2006

Watch Bills

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ASSEMBLY BILL No. 1908

Introduced by Assembly Member Karnette

January 26, 2006

An act to add Section 14105.16 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 1908, as introduced, Karnette. Medi-Cal: pharmacy reimbursement.

Existing law provides for the Medi–Cal program, which is administered by the State Department of Health Services, pursuant to which medical benefits, including prescription drugs, are provided to public assistance recipients and certain other low–income persons.

This bill would require the department to reimburse for medications provided to Medi-Cal recipients for intravenous or infusion drug therapy in a manner that is consistent with the services provided, in order to ensure that patients receiving these services continue to receive appropriate care and continuity of their drug regimen.

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

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

1 SECTION 1. Section 14105.16 is added to the Welfare and
2 Institutions Code, to read:
3 14105.16. The department shall reimburse for medications
4 provided to Medi-Cal recipients for intravenous or infusion drug
5 therapy in a manner that is consistent with the services provided,

1 in order to ensure that patients receiving these services continue
2 to receive appropriate care and continuity of their drug regimen.

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AMENDED IN ASSEMBLY MARCH 23, 2006

AMENDED IN ASSEMBLY MARCH 20, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2057

Introduced by Assembly Member Cogdill

February 15, 2006

An act to amend Sections 11100 and 11106 of~~, and to add Section 11383.5 to,~~ the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2057, as amended, Cogdill. Controlled substances.

~~(1)~~ Existing law generally provides that any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes to any person or entity in this or any other state any of a list of substances shall submit a report to the Department of Justice of all of those transactions, and shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice, as specified. Any person who does not submit a report as required, who submits a false report, or who sells, transfers, or furnishes a substance without a permit is guilty of a crime.

Existing law provides, however, that the above reporting requirements are not applicable to, among others, any specified manufacturer or wholesaler licensed by the California State Board of Pharmacy; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice; and that the above business permit

requirements are not applicable to, among others, any specified manufacturer or wholesaler licensed by the California State Board of Pharmacy and also registered with the federal Drug Enforcement Agency; any state licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food animal drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; or any analytical research facility that is registered with the federal Drug Enforcement Administration of the United States Department of Justice.

This bill would delete the exemption from the reporting requirements for specified manufacturers or wholesalers licensed by the California State Board of Pharmacy; and would revise the exemption from the reporting requirements relating to analytical research facilities to provide that the exemption shall apply to any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than 9 solid grams. Because this bill would make existing crimes applicable to a new category of persons or entities, this bill would impose a state-mandated local program upon local governments.

This bill would furthermore delete the exemptions from the business permit requirements for specified manufacturers or wholesalers licensed by the California State Board of Pharmacy; and for any state licensed health care facility, physician, dentist, podiatrist, veterinarian, or veterinary food animal drug retailer licensed by the California State Board of Pharmacy that administers or furnishes a substance to a patient; and would revise the exemption from the business permit requirements relating to analytical research facilities to provide that the exemption from the business permit requirements shall apply to any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than 9 solid grams. Because this bill would make existing crimes applicable to a new category of persons or entities, this bill would impose a state-mandated local program upon local governments.

~~(2) Existing law further provides, with specified exceptions, that it is a felony for any person, with intent to manufacture methamphetamine, to possess ephedrine or pseudoephedrine, a substance containing ephedrine or pseudoephedrine, or other specified chemicals.~~

~~This bill would, in addition, provide that the possession of more than 1/2 pound of ephedrine or pseudoephedrine or their salts or isomers or other specified chemicals is a felony. The bill would include persons as otherwise authorized by law within an exception to these provisions and would provide that possession of specified chemicals sufficient for the manufacture of a specified derivative substance shall be deemed to be possession of that derivative substance.~~ By creating new crimes or revising existing crimes, this bill would impose a state-mandated local program.

~~(3)~~ The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

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

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

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

1 SECTION 1. Section 11100 of the Health and Safety Code is
2 amended to read:
3 11100. (a) Any manufacturer, wholesaler, retailer, or other
4 person or entity in this state that sells, transfers, or otherwise
5 furnishes any of the following substances to any person or entity
6 in this state or any other state shall submit a report to the
7 Department of Justice of all of those transactions:
8 (1) Phenyl-2-propanone.
9 (2) Methylamine.
10 (3) Ethylamine.
11 (4) D-lysergic acid.
12 (5) Ergotamine tartrate.
13 (6) Diethyl malonate.
14 (7) Malonic acid.
15 (8) Ethyl malonate.

(9) Barbituric acid.
(10) Piperidine.
(11) N-acetylanthranilic acid.
(12) Pyrrolidine.
(13) Phenylacetic acid.
(14) Anthranilic acid.
(15) Morpholine.
(16) Ephedrine.
(17) Pseudoephedrine.
(18) Norpseudoephedrine.
(19) Phenylpropanolamine.
(20) Propionic anhydride.
(21) Isosafrole.
(22) Safrole.
(23) Piperonal.
(24) Thionylchloride.
(25) Benzyl cyanide.
(26) Ergonovine maleate.
(27) N-methylephedrine.
(28) N-ethylephedrine.
(29) N-methylpseudoephedrine.
(30) N-ethylpseudoephedrine.
(31) Chloroephedrine.
(32) Chloropseudoephedrine.
(33) Hydriodic acid.
(34) Gamma-butyrolactone, including butyrolactone; butyrolactone gamma; 4-butyrolactone; 2(3H)-furanone dihydro; dihydro-2(3H)-furanone; tetrahydro-2-furanone; 1,2-butanolide; 1,4-butanolide; 4-butanolide; gamma-hydroxybutyric acid lactone; 3-hydroxybutyric acid lactone and 4-hydroxybutanoic acid lactone with Chemical Abstract Service number (96-48-0).
(35) 1,4-butanediol, including butanediol; butane-1,4-diol; 1,4-butylene glycol; butylene glycol; 1,4-dihydroxybutane; 1,4-tetramethylene glycol; tetramethylene glycol; tetramethylene 1,4-diol with Chemical Abstract Service number (110-63-4).
(36) Red phosphorus, including white phosphorus, hypophosphorous acid and its salts, ammonium hypophosphite, calcium hypophosphite, iron hypophosphite, potassium hypophosphite, manganese hypophosphite, magnesium

hypophosphite, sodium hypophosphite, and phosphorous acid and its salts.

(37) Iodine or tincture of iodine.

(38) Any of the substances listed by the Department of Justice in regulations promulgated pursuant to subdivision (b).

(b) The Department of Justice may adopt rules and regulations in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code that add substances to subdivision (a) if the substance is a precursor to a controlled substance and delete substances from subdivision (a). However, no regulation adding or deleting a substance shall have any effect beyond March 1 of the year following the calendar year during which the regulation was adopted.

(c) (1) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state, prior to selling, transferring, or otherwise furnishing any substance specified in subdivision (a) to any person or business entity in this state or any other state, shall require (A) a letter of authorization from that person or business entity that includes the currently valid business license number or federal Drug Enforcement Administration (DEA) registration number, the address of the business, and a full description of how the substance is to be used, and (B) proper identification from the purchaser. The manufacturer, wholesaler, retailer, or other person or entity in this state shall retain this information in a readily available manner for three years. The requirement for a full description of how the substance is to be used does not require the person or business entity to reveal their chemical processes that are typically considered trade secrets and proprietary information.

(B) For the purposes of this paragraph, "proper identification" for in-state or out-of-state purchasers includes two or more of the following: federal tax identification number; seller's permit identification number; city or county business license number; license issued by the California Department of Health Services; registration number issued by the Federal Drug Enforcement Administration; precursor business permit number issued by the Bureau of Narcotic Enforcement of the California Department of Justice; driver's license; or other identification issued by a state.

(2) (A) Any manufacturer, wholesaler, retailer, or other person or entity in this state that exports a substance specified in subdivision (a) to any person or business entity located in a foreign country shall, on or before the date of exportation, submit to the Department of Justice a notification of that transaction, which notification shall include the name and quantity of the substance to be exported and the name, address, and, if assigned by the foreign country or subdivision thereof, business identification number of the person or business entity located in a foreign country importing the substance.

(B) The department may authorize the submission of the notification on a monthly basis with respect to repeated, regular transactions between an exporter and an importer involving a substance specified in subdivision (a), if the department determines that a pattern of regular supply of the substance exists between the exporter and importer and that the importer has established a record of utilization of the substance for lawful purposes.

(d) (1) Any manufacturer, wholesaler, retailer, or other person or entity in this state that sells, transfers, or otherwise furnishes a substance specified in subdivision (a) to a person or business entity in this state or any other state shall, not less than 21 days prior to delivery of the substance, submit a report of the transaction, which includes the identification information specified in subdivision (c), to the Department of Justice. The Department of Justice may authorize the submission of the reports on a monthly basis with respect to repeated, regular transactions between the furnisher and the recipient involving the substance or substances if the Department of Justice determines that a pattern of regular supply of the substance or substances exists between the manufacturer, wholesaler, retailer, or other person or entity that sells, transfers, or otherwise furnishes the substance or substances and the recipient of the substance or substances, and the recipient has established a record of utilization of the substance or substances for lawful purposes.

(2) The person selling, transferring, or otherwise furnishing any substance specified in subdivision (a) shall affix his or her signature or otherwise identify himself or herself as a witness to the identification of the purchaser or purchasing individual, and

shall, if a common carrier is used, maintain a manifest of the delivery to the purchaser for three years.

(e) This section shall not apply to any of the following:

(1) Any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian.

(2) Any physician, dentist, podiatrist, or veterinarian who administers or furnishes a substance to his or her patients.

(3) Any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than nine solid grams.

(4) A state-licensed health care facility that administers or furnishes a substance to its patients.

(5) (A) Any sale, transfer, furnishing, or receipt of any product that contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder. However, this section shall apply to preparations in solid or liquid dosage form, except pediatric liquid forms, as defined, containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine where the individual transaction involves more than three packages or nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

(B) Any ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine product subsequently removed from exemption pursuant to Section 814 of Title 21 of the United States Code shall similarly no longer be exempt from any state reporting or permitting requirement, unless otherwise reinstated pursuant to subdivision (d) or (e) of Section 814 of Title 21 of the United States Code as an exempt product.

(6) The sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not

exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(7) Any transfer of a substance specified in subdivision (a) for purposes of lawful disposal as waste.

(f) (1) Any person specified in subdivision (a) or (d) who does not submit a report as required by that subdivision or who knowingly submits a report with false or fictitious information shall be punished by imprisonment in a county jail not exceeding six months, by a fine not exceeding five thousand dollars ($5,000), or by both the fine and imprisonment.

(2) Any person specified in subdivision (a) or (d) who has previously been convicted of a violation of paragraph (1) shall, upon a subsequent conviction thereof, be punished by imprisonment in the state prison, or by imprisonment in a county jail not exceeding one year, by a fine not exceeding one hundred thousand dollars ($100,000), or by both the fine and imprisonment.

(g) (1) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any manufacturer, wholesaler, retailer, or other person to sell, transfer, or otherwise furnish a substance specified in subdivision (a) to a person under 18 years of age.

(2) Except as otherwise provided in subparagraph (A) of paragraph (6) of subdivision (e), it is unlawful for any person under 18 years of age to possess a substance specified in subdivision (a).

