To the Members of the California State Assembly:

I am returning Assembly Bill 446 without my signature.

I vetoed a similar bill last year because of the negative effect it would have had on the California economy. This bill further erodes the ability to do business in California by creating more uncertainty regarding litigation by prohibiting any licensee or professional overseen by the Department of Consumer Affairs from including in a civil settlement agreement a provision that prohibits the other party from contacting or filing a complaint with the regulatory agency. When parties who are in dispute agree to settle, there should be some assurances that the dispute has been resolved in a satisfactory and final manner for both parties.

For this reason I am unable to sign this bill.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 446

Passed the Assembly September 7, 2005

_____

Chief Clerk of the Assembly

Passed the Senate September 6, 2005

_____

Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2005, at _____ o'clock ____M.

_____

Private Secretary of the Governor

CHAPTER _____

An act to add Section 143.5 to the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

AB 446, Negrete McLeod. Licensees: settlement agreements.

Existing law provides that it is a cause for suspension, disbarment, or other discipline for an attorney to agree or seek agreement that the professional misconduct or the terms of a settlement of a claim for professional misconduct is not to be reported to the disciplinary agency, or to agree or seek agreement that the plaintiff shall withdraw a disciplinary complaint or not cooperate with an investigation or prosecution conducted by the disciplinary agency.

This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, bureaus, or programs, or an entity or person acting as an authorized agent of a licensee, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program. The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action.

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

SECTION 1. Section 143.5 is added to the Business and Professions Code, to read:

143.5. (a) No licensee who is regulated by a board, bureau, or program within the Department of Consumer Affairs, nor an entity or person acting as an authorized agent of a licensee, shall include or permit to be included a provision in an agreement to

settle a civil dispute, whether the agreement is made before or after the commencement of a civil action, that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A provision of that nature is void as against public policy, and any licensee who includes or permits to be included a provision of that nature in a settlement agreement is subject to disciplinary action by the board, bureau, or program.

(b) Any board, bureau, or program within the Department of Consumer Affairs that takes disciplinary action against a licensee or licensees based on a complaint or report that has also been the subject of a civil action, which has been settled for monetary damages providing for full and final satisfaction of the parties, may not require its licensee or licensees to pay any additional sums to the benefit of any plaintiff in the civil action.

(c) As used in this section, "board" shall have the same meaning as defined in Section 22, and "licensee" means a person that has been granted a license, as that term is defined in Section 23.7.

Blank

Assembly Bill No. 497

CHAPTER 301

An act to amend Sections 4162.5 and 4400 of the Business and Professions Code, relating to pharmacy practices.

[Approved by Governor September 22, 2005. Filed with Secretary of State September 22, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

AB 497, Negrete McLeod. Drug wholesalers and manufacturers: nonresident wholesalers.

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California. Existing law requires a fee of $550, which may be increased up to $600, for a wholesaler or nonresident wholesaler license and annual renewal.

This bill would instead require a single $100,000 surety bond, or an equivalent means of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license. The bill would except from that bond requirement certain nonresident wholesalers to whom an approved new drug application has been issued by the federal Food and Drug Administration, as specified. The bill would also reduce certain application fee amounts required to be paid for a nonresident wholesaler license.

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

SECTION 1. 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 purpose 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 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 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.

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

SEC. 2. Section 4400 of the Business and Professions Code, as added by Section 50 of Chapter 857 of the Statutes of 2004, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600), except as provided in subdivision (j).

(g) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(h) The fee for application and investigation for a designated representative license issued pursuant to Section 4053 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer designated representative, for whom the fee shall be one hundred dollars ($100).

(i) The fee for a designated representative license and annual renewal under Section 4053 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer designated representative license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(2) For nonresident wholesalers who have 21 or more wholesaler facilities operating nationwide the application fees for the first 20 locations shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars ($225) and may be increased to three hundred dollars ($300).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(*l*) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(m) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(n) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(o) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(p) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(q) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(r) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(s) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(t) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(u) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(v) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

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

O

Assembly Bill No. 522

CHAPTER 469

An act to amend Section 1261.6 of the Health and Safety Code, to add Section 290.02 to the Penal Code, and to add Section 14133.225 to the Welfare and Institutions Code, relating to prescription drugs and other therapies, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 4, 2005. Filed with Secretary of State October 4, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

AB 522, Plescia. Automated drug delivery system: Medi-Cal coverage: drugs or other therapies: registered sex offenders.

Existing law provides for skilled nursing and intermediate care facilities to use an automated drug delivery system to store and distribute drugs, and to track the movement of drugs into and out of the system. Existing law regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system.

This bill would clarify existing law to define pharmacy services and to require a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions. This bill would further clarify existing law to prevent licensed personnel from accessing a different drug or dose of a drug than that approved by a pharmacist.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care services, pursuant to a schedule of health care benefits. The Med-Cal program is, in part, governed and funded by federal Medicaid provisions.

Existing law requires a person who has committed one or more designated sex crimes to register with the law enforcement agency of the city, county, city and county, or campus in which the person resides. Existing law provides that the Department of Justice shall make available information concerning specified registered sex offenders to the public via an Internet Web site.

This bill would provide that the State Department of Health Services shall not provide or pay for any prescription drug or therapy to treat erectile dysfunction for any Medi-Cal recipient required to register pursuant to these provisions, except to the extent it is required under federal law.

This bill would require the Department of Justice to identify the names of persons required to register under these provisions from a list of persons provided by the requesting agency, and provide those names and other information necessary to verify proper identification, to any state governmental entity responsible for authorizing or providing publicly

funded prescription drugs or other therapies to treat erectile dysfunction of these persons.

This bill would authorize the Department of Justice to establish a fee for the above requests.

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

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

SECTION 1. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the

prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions which will include all users accessing the system and all drugs added to or removed from the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to the drug as ordered by the prescriber and reviewed by the pharmacist and that is specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall only have access to the drug ordered for that scheduled time of administration.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets or drawers is performed by a pharmacist or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the pockets or drawers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration.

SEC. 2. Section 290.02 is added to the Penal Code, to read:

290.02. (a) Notwithstanding any other law, the Department of Justice shall identify the names of persons required to register pursuant to Section 290 from a list of persons provided by the requesting agency, and provide those names and other information necessary to verify proper identification, to any state governmental entity responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction of those persons. State governmental entities shall use information received pursuant to this section to protect public safety by preventing the use of prescription drugs or other therapies to treat erectile dysfunction by convicted sex offenders.

(b) Use or disclosure of the information disclosed pursuant to this section is prohibited for any purpose other than that authorized by this section or Section 14133.225 of the Welfare and Institutions Code. The Department of Justice may establish a fee for requests, including all actual and reasonable costs associated with the service.

(c) Notwithstanding any other provision of law, any state governmental entity that is responsible for authorizing or providing publicly funded prescription drugs or other therapies to treat erectile dysfunction may use the sex offender database authorized by Section 290.46 to protect public safety by preventing the use of those drugs or therapies for convicted sex offenders.

SEC. 3. Section 14133.225 is added to the Welfare and Institutions Code, to read:

14133.225. Notwithstanding any other law, the department shall not provide or pay for any prescription drug or other therapy to treat erectile dysfunction for any person who is required to register pursuant to Section 290 of the Penal Code, except to the extent required under federal law. The

department may require from the Department of Justice the information necessary to implement this section.

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

In order to prevent funding of drugs or other therapies prescribed for erectile dysfunction for use by high-risk sex offenders and to make statutory changes related to automated drug delivery systems, as soon as possible, it is necessary that this act take effect immediately.

O

Senate Bill No. 644

CHAPTER 417

An act to amend Sections 4314 and 4315 of, and to add Section 733 to, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 29, 2005. Filed with Secretary of State September 29, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SB 644, Ortiz. Dispensing prescription drugs and devices.

(1) Existing law makes certain actions by a health care professional unprofessional conduct subject to disciplinary action by the licensing board regulating the health care professional. Under existing law, the California State Board of Pharmacy is authorized to issue a citation for the violation of the Pharmacy Law or regulations adopted pursuant to it, and the board's executive officer is authorized to issue a letter of admonishment for the violation of those provisions.

