all of his or her duties. The provision of confidential data, information, and case files from health care-related boards and the vendor to the department shall not constitute a waiver of any exemption from disclosure or discovery or of any confidentiality protection or privilege otherwise provided by law that is applicable to the data, information, or case files. It is the Legislature's intent that the audit be completed by June 30, 2010, and on subsequent years thereafter as determined by the department.

SEC. 3. Article 3.6 (commencing with Section 315) is added to Chapter 4 of Division 1 of the Business and Professions Code, to read:

Article 3.6. Uniform Standards Regarding Substance-Abusing Healing
Arts Licensees

315. (a) For the purpose of determining uniform standards that will be used by healing arts boards in dealing with substance-abusing licensees, there is established in the Department of Consumer Affairs the Substance Abuse Coordination Committee. The committee shall be comprised of the executive officers of the department's healing arts boards established pursuant to Division 2 (commencing with Section 500), the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, and a designee of the State Department of Alcohol and Drug Programs. The Director of Consumer Affairs shall chair the committee and may invite individuals or stakeholders who have particular expertise in the area of substance abuse to advise the committee.

(b) The committee shall be subject to the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Division 3 of Title 2 of the Government Code).

(c) By January 1, 2010, the committee shall formulate uniform and specific standards in each of the following areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program:

(1) Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

(2) Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic

evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

(3) Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status and condition.

(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

(5) Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

(6) Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

(7) Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

(8) Procedures to be followed when a licensee tests positive for a banned substance.

(9) Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

(10) Specific consequences for major violations and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation similar to the stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency unless or until the licensee commits a major violation, in which case it is revived and the license is surrendered.

(11) Criteria that a licensee must meet in order to petition for return to practice on a full-time basis.

(12) Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

(13) If a board uses a private-sector vendor that provides diversion services, standards for immediate reporting by the vendor to the board of any and all noncompliance with any term of the diversion contract or probation; standards for the vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors;

standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and standards for a licensee's termination from the program and referral to enforcement.

(14) If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

(15) If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

(16) Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

SEC. 4. Section 1695.1 of the Business and Professions Code is amended to read:

1695.1. As used in this article:

(a) "Board" means the Board of Dental Examiners of California.

(b) "Committee" means a diversion evaluation committee created by this article.

(c) "Program manager" means the staff manager of the diversion program, as designated by the executive officer of the board. The program manager shall have background experience in dealing with substance abuse issues.

SEC. 5. Section 1695.5 of the Business and Professions Code is amended to read:

1695.5. (a) The board shall establish criteria for the acceptance, denial, or termination of licentiates in a diversion program. Unless ordered by the board as a condition of licentiate disciplinary probation, only those licentiates who have voluntarily requested diversion treatment and supervision by a committee shall participate in a diversion program.

(b) A licentiate who is not the subject of a current investigation may self-refer to the diversion program on a confidential basis, except as provided in subdivision (f).

(c) A licentiate under current investigation by the board may also request entry into the diversion program by contacting the board's Diversion Program Manager. The Diversion Program Manager may refer the licentiate requesting participation in the program to a diversion evaluation committee for evaluation of eligibility. Prior to authorizing a licentiate to enter into the diversion program, the Diversion Program Manager may require the licentiate, while under current investigation for any violations of the Dental Practice Act or other violations, to execute a statement of understanding that states that the licentiate understands that his or her violations of the Dental Practice Act or other statutes that would otherwise be the basis for discipline, may still be investigated and the subject of disciplinary action.

(d) If the reasons for a current investigation of a licentiate are based primarily on the self-administration of any controlled substance or dangerous drugs or alcohol under Section 1681 of the Business and Professions Code,

or the illegal possession, prescription, or nonviolent procurement of any controlled substance or dangerous drugs for self-administration that does not involve actual, direct harm to the public, the board shall close the investigation without further action if the licentiate is accepted into the board's diversion program and successfully completes the requirements of the program. If the licentiate withdraws or is terminated from the program by a diversion evaluation committee, and the termination is approved by the program manager, the investigation shall be reopened and disciplinary action imposed, if warranted, as determined by the board.

(e) Neither acceptance nor participation in the diversion program shall preclude the board from investigating or continuing to investigate, or taking disciplinary action or continuing to take disciplinary action against, any licentiate for any unprofessional conduct committed before, during, or after participation in the diversion program.

(f) All licentiates shall sign an agreement of understanding that the withdrawal or termination from the diversion program at a time when a diversion evaluation committee determines the licentiate presents a threat to the public's health and safety shall result in the utilization by the board of diversion treatment records in disciplinary or criminal proceedings.

(g) Any licentiate terminated from the diversion program for failure to comply with program requirements is subject to disciplinary action by the board for acts committed before, during, and after participation in the diversion program. A licentiate who has been under investigation by the board and has been terminated from the diversion program by a diversion evaluation committee shall be reported by the diversion evaluation committee to the board.