(3) Notwithstanding any other law, it is unlawful for any retail distributor to (i) sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or (ii) knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids as defined. Except as otherwise provided in this section, the three package per transaction limitation or nine gram per transaction limitation imposed by this paragraph shall apply to any product that is lawfully sold, transferred, or furnished over the counter without a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.), or regulations adopted thereunder, unless exempted from the requirements of the federal Controlled

Substances Act by the federal Drug Enforcement Administration pursuant to Section 814 of Title 21 of the United States Code.

(4) (A) A first violation of this subdivision is a misdemeanor.

(B) Any person who has previously been convicted of a violation of this subdivision shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) For the purposes of this article, the following terms have the following meanings:

(1) "Drug store" is any entity described in Code 5912 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(2) "General merchandise store" is any entity described in Codes 5311 to 5399, inclusive, and Code 5499 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(3) "Grocery store" is any entity described in Code 5411 of the Standard Industrial Classification (SIC) Manual published by the United States Office of Management and Budget, 1987 edition.

(4) "Pediatric liquid" means a nonencapsulated liquid whose unit measure according to product labeling is stated in milligrams, ounces, or other similar measure. In no instance shall the dosage units exceed 15 milligrams of phenylpropanolamine or pseudoephedrine per five milliliters of liquid product, except for liquid products primarily intended for administration to children under two years of age for which the recommended dosage unit does not exceed two milliliters and the total package content does not exceed one fluid ounce.

(5) "Retail distributor" means a grocery store, general merchandise store, drugstore, or other related entity, the activities of which, as a distributor of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products, are limited exclusively to the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products for personal use both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales. "Retail distributor" includes an entity that makes a direct sale, but does not include the parent company of that entity

if the company is not involved in direct sales regulated by this article.

(6) "Sale for personal use" means the sale in a single transaction to an individual customer for a legitimate medical use of a product containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine in dosages at or below that specified in paragraph (3) of subdivision (g). "Sale for personal use" also includes the sale of those products to employers to be dispensed to employees from first-aid kits or medicine chests.

(i) It is the intent of the Legislature that this section shall preempt all local ordinances or regulations governing the sale by a retail distributor of over-the-counter products containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine.

SEC. 2. Section 11106 of the Health and Safety Code is amended to read:

11106. (a) (1) (A) Any manufacturer, wholesaler, retailer, or any other person or entity in this state that sells, transfers, or otherwise furnishes any substance specified in subdivision (a) of Section 11100 to a person or business entity in this state or any other state or who obtains from a source outside of the state any substance specified in subdivision (a) of Section 11100 shall submit an application to, and obtain a permit for the conduct of that business from, the Department of Justice. For any substance added to the list set forth in subdivision (a) of Section 11100 on or after January 1, 2002, the Department of Justice may postpone the effective date of the requirement for a permit for a period not to exceed six months from the listing date of the substance.

(B) An intracompany transfer does not require a permit if the transferor is a permittee. Transfers between company partners or between a company and an analytical laboratory do not require a permit if the transferor is a permittee and a report as to the nature and extent of the transfer is made to the Department of Justice pursuant to Section 11100 or 11100.1.

(C) This paragraph shall not apply to any pharmacist or other authorized person who sells or furnishes a substance upon the prescription of a physician, dentist, podiatrist, or veterinarian; or any analytical research facility that purchases no more than 200 milliliters of a liquid controlled chemical substance or one

kilogram of a solid controlled chemical substance, except in the case of the purchase of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in which case the facility may purchase no more than nine solid grams.

(D) This paragraph shall not apply to the sale, transfer, furnishing, or receipt of any betadine or povidone solution with an iodine content not exceeding 1 percent in containers of eight ounces or less, or any tincture of iodine not exceeding 2 percent in containers of one ounce or less, that is sold over the counter.

(2) Except as provided in paragraph (3), no permit shall be required of any manufacturer, wholesaler, retailer, or other person or entity for the sale, transfer, furnishing, or obtaining of any product which contains ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine and which is lawfully sold, transferred, or furnished over the counter without a prescription or by a prescription pursuant to the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.) or regulations adopted thereunder.

(3) A permit shall be required for the sale, transfer, furnishing, or obtaining of preparations in solid or liquid dosage form containing ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, unless (A) the transaction involves the sale of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine products by retail distributors as defined by this article over the counter and without a prescription, or (B) the transaction is made by a person or business entity exempted from the permitting requirements of this subdivision under paragraph (1).

(b) (1) The department shall provide application forms, which are to be completed under penalty of perjury, in order to obtain information relating to the identity of any applicant applying for a permit, including, but not limited to, the business name of the applicant or the individual name, and if a corporate entity, the names of its board of directors, the business in which the applicant is engaged, the business address of the applicant, a full description of any substance to be sold, transferred, or otherwise furnished or to be obtained, the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100, the training, experience, or education relating to this use, and any additional information requested by the

department relating to possible grounds for denial as set forth in this section, or by applicable regulations adopted by the department.

(2) The requirement for the specific purpose for the use, sale, or transfer of those substances specified in subdivision (a) of Section 11100 does not require applicants or permittees to reveal their chemical processes that are typically considered trade secrets and proprietary business information.

(c) Applicants and permittees shall authorize the department, or any of its duly authorized representatives, as a condition of being permitted, to make any examination of the books and records of any applicant, permittee, or other person, or visit and inspect the business premises of any applicant or permittee during normal business hours, as deemed necessary to enforce this chapter.

(d) An application may be denied, or a permit may be revoked or suspended, for reasons which include, but are not limited to, the following:

(1) Materially falsifying an application for a permit or an application for the renewal of a permit.

(2) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, is or has been convicted of a misdemeanor or felony relating to any of the substances listed under subdivision (a) of Section 11100, any misdemeanor drug-related offense, or any felony under the laws of this state or the United States.

(3) Failure to maintain effective controls against the diversion of precursors to unauthorized persons or entities.

(4) Failure to comply with this article or any regulations of the department adopted thereunder.

(5) Failure to provide the department, or any duly authorized federal or state official, with access to any place for which a permit has been issued, or for which an application for a permit has been submitted, in the course of conducting a site investigation, inspection, or audit; or failure to promptly produce for the official conducting the site investigation, inspection, or audit any book, record, or document requested by the official.

(6) Failure to provide adequate documentation of a legitimate business purpose involving the applicant's or permittee's use of any substance listed in subdivision (a) of Section 11100.

(7) Commission of any act which would demonstrate actual or potential unfitness to hold a permit in light of the public safety and welfare, which act is substantially related to the qualifications, functions, or duties of a permitholder.

(8) If any individual owner, manager, agent, representative, or employee for the applicant who has direct access, management, or control for any substance listed under subdivision (a) of Section 11100, willfully violates or has been convicted of violating, any federal, state, or local criminal statute, rule, or ordinance regulating the manufacture, maintenance, disposal, sale, transfer, or furnishing of any of those substances.

(e) Notwithstanding any other provision of law, an investigation of an individual applicant's qualifications, or the qualifications of an applicant's owner, manager, agent, representative, or employee who has direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for a permit may include review of his or her summary criminal history information pursuant to Sections 11105 and 13300 of the Penal Code, including, but not limited to, records of convictions, regardless of whether those convictions have been expunged pursuant to Section 1203.4 of the Penal Code, and any arrests pending adjudication.

(f) The department may retain jurisdiction of a canceled or expired permit in order to proceed with any investigation or disciplinary action relating to a permittee.

(g) The department may grant permits on forms prescribed by it, which shall be effective for not more than one year from the date of issuance and which shall not be transferable. Applications and permits shall be uniform throughout the state, on forms prescribed by the department.

(h) Each applicant shall pay at the time of filing an application for a permit a fee determined by the department which shall not exceed the application processing costs of the department.

(i) A permit granted pursuant to this article may be renewed one year from the date of issuance, and annually thereafter, following the timely filing of a complete renewal application with all supporting documents, the payment of a permit renewal

fee not to exceed the application processing costs of the department, and a review of the application by the department.

(j) Selling, transferring, or otherwise furnishing or obtaining any substance specified in subdivision (a) of Section 11100 without a permit is a misdemeanor or a felony.

(k) (1) No person under 18 years of age shall be eligible for a permit under this section.

(2) No business for which a permit has been issued shall employ a person under 18 years of age in the capacity of a manager, agent, or representative.

(*l*) (1) An applicant, or an applicant's employees who have direct access, management, or control of any substance listed under subdivision (a) of Section 11100, for an initial permit shall submit with the application one set of 10-print fingerprints for each individual acting in the capacity of an owner, manager, agent, or representative for the applicant, unless the applicant's employees are exempted from this requirement by the Department of Justice. These exemptions may only be obtained upon the written request of the applicant.

(2) In the event of subsequent changes in ownership, management, or employment, the permittee shall notify the department in writing within 15 calendar days of the changes, and shall submit one set of 10-print fingerprints for each individual not previously fingerprinted under this section.

~~SEC. 3. Section 11383.5 is added to the Health and Safety Code, to read:~~

~~11383.5. (a) Any person who possesses one-half pound or more of ephedrine or pseudoephedrine, or any salts, isomers, or salts of isomers of ephedrine or pseudoephedrine; or who possesses one-half pound or more of a substance containing ephedrine or pseudoephedrine, or any salts, isomers, or salts of isomers of ephedrine or pseudoephedrine; or who possesses at the same time one-half pound or more of the substances specified in subparagraphs (A) to (D), inclusive, of paragraph (1) of subdivision (c) of Section 11383, or a combination product thereof, is guilty of a felony and shall be punished by imprisonment in the state prison for two, four, or six years.~~

~~(b) This section shall not apply to drug manufacturers licensed by this state or persons authorized by regulation of the Board of~~

~~Pharmacy to possess those substances or combination of substances, or persons as otherwise authorized by law.~~

~~SEC. 4.~~

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2373 **VERSION: AMENDED APRIL 5, 2006**

AUTHOR: PLESCIA **SPONSOR: MEDICAL TECHNOLOGIES INC.**

RECOMMENDED POSITION:

SUBJECT: AUTOMATED DRUG DELIVERY SYSTEM

Existing Law:

1) Permits the use of an automated drug delivery system (ADDS) in non-profit clinics licenced by the board under specified circumstances. (B&P 4186)

2) Permits skilled nursing and intermediate care facilities to use an ADDS to store and distribute drugs, and specifies requirements for the use of ADDSs in those facilities. (B&P 4119.1)

3) Defines "health facility" in general, and specifically defines "skilled nursing facility," "intermediate care facility," and "nursing facility." (H&S 1250(c), (d), (k))

4) Provides for skilled nursing and intermediate care facilities to use an ADDS to store and distribute drugs, and to track the movement of drugs into and out of the system. (H&S 1261.6)

5) Regulates the manner in which a pharmacist stocks and oversees the removal of drugs from an automated drug delivery system. (H&S 1261.6)

This Bill:

1) Expands the use of ADDS in nursing facilities. (H&S 1261.6(a)(2) Amended)

2) Deletes the requirement that medications removed from an ADDS be labeled specificly to a patient.