This bill would prohibit a health care licentiate from obstructing a patient in obtaining a prescription drug or device and would require the licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate. The bill would authorize the licentiate to decline to dispense the prescription or order on that basis only if the licentiate notified his or her employer of the objection and it can be reasonably accommodated. The bill would require the licentiate's employer in those circumstances to establish protocols to ensure a patient's timely access to the prescribed drug or device. The bill would authorize the California State Board of Pharmacy to issue a citation for a violation of these provisions and would authorize its executive officer to issue a letter of admonishment for their violation.

(2) The bill would incorporate additional changes to Section 4315 of the Business and Professions Code made by this bill and SB 1111 to take effect if both bills are enacted and this bill is enacted last.

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

SECTION 1. It is the intent of the Legislature that health care professionals dispense prescription drugs and devices in a timely way or provide appropriate referrals for patients to obtain the necessary prescription drugs and devices, despite the health care professional's objection to dispensing the drugs or devices on ethical, moral, or religious grounds.

SEC. 2 Section 733 is added to the Business and Professions Code, to read:

733. (a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient . The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (*l*) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section 4052.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.

SEC. 3. Section 4314 of the Business and Professions Code is amended to read:

4314. (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733 or for any violation of this chapter or regulations adopted pursuant to this chapter, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

(b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.

(c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.

(d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.

SEC. 4. Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

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

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

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

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

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

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

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

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

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

SEC. 5. Section 4315 of the Business and Professions Code is amended to read:

4315. (a) The executive officer, or his or her designee, may issue a letter of admonishment to a licensee for failure to comply with Section 733 or for failure to comply with this chapter or regulations adopted pursuant to this chapter, directing the licensee to come into compliance.

(b) The letter of admonishment shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statutes or regulations violated.

(c) The letter of admonishment shall inform the licensee that within 30 days of service of the order of admonishment the licensee may do either of the following:

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

(A) Upon a timely request, the executive officer, or his or her designee, shall hold an office conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or his or her designee, no individual other than the legal counsel or authorized representative of the licensee may accompany the licensee to the office conference.

(B) Prior to or at the office conference the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the letter of admonishment.

(C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).

(D) The executive officer, or his or her designee, may affirm, modify, or withdraw the letter of admonishment. Within 14 calendar days from the date of the office conference, the executive officer, or his or her designee, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the letter of admonishment.

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

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

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

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

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

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

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

SEC. 6. Section 5 of this bill incorporates amendments to Section 4315 of the Business and Professions Code proposed by both this bill and Senate Bill 1111. It shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2006, (2) each bill amends Section 4315 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1111, in which case Section 4 of this bill shall not become operative.

O

Senate Bill No. 734

CHAPTER 487

An act to amend Sections 11159.2, 11161, 11161.5, 11162.1, 11164, and 11190 of, and to add and repeal Section 11165.5 of, the Health and Safety Code, relating to controlled substances, and making an appropriation therefor.

[Approved by Governor October 4, 2005. Filed with Secretary of State October 4, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SB 734, Torlakson. Controlled substances.

(1) Existing law provides that a prescription for a Schedule II controlled substance for use by a patient who has a terminal illness shall meet specified requirements.

This bill would provide that a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a form that does not contain certain other features, as specified.

(2) Existing law provides that when a practitioner is charged with a felony violation of specified controlled substance offenses, the court, upon the motion of a law enforcement agency, shall issue an order requiring the practitioner to surrender any prescription forms in his or her possession at the time set in the order.

This bill would require the court, in its order, to also prohibit the practitioner from obtaining, ordering, or using any additional prescription forms. The bill would impose a state-mandated local program by requiring the law enforcement agency obtaining the order to notify the Department of Justice of the order. The bill would make clarifying and conforming changes to this and related provisions.

(3) Existing law provides that prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Board of Pharmacy; the board may approve security printer applications after the applicant has provided specified information and the applicant's fingerprints, in a manner specified by the board, for the purpose of completing state and federal criminal background checks.

This bill would revise the latter provision to provide instead that the prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice and that the department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks. The bill would provide that the applicant shall submit his or her fingerprint images and related information to the department for the purpose of the department obtaining information as to

the existence and nature of a record of specified state, federal, or foreign level convictions and arrests. Requests for federal level criminal offender record information received by the department shall be forwarded to the Federal Bureau of Investigation by the department. The bill would provide that the department shall assess the applicant a fee sufficient to cover all processing or maintenance costs of the department associated with providing the background checks, as specified.

(4) Existing law provides that the Board of Pharmacy or the Department of Justice may deny a security printer application for specified reasons, including that the applicant has been convicted of a crime.

This bill would provide that the Department of Justice, but not the Board of Pharmacy, may deny the security printer application for the specified reasons, including if any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant who has direct access, management, or control of controlled substance prescription forms has been convicted of a crime. The bill would also add as a condition for approval as a security printer that the applicant authorize the department to make any examination of books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce the provisions relating to security printers. An approved applicant would be required to submit an exemplar of a controlled substance prescription form, with all security features, to the department within 30 days of initial production.

(5) Existing law provides that prescription forms shall be printed with specified features.

This bill would provide that prescription forms shall also include the feature of an identifying number assigned to the approved security printer by the Department of Justice. The bill would also require the forms to set forth specified information, as appropriate, with respect to multiple prescribers.

(6) Existing law provides that controlled substances in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription.

This bill would require persons who transmit or receive any oral or electronically transmitted prescription to ensure its integrity and confidentiality.

(7) Existing law provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program.

This bill would provide that the Board of Pharmacy shall, contingent upon the availability of adequate funds, evaluate the viability of implementing real time reporting, as defined, and access to data on controlled substances in the operation of CURES. This bill would provide that these provisions shall be implemented to the extent that sufficient nonstate funds are received to cover the costs to the Board of Pharmacy of

providing staff and for the preparation of the report; and that any nonstate funds donated for that purpose are appropriated to the board for that purpose.

(8) Existing law generally provides that a violation of the provisions relating to the prescription of controlled substances is a misdemeanor, punishable as specified. This bill, to the extent it revises existing crimes, would impose a state-mandated local program upon local governments.

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 with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

Appropriation: yes.

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

SECTION 1. Section 11159.2 of the Health and Safety Code is amended to read:

11159.2. (a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:

(1) Contain the information specified in subdivision (a) of Section 11164.

(2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."

(b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.

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

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

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

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

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

SEC. 2. Section 11161 of the Health and Safety Code is amended to read:

11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all controlled substance prescription forms in the practitioner's possession at a time set in the order and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription forms in violation of the order is guilty of a misdemeanor.

(b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using controlled substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.

(c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.

(d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the

defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.

(e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).

(f) This section shall become operative on November 1, 2004.

SEC. 3. Section 11161.5 of the Health and Safety Code is amended to read:

11161.5. (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; and all managing general partners, if any.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, or managing general partner.

(5) (A) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (*l*) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state,

federal, or foreign background checks pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits fingerprints and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.

(d) The department may deny a security printer application on any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, 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 the provisions of Section 1203.4 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances.

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer.

(i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(k) (1) The department may revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

SEC. 4. Section 11162.1 of the Health and Safety Code is amended to read:

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

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

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

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

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

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

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

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

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

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

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

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

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

(11) An identifying number assigned to the approved security printer by the Department of Justice.

(12) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by their name.

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

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons preprinted on the form.

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

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

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to the requirements set forth in subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's

name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

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

SEC. 5. Section 11164 of the Health and Safety Code is amended to read:

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

(a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:

(1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the person for whom the controlled substance is prescribed; and the name, quantity, strength, and directions for use of the controlled substance prescribed.

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

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

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

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

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

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

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

SEC. 6. Section 11165.5 is added to the Health and Safety Code, to read:

11165.5. (a) The Board of Pharmacy shall, contingent upon the availability of adequate funds, evaluate the viability of the implementing real time reporting and access to data on prescriptions for controlled substances in the operation of the Controlled Substances Utilization Review and Evaluation System (CURES). For the purposes of this subdivision, "real time reporting" means the ability to send and access prescription data instantaneously in the operation of CURES.

(b) The Board of Pharmacy, in consultation with the Medical Board of California and Department of Justice, shall contract with a vendor to prepare a feasibility study report in accordance with the State Administrative Manual (SAM) to analyze the costs, benefits, and processes necessary to implement real time reporting of controlled substances in the operation of CURES.