SEC. 6. Section 1695.6 of the Business and Professions Code is amended to read:

1695.6. A committee created under this article operates under the direction of the program manager. The program manager has the primary responsibility to review and evaluate recommendations of the committee. Each committee shall have the following duties and responsibilities:

(a) To evaluate those licentiates who request to participate in the diversion program according to the guidelines prescribed by the board and to make recommendations. In making the recommendations, a committee shall consider the recommendations of any licentiates designated by the board to serve as consultants on the admission of the licentiate to the diversion program.

(b) To review and designate those treatment facilities to which licentiates in a diversion program may be referred.

(c) To receive and review information concerning a licentiate participating in the program.

(d) To consider in the case of each licentiate participating in a program whether he or she may with safety continue or resume the practice of dentistry.

(e) To perform such other related duties, under the direction of the board or program manager, as the board may by regulation require.

SEC. 7. Section 1697 of the Business and Professions Code is amended to read:

1697. Each licentiate who requests participation in a diversion program shall agree to cooperate with the treatment program designed by the committee and approved by the program manager and to bear all costs related to the program, unless the cost is waived by the board. Any failure to comply with the provisions of a treatment program may result in termination of the licentiate's participation in a program.

SEC. 8. Section 1698 of the Business and Professions Code is amended to read:

1698. (a) After the committee and the program manager in their discretion have determined that a licentiate has been rehabilitated and the diversion program is completed, the committee shall purge and destroy all records pertaining to the licentiate's participation in a diversion program.

(b) Except as authorized by subdivision (f) of Section 1695.5, all board and committee records and records of proceedings pertaining to the treatment of a licentiate in a program shall be kept confidential and are not subject to discovery or subpoena.

SEC. 9. Section 2361 of the Business and Professions Code is amended to read:

2361. As used in this article:

(a) "Board" means the Osteopathic Medical Board of California.

(b) "Diversion program" means a treatment program created by this article for osteopathic physicians and surgeons whose competency may be threatened or diminished due to abuse of drugs or alcohol.

(c) "Committee" means a diversion evaluation committee created by this article.

(d) "Participant" means a California licensed osteopathic physician and surgeon.

(e) "Program manager" means the staff manager of the diversion program, as designated by the executive officer of the board. The program manager shall have background experience in dealing with substance abuse issues.

SEC. 10. Section 2365 of the Business and Professions Code is amended to read:

2365. (a) The board shall establish criteria for the acceptance, denial, or termination of participants in the diversion program. Unless ordered by the board as a condition of disciplinary probation, only those participants who have voluntarily requested diversion treatment and supervision by a committee shall participate in the diversion program.

(b) A participant who is not the subject of a current investigation may self-refer to the diversion program on a confidential basis, except as provided in subdivision (f).

(c) A participant under current investigation by the board may also request entry into the diversion program by contacting the board's Diversion Program Manager. The Diversion Program Manager may refer the participant requesting participation in the program to a diversion evaluation committee for evaluation of eligibility. Prior to authorizing a licentiate to enter into the

diversion program, the Diversion Program Manager may require the licensee, while under current investigation for any violations of the Medical Practice Act or other violations, to execute a statement of understanding that states that the licensee understands that his or her violations of the Medical Practice Act or other statutes that would otherwise be the basis for discipline may still be investigated and the subject of disciplinary action.

(d) If the reasons for a current investigation of a participant are based primarily on the self-administration of any controlled substance or dangerous drugs or alcohol under Section 2239, or the illegal possession, prescription, or nonviolent procurement of any controlled substance or dangerous drugs for self-administration that does not involve actual, direct harm to the public, the board may close the investigation without further action if the licensee is accepted into the board's diversion program and successfully completes the requirements of the program. If the participant withdraws or is terminated from the program by a diversion evaluation committee, and the termination is approved by the program manager, the investigation may be reopened and disciplinary action imposed, if warranted, as determined by the board.

(e) Neither acceptance nor participation in the diversion program shall preclude the board from investigating or continuing to investigate, or taking disciplinary action or continuing to take disciplinary action against, any participant for any unprofessional conduct committed before, during, or after participation in the diversion program.

(f) All participants shall sign an agreement of understanding that the withdrawal or termination from the diversion program at a time when a diversion evaluation committee determines the licensee presents a threat to the public's health and safety shall result in the utilization by the board of diversion treatment records in disciplinary or criminal proceedings.

(g) Any participant terminated from the diversion program for failure to comply with program requirements is subject to disciplinary action by the board for acts committed before, during, and after participation in the diversion program. A participant who has been under investigation by the board and has been terminated from the diversion program by a diversion evaluation committee shall be reported by the diversion evaluation committee to the board.

SEC. 11. Section 2366 of the Business and Professions Code is amended to read:

2366. A committee created under this article operates under the direction of the diversion program manager. The program manager has the primary responsibility to review and evaluate recommendations of the committee. Each committee shall have the following duties and responsibilities:

(a) To evaluate those licensees who request participation in the program according to the guidelines prescribed by the board, and to make recommendations.

(b) To review and designate those treatment facilities and services to which a participant in the program may be referred.

(c) To receive and review information concerning participants in the program.

(d) To consider whether each participant in the treatment program may safely continue or resume the practice of medicine.