(H&S 1261.6(f)(6) Amended)

3) Permits the use of blister pack cards in an ADDS. (H&S 1261.6(i) Amended)

Comment:

1) Author's Intent. The author's intent is to broaden the use and type of automated drug delivery systems used in long-term care facilities. A letter written by the sponsor of the bill states that "the system description currently provided in H&S code 1261.6 does not specifically address a major type of standard industry packaging and a portion of the language in 1261.6(f)(6) is too limiting to enable the use of certain systems. As a result, few pharmacies/facilities are willing to undergo the expense required to install one of these systems. Specifically, the bill would include "blister pack" cards as an approved packaging technology

and clarify that facility or contract personnel licensed by law to administer drugs have access to the entire inventory of drugs stored in the system after the review and approval of a licensed pharmacist."

2) Suggested Amendment: If the board supports the measure then B&P section 4119.1, should be amended to allow nursing facilities use an ADDS to store and distribute drugs. This amendment would make the B&P code consistent with H&S 1261.6, as amended.

3) Previous Legislation. AB 809 (Chapter 310, Statutes of 2001), Automated Drug Delivery Systems, permitted the use of ADDs in clinics licensed by the board. AB 2184 (Chapter 342, Statutes of 2004), Automated Drug Delivery Systems, expanded the use of automated drug delivery system in skilled nursing facilities. AB 522 (Chapter 469, Statutes of 2005) revised existing law by 1) defining "pharmacy services" as the provision of both routine and emergency drugs and biologicals to meet the needs of the patient; 2) requiring a pharmacist reviewing an order for a drug to check for contraindications and adverse drug reactions when an automated drug delivery system is used; and 3) limiting access by licensed personnel to an automated drug delivery system to the prescribed drug authorized by the pharmacist and specific to the patient.

4) Support / Opposition.

Support: California Association of Health Facilities
Crestwood Manor
Modern Health, Inc.
Omnicare
Pacific West Pharmacy, Inc.

Opposition: None on file.

5) History.

2006

Apr. 19 From committee: Do pass, and re-refer to Com. on B. & P.Re-referred. (Ayes 12. Noes 0.) (April 18).Apr. 6 Re-referred to Com. on HEALTH.
Apr. 5 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 14 Referred to Coms. on HEALTH and B. & P.
Feb. 24 From printer. May be heard in committee March 26.
Feb. 23 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 5, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2373

Introduced by Assembly Member Plescia

February 23, 2006

An act to amend Section 1261.6 of the Health and Safety Code, relating to health facilities.

LEGISLATIVE COUNSEL'S DIGEST

AB 2373, as amended, Plescia. Automated drug delivery system.

Existing law provides for skilled nursing and intermediate care facilities that use an automated drug delivery system to store and distribute drugs to accurately track the movement of drugs into and out of the system.

This bill would include nursing facilities within the scope of that requirement.

~~Existing law provides that individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.~~

~~This bill would further limit that access to those persons described above when operating within their professional scope of practice.~~

~~Existing law requires that 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 specifies that the review include specified inspections and reviews.~~

~~This bill would extend the scope of the review to include a related discussion with facility staff using the system.~~

Existing law requires that a pharmacist stock an automated drug delivery system, unless the system utilizes removable pockets,

drawers, or similar technology, in which case stocking may be done outside the facility and delivered to the facility under specified conditions.

This bill would specify that this exception applies to the use of removable pockets, cards, drawers, or similar technology.

Existing law exempts drugs dispensed from an automated drug delivery system that meets specified requirements from certain drug container labeling requirements if, among other things, those drugs are contained in unit dose packaging.

This bill would include within the definition of unit dose packaging drugs packaged in blister pack cards.

Existing law makes a violation of statutory requirements applicable to licensing of the above facilities a crime. By expanding the scope of the application of the above requirements to include nursing facilities that have an automated drug delivery system, this bill would change the definition of a crime, thereby imposing a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 1261.6 of the Health and Safety Code is
2 amended to read:
3 1261.6. (a) (1) For purposes of this section and Section
4 1261.5, an "automated drug delivery system" means a
5 mechanical system that performs operations or activities, other
6 than compounding or administration, relative to the storage,
7 dispensing, or distribution of drugs. An automated drug delivery
8 system shall collect, control, and maintain all transaction
9 information to accurately track the movement of drugs into and
10 out of the system for security, accuracy, and accountability.
11 (2) For purposes of this section, "facility" means a health
12 facility licensed pursuant to subdivision (c), (d), or (k), 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 ~~and operating within the scope of their professional scope of practice~~.

(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 that 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.~~ *shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist.* 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~~ *pockets, cards,* 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~~ *pockets, cards,* 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~~ *pockets, cards,* 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~~ *pockets, cards,* 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, and a related discussion with facility staff using 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. *For purposes of this section, unit dose packaging includes blister pack cards.*

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

1 crime within the meaning of Section 6 of Article XIII B of the
2 California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2730 **VERSION: INTRODUCED**

AUTHOR: NATION **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: MEDI-CAL: CONTRACT DRUG LIST: ADVERTISING

Existing Law:

1) Permits the Department of Health Services (DHS) to enter into contracts with manufacturers of drugs, and requires DHS to maintain a list of those drugs for which contracts have been executed, known as the Medi-Cal contract drug list. Allows patients who are Medi-Cal eligible who lack prescription drug coverage, to purchase drugs at the Medi-Cal rate. (B&P 4425-4426)

2) Requires the Food and Drug Administration (FDA) to regulate the promotion of prescription drugs including the content of direct-to-consumer (DTC) advertising. (21 USC 502(n))

3) Requires advertisers to present accurate information and fairly represent both the benefits and risk of advertised drugs. (21 CFR 202.1(e))

4) Requires pharmaceutical companies to submit all drug advertisements to the FDA when they are first broadcast, published, or distributed through other means. (21 CFR 314.81(b)(3)(i))

This Bill:

1) Prohibits DHS from entering into a contract for a drug, or placing a drug on the Medi-Cal contract drug list, if the drug has been promoted through the use of direct-to-consumer advertising in California, unless either of the following conditions exists:

a. DHS is required to reimburse a provider for a drug that has been promoted through the use of direct-to-consumer advertising in California if the provider has obtained prior authorization from the department to prescribe the drug.
b. Regardless of whether prior authorization was obtained, DHS is required to reimburse a provider who submits an otherwise valid claim for the cost of a drug that was provided to a Medi-Cal beneficiary who began using the drug prior to January 1, 2007, as part of a prescribed therapy, unless that drug is no longer prescribed for the beneficiary's therapy.

2) Defines "direct-to-consumer advertising" as any promotional message or material regarding a drug that may be obtained only by prescription that satisfies each of the following:

a. Employs the brand or pharmacological name of the drug, or employs a description of the drug or its effects without identifying it by name.

b. Is distributed or made available to an audience that is not composed primarily of physicians and surgeons, or other medical professionals authorized to write prescriptions.
c. Takes place through in-person contact, or appears in any form of communications media, including the following:
    i. Print media, such as magazines, journals, and other periodicals, newspapers, and printed material distributed directly to consumers.
    ii. Broadcast media, such as radio and television.
    iii. Electronic media, such as the Internet.
    iv. Telephone communications systems, such as fax machines.

(Welfare and Institutions 14105.331 Added)

Comment:

1) Author's Intent. The author's intent is to "curtail wasteful spending on drug advertising. Pharmaceutical companies are advertising their products to the public without disclosing, among other details, all the side effects associated with the drug or the actual purpose of the drug. As a result, runaway advertising is driving up costs of products and health care."

2) DTC Snapshot. The following information is primarily from a 2002 Government Accounting Office Report, *Prescription Drugs, FDA Oversight of D-T-C Advertising Has Limitations.* (An excerpt of the report is attached.)

Advertising Budgets. In 2001, pharmaceutical companies spent a total of $49.4 billion on research and development (R&D) on new drugs and promotional advertising of existing drugs; $30.3 billion on R&D and $19.1 billion on total promotion. Of the $19.1 billion spent on promotion 80% ($15.3 billion) was targeted at physicians in the form of providing samples and sending sales representatives to meet with physicians; the remaining 20% ($2.7 billion) was spent on DTC advertising.

The GAO report states that between 1999 and 200, the number of prescription drugs dispensed fro the heavily advertised drugs rose 25%, but increased 4% for drugs that were not heavily advertised. Over the same period, prices rose 6% for the most heavily advertised drugs and 9% for the others.

Effectiveness of DTC Advertising. A 2003, report from the Harvard School of Public Health, *Demand Effects of Recent Changes in Prescription Drug Promotion*, May 29, 2003, found that advertising had an elasticity of .10, in five therapeutic classes that were studied, "which means that on average a 10% increase in DTC advertising of a drug within a class results in a 1% increase in sales in the class." While it's not surprising that advertising is effective, it is interesting that DTC advertising did not increase sales of individual drugs. "One possible explanation for this finding is that DTC advertising prompts previously untreated patients to talk to their doctors about advertised treatments, but the discussions may not lead to a prescription for a particular drug."

Types of Advertisements: The FDA permits three types of DTC advertisements, product claim ads, reminder ads, and help-seeking ads. Only the product claim ad is required to mention a drug by name, safety and effectiveness of the drug, a brief summary of benefit and risk, a major statement of risk, and provisions for finding out more information, such as a toll-free number.

Regulation and Enforcement: The FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) is responsible for overseeing and implementing regulations governing DTC advertisement. When the DDMAC finds an advertisement is in violation of the law, the DDMAC will send one of two enforcement letters to the pharmaceutical company; either an untitled or a warning letter. A company that receives a letter is asked to

submit a written response to the DDMAC describing the remedial action it has taken. The GAO found that "the FDA's oversight is generally effective in halting the dissemination of advertisements it views and identifies as misleading." In 2002, DDMAC's internal procedures for drafting regulatory letters were changed. The new procedures lengthen the time it takes DDMAC to draft and send letters to pharmaceutical companies. The increase time has resulted in letters arriving after advertising campaigns have run their course. As a result, consumers never see corrected advertisements.

5) History.

2006

Apr. 18	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 14	Referred to Com. on HEALTH.
Feb. 27	Read first time.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

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ASSEMBLY BILL No. 2730

Introduced by Assembly Member Nation

February 24, 2006

An act to add Section 14105.331 to the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 2730, as introduced, Nation. Medi-Cal: contract drug list: advertising.

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 prescription drug benefits.

Existing law allows the department to enter into contracts with manufacturers of drugs, and requires the department to maintain a list of those drugs for which contracts have been executed, known as the Medi-Cal contract drug list.

This bill would make certain findings and declarations regarding direct-to-consumer advertising of prescription drugs. It would prohibit the department from entering into a contract for a drug, and from placing a drug on the Medi-Cal contract drug list, if the drug has been promoted in California through the use of direct-to-consumer advertising, as defined. The bill would, however, require the department to reimburse a provider for such a drug if the provider has obtained prior authorization from the department to prescribe the drug, or if the drug was provided to a Medi-Cal beneficiary who began using it before January 1, 2007, as part of a prescribed therapy, unless that drug is no longer prescribed for the beneficiary's therapy.