(c) This section shall be implemented to the extent that sufficient nonstate funds are received to cover the costs to the Board of Pharmacy of providing staff, and for the preparation of the report. The costs incurred by the Board of Pharmacy implementing this section shall be solicited and funded from nongovernmental entities. It is not the responsibility of the Board of Pharmacy to solicit the funds for this study. The costs for the feasibility study report and the staff to support the preparation of the report shall be no more than two hundred fifty thousand dollars ($250,000). Any nonstate funds donated for that purpose are appropriated to the Board of Pharmacy for that purpose.

(d) The board shall submit the feasibility study report to the Legislature on or before July 1, 2007, or within 18 months of receipt of sufficient funding, whichever date is later.

(e) This section shall remain in effect until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2008, deletes or extends that date.

SEC. 7. Section 11190 of the Health and Safety Code is amended to read:

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

(1) The name and address of the patient.

(2) The date.

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

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

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

(A) Full name, address, gender, and date of birth of the patient.

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

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

(D) Quantity of the controlled substance dispensed.

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

(F) Date of dispensing of the prescription.

(2) Each prescriber that dispenses controlled substances shall provide the Department of Justice the information required by this subdivision on a monthly basis in a format set by the Department of Justice pursuant to regulation.

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

SEC. 8. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, 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.

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

O

To the Members of the California State Senate:

I am signing Senate Bill 798, which will establish a voluntary, county-option drug repository and distribution program to distribute surplus medications to persons in need of financial assistance. This program will utilize drugs that would otherwise be discarded to provide free prescriptions to medically indigent patients.

I share the author's concern that some Californians are unable to purchase needed prescription drugs, which is why I proposed the California Pharmacy Assistance Program (Cal Rx) to provide prescription drug discounts to uninsured Californians. The adverse effects of not having access to affordable prescription drugs are serious - increased severity of disease, reduced productivity, and compromised quality of life. While SB 798 is not a comprehensive solution to this important problem; it provides a creative mechanism to take advantage of surplus medication that would otherwise be discarded, and get it in the hands of uninsured low-income Californians who need it.

For these reasons, I am pleased to sign Senate Bill 798.

Sincerely,

Arnold Schwarzenegger

Blank

Senate Bill No. 798

CHAPTER 444

An act to add Division 116 (commencing with Section 150200) to the Health and Safety Code, relating to pharmaceuticals.

[Approved by Governor September 30, 2005. Filed with Secretary of State September 30, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SB 798, Simitian. Prescription drugs: collection and distribution program.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to dispense a medication on prescription in a container that meets the requirements of state and federal law and is correctly labeled.

This bill would authorize a county to establish, by ordinance, a repository and distribution program for purposes of distributing surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. The bill would limit the program to pharmacies owned by or contracting with the county. It would require a county that elects to establish a repository and distribution program to establish procedures for, at a minimum, (1) establishing eligibility for medically indigent patients who may participate in the program, (2) ensuring that eligible patients are not charged for any medications provided under the program, (3) developing a formulary of appropriate medications for the program, (4) ensuring proper safety and management of any medications collected by and maintained under the authority of a licensed pharmacy, and (5) ensuring the privacy of individuals for whom the medication was originally prescribed. The bill would authorize any drug manufacturer legally authorized under federal law to manufacture or sell pharmaceutical drugs, or a licensed health facility, pharmacy wholesaler, or pharmacy to donate medications pursuant to these provisions. Except in cases of noncompliance with the bill, bad faith, or gross negligence, the bill would prohibit certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the bill's provisions.

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

SECTION 1. Division 116 (commencing with Section 150200) is added to the Health and Safety Code, to read:

DIVISION 116. SURPLUS MEDICATION COLLECTION AND DISTRIBUTION

150200. It is the intent of the Legislature in enacting this division to authorize the establishment of a voluntary drug repository and distribution program for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

150201. For purposes of this division, "medication" or "medications" means a dangerous drug, as defined in Section 4022 of the Business and Professions Code.

150202. Notwithstanding any other provision of law, a licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease, may donate unused medications under a program established pursuant to this division.

150203. Notwithstanding any other provision of law, a wholesaler licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code and a drug manufacturer that is legally authorized under federal law to manufacture and sell pharmaceutical drugs may donate unused medications under the voluntary drug repository and distribution program established by a county pursuant to this division.

150204. (a) A county may establish, by ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division may participate in this program to dispense medication donated to the drug repository and distribution program.

(b) A county that elects to establish a repository and distribution program pursuant to this division shall establish procedures for, at a minimum, all of the following:

(1) Establishing eligibility for medically indigent patients who may participate in the program.

(2) Ensuring that patients eligible for the program shall not be charged for any medications provided under the program.

(3) Developing a formulary of medications appropriate for the repository and distribution program.

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a county-owned or county-contracted, licensed pharmacy.

(5) Ensuring the privacy of individuals for whom the medication was originally prescribed.

(c) Any medication donated to the repository and distribution program shall comply with the requirements specified in this division. Medication donated to the repository and distribution program shall meet all of the following criteria:

(1) The medication shall not be a controlled substance.

(2) The medication shall not have been adulterated, misbranded, or stored under conditions contrary to standards set by the United States Pharmacopoeia (USP) or the product manufacturer.

(3) The medication shall not have been in the possession of a patient or any individual member of the public, and in the case of medications donated by a skilled nursing facility, shall have been under the control of staff of the skilled nursing facility.

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

(e) A pharmacist shall use his or her professional judgment in determining whether donated medication meets the standards of this division before accepting or dispensing any medication under the repository and distribution program.

(f) A pharmacist shall adhere to standard pharmacy practices, as required by state and federal law, when dispensing all medications.

(g) Medication that is donated to the repository and distribution program shall be handled in any of the following ways:

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(h) Medication that is donated to the repository and distribution program that does not meet the requirements of this division shall not be distributed under this program and shall be either destroyed or returned to a reverse distributor. This medication shall not be sold, dispensed, or otherwise transferred to any other entity.

(i) Medication donated to the repository and distribution program shall be maintained in the donated packaging units until dispensed to an eligible patient under this program, who presents a valid prescription. When dispensed to an eligible patient under this program, the medication shall be in a new and properly labeled container, specific to the eligible patient and ensuring the privacy of the individuals for whom the medication was initially dispensed. Expired medication shall not be dispensed.

(j) Medication donated to the repository and distribution program shall be segregated from the pharmacy's other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) The pharmacy shall keep complete records of the acquisition and disposition of medication donated to and dispensed under the repository and distribution program. These records shall be kept separate from the pharmacy's other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000), of Division 2 of the Business and Professions Code), including being readily retrievable.

(*l*) Local and county protocols established pursuant to this act shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

(m) County protocols established for packaging, transporting, storing, and dispensing medications that require refrigeration, including, but not limited to, any biological product as defined in Section 351 of the Public Health and Service Act (42 U.S.C. Sec. 262), an intravenously injected drug, or an infused drug, include specific procedures to ensure that these medications are packaged, transported, stored, and dispensed at their appropriate temperatures and in accordance with USP standards and the Pharmacy Law.

(n) Notwithstanding any other provision of law, a participating county-owned or county-contracted pharmacy shall follow the same procedural drug pedigree requirements for donated drugs as it would follow for drugs purchased from a wholesaler or directly from a drug manufacturer.

150205. The following persons and entities shall not be subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with this division:

(a) A prescription drug manufacturer, wholesaler, governmental entity, county-owned or county-contracted licensed pharmacy, or skilled nursing facility.

(b) A pharmacist or health care professional who accepts or dispenses prescription drugs.

150206. The immunities provided in Section 150205 shall not apply in cases of noncompliance with this division, bad faith, or gross negligence.

150207. Nothing in this division shall affect disciplinary actions taken by licensing and regulatory agencies.

O

Senate Concurrent Resolution No. 49

RESOLUTION CHAPTER 123

Senate Concurrent Resolution No. 49—Relative to medication errors.

[Filed with Secretary of State September 14, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, Speier. Medication errors panel.