(e) To prepare quarterly reports to be submitted to the board, which include, but are not limited to, information concerning the number of cases accepted, denied, or terminated with compliance or noncompliance and a cost analysis of the program.

(f) To promote the program to the public and within the profession, including providing all current licentiates with written information concerning the program.

(g) To perform such other related duties, under the direction of the board or the program manager, as the board may by regulation require.

SEC. 12. Section 2367 of the Business and Professions Code is amended to read:

2367. (a) Each licensee who requests participation in a treatment program shall agree to cooperate with the treatment program designed by the committee and approved by the program manager. The committee shall inform each participant in the program of the procedures followed, the rights and responsibilities of the participant, and the possible results of noncompliance with the program. Any failure to comply with the treatment program may result in termination of participation.

(b) Participation in a program under this article shall not be a defense to any disciplinary action which may be taken by the board. Further, no provision of this article shall preclude the board from commencing disciplinary action against a licensee who is terminated from a program established pursuant to this article.

SEC. 13. Section 2369 of the Business and Professions Code is amended to read:

2369. (a) After the committee and the program manager, in their discretion, have determined that a participant has been rehabilitated and the program is completed, the committee shall purge and destroy all records pertaining to the participation in a treatment program.

(b) Except as authorized by subdivision (f) of Section 2365, all board and committee records and records of proceedings pertaining to the treatment of a participant in a program shall be confidential and are not subject to discovery or subpoena except in the case of discovery or subpoena in any criminal proceeding.

SEC. 14. Section 2663 of the Business and Professions Code is amended to read:

2663. The board shall establish and administer a diversion program for the rehabilitation of physical therapists and physical therapist assistants whose competency is impaired due to the abuse of drugs or alcohol. The board may contract with any other state agency or a private organization to perform its duties under this article. The board may establish one or more diversion evaluation committees to assist it in carrying out its duties under this article. Any diversion evaluation committee established by the board shall operate under the direction of the diversion program manager, as designated by the executive officer of the board. The program manager has

the primary responsibility to review and evaluate recommendations of the committee.

SEC. 15. Section 2665 of the Business and Professions Code is amended to read:

2665. Each diversion evaluation committee has the following duties and responsibilities:

(a) To evaluate physical therapists and physical therapist assistants who request participation in the program and to make recommendations. In making recommendations, the committee shall consider any recommendations from professional consultants on the admission of applicants to the diversion program.

(b) To review and designation of treatment facilities to which physical therapists and physical therapist assistants in the diversion program may be referred.

(c) To receive and review information concerning physical therapists and physical therapist assistants participating in the program.

(d) Calling meetings as necessary to consider the requests of physical therapists and physical therapist assistants to participate in the diversion program, to consider reports regarding participants in the program, and to consider any other matters referred to it by the board.

(e) To consider whether each participant in the diversion program may with safety continue or resume the practice of physical therapy.

(f) To set forth in writing the terms and conditions of the diversion agreement that is approved by the program manager for each physical therapist and physical therapist assistant participating in the program, including treatment, supervision, and monitoring requirements.

(g) Holding a general meeting at least twice a year, which shall be open and public, to evaluate the diversion program's progress, to prepare reports to be submitted to the board, and to suggest proposals for changes in the diversion program.

(h) For the purposes of Division 3.6 (commencing with Section 810) of Title 1 of the Government Code, any member of a diversion evaluation committee shall be considered a public employee. No board or diversion evaluation committee member, contractor, or agent thereof, shall be liable for any civil damage because of acts or omissions which may occur while acting in good faith in a program established pursuant to this article.

SEC. 16. Section 2666 of the Business and Professions Code is amended to read:

2666. (a) Criteria for acceptance into the diversion program shall include all of the following:

(1) The applicant shall be licensed as a physical therapist or approved as a physical therapist assistant by the board and shall be a resident of California.

(2) The applicant shall be found to abuse dangerous drugs or alcoholic beverages in a manner which may affect his or her ability to practice physical therapy safely or competently.

(3) The applicant shall have voluntarily requested admission to the program or shall be accepted into the program in accordance with terms and conditions resulting from a disciplinary action.

(4) The applicant shall agree to undertake any medical or psychiatric examination ordered to evaluate the applicant for participation in the program.

(5) The applicant shall cooperate with the program by providing medical information, disclosure authorizations, and releases of liability as may be necessary for participation in the program.

(6) The applicant shall agree in writing to cooperate with all elements of the treatment program designed for him or her.

Any applicant may be denied participation in the program if the board, the program manager, or a diversion evaluation committee determines that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety, or welfare.

(b) A participant may be terminated from the program for any of the following reasons:

(1) The participant has successfully completed the treatment program.

(2) The participant has failed to comply with the treatment program designated for him or her.

(3) The participant fails to meet any of the criteria set forth in subdivision (a) or (c).