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

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

1 SECTION 1. The Legislature finds and declares the
2 following:
3 (a) The United States is one of only a few countries that allow
4 pharmaceutical companies to advertise prescription drugs.
5 (b) Direct-to-consumer prescription drug advertising is a
6 category of promotional information about specific drug
7 treatments provided directly to consumers by or on behalf of
8 drug companies.
9 (c) Advertisements disseminated to the public are not required
10 in order for pharmaceutical companies to sell their products.
11 (d) Since pharmaceutical companies have been allowed to
12 broadcast advertisements that mention a prescription medication
13 by name without disclosing all of the risks of that medication,
14 consumer demand for medications has increased, resulting in a
15 corresponding increase in the cost of prescriptions and health
16 care delivery.
17 (e) While the pharmaceutical community has tried to convince
18 the public, the United States Congress, and the federal Food and
19 Drug Administration (FDA) that direct-to-consumer
20 advertisements are educational rather than promotional, the goal
21 of these ads is to ensure that patients obtain prescriptions from
22 their doctors for a particular brand of medication, rather than for
23 a competitor's product or for another form of therapy that may be
24 more suitable for an individual patient.
25 (f) Physicians are under increasing pressure from patients who
26 already suspect that health maintenance organization formularies
27 restrict physicians from prescribing the best medication for each
28 patient.
29 (g) The consequences of direct-to-consumer advertising of
30 pharmaceutical drugs include the fact that a physician must spend
31 time defending the reasons why the advertised drug is either
32 unnecessary or detrimental to the patient's health, and the
33 possibility that, if the physician declines to issue a prescription,
34 the patient may turn to other sources, including the Internet, to
35 obtain the product.

(h) According to the United States General Accounting Office, the investigational arm of Congress, pharmaceutical manufacturers spent 1.1 billion dollars in 1997, increasing to about 2.7 billion dollars in 2001, on direct-to-consumer prescription drug advertising alone, with expenditures increasing at double digit rates every year.

(i) Numerous studies have linked the increase in direct-to-consumer advertising to the exponential growth in prescription drug expenditures.

(j) In 1997, the FDA relaxed restrictions on the content of direct-to-consumer prescription drug advertising, withdrawing the prior requirement for a summary of side-effect and adverse reaction information and replacing it with a requirement for a statement about "major risks," but not "all risks," thereby making direct-to-consumer advertisements about prescription drugs more practicable.

SEC. 2. Section 14105.331 is added to the Welfare and Institutions Code, to read:

14105.331. (a) (1) Notwithstanding any other provision of this chapter, and except as provided in paragraphs (2) and (3), the department shall not enter into a contract for a drug, nor place a drug on the Medi-Cal contract drug list, if the drug has been promoted through the use of direct-to-consumer advertising in California.

(2) The department shall reimburse a provider for a drug that has been promoted through the use of direct-to-consumer advertising in California if the provider has obtained prior authorization from the department to prescribe the drug.

(3) Notwithstanding paragraph (2), regardless of whether prior authorization has been obtained, the department shall reimburse a provider who submits an otherwise valid claim for the cost of a drug that was provided to a Medi-Cal beneficiary who began using the drug prior to January 1, 2007, as part of a prescribed therapy, unless that drug is no longer prescribed for the beneficiary's therapy.

(b) For purposes of this section, "direct-to-consumer-advertising" means any promotional message or material regarding a drug that may be obtained only by prescription that satisfies each of the following:

(1) Employs the brand or pharmacological name of the drug, or employs a description of the drug or its effects without identifying it by name.

(2) Is distributed or made available to an audience that is not composed primarily of physicians and surgeons, or other medical professionals authorized to write prescriptions.

(3) Takes place through in-person contact, or appears in any form of communications media, including the following:

(A) Print media, such as magazines, journals, and other periodicals, newspapers, and printed material distributed directly to consumers.

(B) Broadcast media, such as radio and television.

(C) Electronic media, such as the Internet.

(D) Telephone communications systems, such as fax machines.

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United States General Accounting Office

GAO

Report to Congressional Requesters

October 2002

PRESCRIPTION DRUGS

FDA Oversight of Direct-to-Consumer Advertising Has Limitations

GAO

Accountability * Integrity * Reliability

GAO-03-177

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Abbreviations

CDER	Center for Drug Evaluation and Research
DDMAC	Division of Drug Marketing, Advertising, and Communications
DTC	direct-to-consumer
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug and Cosmetic Act
HHS	Department of Health and Human Services
NIHCM	National Institute for Health Care Management Foundation
OCC	Office of the Chief Counsel
PhRMA	Pharmaceutical Research and Manufacturers of America

GAO
Accountability * Integrity * Reliability
United States General Accounting Office
Washington, DC 20548

October 28, 2002

The Honorable Susan Collins
The Honorable Barbara Mikulski
The Honorable James Jeffords
United States Senate

The Honorable Nick Rahall
The Honorable Joseph M. Hoeffel
House of Representatives

Prescription drug spending increased at an annual rate of about 18 percent from 1997 through 2001 and is the fastest growing component of health care spending in the United States. Among the many reasons cited for this increase are growth in the number of patients diagnosed with conditions that can be treated with pharmaceuticals and the development of innovative drugs for some conditions.[1] Spending on direct-to-consumer (DTC) advertising of prescription drugs has tripled in recent years. Pharmaceutical companies promote their products directly to consumers through advertisements in magazines, newspapers, and consumer brochures; on the Internet; and on radio and television. They also promote their products to physicians by sending sales representatives to their offices, providing free samples for distribution to patients, and advertising in professional journals.

The potential consequences of print and broadcast DTC advertising have prompted much debate. Supporters of DTC advertising maintain that it educates consumers about medical conditions and care options and that the increased use of prescription drugs that DTC advertising encourages has improved the public's health. Critics of DTC advertising contend that it is sometimes misleading, leads consumers to seek prescription drugs when other treatments may be more appropriate, and causes some patients to ask their physician to prescribe new drugs that are more expensive but may not be more effective than older drugs. Critics also argue that pharmaceutical companies spend too much money on drug promotion rather than on research and development initiatives.

[1]Robert W. Dubois, Anita J. Chawla, Cheryl A. Neslusan, Mark W. Smith, and Sally Wade, "Explaining Drug Spending Trends: Does Perception Match Reality?" *Health Affairs*, vol. 19 (2000), 231-39.

The Food and Drug Administration (FDA) regulates the promotion of prescription drugs, including the content of DTC advertisements, under the authority of the Federal Food, Drug and Cosmetic Act (FFDCA).[2] The act sets general standards for FDA's regulation of prescription drug advertising directed to consumers and physicians. Regulations implementing the act require that advertisements present accurate information and fairly represent both the benefits and the risks of the advertised drug.[3] The Division of Drug Marketing, Advertising, and Communications (DDMAC) within FDA's Center for Drug Evaluation and Research (CDER) is responsible for implementing the regulations governing DTC advertising. Under the regulations, pharmaceutical companies are required to submit all drug advertisements to FDA when they are first disseminated to the public (that is, broadcast, published, or otherwise distributed).[4] In 1997, FDA issued draft guidance to clarify and offer options on how these regulations applied to advertisements broadcast directly to consumers on radio and television.[5] Since that time, the number of broadcast advertisements for prescription drugs has increased greatly. At the same time, the number of regulatory letters sent by FDA to pharmaceutical companies requesting that the companies remove misleading advertisements from circulation has decreased, leading some observers to question FDA's ability to enforce its regulations. Others argue that this decrease has occurred because pharmaceutical companies are doing a better job of meeting FDA's requirements.

In light of these developments, you asked us to (1) compare spending by pharmaceutical companies on DTC advertising with spending on all promotional activities and on research and development, (2) evaluate the effect of DTC advertising on prescription drug spending and utilization, and (3) evaluate the extent and effectiveness of FDA's oversight of DTC advertising since FDA issued its 1997 draft guidance for broadcast advertisements.

To assess the trends in spending on DTC advertising, overall promotion, and research and development, we reviewed recent reports from the pharmaceutical industry and other organizations. To analyze the effect of

[2]21 U.S.C. § 502(n).

[3]21 C.F.R. § 202.1(e).

[4]21 C.F.R. § 314.81(b)(3)(i).

[5]The guidance was finalized in 1999.

DTC advertising on drug spending and utilization, we reviewed studies on pharmaceutical sales, examined surveys of consumer responses to DTC advertising, and reviewed studies on the impact of DTC advertising.[6] To evaluate the extent and effectiveness of FDA's oversight of DTC advertising, we reviewed federal regulations, and regulatory letters, and interviewed officials from several offices within FDA, including DDMAC. We also interviewed pharmaceutical industry representatives and other key stakeholders, including public interest groups and representatives of the advertising industry. We conducted our work from February 2002 through September 2002 in accordance with generally accepted government auditing standards. See appendix I for a detailed discussion of our scope and methodology.

Results in Brief

Pharmaceutical companies spend more on research and development initiatives than on all drug promotional activities, including DTC advertising. According to industry estimates, pharmaceutical companies spent $30.3 billion on research and development and $19.1 billion on all promotional activities, which includes $2.7 billion on DTC advertising, in 2001. Pharmaceutical companies have increased spending on DTC advertising more rapidly than they have increased spending on research and development. Between 1997 and 2001, DTC advertising spending increased 145 percent, while research and development spending increased 59 percent. Promotion to physicians accounted for more than 80 percent of all promotional spending by pharmaceutical companies in 2001. Total promotional spending was equivalent to 12 percent of drug sales in the United States in 2001.

DTC advertising appears to increase prescription drug spending and utilization. Drugs that are promoted directly to consumers often are among the best-selling drugs, and sales for DTC-advertised drugs have increased faster than sales for drugs that are not heavily advertised to consumers. Most of the spending increase for heavily advertised drugs is the result of increased utilization, not price increases. For example, between 1999 and 2000, the number of prescriptions dispensed for the most heavily advertised drugs rose 25 percent, but increased only 4 percent for drugs that were not heavily advertised. Over the same period,

[6]In this report, we use three terms to describe the magnitude of prescription drug use. "Utilization" refers to the number of prescriptions dispensed. "Spending" and "sales" refer to the amount of money spent for prescription drugs and are a function of both utilization and price.

prices rose 6 percent for the most heavily advertised drugs and 9 percent for the others. The concentration of DTC spending on a small number of drugs for chronic diseases that are likely to have high sales anyway and the simultaneous promotion of these drugs to physicians may contribute to increased utilization and thereby increase sales of DTC-advertised drugs. The recent research literature shows that DTC advertising may cause increases in drug utilization and sales in some cases. In addition, consumer surveys have consistently found that about 5 percent of consumers (or, by our estimate, about 8.5 million consumers annually) have both requested and received from their physician a prescription for a particular drug in response to seeing a DTC advertisement.

While generally effective at halting the dissemination of advertisements it reviews and identifies as misleading, FDA's oversight of DTC advertising has limitations. DDMAC focuses on advertisements that will be widely circulated or that are the most likely to impart misleading impressions of a drug to consumers. For example, DDMAC reviews all broadcast DTC advertisements because of the large number of people who will see them. FDA issues regulatory letters for a small percentage of the advertisements it reviews. From August 1997 through August 2002, FDA issued 88 regulatory letters for violative DTC advertisements. FDA officials told us that pharmaceutical companies that have received regulatory letters have invariably ceased dissemination of the misleading advertisement. However, FDA's oversight has not prevented some pharmaceutical companies from repeatedly disseminating new misleading advertisements for the same drug, and some pharmaceutical companies have failed to submit in a timely manner all newly disseminated advertisements to FDA for review. Furthermore, FDA's oversight has been adversely affected by a January 2002 change in its procedures for reviewing draft regulatory letters that was directed by the Department of Health and Human Services (HHS). This change has significantly increased the time between DDMAC's identification of a misleading advertisement and FDA's request to remove it from dissemination, with the result that some regulatory letters may not be issued until after the advertising campaign has run its course.