This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

WHEREAS, Numerous studies establish that medication errors cause injury and death to patients and consumers; and

WHEREAS, The Institute of Medicine estimates the cost for treatment of drug-related morbidity and mortality may run nearly $77 billion a year nationally; and

WHEREAS, Research demonstrates that most injuries resulting from medication errors are not the fault of any individual health care professional, but rather represent the failure of a complex health care system; and

WHEREAS, The Federal Food and Drug Administration has approved 122 chemical compounds since 2002, and over 17,000 existing trade and generic names of products exist, many of which sound alike or are spelled alike; and

WHEREAS, These products are also packaged and distributed in similar shapes and forms; and

WHEREAS, The demand for prescription drugs is expected to substantially increase; and

WHEREAS, Medication errors occur in all settings in which prescription drug products are prescribed, dispensed, furnished, ordered, or otherwise provided; and

WHEREAS, Many factors contribute to a poor understanding by many consumers and patients about their prescriptions, including frequent switching of generic brands that are each different colors and shapes so that the same drug looks different and confuses the patient making it hard to easily spot mistakes; overworked pharmacists; reduced time with physicians for patients to be given important drug information; patients seeing multiple physicians that may be unaware of each other's care plans;

patients often using vitamins, herbs, and over-the-counter drugs that can react with the medications they take and that both the physician and pharmacist do not know about; and

WHEREAS, Research has demonstrated that improved communication between patients and their health professionals is the most effective means of reducing errors and drug misadventures and improving health care outcomes; now, therefore, be it

Resolved by the Senate of the State of California, the Assembly thereof concurring, That a special panel be formed to study causes of medication errors; and be it further

Resolved, That the Legislature shall convene the panel no later than October 1, 2005; and be it further

Resolved, That the panel shall recommend improvements, additions, or changes to be constructed and implemented for the significant improvement of the health care system by reducing errors associated with the delivery of prescription and over-the-counter medications to consumers; and be it further

Resolved, That the Speaker of the Assembly shall appoint to the panel a member of the faculty of a school of pharmac

To the Members of the California State Assembly:

I am returning Assembly Bill 73 without my signature.

This bill would require the Department of Health Services to establish a Web site to facilitate purchasing prescription drugs, including links to Canadian, United Kingdom, and Irish pharmacies. I am supportive of reducing the cost of prescription medications for California residents; however, this bill over-simplifies the complex safety, trade, supply, and pricing issues involved in this marketplace. I am concerned that this bill would establish a mechanism to facilitate an illegal practice, expose the state to potential tort liability, and potentially jeopardize patient safety. Finally, there would be increased fiscal impact on the General Fund for development and implementation of a state drug importation safety program.

Much more can and should be done to assist Californians in receiving cost-effective, quality healthcare. My Administration worked with Senators Ortiz and Poochigian to author Senate Bill 19 and provide safe and legal prescription drugs to over 5 million uninsured Californians at an estimated 40 percent discount. In addition to support from doctors and pharmacists, this effort was supported by consumer groups like the AARP, the AIDS Healthcare Foundation, the Mental Health Association of California, National Multiple Sclerosis Society, California Arthritis Foundation Council, Epilepsy Foundation of Northern California and the Alzheimer's Aid Society.

Unfortunately, despite the overwhelming support from these consumer groups the measure was blocked by the Legislature, so more work needs to be done.

My administration will continue to work to find ways to help California's uninsured have access to safe, legal and affordable prescription drugs.

For these reasons, I am returning this bill without my signature.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 73

Passed the Assembly June 2, 2005

_____

Chief Clerk of the Assembly

Passed the Senate September 8, 2005

_____

Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2005, at _____ o'clock ____M.

_____

Private Secretary of the Governor

CHAPTER _____

An act to add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 73, Frommer. Prescription drugs: importation: procurement.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

Existing law, the Pharmacy Law, provides that any pharmacy located outside of this state that delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state is considered a nonresident pharmacy and requires a nonresident pharmacy to register with the California State Board of Pharmacy and comply with all lawful directions of, and requests for information from, the state in which it is a resident.

Existing federal law requires any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug that is imported or offered for import into the United States to register with the federal Secretary of Health and Human Services, report a list of each drug introduced for commercial distribution, and provide required information and statements.

This bill would establish the California Rx Prescription Drug Web Site Program. The bill would require the State Department of Health Services to administer the program and establish a Web site on or before July 1, 2006, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would require that the Web site, at a minimum, provide information about, and establish electronic links to, certain federal, state, and pharmaceutical programs, pharmacies that are located in Canada, the United Kingdom, and Ireland and that meet specified requirements, and other Web sites.

This bill would authorize the department to assess a fee on international pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing those pharmacies. The bill would require the department's Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site.

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

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

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) The United States is the largest trade market for pharmaceuticals in the world, yet American consumers pay the highest prices for brand name pharmaceuticals in the world.

(c) Increased spending on prescription drugs is a significant driver of increases in overall health care costs, with spending nationwide on prescription drugs rising over 15 percent each year from 2000 to 2002.

(d) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as evidenced by federal government statistics that show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(e) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that year.

(f) The rising cost of prescription drugs also places a significant burden on state government, with the cost of providing prescription drugs to Medi-Cal beneficiaries, to inmates of the Department of Corrections, and to other participants in state programs growing in some cases at over 20 percent annually in recent years.

(g) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy, as shown by a study by the RAND Corporation that found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over 20 percent and subsequently experienced higher rates of emergency room visits and hospital stays.

(h) The rising cost of prescription drugs places a disproportionate burden on communities of color, as shown in a report from the Center for Studying Health System Change that found that African-Americans are about 75 percent and Latinos about 50 percent more likely than nonminorities to not have purchased a prescription drug in 2001 because of cost issues.

(i) A prescription drug is neither safe nor effective to an individual who cannot afford it.

(j) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Prescription Drug Web Site Program

110242. (a) The California Rx Prescription Drug Web Site Program is hereby established.

(b) The State Department of Health Services shall administer the program. The purpose of the program shall be to provide information to California residents and health care providers about options for obtaining prescription drugs at affordable prices.

(c) The department shall establish a Web site on or before July 1, 2006, which shall, at a minimum, provide information about, and electronic links to, all of the following:

(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program.

(2) State programs that provide drugs at discounted prices for California residents.

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

(4) International pharmacies that provide mail-order service to the United States and who meet the requirements of paragraph (2) of subdivision (d).

(5) Other Web sites as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

(d) (1) The Web site shall include price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by international pharmacies that provide mail-order service to the United States and whose Web sites are linked to the department's Web site pursuant to paragraph (2).

(2) The Web site shall provide information about, and establish electronic links to, pharmacies that are located in Canada, the United Kingdom, and Ireland that provide mail-order services to the United States and that meet all of the following requirements:

(A) Are licensed by the province or country, as appropriate, in which they are located.

(B) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, except that for purposes of this section all references to "state" in subdivision (d) of Section 4112 of the Business and Professions Code shall be deemed to refer to the province or other licensing jurisdiction in which the pharmacy is located. Compliance with this subparagraph shall be determined by the department in consultation with the California State Board of Pharmacy.

(C) Require a prescription from a patient's personal physician, who is licensed to practice in the United States.

(D) Require the completion of a relevant medical history profile.

(E) Require a signed patient agreement.

(F) Ship prescription drugs in tamperproof original manufacturer containers to individuals in the United States,

unless the consumer requests to receive the drug in a childproof container.

(G) Include a physical address and pharmacy license number on its company Web site.

(H) Do not furnish any of the following:

(i) A controlled substance.

(ii) A biological product, as defined in Section 351 of the Public Health Service Act (42 U.S.C. Sec. 262).

(iii) An infused drug, including, a peritoneal dialysis solution.

(iv) An intravenously injected drug.

(v) A drug that is inhaled during surgery.

(vi) A drug that requires refrigeration or cannot be safely shipped by mail.

(vii) More than the prescribed amount of a drug or more than a three-month supply of any drug.

(viii) A drug that the consumer indicates he or she has not previously taken.

(ix) A drug for which there is no equivalent drug approved for sale in the United States by the federal Food and Drug Administration.

(I) Sell only prescription drugs that have been approved for sale in the country in which the pharmacy is located by the agency responsible for ensuring the safety of prescription drugs in that country.

(J) Comply with state law regarding the documentation of the pedigree of prescription drugs.

(K) Does not require a consumer to sign a waiver of liability or a release of liability for a negligent act by the pharmacy.

(L) Maintain a service department to respond to consumer inquiries and provide information to consumers about how they may file complaints with the provincial or other applicable licensing authority.

(M) Ensure that all physicians, pharmacists, and technicians in its employ are properly licensed and their licenses are in good standing.

(N) Comply with all personal health and medical information privacy laws applicable to pharmacies located in California.

(O) Any other requirement established by the department to ensure the safety, accessibility, and affordability of prescription drugs.