(4) It is determined that the participant has not substantially benefited from participation in the program or that his or her continued participation in the program creates too great a risk to the public health, safety, or welfare. Whenever an applicant is denied participation in the program or a participant is terminated from the program for any reason other than the successful completion of the program, and it is determined that the continued practice of physical therapy by that individual creates too great a risk to the public health, safety, and welfare, that fact shall be reported to the executive officer of the board and all documents and information pertaining to and supporting that conclusion shall be provided to the executive officer. The matter may be referred for investigation and disciplinary action by the board. Each physical therapist or physical therapy assistant who requests participation in a diversion program shall agree to cooperate with the recovery program designed for him or her. Any failure to comply with that program may result in termination of participation in the program.

The diversion evaluation committee shall inform each participant in the program of the procedures followed in the program, of the rights and responsibilities of a physical therapist or physical therapist assistant in the program, and the possible results of noncompliance with the program.

(c) In addition to the criteria and causes set forth in subdivision (a), the board may set forth in its regulations additional criteria for admission to the program or causes for termination from the program.

SEC. 17. Section 2770.1 of the Business and Professions Code is amended to read:

2770.1. As used in this article:

(a) "Board" means the Board of Registered Nursing.

(b) "Committee" means a diversion evaluation committee created by this article.

(c) "Program manager" means the staff manager of the diversion program, as designated by the executive officer of the board. The program manager shall have background experience in dealing with substance abuse issues.

SEC. 18. Section 2770.7 of the Business and Professions Code is amended to read:

2770.7. (a) The board shall establish criteria for the acceptance, denial, or termination of registered nurses in the diversion program. Only those registered nurses who have voluntarily requested to participate in the diversion program shall participate in the program.

(b) A registered nurse under current investigation by the board may request entry into the diversion program by contacting the board. Prior to authorizing a registered nurse to enter into the diversion program, the board may require the registered nurse under current investigation for any violations of this chapter or any other provision of this code to execute a statement of understanding that states that the registered nurse understands that his or her violations that would otherwise be the basis for discipline may still be investigated and may be the subject of disciplinary action.

(c) If the reasons for a current investigation of a registered nurse are based primarily on the self-administration of any controlled substance or dangerous drug or alcohol under Section 2762, or the illegal possession, prescription, or nonviolent procurement of any controlled substance or dangerous drug for self-administration that does not involve actual, direct harm to the public, the board shall close the investigation without further action if the registered nurse is accepted into the board's diversion program and successfully completes the requirements of the program. If the registered nurse withdraws or is terminated from the program by a diversion evaluation committee, and the termination is approved by the program manager, the investigation shall be reopened and disciplinary action imposed, if warranted, as determined by the board.

(d) Neither acceptance nor participation in the diversion program shall preclude the board from investigating or continuing to investigate, or taking disciplinary action or continuing to take disciplinary action against, any registered nurse for any unprofessional conduct committed before, during, or after participation in the diversion program.

(e) All registered nurses shall sign an agreement of understanding that the withdrawal or termination from the diversion program at a time when the program manager or diversion evaluation committee determines the licensee presents a threat to the public's health and safety shall result in the utilization by the board of diversion treatment records in disciplinary or criminal proceedings.

(f) Any registered nurse terminated from the diversion program for failure to comply with program requirements is subject to disciplinary action by the board for acts committed before, during, and after participation in the

diversion program. A registered nurse who has been under investigation by the board and has been terminated from the diversion program by a diversion evaluation committee shall be reported by the diversion evaluation committee to the board.

SEC. 19. Section 2770.8 of the Business and Professions Code is amended to read:

2770.8. A committee created under this article operates under the direction of the diversion program manager. The program manager has the primary responsibility to review and evaluate recommendations of the committee. Each committee shall have the following duties and responsibilities:

(a) To evaluate those registered nurses who request participation in the program according to the guidelines prescribed by the board, and to make recommendations.

(b) To review and designate those treatment services to which registered nurses in a diversion program may be referred.

(c) To receive and review information concerning a registered nurse participating in the program.

(d) To consider in the case of each registered nurse participating in a program whether he or she may with safety continue or resume the practice of nursing.

(e) To call meetings as necessary to consider the requests of registered nurses to participate in a diversion program, and to consider reports regarding registered nurses participating in a program.

(f) To make recommendations to the program manager regarding the terms and conditions of the diversion agreement for each registered nurse participating in the program, including treatment, supervision, and monitoring requirements.

SEC. 20. Section 2770.11 of the Business and Professions Code is amended to read:

2770.11. (a) Each registered nurse who requests participation in a diversion program shall agree to cooperate with the rehabilitation program designed by the committee and approved by the program manager. Any failure to comply with the provisions of a rehabilitation program may result in termination of the registered nurse's participation in a program. The name and license number of a registered nurse who is terminated for any reason, other than successful completion, shall be reported to the board's enforcement program.

(b) If the program manager determines that a registered nurse, who is denied admission into the program or terminated from the program, presents a threat to the public or his or her own health and safety, the program manager shall report the name and license number, along with a copy of all diversion records for that registered nurse, to the board's enforcement program. The board may use any of the records it receives under this subdivision in any disciplinary proceeding.

SEC. 21. Section 2770.12 of the Business and Professions Code is amended to read:

2770.12. (a) After the committee and the program manager in their discretion have determined that a registered nurse has successfully completed the diversion program, all records pertaining to the registered nurse's participation in the diversion program shall be purged.