In light of the delay caused by the change in policy for review of draft DTC regulatory letters, we are recommending that HHS expedite the review of these letters to ensure that misleading DTC advertisements are withdrawn as soon as possible once identified. In its comments on a draft of this report, HHS explained that the purpose of the change in procedure was to ensure that the letters are based on a solid legal foundation and promote voluntary compliance. HHS agreed that it is important to issue DTC

regulatory letters quickly and said that it intends to reduce the number of days that the letters are under review.

Background

Prescription drug spending and utilization have increased rapidly in recent years. Part of the increase is due to growth in the number of patients diagnosed with conditions that can be treated with pharmaceuticals and the development of innovative drugs for some conditions. The promotion of prescription drugs is regulated by FDA. FDA's regulations and subsequently issued guidance contain specific requirements and explanations regarding the content of advertisements that promote prescription drugs. When requirements are not met, FDA may issue a regulatory letter requesting that the advertisement be withdrawn or revised.

Reasons for Increased Prescription Drug Spending and Utilization

Prescription drug spending has risen steadily over the past decade. Spending on prescription drugs now represents 10 percent of health care expenditures in the United States, and adults aged 65 and older spend nearly 3 percent of their total household expenditures on medications.[7] Increases in overall drug spending are the result of three types of changes in drug prices and drug use: increases in utilization, that is, the number of prescriptions dispensed; price increases; and a shift from older drugs to new, more expensive drugs (newly marketed drugs are generally more expensive than older drugs in the same class). The National Institute for Health Care Management Foundation (NIHCM) reported that overall spending on prescription drugs in the United States increased 17.1 percent from 2000 to 2001: an increase in the number of prescriptions accounted for a 6.7 percent increase, price increases for a 6.3 percent increase, and shifts to higher-cost drugs for a 4.1 percent increase.[8]

Prescription drug utilization in the United States has shown a steady increase over the past decade. The number of prescriptions dispensed in retail pharmacies has grown at an average annual rate of 6 percent since

[7]David H. Kreling, David A. Mott, Joseph B. Wiederholt, Janet Lundy, and Larry Levitt, *Prescription Drug Trends: A Chartbook Update*, pub. no. 3112 (Washington, D.C.: The Henry J. Kaiser Family Foundation, 2001).

[8]NIHCM Foundation, *Prescription Drug Expenditures in 2001: Another Year of Escalating Costs* (Washington, D.C.: NIHCM Foundation, 2002).

1992, reaching nearly 3 billion in 2000.[9] Among the factors besides DTC advertising and promotion to physicians that may contribute to this increased utilization are an aging population that is more dependent on multiple medications for treatment; new medications for conditions that had less effective previous treatments, such as high cholesterol; and increased insurance coverage for medications. In addition, the number of patients diagnosed with chronic conditions for which pharmaceutical treatments are available has increased dramatically. For example, the number of people with arthritis, one of the most frequent causes of disability in the United States, increased from an estimated 38 million in 1990 to 43 million in 1997.[10] Furthermore, for some conditions, such as high cholesterol, increased drug utilization has resulted from biomedical research that has led to a broadening of the guidelines for treatment with drugs.[11]

Countries that do not allow DTC advertising and have publicly funded health systems have also experienced increased drug utilization, and therefore increased spending, because of these same factors. According to a drug marketing research firm, retail pharmacy sales from April 2001 through April 2002 rose 16 percent in the United States, 16 percent in Canada, 10 percent in Germany, and 12 percent in the United Kingdom.[12]

FDA's Requirements for the Content of DTC Advertisements

FDA regulations describe several types of prescription drug advertisements, including DTC advertisements, and the extent to which they are subject to regulation. One type, product claim advertisements, usually mentions a drug's name and the condition it is intended to treat and describes the risks and benefits associated with taking the medication.

[9]Kreling, Mott, Wiederholt, Lundy, and Levitt, *Prescription Drug Trends: A Chartbook Update*, 8.

[10]Centers for Disease Control and Prevention, "Prevalence of Arthritis—United States, 1997," *MMWR*, vol. 50 (2001), 334-6.

[11]National Institutes of Health, *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III), Executive Summary*, NIH pub. no. 01-3670 (Rockville, Md.: NIH, May 2001.)

[12]IMS Health, Inc.,"IMS Health Reports 11% Growth in Retail Pharmacy Drug Sales for the 12 Months to April 2002" (Fairfield, Ct.: IMS Health, 2002), http://www.imshealth.com/public/structu (downloaded September 26, 2002). Based on sales from wholesalers to retail pharmacies, with sales measured in U.S. dollars at a constant exchange rate.

The regulations specify, among other things, that product claim advertisements (1) cannot be false or misleading; (2) must present a fair balance between the risks and the benefits of a drug product; (3) must reveal facts that are material to the representations made in the advertisement or the consequences of using the product as advertised; and (4) must, depending on the medium, either disclose all the risks listed in the product's labeling or make "adequate provision" to disseminate the approved product labeling through other means to the advertisement's audience. Table 1 shows some of the requirements for print and broadcast product claim advertisements.

Table 1: Selected Requirements for Contents of Print and Broadcast Product Claim Advertisements

Advertising medium	Regulatory requirements	Explanation
Print and broadcast	Cannot be false or misleading	Must present information that is not inconsistent with product label
	Must present fair balance	Must include risks and benefits of a drug product
	Must present "facts material"	Must present information relevant to representations made, and describe consequences that may result from recommended use
Print only	Must describe risks	Must disclose all risks in a product's labeling
Broadcast only	Must describe risks	Must present major side effects and contraindications[a] in audio or audio and visual form
	Must make "adequate provision" for directing consumers to labeling information, or provide a brief summary of all necessary information related to risks	Must provide additional sources where consumers can find complete information, such as a toll-free telephone number, a Web site, and a print advertisement in a magazine, and by contacting their physicians; otherwise must summarize risks

[a]Contraindications are symptoms or conditions that make a drug treatment inadvisable.

Sources: 21 C.F.R. § 202; FDA, *Guidance for Industry: Consumer-directed Broadcast Advertisements* (Washington, D.C.: FDA, Aug. 1997).

In 1997, FDA issued draft guidance on how broadcast product claim DTC advertisements could communicate information about the risks of using a drug by finding mechanisms by which to get the product labeling

information to consumers, and thereby meet the adequate provision portion of its regulations.[13] Before this provision of the regulation was clarified in 1997, pharmaceutical companies generally had to provide all of the risk information associated with the medication during the broadcast advertisement. Including all of this risk information in a broadcast DTC advertisement increased the length of the advertisement to the point that such advertising was largely impractical. After the guidance was issued, pharmaceutical companies had an alternative to the requirement that all risks in broadcast advertisements be disclosed. Pharmaceutical companies could meet the regulatory requirements by presenting the major side effects, either in audio or in audio and visual form, and by telling consumers where to find additional information, including how or where to obtain the approved product labeling.

A second type of advertisement is reminder advertisements. These may disclose the name of the product and dosage form (e.g., tablet, syrup) or cost information, but they are not permitted to present its intended use or to make any claims or representations about the product. Under FDA regulations, reminder advertisements are exempt from the risk disclosure requirements.

A third type of advertisement is help-seeking advertisements, which are not regulated by FDA. They do not identify drugs by name and generally discuss a disease or condition and advise the print or broadcast audience to "see your doctor" for possible treatments.

FDA Regulatory Letters

In an effort to stop dissemination of misleading DTC advertisements, FDA sends regulatory letters to companies that are in violation of its regulations. These letters are of two types—untitled letters and warning letters. Untitled letters address violations such as overstating the effectiveness of the drug, suggesting a broader range of indicated uses than the drug has been approved for, and making misleading claims because of inadequate context or lack of balanced risk information. Warning letters address more serious violations, including safety or health risks, or continued violations of the act. Warning letters advise a pharmaceutical firm that FDA may take further enforcement actions, such as seeking judicial remediation, without notifying the company, and

[13]FDA, *Guidance for Industry: Consumer-directed Broadcast Advertisements* (Washington, D.C.: FDA, Aug. 1997).

generally ask the firm to conduct a new advertising campaign to correct inaccurate impressions left by the advertisement. A company that receives either type of letter from FDA is asked to submit a written response to the agency within 14 days describing the remedial actions it has taken.

Pharmaceutical Companies Spend More on Research and Development than on DTC Advertising

Pharmaceutical companies spend more on research and development than on DTC advertising or on all promotional activities combined, according to industry sources. Nonetheless, spending for DTC advertising has increased much faster than spending for all promotional activities or for research and development. More than 80 percent of all promotional spending is directed toward physicians rather than consumers.

Despite Rapid Growth in Spending on DTC Advertising, Pharmaceutical Companies Spend More on Research and Development

According to industry analyses, spending on research and development was more than 10 times higher than spending on DTC advertising in 2001.[14] Pharmaceutical companies spent an estimated $30.3 billion on research and development and $19.1 billion on all promotional activities, including $2.7 billion on DTC advertising in 2001. However, the growth rate of spending on DTC advertising is higher than the rate of increase for spending on total promotion or spending on research and development. As table 2 shows, from 1997 through 2001, spending on DTC advertising increased from $1.1 billion to an estimated $2.7 billion, spending on total promotion increased from $11.0 billion to an estimated $19.1 billion, and research and development spending increased from $19.0 billion to an estimated $30.3 billion.

[14]Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2002* (Washington, D.C.: Pharmaceutical Research and Manufacturers of America, 2002); IMS Health Integrated Promotional Services, "Total U.S. Promotional Spending by Type, 2001" (Fairfield, Ct.: IMS Health, 2002), http://www.imshealth.com/public/structu (downloaded July 17, 2002). We did not independently verify the amounts reported by the Pharmaceutical Research and Manufacturers of America and IMS Health. However, many researchers have consistently cited these data sources, and they represent the best available information.

Table 2: DTC Advertising Spending Compared to Spending on Total Promotion and Research and Development from 1997 to 2001

Dollars in billions

	1997	1998	1999	2000	2001	Percentage spending increase, 1997-2001
DTC	$1.1	$1.3	$1.8	$2.5	$2.7	145
Total promotion[a]	11.0	12.5	13.9	15.7	19.1	74
Research and development	19.0	21.1	22.7	26.0	30.3[b]	59

[a]Total promotion includes DTC advertising.

[b]Estimated spending on research and development.

Sources: For 1997 to 2000 data, Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2002*, 18, 75; for 2001 promotional spending estimates, IMS Health, "Total U.S. Promotional Spending by Type, 2001."

In recent years there has been a shift of DTC advertising from print media to television broadcasts.[15] The percentage of DTC spending devoted to print advertisements declined from 74 percent in 1997 to 35 percent in 2001. Conversely, spending on television advertising increased from 25 percent of all DTC spending in 1997 to 64 percent in 2001. Prescription drug promotion on television escalated from 25 percent to 53 percent of the total spending on DTC advertising from 1997 to 1998.