(3) A pharmacy that seeks to be linked to the department's Web site pursuant to paragraph (2) shall apply to the department. The department may enter into a contract with a pharmacy that it determines meets the requirements of paragraph (2). A contract may be renewed annually upon payment of the fee specified in paragraph (5) provided that the pharmacy continues to comply with the requirements of paragraph (2).

(4) The department may terminate a contract with, and delete an electronic link to, or information about, a pharmacy that the department determines no longer complies with the requirements of paragraph (2). The department shall review within 30 business days any information that it receives regarding a pharmacy's compliance with the requirements of paragraph (2) and shall determine whether the information constitutes grounds for removal of the pharmacy from the Web site.

(5) The department may assess a fee on international pharmacies that the department reviews pursuant to paragraph (2) to offset the cost of reviewing those pharmacies.

(e) The department shall ensure that the Web site established pursuant to this section is coordinated with, and does not duplicate, other Web sites that provide information about prescription drug options and costs.

(f) Any information, including the identity of an international pharmacy, to be posted on the Web site shall first be approved by professional staff of the department before it is posted.

(g) The department shall include on the Web site a notice that informs consumers about state and federal laws governing the importation of prescription drugs and the federal Food and Drug Administration's policy governing personal importation. The notice shall also inform consumers that a pharmacy linked to the Web site is licensed in the country in which it is located and that the department has the right to remove a pharmacy from the Web site if it violates the requirements of paragraph (2) of subdivision (d) or the terms of any agreement between the department and the pharmacy. In addition, the notice shall include a statement that the state accepts no legal liability with respect to any product offered or pharmaceutical services provided by a pharmacy linked to the Web site.

Assembly Bill No. 77

CHAPTER 503

An act to amend Section 14132.01 of the Welfare and Institutions Code, relating to Medi-Cal.

[Approved by Governor October 4, 2005. Filed with Secretary of State October 4, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

AB 77, Frommer. Medi-Cal: clinics: reimbursement.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care benefits, including drugs, prosthetic and orthotic devices, durable medical equipment, medical supplies, and enteral formulae.

Pursuant to a federal waiver, the Medi-Cal program administers a program known as the Family Planning, Access, Care, and Treatment (Family PACT) Waiver Program, under which comprehensive clinical family planning services are provided to any person who has a family income at or below 200% of the federal poverty level and who is eligible to receive those services pursuant to the terms of the waiver.

Under this program, reimbursement for take-home drugs and supplies provided by a licensed community clinic or free clinic, or an intermittent clinic, is required to be the lesser of the amount billed or the Medi-Cal reimbursement rate and shall not exceed the net cost of the drugs or products as provided to retail pharmacies under the Medi-Cal program.

This bill would revise this reimbursement formula and would provide that reimbursement to these clinics for take-home drugs and supplies covered under these provisions shall be reimbursed as described in the bill.

Existing law exempts from the reimbursement formula federally qualified health centers and rural health clinics that have elected to be reimbursed for pharmacy costs based on certain other provisions.

This bill would authorize federally qualified health centers and rural health clinics electing under this provision to bill and be reimbursed pursuant to the bill.

Existing law also requires these clinics to comply with billing amount standards for take-home drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program.

This bill would revise the billing amount standards. The bill would require these clinics to bill the Medi-Cal program and Family PACT Waiver Program for drugs and supplies covered under these programs at the lesser of cost or the clinic's usual charge made to the general public. The bill would define "cost" for purposes of this provision.

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

SECTION 1. Section 14132.01 of the Welfare and Institutions Code is amended to read:

14132.01. (a) Notwithstanding any other provision of law, a community clinic or free clinic licensed pursuant to subdivision (a) of Section 1204 of the Health and Safety Code or an intermittent clinic operating pursuant to subdivision (h) of Section 1206 of the Health and Safety Code, that has a valid license pursuant to Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code shall bill and be reimbursed, as described in this section, for drugs and supplies covered under the Medi-Cal program and Family PACT Waiver Program.

(b) (1) A clinic described in subdivision (a) shall bill the Medi-Cal program and Family PACT Waiver Program for drugs and supplies covered under those programs at the lesser of cost or the clinic's usual charge made to the general public.

(2) For purposes of this section, "cost" means an aggregate amount equivalent to the sum of the actual acquisition cost of a drug or supply plus a clinic dispensing fee not to exceed twelve dollars ($12) per billing unit as identified in either the Family PACT Policies, Procedures, and Billing Instructions Manual, or the Medi-Cal Inpatient/Outpatient Provider Manual governing outpatient clinic billing for drugs and supplies, as applicable. For purposes of this section, "cost" for a take-home drug that is dispensed for use by the patient within a specific timeframe of five or less days from the date medically indicated means actual acquisition cost for that drug plus a clinic dispensing fee, not to exceed seventeen dollars ($17) per prescription. Reimbursement shall be at the lesser of the amount billed or the Medi-Cal reimbursement rate, and shall not exceed the net cost of these drugs or supplies when provided by retail pharmacies under the Medi-Cal program.

(c) A clinic described in subdivision (a) that furnishes services free of charge, or at a nominal charge, as defined in subsection (a) of Section 413.13 of Title 42 of the Code of Federal Regulations, or that can demonstrate to the department, upon request, that it serves primarily low-income patients, and its customary practice is to charge patients on the basis of their ability to pay, shall not be subject to reimbursement reductions based on its usual charge to the general public.

(d) Federally qualified health centers and rural health clinics that are clinics as described in subdivision (a) may bill and be reimbursed as described in this section, upon electing to be reimbursed for pharmaceutical goods and services on a fee-for-service basis, as permitted by subdivision (k) of Section 14132.100.

(e) A clinic that otherwise meets the qualifications set forth in subdivision (a), that is eligible to, but that has elected not to, utilize drugs purchased under the 340B Discount Drug Program for its Medi-Cal patients, shall provide notification to the Health Resources and Services

Administration's Office of Pharmacy Affairs that it is utilizing non-340B drugs for its Medi-Cal patients in the manner and to the extent required by federal law.

O

To the Members of the California State Assembly:

I am returning Assembly Bill (AB) 78 without my signature.

This bill would require pharmacy benefit managers (PBMs) to provide their clients access to detailed information about rebates and other revenue that the pharmacy benefit manager receives from pharmaceutical manufacturers, brokers, consultants or other intermediaries.

This measure is a variation on AB 1960 from 2004 which I vetoed. Although different in details, the main point of AB 78, as with AB 1960, is to compel PBMs to reveal their internal financial arrangements to their clients and potential clients. I vetoed AB 1960 because I believed then that it would have the unintended consequence of increasing drug costs to health plans and other purchasers without providing any real consumer benefit. I have seen no new information to cause me to change that opinion.

Sincerely,

Arnold Schwarzenegger

Assembly Bill No. 78

Passed the Assembly September 7, 2005

_____

Chief Clerk of the Assembly

Passed the Senate September 6, 2005

_____

Secretary of the Senate

This bill was received by the Governor this _____ day of _____, 2005, at _____ o'clock ____M.

_____

Private Secretary of the Governor

CHAPTER _____

An act to add Division 113 (commencing with Section 150000) to the Health and Safety Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 78, Pavley. Pharmacy benefits management.

Existing law provides for the regulation of health care benefits.

This bill would define the term "pharmacy benefits management" as the administration or management of prescription drug benefits. The bill would also define the term "pharmacy benefits manager" as an entity that performs pharmacy benefits management, with 2 exceptions. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers, including specified information about the pharmacy benefit manager's revenues. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts.

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

SECTION 1. Division 113 (commencing with Section 150000) is added to the Health and Safety Code, to read:

DIVISION 113. PHARMACY BENEFITS MANAGEMENT

150000. For purposes of this division, the following definitions shall apply:

(a) "Labeler" means any person who receives prescription drugs from a manufacturer or wholesaler and repackages those drugs for later retail sale and who has a labeler code from the federal Food and Drug Administration under Section 207.20 of Title 21 of the Code of Federal Regulations.

(b) "Pharmacy benefits management" is the administration or management of prescription drug benefits. Pharmacy benefits management shall include all of the following: the procurement of prescription drugs at a negotiated rate for dispensation within

this state, the processing of prescription drug claims, and the administration of payments related to prescription drug claims.

(c) "Pharmacy benefits manager" is any entity that performs pharmacy benefits management.