(b) All board and committee records and records of a proceeding pertaining to the participation of a registered nurse in the diversion program shall be kept confidential and are not subject to discovery or subpoena, except as specified in subdivision (b) of Section 2770.11 and subdivision (c).

(c) A registered nurse shall be deemed to have waived any rights granted by any laws and regulations relating to confidentiality of the diversion program, if he or she does any of the following:

(1) Presents information relating to any aspect of the diversion program during any stage of the disciplinary process subsequent to the filing of an accusation, statement of issues, or petition to compel an examination pursuant to Article 12.5 (commencing with Section 820) of Chapter 1. The waiver shall be limited to information necessary to verify or refute any information disclosed by the registered nurse.

(2) Files a lawsuit against the board relating to any aspect of the diversion program.

(3) Claims in defense to a disciplinary action, based on a complaint that led to the registered nurse's participation in the diversion program, that he or she was prejudiced by the length of time that passed between the alleged violation and the filing of the accusation. The waiver shall be limited to information necessary to document the length of time the registered nurse participated in the diversion program.

SEC. 22. Section 3501 of the Business and Professions Code is amended to read:

3501. As used in this chapter:

(a) "Board" means the Medical Board of California.

(b) "Approved program" means a program for the education of physician assistants that has been formally approved by the committee.

(c) "Trainee" means a person who is currently enrolled in an approved program.

(d) "Physician assistant" means a person who meets the requirements of this chapter and is licensed by the committee.

(e) "Supervising physician" means a physician and surgeon licensed by the board or by the Osteopathic Medical Board of California who supervises one or more physician assistants, who possesses a current valid license to practice medicine, and who is not currently on disciplinary probation for improper use of a physician assistant.

(f) "Supervision" means that a licensed physician and surgeon oversees the activities of, and accepts responsibility for, the medical services rendered by a physician assistant.

(g) "Committee" or "examining committee" means the Physician Assistant Committee.

(h) "Regulations" means the rules and regulations as contained in Chapter 13.8 (commencing with Section 1399.500) of Title 16 of the California Code of Regulations.

(i) "Routine visual screening" means uninvasive nonpharmacological simple testing for visual acuity, visual field defects, color blindness, and depth perception.

(j) "Program manager" means the staff manager of the diversion program, as designated by the executive officer of the board. The program manager shall have background experience in dealing with substance abuse issues.

SEC. 23. Section 3534.1 of the Business and Professions Code is amended to read:

3534.1. The examining committee shall establish and administer a diversion program for the rehabilitation of physician assistants whose competency is impaired due to the abuse of drugs or alcohol. The examining committee may contract with any other state agency or a private organization to perform its duties under this article. The examining committee may establish one or more diversion evaluation committees to assist it in carrying out its duties under this article. As used in this article, "committee" means a diversion evaluation committee. A committee created under this article operates under the direction of the diversion program manager, as designated by the executive officer of the examining committee. The program manager has the primary responsibility to review and evaluate recommendations of the committee.

SEC. 23. Section 3534.3 of the Business and Professions Code is amended to read:

3534.3. Each committee has the following duties and responsibilities:

(a) To evaluate physician assistants who request participation in the program and to make recommendations to the program manager. In making recommendations, a committee shall consider any recommendations from professional consultants on the admission of applicants to the diversion program.

(b) To review and designate treatment facilities to which physician assistants in the diversion program may be referred, and to make recommendations to the program manager.

(c) The receipt and review of information concerning physician assistants participating in the program.

(d) To call meetings as necessary to consider the requests of physician assistants to participate in the diversion program, to consider reports regarding participants in the program, and to consider any other matters referred to it by the examining committee.

(e) To consider whether each participant in the diversion program may with safety continue or resume the practice of medicine.

(f) To set forth in writing the terms and conditions of the diversion agreement that is approved by the program manager for each physician assistant participating in the program, including treatment, supervision, and monitoring requirements.

(g) To hold a general meeting at least twice a year, which shall be open and public, to evaluate the diversion program's progress, to prepare reports to be submitted to the examining committee, and to suggest proposals for changes in the diversion program.

(h) For the purposes of Division 3.6 (commencing with Section 810) of Title 1 of the Government Code, any member of a committee shall be considered a public employee. No examining committee or committee member, contractor, or agent thereof, shall be liable for any civil damage because of acts or omissions which may occur while acting in good faith in a program established pursuant to this article.

SEC. 24. Section 3534.4 of the Business and Professions Code is amended to read:

3534.4. Criteria for acceptance into the diversion program shall include all of the following: (a) the applicant shall be licensed as a physician assistant by the examining committee and shall be a resident of California; (b) the applicant shall be found to abuse dangerous drugs or alcoholic beverages in a manner which may affect his or her ability to practice medicine safely or competently; (c) the applicant shall have voluntarily requested admission to the program or shall be accepted into the program in accordance with terms and conditions resulting from a disciplinary action; (d) the applicant shall agree to undertake any medical or psychiatric examination ordered to evaluate the applicant for participation in the program; (e) the applicant shall cooperate with the program by providing medical information, disclosure authorizations, and releases of liability as may be necessary for participation in the program; and (f) the applicant shall agree in writing to cooperate with all elements of the treatment program designed for him or her.