Most Promotional Spending Is Directed to Physicians

Most promotional spending is targeted to physicians. In each year from 1997 to 2001, providing samples to office-based and hospital-based physicians and sending sales representatives to meet with physicians (practices known as sampling and detailing, respectively) accounted for more than 80 percent of expenditures on promotional activities.[16] (See fig. 1.) The ratio of total promotional spending to drug sales remained fairly

[15]Television broadcasts constitute the majority of nonprint DTC advertising spending.

[16]Kreling, Mott, Wiederholt, Lundy, and Levitt, *Prescription Drug Trends: A Chartbook Update*; IMS Health Integrated Promotional Services, "Total U.S. Promotional Spending by Type, 2001." These figures do not include educational meetings arranged by pharmaceutical companies for physicians, which are not generally considered to be promotional activities. Pharmaceutical companies spent about $1.9 billion on educational meetings in 2000. (See NIHCM Foundation, *Prescription Drugs and Mass Media Advertising, 2000* (Washington, D.C.: NIHCM Foundation, 2001)).

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2856 **VERSION: INTRODUCED**

AUTHOR: HANCOCK **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: INFORMED CONSENT: PRESCRIPTION MEDICATION OFF-LABEL USE

Existing Law:

Food and Drug Administration's (FDA) general position is to allow off-label prescribing if the off-label use is generally accepted practice and there is some scientific evidence that the use is effective.

This Bill:

1) Requires a physician and surgeon to obtain informed consent from a patient before prescribing, administering, or furnishing a prescription medication for an off-label use.
(B&P 2295 Added)

2) Requires a physician and surgeon to inform the patient verbally, in easily understood terms, of all of the following information:

i. The medication is furnished to treat a condition that is not within the indications approved for that medication by the Food and Drug Administration.
ii. The nature, degree, duration, and probability of the side effects and the significant risks of the medication that are commonly known by the medical profession, including the medication's adjuvants, and the degree to which the side effects of the medication may be controlled.
iii. A division of opinion exists as to the efficacy of the use of the medication.
iv. A description of the effect of the medication on the human body.
v. The dosage deemed medically necessary to treat the patient's condition.
vi. The median age group for which the medication is prescribed.
vii. Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommendations the medication instead.
viii. Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommends the medication instead

3) Requires a physician or surgeon to advise the patient that he or she is free to withhold or withdraw consent at any time to the prescribing, administering, or furnishing of the medication.
(B&P 2295 Added)

4) Defines "off-label use" to mean prescribing, administering, or furnishing a prescription medication to treat a condition that is not within the indications for that medication approved by the federal Food and Drug Administration. (B&P 2295 Added)

Comment:

1) Author's Intent. The author's intent is to "promote patient awareness by providing patients full and complete information about medications being prescribed for an off-label use so they can make an informed health care decision. Off-label treatments have medical risks, and patients should be informed of the medical risks especially since some off-label treatments have been linked to deaths or severe side effects. Armed with the knowledge that a prescription is off-label, patients might ask more questions; seek other sources of information, such as the Web; watch more closely for side effects; or ask for an approved treatment instead."

2) Off Label Use. Off-label use, the practice of prescribing a drug for conditions other than those approved by the FDA, is a widely accepted and generally safe practice. The use of off-label prescribing for infants, children, and adolescents is common practice because so few drugs (about twenty percent of all drugs) approved by the FDA are approved for use by children. The American Medical Association (AMA) estimates that about forty percent of the all prescriptions are for off-label uses.

3) History.

2006

Apr. 18	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 20	Referred to Coms. on HEALTH and JUD.
Feb. 27	Read first time.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

ASSEMBLY BILL No. 2856

Introduced by Assembly Member Hancock

February 24, 2006

An act to add Section 2295 to the Business and Professions Code, relating to medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 2856, as introduced, Hancock. Informed consent: prescription medication off-label use.

Existing law, the Medical Practice Act, creates the Medical Board of California that, through its divisions, is responsible for the licensure and regulation of physicians and surgeons. The act imposes certain requirements on physicians and surgeons, including requiring that they provide specified information to patients for particular treatments, and the act makes a violation of those requirements a crime.

This bill would require a physician and surgeon to obtain informed consent from a patient before prescribing, administering, or furnishing a prescription medication for an off-label use, as defined. The bill would specify information that a physician and surgeon is required to provide in order to obtain the patient's informed consent.

Because the bill would specify an additional regulatory requirement under the Medical Practice Act, the violation of which is a crime, it would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. (a) The Legislature finds and declares the
2 following:
3 (1) The right of every patient to receive the basic information
4 that is required to provide full and informed consent is a
5 fundamental tenet of good public health policy and an established
6 principle of law.
7 (2) Existing law requires health care providers to explain to
8 patients medical procedures and treatments before administering
9 those procedures and treatments.
10 (b) It is the intent of the Legislature that every patient be
11 provided full and complete information about medical procedures
12 so that the patient is able to make an informed health care
13 decision. In particular, it is the intent of the Legislature to specify
14 procedures for obtaining informed consent from a patient before
15 prescribing, administering, or furnishing a prescription
16 medication for a use that has not been approved by the federal
17 Food and Drug Administration.
18 SEC. 2. Section 2295 is added to the Business and
19 Professions Code, to read:
20 2295. (a) Before prescribing, administering, or furnishing a
21 prescription medication for an off-label use, a physician and
22 surgeon shall obtain informed consent from the patient. For these
23 purposes, the physician and surgeon shall inform the patient
24 verbally, in easily understood terms, of all of the following
25 information:
26 (1) The medication is furnished to treat a condition that is not
27 within the indications approved for that medication by the federal
28 Food and Drug Administration.
29 (2) The nature, degree, duration, and probability of the side
30 effects and the significant risks of the medication that are
31 commonly known by the medical profession, including the
32 medication's adjuvants, and the degree to which the side effects
33 of the medication may be controlled.

(3) A division of opinion exists as to the efficacy of the use of the medication.

(4) A description of the effect of the medication on the human body.

(5) The dosage deemed medically necessary to treat the patient's condition.

(6) The median age group for which the medication is prescribed.

(7) Available and appropriate medical alternatives to the medication and the reasons the physician and surgeon recommends the medication instead.

(b) After providing the information described in subdivision (a), the physician and surgeon shall advise the patient that he or she is free to withhold or withdraw consent at any time to the prescribing, administering, or furnishing of the medication.

(c) "Off-label use" for purposes of this section, means prescribing, administering, or furnishing a prescription medication to treat a condition that is not within the indications for that medication approved by the federal Food and Drug Administration.

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2877 **VERSION: AMENDED APRIL 6, 2006**

AUTHOR: FROMMER **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: PRESCRIPTION DRUGS: IMPORTATION: PROCUREMENT.

Existing Law:

1) Requires non-resident pharmacies to be licensed by the board. (B&P 4112)

2) Prohibits the importation of prescription drugs except by a drug manufacturer. (21CFR 381)

3) Authorizes the Department of General Services (DGS) to enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs, and authorizes the department to obtain from them discounts, rebates, or refunds as permissible under federal law. (Govt Code 14977-14981)

4) Requires four state agencies to participate in the program and authorizes other state, local, and public agency governmental entities to elect to participate in the program. (Govt Code 14977-14981)

This Bill:

1) Makes a number of legislative findings about the costs and necessity of prescription drugs.

2) Establishes the California Rx Prescription Drug Web Site Program. (H&S 110242 Added)

3) Requires the Department of Health Services (DHS) to establish a Web Site on or before July 1, 2007 that will provide consumers with information on how to purchase prescription drugs more affordably. The Web Site would include the following information:

a. The availability of a prescription drug benefit through Medicare, including the Voluntary Prescription Drug Benefit.
b. Discount drug programs available through the state.
c. Discount drug programs operated by drug manufacturers.
d. Canadian pharmacies that are approved by the department.
e. International pharmacies (Canada, England, and Ireland) that provide mail order service to the Untied States and contract with the department.
f. Links to any other Web sites deemed appropriate by the department.

(H&S 110242 Added)

4) Requires the Web Site to include price comparisons between typical pharmacy prices and international pharmacy prices for the 50 most commonly prescribed drugs. (H&S 110242 Added)

5) Establishes the requirements that must be met for DHS to "certify" a pharmacy located in Canada, England, or Ireland to include:

a. Verification of licensure by the appropriate province or country.
b. Compliance with the requirements that must be met by non-resident pharmacies. This determination will be made in consultation with the board.
c. Requires a prescription from the patient's personal physician.
d. Requires a patient medical history.
e. Requires a signed patient agreement.
f. Requires prescriptions to be mailed in original packaging.
g. Requires physical address and phone number for the pharmacy on the pharmacy Web site.
h. Prohibits the pharmacy from furnishing the following drugs:
    i. Controlled substances.
    ii. Biologics.
    iii. Infused drugs.
    iv. Intravenous drugs.
    v. Drugs inhaled during surgery.
    vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.
i. Sale of only drugs approved by the country in which the pharmacy is located.
j. Comply with California law relating to drug pedigree.
k. Prohibits requiring patients to sign a waiver of liability.
l. Requires the pharmacy to maintain a customer service department.
m. Requires the pharmacy to employ professionals that are licensed in good standing.
n. Requires the pharmacy to comply with California privacy laws.
o. Prohibits filling a prescription if the patient hasn't taken the drug previously.
p. Prohibits furnishing drugs that have no equivalent approved by the FDA.

(H&S 110242 Added)

6) Permits the department to remove approved pharmacies from the Web site if the pharmacy fails to meet any of the above listed requirements. (H&S 110242 Added)

7) Permits the department to assess a fee on international pharmacies to fund this act. (H&S 110242 Added)

8) Requires the DHS to establish the California Rx Prescription Drug Hotline (hotline) to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. (H&S 1010243 Added)

9) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the same information as the California Rx Prescription Drug Web Site. (H&S 1010243 Added)

10) Requires DGS to develop strategies for the state to achieve savings through greater use of generic drugs and would revise the report requirements. (Govt Code 14982 Amended)

11) Repeals an outdate provision requiring DGS to submit a report to the Legislature relating to the department's drug purchasing program. (Govt Code 14981 Repealed)

Comment:

1) Author's Intent. The author's intent is to provide relief for Californians who are "fed up with sky-high pharmaceutical drug prices and concerned about the safety of those drugs." This bill is a conglomeration of AB 74, AB 76, and AB 306.

2) Importation. Existing federal law generally restricts the importation of prescription drugs to drug manufacturers. Federal law can permit the importation of prescription drugs by drug wholesalers and pharmacies if the Secretary of Health and Human Services (Secretary) issues a finding that such a practice would be safe. Such a finding has not been issued by the Secretary.

The Food and Drug Administration (FDA) has for many years allowed individuals to purchase drugs abroad in limited amounts and bring them into the United States for personal use. Recent statements by FDA officials have reinforced that the FDA does not intend to prosecute individuals who import drugs for their own use. However, the FDA has taken legal action against some storefronts that assist consumers in ordering drugs from Canadian pharmacies at lower prices. The FDA has also taken legal action against entities that serve as middlemen between Canadian drug suppliers and those state and local governments that have sought to purchase Canadian drugs for their beneficiaries. In recent months the FDA has also stpeed up confiscation of drugs mailed to the US from non US pharmacies.

3) Price Controls. Consumers seek to purchase drugs from Canadian and EC pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. ***Branded*** drugs can commonly be purchased from Canadian pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board has been sympathetic to the difficulty of those without drug insurance have to obtain the drugs they need.