(d) "Purchaser" is any entity that enters into an agreement with a pharmacy benefits manager for the provision of pharmacy benefit management services.

150001. This division shall not apply to either of the following:

(a) A health care service plan or health insurer if the health care service plan or health insurer offers, administers, or provides pharmacy benefits management services and if those services are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits offered, administered, or provided by that health care service plan or health insurer, nor does the term include an affiliate, subsidiary, or other related entity of the health care service plan or health insurer that would otherwise qualify as a pharmacy benefits manager, as long as the services offered, administered, or provided by the related entity are offered or provided only to enrollees, subscribers, or insureds who are also covered by the health benefits offered, administered, or provided by that health care service plan or health insurer.

(b) The State Department of Health Services, with respect to the implementation of a drug assistance program, including, but not limited to, the implementation of the Aids Drug Assistance Program under Chapter 6 (commencing with Section 120950) of Part 4 of Division 105 and the Medi-Cal program under Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

150002. (a) The contract entered into between the pharmacy benefits manager and the purchaser shall include both of the following:

(1) A disclosure in writing of any fees to be charged for drug utilization reports requested by the purchaser.

(2) The terms of confidentiality for any information received by the purchaser pursuant to subdivision (b).

(b) Except as provided in Section 150003, a pharmacy benefits manager shall provide all of the following information no less frequently than once each year and, at the request of the

purchaser, within 30 days of receipt of the request by the purchaser:

(1) The aggregate amount, for a list of drugs to be specified in the contract, of all rebates and other retrospective utilization discounts that the pharmacy benefits manager receives, directly or indirectly, from pharmaceutical manufacturers or labelers in connection with the purchasing or dispensing of prescription drugs for individuals receiving services under the purchaser's contract.

(2) The nature, type, and amount of all revenue the pharmacy benefits manager receives, directly or indirectly, from each pharmaceutical manufacturer or labeler for any other products or services provided by the pharmacy benefits manager with respect to programs that the purchaser contracts with the pharmaceutical benefits manager to provide.

(3) Any prescription drug utilization information requested by the purchaser relating to utilization by the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

(4) Any financial arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, or other entities that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(5) Any financial arrangements related to the provision of pharmacy benefits management for the purchaser that exist between the pharmacy benefits manager and any brokers, consultants, consulting companies, or other intermediaries.

150003. (a) (1) Subject to paragraph (2), a pharmacy benefits manager is not required to make the disclosures required in Section 150002 unless and until the purchaser agrees in writing to maintain the disclosed information as confidential proprietary information. The agreement may provide for equitable and legal remedies in the event of a violation of this confidentiality provision. The agreement may authorize the purchaser to disclose the confidential proprietary information to persons or entities with whom the purchaser contracts to provide consultation regarding pharmacy services and may require those persons or entities to treat the information as confidential proprietary information.

(2) In an effort to avoid the disclosures required by Section 150002, a pharmacy benefits manager may not refuse to execute a confidentiality agreement with a purchaser as required under paragraph (1) that conforms with accepted industry standards and may not insist upon onerous or unreasonable terms.

(b) For purposes of this section, "proprietary information" includes trade secrets and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers, and personnel held by a pharmacy benefits manager and used for its business purposes.

(c) Nothing in this division shall be construed to prevent a purchaser from disclosing confidential proprietary information as required by law or court order.

Assembly Bill No. 302

CHAPTER 506

An act to amend Sections 3613, 3624.5, 3627, 3628, 3633.1, 3635, 3640, 3640.1, 3640.5, 4024, 4039, 4040, 4059, 4059.5, 4060, 4061, 4076, 4142, 4170, 4174, and 4175 of, to add Sections 5588.1, 5588.2, 5588.3, and 5588.4 to, to repeal Section 5589 of, and to repeal and add Section 5588 of, the Business and Professions Code, and to amend Sections 11150, 11165, and 11210 of the Health and Safety Code, relating to professions and vocations, and declaring the urgency thereof, to take effect immediately.

[Approved by Governor October 4, 2005. Filed with Secretary of State October 4, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

AB 302, Committee on Business and Professions. Professions and vocations.

(1) Existing law, the Naturopathic Doctors Act, provides for the licensure and regulation of naturopathic doctors by the Bureau of Naturopathic Medicine in the Department of Consumer Affairs. Existing law authorizes the bureau to license an applicant who graduated prior to 1986 if the applicant passed a state naturopathic licensing examination and certain requirements are satisfied.

This bill would also authorize the bureau to license an applicant who graduated prior to 1986 if the applicant passed a Canadian Province naturopathic licensing examination.

(2) Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy and makes a violation of its provisions a crime. Existing law prohibits a person from furnishing any dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. Existing law, the Uniform Controlled Substances Act, authorizes a pharmacist, in specified circumstances, to write or issue a prescription. Existing law, the Naturopathic Doctors Act, authorizes naturopathic doctors to prescribe or order drugs in specified circumstances.

This bill would add naturopathic doctors who prescribe or order drugs in those specified circumstances to the list of persons authorized to furnish dangerous drugs and write or issue prescriptions under the Pharmacy Law and the Uniform Controlled Substances Act. The bill would charge the Bureau of Naturopathic Medicine with certain responsibilities with respect to compliance with and enforcement of the Pharmacy Law with respect to its licensees. The bill would also make related changes.

(3) Existing law provides for the licensing and regulation of architects by the California Architects Board. Existing law requires that a settlement

or arbitration award in excess of $5,000 of a claim or action for damages caused by a licensee's fraud, deceit, negligence, incompetence, or recklessness in practice be reported to the board by insurers and licensees.

This bill would delete these requirements and would instead require a licensee, a liability insurer, or a governmental agency that self insures a licensee to submit a report to the board meeting certain requirements where there is a civil action judgment, settlement, arbitration award, or administrative action resulting in a judgment, settlement, or arbitration award against the licensee in an action alleging fraud, deceit, misrepresentation, breach or violation of contract, negligence, incompetence, or recklessness by the licensee in the practice of architecture if the amount or value of the judgment, settlement, or award is $5,000 or more. The bill would authorize the board to adopt regulations defining the reporting requirements.

(4) Existing law provides for the licensing and regulation of architects by the California Architects Board. Existing law requires that a settlement or arbitration award in excess of $5,000 of a claim or action for damages caused by a licensee's fraud, deceit, negligence, incompetence, or recklessness in practice be reported to the board by insurers and licensees.

This bill would delete these requirements and would instead require a licensee, a liability insurer, or a governmental agency that self insures a licensee to submit a report to the board meeting certain requirements where there is a civil action judgment, settlement, arbitration award, or administrative action resulting in a judgment, settlement, or arbitration award against the licensee in an action alleging fraud, deceit, misrepresentation, breach or violation of contract, negligence, incompetence, or recklessness by the licensee in the practice of architecture if the amount or value of the judgment, settlement, or award is $5,000 or more. The bill would authorize the board to adopt regulations defining the reporting requirements.

(5) Because a violation of the provisions relating to pharmacy would be a crime, the bill 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.

(6) The bill would declare that it is to take effect immediately as an urgency statute.

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

SECTION 1. Section 3613 of the Business and Professions Code is amended to read:

3613. The following definitions apply for the purposes of this chapter:

(a) "Bureau" means the Bureau of Naturopathic Medicine within the Department of Consumer Affairs.

(b) "Naturopathic childbirth attendance" means the specialty practice of natural childbirth by a naturopathic doctor that includes the management of normal pregnancy, normal labor and delivery, and the normal postpartum period, including normal newborn care.

(c) "Naturopathic medicine" means a distinct and comprehensive system of primary health care practiced by a naturopathic doctor for the diagnosis, treatment, and prevention of human health conditions, injuries, and disease.

(d) "Naturopathic doctor" means a person who holds an active license issued pursuant to this chapter.

(e) "Naturopathy" means a noninvasive system of health practice that employs natural health modalities, substances, and education to promote health.

(f) "Drug" means any substance defined as a drug by Section 11014 of the Health and Safety Code.

SEC. 2. Section 3624.5 of the Business and Professions Code is amended to read:

3624.5. (a) This chapter does not apply to a practitioner licensed as a naturopathic doctor in another state or country who meets both of the following requirements:

(1) The practitioner is in consultation with a licensed practitioner of this state, or is an invited guest of any of the following for the purpose of professional education through lectures, clinics, or demonstrations:

(A) The California Medical Association.