An applicant may be denied participation in the program if the examining committee, the program manager, or a committee determines that the applicant will not substantially benefit from participation in the program or that the applicant's participation in the program creates too great a risk to the public health, safety, or welfare.

SEC. 25. Section 3534.9 of the Business and Professions Code is amended to read:

3534.9. If the examining committee contracts with any other entity to carry out this section, the executive officer of the examining committee or the program manager shall review the activities and performance of the contractor on a biennial basis. As part of this review, the examining committee shall review files of participants in the program. However, the names of participants who entered the program voluntarily shall remain confidential, except when the review reveals misdiagnosis, case mismanagement, or noncompliance by the participant.

SEC. 26. Section 4371 of the Business and Professions Code is amended to read:

4371. (a) The executive officer of the board shall designate a program manager of the pharmacists recovery program. The program manager shall have background experience in dealing with substance abuse issues.

(b) The program manager shall review the pharmacists recovery program on a quarterly basis. As part of this evaluation, the program manager shall review files of all participants in the pharmacists recovery program.

(c) The program manager shall work with the contractor administering the pharmacists recovery program to evaluate participants in the program according to established guidelines and to develop treatment contracts and evaluate participant progress in the program.

SEC. 27. The responsibilities imposed on a licensing board by this act shall be considered a current operating expense of that board, and shall be paid from the fund generally designated to provide operating expenses for that board, subject to the appropriation provisions applicable to that fund.

Senate Bill No. 377

CHAPTER 378

An act to amend Section 101.7 of the Streets and Highways Code, relating to transportation.

[Approved by Governor September 27, 2008. Filed with Secretary of State September 27, 2008.]

LEGISLATIVE COUNSEL'S DIGEST

SB 377, Aanestad. Highway signs: pharmacies and attractions.

Existing law requires the Department of Transportation to adopt rules and regulations that allow the placement, near exits on freeways in rural areas, of information signs identifying specific roadside businesses offering fuel, food, lodging, or camping and that prescribe the standards for those signs.

This bill would require the department to additionally adopt rules and regulations governing the placement and standards for signs in those locations relative to approved 24-hour pharmacy services and specified categories of approved attractions.

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

SECTION 1. Section 101.7 of the Streets and Highways Code is amended to read:

101.7. (a) The department shall adopt rules and regulations that allow the placement, near exits on freeways located in rural areas, of information signs identifying specific roadside businesses offering fuel, food, lodging, camping services, approved 24-hour pharmacy services, or approved attractions, and that prescribe the standards for those signs.

(b) The department shall provide equal access to all business applicants.

(c) The department shall not approve the placement of any sign within any urban area designated by the United States Bureau of the Census as having a population of 5,000 or more.

The department may not remove an information sign that was placed before January 1, 2003, due solely to population growth in an urban area that results in a population of 5,000 or more but less than 10,000.

(d) The information signs may be placed near the freeway exits in addition to, or in lieu of, other highway signs of the department, but not in lieu of on-premises or off-premises highway oriented business signs and directional signs.

(e) The department shall establish and charge a fee to place and maintain information signs in an amount not less than 25 percent above its estimated

cost in placing and maintaining the information signs. The department shall annually review the amount of that fee and revise it as necessary. Funds derived from the imposition of the fee, after deduction of the cost to the department for the placement and maintenance of the information signs, shall be available, upon appropriation by the Legislature, for safety roadside rest purposes.

(f) The department shall incorporate the use of an “RV-friendly” symbol on an information sign placed pursuant to subdivision (a) for a specific roadside business that meets criteria of the department regarding sufficiency for recreational vehicles with respect to the parking spaces and surfaces, vertical clearance, turning radius, and entrances and exits of the facility. A specific roadside business otherwise qualified for a sign pursuant to subdivision (a) may qualify for and request an “RV-friendly” symbol for that sign. The department shall adopt rules and regulations for an “RV-friendly” symbol consistent with this section as well as the Federal Highway Administration’s Interim Approval for Addition of RV-friendly Symbol to Specific Service Signs. The rules and regulations adopted by the department shall include a provision for the roadside business to acknowledge that overnight occupancy is not permitted unless the roadside business is licensed as a special occupancy park as defined in Section 18862.43 of the Health and Safety Code. The department shall establish and charge an additional fee pursuant to subdivision (e) to place and maintain the symbol.

(g) The department shall develop rules and regulations governing signs for approved attractions, which shall include amusement parks, botanical and zoological facilities, business districts and main street communities, education centers, golf courses, historical sites, museums, religious sites, resorts, ski areas, marinas, “u-pick” farms and orchards, farmers’ markets, and wineries, viticulture areas, and vineyards.