Much of the public debate regarding the importation of drugs from Canada has focused on the legality of importing drugs. Consumers are seeking Canadian and European Community drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies.

5) Other States. Seven states (Illinois, Minnesota, Nevada, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites.

6) Previous Legislation. AB 73 (Frommer et.al. 2005) and AB 1957 (Frommer et.al. 2004), Drug Importation, are similar if not exact to importation provisions in AB 2877. AB 73 and AB 1957 both made it through the legislature and onto the Governor's desk; both bills were vetoed by the Governor. <u>The board opposed AB 1957, as well as AB 73.</u>

AB 74 (Gordon) California Rx Prescription Drug Hotline would have established a hotline that state residents could call for information about state and federal prescription drug discount programs. AB 74 was recently gutted and amended into a bill relating to the Butte County Healthy Communities Fund.

AB 308 (Baca) Purchasing Pool for Prescription Drugs, would have established a prescription drug purchasing pool that would allow employer health plans and the uninsured to join with state and local governments in the purchase of prescription drugs. AB 308 was gutted and amended into a bill relating to Military service, benefits. The measure was chaptered on September 22, 2005.

7) Support & Opposition.

Support: California Alliance of Retired Americans
California Labor Federation
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Gray Panthers
Greenlining Institute
Health Access California

Oppose: California Health Institute
Pharmaceutical Research and Manufacturers of America

8) History.

2006

Apr. 19	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 3.) (April 18).
Apr. 17	Re-referred to Com. on HEALTH.
Apr. 6	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 15	Referred to Coms. on HEALTH and B. & P.
Feb. 27	Read first time.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

AMENDED IN ASSEMBLY APRIL 6, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2877

Introduced by Assembly Member Frommer

February 24, 2006

An act to *amend Section 14982 of, and to repeal Section 14981 of, the Government Code, and 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 2877, as amended, Frommer. Prescription drugs: importation: procurement.

~~Existing~~

(1) Existing law authorizes the Department of General Services to enter into exclusive or nonexclusive contracts on a bid or negotiated basis with manufacturers and suppliers of single source or multisource drugs. Existing law requires specified state agencies to participate in the prescription drug bulk purchasing program. Existing law requires the department to submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been, or will be, undertaken pursuant to these provisions.

This bill would, among other things, require the department to develop strategies for the state to achieve savings through greater use of generic drugs and would revise the report requirements.

(2) 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 ℞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, 2007, to provide information to California residents about options for obtaining prescription drugs at affordable prices. The bill would, *except as specified,* 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.

This bill would also require the department to establish the California ℞ Prescription Drug Hotline, on or before July 1, 2007, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

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

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

1 SECTION 1. The Legislature finds and declares all of the
2 following:
3 (a) Prescription drugs have become essential for ensuring the
4 health of millions of Californians.
5 (b) The United States is the largest trade market for
6 pharmaceuticals in the world, yet American consumers pay the
7 highest prices for brand name pharmaceuticals in the world.
8 (c) Increased spending on prescription drugs is a significant
9 driver of increases in overall health care costs, with spending
10 nationwide on prescription drugs rising over 15 percent each year
11 from 2000 to 2002.
12 (d) Rising out-of-pocket costs for prescription drugs are
13 placing a growing burden on California consumers, as evidenced
14 by federal government statistics that show that in 2002 the
15 increase in consumers' out-of-pocket costs for prescription drugs
16 was greater than the increase in out-of-pocket costs for all other
17 health care expenditures.
18 (e) The price of brand name drugs is rising faster than the rate
19 of inflation, with a recent study showing that the price of 30
20 drugs most frequently used by the elderly rose by over four times
21 the rate of inflation in 2003 and that some drugs increased in
22 price by 10 times the rate of inflation in that year.
23 (f) The rising cost of prescription drugs jeopardizes the health
24 of seniors, the disabled, and other consumers who cannot afford
25 the medication they need to stay healthy, as shown by a study by
26 the RAND Corporation that found that when out-of-pocket
27 payments for prescription drugs doubled, patients with diabetes
28 and asthma cut back on their use of drugs by over 20 percent and
29 subsequently experienced higher rates of emergency room visits
30 and hospital stays.
31 (g) The rising cost of prescription drugs places a
32 disproportionate burden on communities of color, as shown in a
33 report from the Center for Studying Health System Change that
34 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.

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

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

SEC. 2. Section 14981 of the Government Code is repealed.

~~14981. On or before February 1, 2005, the department shall submit a report to the appropriate policy and fiscal committees of the Legislature on activities that have been or will be undertaken pursuant to this chapter. The report shall include, but not be limited to, all of the following:~~

~~(a) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14977.1, including any discounts, rebates, or refunds obtained.~~

~~(b) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to Section 14977.5.~~

~~(c) Other options and strategies that have been or will be implemented pursuant to Sections 14978 and 14980.~~

~~(d) Estimated costs and savings attributable to activities that have been or will be undertaken pursuant to this chapter.~~

SEC. 3. Section 14982 of the Government Code is amended to read:

14982. (a) It is the intent of the Legislature that the Department of General Services, University of California, and the Public ~~Employees~~ *Employees'* Retirement System regularly meet and share information regarding each agency's procurement of prescription drugs in an effort to identify and implement opportunities for cost savings in connection with this procurement. It is the intent of the Legislature that the University of California and the Public ~~Employees~~ *Employees'* Retirement System cooperate with the department in order to reduce each agency's costs for prescription drugs.

(b) The department shall do all of the following:

(1) Share information on a regular basis with the University of California and the Public ~~Employees~~ *Employees'* Retirement System regarding each agency's procurement of prescription

drugs, including, but not limited to, prices paid for the same or similar drugs and information regarding drug effectiveness.

(2) Identify opportunities for the department, the University of California, and the Public ~~Employees~~ *Employees'* Retirement System to consolidate drug procurement or engage in other joint activities that will result in cost savings in the procurement of prescription drugs.

(3) Participate in at least one independent association that develops information on the relative effectiveness of prescription drugs.

(4) *Develop strategies, in consultation with the affected agencies, for the state to achieve savings through greater use of generic drugs.*

(5) No later than January 1, 2006, and annually thereafter, develop a work plan that includes, but is not limited to, a description of the department's annual activities to reduce the state's costs for prescription drugs and an estimate of cost savings.

~~(5)~~

(6) No later than January 10, 2006, and annually thereafter, report to the chairperson of the Joint Legislative Budget Committee and the chairs of the fiscal committees of the Legislature ~~on any joint activities of the department, the University of California, and the Public Employees Retirement System in the last 12 months in connection with procurement of prescription drugs and any resulting cost savings. This report shall include the work plan described in paragraph (4)~~ *and the appropriate fiscal committees of the Legislature on activities that have been, or will be, undertaken pursuant to this chapter. The report shall include, but not be limited to, all of the following:*

(A) The number and a description of contracts entered into with manufacturers and suppliers of drugs pursuant to Section 14977.1, including any discounts, rebates, or refunds obtained.

(B) The number and a description of entities that elect to participate in the coordinated purchasing program pursuant to Section 14977.5.

(C) A description of any joint activities of the department, the University of California, and the Public Employees' Retirement System in the last 12 months in connection with procurement of prescription drugs.

(D) Other options and strategies that have been or will be implemented pursuant to this chapter.

(E) Estimated costs and savings attributable to activities that have been, or will be, undertaken pursuant to this chapter.

(F) The work plan that the department is required to develop pursuant to paragraph (5).

(c) Nothing in this section shall be construed to require sharing of information that is prohibited by any other provision of law or contractual agreement, or the disclosure of information that may adversely affect potential drug procurement by any state agency.

~~SEC. 2.~~

SEC. 4. 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 ~~R~~ Prescription Drug Web Site Program

110242. (a) The California ~~R~~ 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, 2007, 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). *If the federal government enacts, by October 15, 2006, procedures for individuals to obtain*

prescription drugs from international pharmacies, this paragraph shall not apply to the department Web site.

(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,~~

(d) (1) Unless the federal government enacts, by October 15, 2006, procedures for individuals to obtain prescription drugs from international pharmacies, the department's Web site shall include price comparisons of at least 150 commonly prescribed 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.

110243. (a) The State Department of Health Services shall establish the California ℞ Prescription Drug Hotline to provide

1 *information to consumers and health care providers about*
2 *options for obtaining prescription drugs at affordable prices.*
3 *(b) The department shall establish a low-cost 1-900 telephone*
4 *number on or before July 1, 2007. Callers shall be provided*
5 *information about options for obtaining prescription drugs at*
6 *affordable prices. The cost per call to the hotline shall not exceed*
7 *50 cents ($0.50) and the hotline shall, at a minimum, provide the*
8 *same type of information described in subdivision (c) of Section*
9 *110242.*

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2911 **VERSION:** INTRODUCED

AUTHOR: NUNEZ **SPONSOR:** AUTHOR

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1) Establishes the California Discount Prescription Drug Program (program) within DHS to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for eligible Californians. (H&S 130502 Added)

2) Defines the terms: department, eligible Californian, fund, manufacturer, manufacturer's rebate, multiple-source drug, national drug code, participating manufacturer, participating pharmacy, pharmacy contract rate, prescription drug, private discount drug program, program, therapeutic category. (H&S 130501 Added)

3) Establishes eligibility criteria for the program as a person that meets at least one of the following conditions:

i. A resident of the state whose total unreimbursed medical expenses equal 10 percent or more of family income and whose family income does not exceed 200 percent of the median family income in the state.

ii. An individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare or by an individual's private drug plan or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.

iii. A resident of the state who has a family income equal to or less than 350 percent of the federal poverty guidelines and does not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program, the Healthy Families Program, or other program funded by the state.

(H&S 130501 Added)

4) Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130541 Added)

5) Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within twenty-four hours of receipt of a completed application. (H&S 130520 Added)

6) Sets a fee of $10 for application to the program. (H&S 130520 Added)

7) Requires DHS to negotiate drug rebate agreements with drug manufacturer's to provide for discounts for prescription drugs purchased through the program; the first set of agreements would be in effect for no more than three years. (H&S 130506 Added)

8) Gives DHS additional authority and tools to negotiate lower net prices on prescription drugs if certain criteria are met. (H&S 130508 and 13509 Added)

9) Sets the amount a recipient pays for a drug within program to be equal to the participating provider's usual and customary charge or the pharmacy contract rate, less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program. (H&S 130505 Added)

10) Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. (H&S 130521 Added)

11) Requires a drug dispensed pursuant to prescription to be accompanied by California Discount Prescription Drug Program participation information. Requires information to include advice to consult a health care provider or pharmacist about access to drugs at lower prices. Distribution of the information may be met by the distribution of a separate information form that is approved by, or produced and distributed by DHS. (H&S 1305022 Added)

12) Establishes the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would continuously appropriate the fund to the DHS for purposes of the program. (H&S 130542 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Technical Problems with the Measure. There are two technical problems with the bill that relate to pharmacy law. The first problem is the definition of "prescription drug" in the measure. While the definition is similar to B&P 4022 definition of "dangerous drug," it is not exact. The difference in terms and definitions may create confusion among health care professionals and those involved in the program established by the bill. Rather than having two separate terms and definitions that are attempting to define the same thing, it might be best if AB 2911 were amended to delete the term "prescription drug" and in its place define "dangerous drug" as defined in B&P 4022.