(B) The California Podiatric Medical Association.

(C) The California Naturopathic Doctors Association.

(D) A component county society of subparagraph (A), (B), or (C).

(2) The practitioner does not open an office, appoint a place to meet patients, receive calls from patients, give orders, or have ultimate authority over the care or primary diagnosis of a patient.

SEC. 2.1. Section 3627 of the Business and Professions Code is amended to read:

3627. (a) The bureau shall establish a naturopathic formulary advisory committee to determine a naturopathic formulary based upon a review of naturopathic medical education and training.

(b) The naturopathic formulary advisory committee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, pharmacists, and naturopathic doctors.

(c) The naturopathic formulary advisory committee shall review naturopathic education, training, and practice and make specific recommendations regarding the prescribing, ordering, and furnishing authority of a naturopathic doctor and the required supervision and protocols for those functions.

(d) The bureau shall make recommendations to the Legislature not later than January 1, 2007, regarding the prescribing and furnishing authority of

a naturopathic doctor and the required supervision and protocols, including those for the utilization of intravenous and ocular routes of prescription drug administration. The naturopathic formulary advisory committee and the bureau shall consult with physicians and surgeons, pharmacists, and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

SEC. 2.2. Section 3628 of the Business and Professions Code is amended to read:

3628. (a) The bureau shall establish a naturopathic childbirth attendance advisory committee to issue recommendations concerning the practice of naturopathic childbirth attendance based upon a review of naturopathic medical education and training.

(b) The naturopathic childbirth attendance advisory committee shall be composed of an equal number of representatives from the clinical and academic settings of physicians and surgeons, midwives, and naturopathic doctors.

(c) The naturopathic childbirth attendance advisory committee shall review naturopathic education, training, and practice and make specific recommendations to the Legislature regarding the practice of naturopathic childbirth attendance.

(d) The bureau shall make recommendations to the Legislature not later than January 1, 2007. The naturopathic childbirth attendance advisory committee and the bureau shall consult with physicians and surgeons, midwives, and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

SEC. 3. Section 3633.1 of the Business and Professions Code is amended to read:

3633.1. The bureau may grant a license to an applicant who meets the requirements of Section 3630, but who graduated prior to 1986, pre-NPLEX, and passed a state or Canadian Province naturopathic licensing examination. Applications under this section shall be received no later than December 31, 2007.

SEC. 4. Section 3635 of the Business and Professions Code is amended to read:

3635. (a) In addition to any other qualifications and requirements for licensure renewal, the bureau shall require the satisfactory completion of 60 hours of approved continuing education biennially. This requirement is waived for the initial license renewal. The continuing education shall meet the following requirements:

(1) At least 20 hours shall be in pharmacotherapeutics.

(2) No more than 15 hours may be in naturopathic medical journals or osteopathic or allopathic medical journals, or audio or videotaped presentations, slides, programmed instruction, or computer-assisted instruction or preceptorships.

(3) No more than 20 hours may be in any single topic.

(4) No more than 15 hours of the continuing education requirements for the specialty certificate in naturopathic childbirth attendance shall apply to the 60 hours of continuing education requirement.

(b) The continuing education requirements of this section may be met through continuing education courses approved by the California Naturopathic Doctors Association, the American Association of Naturopathic Physicians, the Medical Board of California, the California State Board of Pharmacy, the State Board of Chiropractic Examiners, or other courses approved by the bureau.

SEC. 5. Section 3640 of the Business and Professions Code is amended to read:

3640. (a) A naturopathic doctor may order and perform physical and laboratory examinations for diagnostic purposes, including, but not limited to, phlebotomy, clinical laboratory tests, speculum examinations, orificial examinations, and physiological function tests.

(b) A naturopathic doctor may order diagnostic imaging studies, including X-ray, ultrasound, mammogram, bone densitometry, and others, consistent with naturopathic training as determined by the bureau, but shall refer the studies to an appropriately licensed health care professional to conduct the study and interpret the results.

(c) A naturopathic doctor may dispense, administer, order, and prescribe or perform the following:

(1) Food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, all dietary supplements and nonprescription drugs as defined by the federal Food, Drug, and Cosmetic Act, consistent with the routes of administration identified in subdivision (d).

(2) Hot or cold hydrotherapy; naturopathic physical medicine inclusive of the manual use of massage, stretching, resistance, or joint play examination but exclusive of small amplitude movement at or beyond the end range of normal joint motion; electromagnetic energy; colon hydrotherapy; and therapeutic exercise.

(3) Devices, including, but not limited to, therapeutic devices, barrier contraception, and durable medical equipment.

(4) Health education and health counseling.

(5) Repair and care incidental to superficial lacerations and abrasions, except suturing.

(6) Removal of foreign bodies located in the superficial tissues.

(d) A naturopathic doctor may utilize routes of administration that include oral, nasal, auricular, ocular, rectal, vaginal, transdermal, intradermal, subcutaneous, intravenous, and intramuscular.

(e) The bureau may establish regulations regarding ocular or intravenous routes of administration that are consistent with the education and training of a naturopathic doctor.

(f) Nothing in this section shall exempt a naturopathic doctor from meeting applicable licensure requirements for the performance of clinical laboratory tests.

(g) The authority to use all routes for furnishing prescription drugs as described in Section 3640.5 shall be consistent with the oversight and supervision requirements of Section 2836.1.

SEC. 5.1. Section 3640.1 of the Business and Professions Code is amended to read:

3640.1. The bureau shall make recommendations to the Legislature not later than January 1, 2007, regarding the potential development of scope and supervision requirements of a naturopathic doctor for the performance of minor office procedures. The bureau shall consult with physicians and surgeons and licensed naturopathic doctors in developing the findings and recommendations submitted to the Legislature.

SEC. 6. Section 3640.5 of the Business and Professions Code is amended to read:

3640.5. Nothing in this chapter or any other provision of law shall be construed to prohibit a naturopathic doctor from furnishing or ordering drugs when all of the following apply:

(a) The drugs are furnished or ordered by a naturopathic doctor in accordance with standardized procedures or protocols developed by the naturopathic doctor and his or her supervising physician and surgeon.

(b) The naturopathic doctor is functioning pursuant to standardized procedure, as defined by subdivisions (a), (b), (d), (e), (h), and (i) of Section 2836.1 and paragraph (1) of subdivision (c) of Section 2836.1, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the naturopathic doctor, and, where applicable, the facility administrator or his or her designee.

(c) The standardized procedure or protocol covering the furnishing of drugs shall specify which naturopathic doctors may furnish or order drugs, which drugs may be furnished or ordered under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the naturopathic doctor's competence, including peer review, and review of the provisions of the standardized procedure.

(d) The furnishing or ordering of drugs by a naturopathic doctor occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(1) Collaboration on the development of the standardized procedure.

(2) Approval of the standardized procedure.

(3) Availability by telephonic contact at the time of patient examination by the naturopathic doctor.

(e) For purposes of this section, a physician and surgeon shall not supervise more than four naturopathic doctors at one time.

(f) Drugs furnished or ordered by a naturopathic doctor may include Schedule III through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the naturopathic doctor and

physician and surgeon as specified in the standardized procedure. When Schedule III controlled substances, as defined in Section 11056 of the Health and Safety Code, are furnished or ordered by a naturopathic doctor, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the naturopathic doctor's standardized procedure relating to controlled substances shall be provided upon request, to a licensed pharmacist who dispenses drugs, when there is uncertainty about the naturopathic doctor furnishing the order.

(g) The bureau has certified that the naturopathic doctor has satisfactorily completed adequate coursework in pharmacology covering the drugs to be furnished or ordered under this section. The bureau shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term "furnishing" in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include both of the following:

(1) Ordering a drug in accordance with the standardized procedure.

(2) Transmitting an order of a supervising physician and surgeon.

(i) For purposes of this section, "drug order" or "order" means an order for medication which is dispensed to or for an ultimate user, issued by a naturopathic doctor as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations.

(j) Notwithstanding any other provision of law, the following apply:

(1) A drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician.

(2) All references to prescription in this code and the Health and Safety Code shall include drug orders issued by naturopathic doctors.

(3) The signature of a naturopathic doctor on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 7. Section 4024 of the Business and Professions Code is amended to read:

4024. (a) Except as provided in subdivision (b), "dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or upon an order to furnish drugs or transmit a prescription from a certified nurse-midwife, nurse practitioner, physician assistant, naturopathic doctor pursuant to Section 3640.5, or pharmacist acting within the scope of his or her practice.