Attachment 3

- *Vetoed Bills Impacting the Board's Jurisdiction or Practice of Pharmacy*
- *Veto Messages*

CHAPTER _____

An act to amend Sections 27, 101, 128.5, 144, 146, 149, 683, 733, 800, 801, 801.01, 803, 2089.5, 2096, 2102, 2107, 2135, 2168.4, 2175, 2221, 2307, 2335, 2486, 2488, 2570.5, 2570.6, 2570.7, 2760.1, 3503, 3517, 3518, 3625, 3633.1, 3635, 3636, 3685, 3750.5, 3753.5, 3773, 4022.5, 4027, 4040, 4051, 4059.5, 4060, 4062, 4076, 4081, 4110, 4111, 4126.5, 4161, 4174, 4231, 4301, 4305, 4329, 4330, 4857, 4980.03, 4980.30, 4980.43, 4982, 4989.54, 4992.3, 4996.2, 4996.17, 4996.18, 4996.23, 5801, 6534, 6536, 6561, 7616, 7629, 8740, and 8746 of, to amend and renumber Section 2570.185 of, to add Sections 2169, 2570.36, 4036.5, 4980.04, 4990.09, 5515.5, and 9855.1.5 to, and to repeal Sections 2172, 2173, 2174, 4981, 4994.1, 4996.20, 4996.21, and 6761 of, the Business and Professions Code, to amend Section 8659 of the Government Code, to amend Sections 8778.5, 11150, and 11165 of the Health and Safety Code, and to amend Section 14132.100 of the Welfare and Institutions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 1779, Committee on Business, Professions and Economic Development. Professions and vocations.

(1) Existing law provides for the licensure and regulation of various professions and vocations by boards and bureaus within the Department of Consumer Affairs.

Existing law requires certain boards and bureaus to disclose on the Internet information on licensees.

This bill would require the Cemetery and Funeral Bureau to disclose on the Internet information on specified licensees.

(2) Under existing law, if, upon investigation, a specified state regulatory agency has probable cause to believe that a person is advertising in a telephone directory with respect to the offering or performance of services, without being properly licensed by or registered with that agency, the agency is authorized to issue a specified citation.

This bill would add the Physical Therapy Board of California to those authorized agencies.

right of enforcement shall be in addition to any other rights the board may have as to any practitioner directed to pay costs.

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

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

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

SEC. 45. Section 3773 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 46. Section 4022.5 of the Business and Professions Code is amended to read:

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

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

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

SEC. 47. Section 4027 of the Business and Professions Code is amended to read:

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

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

(c) As used in Section 4052.2, “health care facility” means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; “licensed home health agency” means a private or public organization licensed by the State Department of Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and “licensed clinic” means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

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

SEC. 48. Section 4036.5 is added to the Business and Professions Code, to read:

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

SEC. 49. Section 4040 of the Business and Professions Code is amended to read:

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

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

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

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

(C) The date of issue.

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

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

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

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

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug

prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

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

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

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

SEC. 50. Section 4051 of the Business and Professions Code is amended to read:

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

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

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

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

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

SEC. 51. Section 4059.5 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 52. Section 4060 of the Business and Professions Code is amended to read:

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

or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer.

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

SEC. 53. Section 4062 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

SEC. 54. Section 4076 of the Business and Professions Code is amended to read:

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

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

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

(3) The name of the patient or patients.

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

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

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

policy, procedure, or protocol pursuant to either Section 4052.1 or 4052.2.

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

SEC. 55. Section 4081 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 56. Section 4110 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

SEC. 57. Section 4111 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

SEC. 58. Section 4126.5 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

(7) To another pharmacy under common control.

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

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

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

SEC. 59. Section 4161 of the Business and Professions Code is amended to read:

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

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

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, or delivered to a site located in this state or sold, brokered, or distributed within this state. A license shall be renewed annually and shall not be transferable.

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

(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.

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

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

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

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

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

(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license

in this state shall include a license verification from the licensing authority in the applicant's state of residence.

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

(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.

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

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

SEC. 60. Section 4174 of the Business and Professions Code is amended to read:

4174. Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug

order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, or 4052.3.

SEC. 61. Section 4231 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 62. Section 4301 of the Business and Professions Code is amended to read:

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

- (a) Gross immorality.
- (b) Incompetence.
- (c) Gross negligence.
- (d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.
- (e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.
- (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
- (g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.
- (h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.
- (i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.
- (j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.
- (k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

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

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

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

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

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

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

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

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

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

SEC. 63. Section 4305 of the Business and Professions Code is amended to read:

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

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

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

SEC. 64. Section 4329 of the Business and Professions Code is amended to read:

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

SEC. 65. Section 4330 of the Business and Professions Code is amended to read:

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

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

SEC. 65.5. Section 4857 of the Business and Professions Code is amended to read:

4857. (a) A veterinarian licensed under the provisions of this chapter shall not disclose any information concerning an animal receiving veterinary services, the client responsible for the animal receiving veterinary services, or the veterinary care provided to an animal, except under any one of the following circumstances:

BILL NUMBER: SB 1779
VETOED DATE: 09/27/2008

To the Members of the California State Senate:

I am returning Senate Bill 1779 without my signature.

The historic delay in passing the 2008-2009 State Budget has forced me to prioritize the bills sent to my desk at the end of the year's legislative session. Given the delay, I am only signing bills that are the highest priority for California. This bill does not meet that standard and I cannot sign it at this time.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 501

Passed the Assembly August 13, 2008

Chief Clerk of the Assembly

Passed the Senate July 14, 2008

Secretary of the Senate

This bill was received by the Governor this _____ day
of _____, 2008, at _____ o'clock _____ M.

Private Secretary of the Governor

CHAPTER _____

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

LEGISLATIVE COUNSEL'S DIGEST

AB 501, Swanson. Pharmaceutical devices.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Under existing law, certain items, such as home-generated sharps waste, as defined, are specifically excluded from the definition of medical waste. The act prohibits, on or after September 1, 2008, a person from knowingly placing home-generated sharps waste in certain types of containers, provides that home-generated sharps waste is to be transported only in a sharps container, as defined, or other container approved by the department or local enforcement agency, and requires this waste to only be managed at specified locations consistent with existing law.

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

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

SECTION 1. The Legislature finds and declares all of the following:

(a) An estimated 1 million Californians must self-inject prescription medications annually to treat a broad range of serious health problems.

(b) The use of prefilled syringes, prefilled pens, and other prefilled devices with needles is an effective method of prescription drug delivery and is expected to increase significantly in the future. Prefilled syringes, prefilled pens, and other prefilled devices with needles are clearly identified and linked to specific pharmaceutical manufacturers for the provision of their product to California residents.

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

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

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

118288. (a) Upon request of a consumer who has been dispensed a prefilled syringe, prefilled pen, or other prefilled injection device for administration at home, a pharmaceutical manufacturer shall arrange to provide the consumer with either of the following:

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

(2) A sharps container for the safe storage of, and transport to, a sharps consolidation location that is approved by the State

Department of Public Health or to a clinic, physician, or pharmacy that accepts home-generated sharps waste.

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

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

(c) As a means of meeting the requirements of subdivision (a), a manufacturer may do either of the following:

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

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

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

BILL NUMBER: AB 501
VETOED DATE: 09/27/2008

To the Members of the California State Assembly:

I am returning Assembly Bill 501 without my signature.

While I support the safe and proper disposal of home-generated sharps waste, this bill only applies to the disposal of prefilled injection devices. Although the use of these devices is increasing, omitting other types of home-generated sharps from the bill could potentially create an unintentional disincentive for the production and use of these prefilled injection devices. Limiting the types of sharps in this way, making the bill's provisions take effect only upon the request of consumers, and the options provided to the manufacturers of these devices will likely reduce the efficacy of this bill. Lastly, and most importantly, this bill is unclear as to who bears the ultimate cost of these containers. This problem requires a solution that must be shared among all the stakeholders, not just the manufacturers of one type of device.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 1574

Passed the Assembly August 18, 2008

Chief Clerk of the Assembly

Passed the Senate August 12, 2008

Secretary of the Senate

This bill was received by the Governor this ____ day
of _____, 2008, at ____ o'clock ____ M.

Private Secretary of the Governor

CHAPTER _____

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

LEGISLATIVE COUNSEL'S DIGEST

AB 1574, Plescia. Surgical clinics: licensure.

Existing law, with certain exceptions, provides for the licensure and regulation of clinics, including specialty clinics, by the State Department of Public Health. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. The Pharmacy Law, the knowing violation of which is a misdemeanor, provides that a surgical clinic may not operate and is not entitled to the benefits of specified provisions of the Pharmacy Law without a license issued by the California State Board of Pharmacy. Existing law authorizes the board to inspect a clinic at any time.

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

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

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

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

SECTION 1. This act shall be known, and may be cited, as the California Outpatient Pharmacy Patient Safety and Improvement Act.

SEC. 2. Section 4190 of the Business and Professions Code is amended to read:

4190. (a) For the purposes of this section, "clinic" means a surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code, an outpatient setting accredited by an accreditation agency, as defined in Section 1248 of the Health and Safety Code, or an ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(b) Notwithstanding any other provision of this chapter, a clinic may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic, as provided in subdivision (c). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

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

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

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

any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(f) (1) The board shall inspect an outpatient setting or ambulatory surgical center within 120 days of the issuance of a clinic license pursuant to this article, and at least annually thereafter.

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

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

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

BILL NUMBER: AB 1574
VETOED DATE: 09/27/2008

To the Members of the California State Assembly:

I am returning Assembly Bill 1574 without my signature.

If this bill were enacted, the Board of Pharmacy would be authorized to issue a limited pharmaceutical license to a physician-owned surgical clinic without it being licensed by the state Department of Public Health (Department). Licensure by the Department ensures that clinics operate in compliance with state and federal standards and provide patients with quality medical and surgical care. This bill fails to address the larger issue of a recent court ruling prohibiting the Department from issuing licenses to surgical clinics that are partially or wholly-owned by physicians. This bill also fails to enact patient safety standards that have been the subject of two previous vetoes.

I will not support a partial solution to a much larger problem, especially when I have requested a comprehensive solution that resolves the quality and licensure issues for physician-owned clinics.

For these reasons, I am not able to sign this measure.

Sincerely,

Arnold Schwarzenegger