(b) "Dispense" also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, podiatrist, or veterinarian, or by a certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant acting within the scope of his or her practice.

SEC. 8. Section 4039 of the Business and Professions Code is amended to read:

4039. "Physicians," "dentists," "optometrists," "pharmacists," "podiatrists," "veterinarians," "veterinary surgeons," "registered nurses," "naturopathic doctors," and "physician's assistants" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California, and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065, when acting within the scope of that section.

SEC. 9. 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 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(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 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 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 (3) of subdivision (b) 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. 10. Section 4059 of the Business and Professions Code is amended to read:

4059. (a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices

distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Health Services. The physician prescribing the dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Examining Committee of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

SEC. 11. Section 4059.5 of the Business and Professions Code, as added by Section 11.5 of Chapter 857 of the Statutes of 2004, 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 may 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. 12. 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 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. 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. 13. Section 4061 of the Business and Professions Code is amended to read:

4061. (a) No manufacturer's sales representative shall distribute any dangerous drug or dangerous device as a complimentary sample without the written request of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. However, a certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to a protocol described in Section 3502.1, or a naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, may sign for the request and receipt of complimentary samples of a dangerous drug or dangerous device that has been identified in the standardized procedure, protocol, or practice agreement. Standardized procedures, protocols, and practice agreements shall include specific approval by a physician. A review process, consistent with the requirements of Section 2725, 3502.1, or 3640.5, of the complimentary samples requested and received by a nurse practitioner, certified nurse-midwife, physician assistant, or naturopathic doctor, shall be defined within the standardized procedure, protocol, or practice agreement.

(b) Each written request shall contain the names and addresses of the supplier and the requester, the name and quantity of the specific dangerous drug desired, the name of the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor, if applicable, receiving the samples pursuant to this section, the date of receipt, and the name and quantity of the dangerous drugs or dangerous devices provided. These records shall be preserved by the supplier with the records required by Section 4059.

(c) Nothing in this section is intended to expand the scope of practice of a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor.

SEC. 14. 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 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 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 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(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 subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(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. 15. Section 4142 of the Business and Professions Code is amended to read:

4142. Except as otherwise provided by this article, no hypodermic needle or syringe shall be sold at retail except upon the prescription of a physician, dentist, veterinarian, podiatrist, or naturopathic doctor pursuant to Section 3640.7.

SEC. 16. Section 4170 of the Business and Professions Code is amended to read:

4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

(1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.

(2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.

(3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.

(4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.

(5) The prescriber does not use a dispensing device unless he or she personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).

(6) The prescriber, prior to dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.

(7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.

(8) A certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.

(b) The Medical Board of California, the State Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Committee shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c) "Prescriber," as used in this section, means a person, who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, or a certificate to practice podiatry, and who is duly registered by the Medical Board of California, the State

Board of Optometry, the Bureau of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, or the Board of Osteopathic Examiners of this state.

SEC. 17. 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.

SEC. 18. Section 4175 of the Business and Professions Code is amended to read:

4175. (a) The California State Board of Pharmacy shall promptly forward to the appropriate licensing entity, including the Medical Board of California, the Veterinary Medical Board, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Bureau of Naturopathic Medicine, or the Physician Assistant Committee, all complaints received related to dangerous drugs or dangerous devices dispensed by a prescriber, certified nurse-midwife, nurse practitioner, naturopathic doctor, or physician assistant pursuant to Section 4170.

(b) All complaints involving serious bodily injury due to dangerous drugs or dangerous devices dispensed by prescribers, certified nurse-midwives, nurse practitioners, naturopathic doctors, or physician assistants pursuant to Section 4170 shall be handled by the Medical Board of California, the Dental Board of California, the State Board of Optometry, the Osteopathic Medical Board of California, the Bureau of Naturopathic Medicine, the Board of Registered Nursing, the Veterinary Medical Board, or the Physician Assistant Committee as a case of greatest potential harm to a patient.

SEC. 19. Section 5588 of the Business and Professions Code is repealed.

SEC. 20. Section 5588 is added to the Business and Professions Code, to read:

5588. (a) A licensee shall report to the board in writing within 30 days of the date the licensee has knowledge of any civil action judgment, settlement, arbitration award, or administrative action resulting in a judgment, settlement, or arbitration award against the licensee in any action alleging fraud, deceit, negligence, incompetence, or recklessness by the licensee in the practice of architecture if the amount or value of the judgment, settlement, or arbitration award is five thousand dollars ($5,000) or greater.

(b) The report required by subdivision (a) shall be signed by the licensee and shall set forth the facts that constitute the reportable event. If

the reportable event involves the action of an administrative agency or court, the report shall set forth all of the following:

(1) The title of the matter.

(2) The court or agency name.

(3) The docket number.

(4) The claim or file number.

(5) The date on which the reportable event occurred.

(c) A licensee shall promptly respond to oral or written inquiries from the board concerning the reportable events, including inquiries made by the board in conjunction with license renewal.

(d) Failure of a licensee to report to the board in the time and manner required by this section shall be grounds for disciplinary action.

SEC. 21. Section 5588.1 is added to the Business and Professions Code, to read:

5588.1. (a) Within 30 days of payment of all or any portion of a civil action judgment, settlement, or arbitration award described in Section 5588 against a licensee of the board in which the amount or value of the judgment, settlement, or arbitration award is five thousand dollars ($5,000) or greater, any insurer providing professional liability insurance to that licensee or architectural entity shall report to the board all of the following:

(1) The name of the licensee.

(2) The claim or file number.

(3) The amount or value of the judgment, settlement, or arbitration award.

(4) The amount paid by the insurer.

(5) The identity of the payee.

(b) Within 30 days of payment of all or any portion of any civil action judgment, settlement, or arbitration award described in Section 5588 against a licensee of the board in which the amount or value of the judgment, settlement, or arbitration award is five thousand dollars ($5,000) or greater, any state or local governmental agency that self insures that licensee shall report to the board all of the following:

(1) The name of the licensee.

(2) The claim or file number.

(3) The amount or value of the judgment, settlement, or arbitration award.

(4) The amount paid.

(5) The identity of the payee.

SEC. 22. Section 5588.2 is added to the Business and Professions Code, to read:

5588.2. The requirements of Section 5588 and 5588.1 shall apply if a party to the civil action, settlement, arbitration award, or administrative action is or was a sole proprietorship, partnership, firm, corporation, or state or local governmental agency in which a licensee is or was an owner, partner, member, officer, or employee and is or was a licensee in

responsible control of that portion of the project that was the subject of the civil judgment, settlement, arbitration award, or administrative action.

SEC. 23. Section 5588.3 is added to the Business and Professions Code, to read:

5588.3. Notwithstanding any other provision of law, a licensee shall not be considered to have violated a confidential settlement agreement or other confidential agreement by providing a report to the board as required by this article.

SEC. 24. Section 5588.4 is added to the Business and Professions Code, to read:

5588.4. The board may adopt regulations to further define the reporting requirements of Sections 5588 and 5588.1.

SEC. 25. Section 5589 of the Business and Professions Code is repealed.

SEC. 26. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

SEC. 27. Section 11165 of the Health and Safety Code is amended to read:

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

for the electronic monitoring of the prescribing and dispensing of Schedule II and Schedule III controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

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

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

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

(1) Full name, address, gender, and date of birth of the patient.

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

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

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

(5) Quantity of the controlled substance dispensed.

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

(7) Date of issue of the prescription.

(8) Date of dispensing of the prescription.

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

SEC. 28. Section 11210 of the Health and Safety Code is amended to read:

11210. A physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code may prescribe for, furnish to, or administer controlled substances to his or her patient when the patient is suffering from a disease, ailment, injury, or infirmities attendant upon old age, other than addiction to a controlled substance.

The physician, surgeon, dentist, veterinarian, naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only when in good faith he or she believes the disease, ailment, injury, or infirmity requires the treatment.

The physician, surgeon, dentist, veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or podiatrist, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, or a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code shall prescribe, furnish, or administer controlled substances only in the quantity and for the length of time as are reasonably necessary.

SEC. 29. 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.

SEC. 30. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to make needed changes to licensing and regulatory provisions relative to professions and vocations as soon as possible, it is necessary that this act take effect immediately.

O