The second problem with the bill is the requirement that information on the program be distributed with dispensed medications. The provision is not specific to drugs dispensed through the program; as a result the provision implies that information is to be distributed with all medications dispensed in California. In 2004, approximately 260 million prescription drugs were filled at retail pharmacies in California. The provision as introduced is likely to be burdensome

on California retail pharmacies. Additionally, the provision is in the Health and Safety Code so enforcement for the provision would be the responsibility of DHS, not the board.

3) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation 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 twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months, 35 percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

4) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

5) Amended on April 17th. Several amendments were made to the bill on April 17, 2006, the most significant amendment was the removal of a provision that would have prohibited DHS from entering into a new contract or extend an existing contract with a drug manufacturer for the Medi-Cal program if the drug manufacturer does not provide to the California Discount Prescription Drug Program a rate comparable to or lower than the Medicaid best price. This prohibition would not apply to a drug for which there is no therapeutic equivalent.

6) Previous Legislation. Two bills, AB 75 and SB 19, were introduced in 2005 that would have established a drug discount program in California. Language similar to both bills was placed on the November 8, 2005 ballot in the form of Propositions (Proposition 79 and Proposition 78). Voters voted down both propositions.

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish the California Rx Plus State Pharmacy Assistance Program within DHS. AB 75 requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure establishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines. AB 75 is a two-year bill, however it is unlikely the bill will move forward this session.

SB 19 (Ortiz) California Rx Program was introduced last year and sponsored by the Governor. SB 19 would have established a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is dead for the legislative session.

7) History.

2006

Apr. 18	Re-referred to Com. on HEALTH.
Apr. 17	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 23	Referred to Com. on HEALTH.
Feb. 27	Read first time.
Feb. 25	From printer. May be heard in committee March 27.
Feb. 24	Introduced. To print.

AMENDED IN ASSEMBLY APRIL 17, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 2911

Introduced by Assembly Member Nunez
(Coauthor: Senator Perata)

February 24, 2006

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to pharmacy assistance, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2911, as amended, Nunez. California Discount Prescription Drug Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Discount Prescription Drug Program within the department. The bill would require the department to negotiate drug discount agreements with drug manufacturers and pursue manufacturer rebate agreements for drugs in each therapeutic category. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to participate in the program. The bill would establish eligibility criteria and application procedures for eligible Californians to participate in the program. The application process would require an applicant to attest to information provided

under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program.

The bill would establish the California Discount Prescription Drug Program Fund into which all payments received under the program would be deposited. The bill would continuously appropriate the fund to the department for purposes of the program.

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

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

Vote: ⅔. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

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

1 SECTION 1. The Legislature hereby finds and declares all of
2 the following:
3 (a) The people of California find that affordability is critical in
4 providing access to prescription drugs for California residents,
5 particularly the uninsured and those with inadequate insurance.
6 (b) The California Discount Prescription Drug Program is
7 enacted by the people to enable the state to take steps to make
8 prescription drugs more affordable for qualified California
9 residents, thereby increasing the overall health of California
10 residents, promoting healthy communities, and protecting the
11 public health and welfare.
12 (c) It is not the intent of the state to discourage employers
13 from offering or paying for prescription drug benefits for their
14 employees or to replace employer-sponsored prescription drug
15 benefit plans that provide benefits comparable to those made
16 available to qualified California residents under this program.
17 SEC. 2. Division 112 (commencing with Section 130500) is
18 added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA DISCOUNT PRESCRIPTION DRUG PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. This division shall be known, and may be cited, as the California Discount Prescription Drug Program.

130501. For purposes of this division, the following definitions shall apply:

(a) "Department" means the State Department of Health Services.

(b) "Eligible Californian" means any one or more of the following:

(1) A resident of the state whose total unreimbursed medical expenses equal 10 percent or more of family income and whose family income does not exceed 200 percent of the median family income in the state.

(2) An individual enrolled in Medicare who may participate in this program, to the extent allowed by federal law, for prescription drugs not covered by Medicare *or by an individual's private drug plan* or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.

(3) A resident of the state who has a family income equal to or less than 350 percent of the federal poverty guidelines and does not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program, the Healthy Families Program, or other program funded by the state.

(4) For purposes of this subdivision, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(c) "Fund" means the California Discount Prescription Drug Program Fund.

(d) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(e) "Manufacturer's rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(f) "Multiple-source drug" means the same drug in the same dosage form and strength manufactured by two or more manufacturers, which is approved by the United States Food and Drug Administration under provisions pertaining to the Abbreviated New Drug Applications (ANDA) process.

(g) "National Drug Code" or "NDC" means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(h) "Participating manufacturer" means a drug manufacturer that has contracted with the department to provide an individual drug or group of drugs for the program.

(i) "Participating pharmacy" means a pharmacy that has executed a pharmacy provider agreement with the department for this program.

(j) "Pharmacy contract rate" means the negotiated per prescription reimbursement rate for drugs dispensed to eligible Californians.

(k) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

(*l*) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

(m) "Program" means the California Discount Prescription Drug Program.

(n) "Therapeutic category" means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

130502. The California Discount Prescription Drug Program is hereby established within the State Department of Health Services to use manufacturer rebates and pharmacy discounts to reduce prescription drug prices for *eligible* Californians. The purpose of the program is to reduce prescription drug prices and improve the quality of health care for eligible Californians.

CHAPTER 2. PRESCRIPTION DRUG DISCOUNTS

130505. (a) The amount a participating, eligible Californian pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the ~~drug's manufacturer and the state's share of the discount.~~ *drug's manufacturer.*

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130506. (a) The department shall negotiate drug discount agreements with drug manufacturers to provide for discounts for prescription drugs purchased through this program. The department shall pursue manufacturer rebate agreements for drugs in each therapeutic category.

(b) The department shall attempt to obtain discounts for eligible Californians that on an average equal or exceed ~~50 percent of the list price, or that average 80 percent of the lowest~~ *Medicaid best price or a price that averages 80 percent of the lowest* wholesale acquisition cost price, for a drug published by a wholesaler in the state generally available to the retail class of trade in the state.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(d) The drug rebate agreements negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by program participants.

(e) (1) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(2) Any drug manufacturer may participate in the program.

130507. (a) The department shall attempt to negotiate drug discount agreements with drug manufacturers for a period not to exceed three years from January 1, 2007. At that time, the department shall make a determination as to whether:

(1) The number and type of drugs available through the program is sufficient to give eligible Californians a formulary comparable to that provided to Medi-Cal beneficiaries or, if this information is available to the department, a formulary comparable to that provided to CalPERS enrollees.

(2) The discounts for the drugs on an average equal or exceed the threshold in subdivision (b) of Section 130506.

(3) Manufacturer participation has been sufficient to provide discounts on a range of drugs consistent with this section.

(b) If the department determines that any one of the thresholds in this section is not met, then the department shall implement Sections 130508 and 130509.

130508. (a) Consistent with federal law, the department shall seek to contract for that result in a net price comparable to or lower than the Medicaid best price for drugs covered by the California Discount Prescription Drug Program. ~~The department shall also seek to contract a net price comparable to or lower than the price for prescription drugs provided to the federal government.~~

~~(b) The department shall seek a state plan amendment that maximizes the number of eligible Californians able to receive discounts consistent with this section.~~

~~(c) If the federal Centers for Medicare and Medicaid Services deny approval of a state plan amendment or federal waiver for any Californians eligible under state law for drug discounts, then the department shall continue to operate a discount drug program for these persons consistent with Section 130507. To the~~

(b) To the maximum extent possible, the department shall assure that enrollment and other administrative actions are seamless to all eligible Californians, whether the eligible Californian is enrolled in a program administered consistent with this section or with Section 130507.

130509. (a) ~~Subject to this section, the department shall not enter into a new contract or extend an existing contract with a drug manufacturer for the Medi-Cal program if the drug manufacturer does not provide to the California Discount Prescription Drug Program a rate comparable to or lower than the Medicaid best price. This prohibition shall not apply to a drug for which there is no therapeutic equivalent.~~

~~(b)~~ To the extent permitted by federal law, the department may require prior authorization in the Medi-Cal program for any drug of a manufacturer that fails to agree to a price comparable to or lower than the Medi-Cal best price for prescription drugs purchased under this division.

~~(c) If a contract with a manufacturer is prohibited by subdivision (a) or if~~

(b) If prior authorization is required for a drug pursuant to this section, a Medi-Cal beneficiary shall not be denied the continued use of a drug that is part of a prescribed therapy until that drug is no longer prescribed for that beneficiary's therapy. The department shall approve or deny requests for prior authorization necessitated by this section as required by state or federal law.

~~(d)~~

(c) This section shall be implemented in a manner consistent with federal law.

130510. The names of manufacturers that do or do not enter into rebate agreements with the department pursuant to this division shall be public information~~, shall be released to the public,~~ and shall be posted on the department's Internet Web site at the time when the rebate agreements are reached, commencing within six months after the initial implementation date of this article and updated on the first of each month thereafter.

130511. (a) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement if there is a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a program participant.

(4) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(5) Require the manufacturer to provide, upon the request of the department, documentation to validate the rebate.

(6) Permit a manufacturer to audit claims for the drugs the manufacturer provides under the program. Claims information provided to manufacturers shall comply with all federal and state

privacy laws that protect a program participant's health information.

(b) The department may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be specified in the drug rebate agreements.

(c) (1) Manufacturers shall calculate and pay interest on late or unpaid rebates. The interest shall not apply to any prior period adjustments of unit rebate amounts or department utilization adjustments.

(2) For state rebate payments, manufacturers shall calculate and pay interest on late or unpaid rebates for quarters that begin on or after January 1, 2007.

(d) Interest required by subdivision (c) shall begin accruing 38 calendar days from the date of mailing of the invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date of mailing of the manufacturer's payment. Interest rates and calculations for purposes of this section shall be at ____ percent.

(e) A participating manufacturer shall clearly identify all rebates, interest, and other payments, and payment transmittal forms for the program, in a manner designated by the department.

130512. (a) The department shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A summary of the problems or complaints reported regarding the program.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130513. (a) The department shall establish and maintain a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of this division.

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards provided in federal law.

(b) The department shall pay a participating pharmacy the discount provided to program participants pursuant to this division by a date that is not later than two weeks after the claim is received.

(c) The department shall develop a mechanism for the program participants to report problems or complaints.

Chapter 3. Application, Enrollment, and Outreach

130520. (a) The department shall develop an application and reapplication form for the determination of a resident's eligibility for the program. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

(b) The application shall, at a minimum, do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Specify that the application fee due upon submission of the applicable form is ten dollars ($10) *annually*.

(c) In assessing the income requirement for eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) An application may be completed at any pharmacy, physician office, or clinic participating in the program through an Internet Web site or call center staffed by trained operators approved by the department. A pharmacy, physician's office, clinic, or nonprofit community organization that completes the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in the program, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a program participant.

(e) The department shall utilize a secure electronic application process that can be used by a pharmacy, physician's office, or clinic, by an Internet Web site, by a call center staffed by trained operators, by a nonprofit community organization, or through the third-party vendor to enroll applicants in the program.

(f) During the department's normal working hours, the department shall make a determination of eligibility within 24 hours of receipt by the program of a completed application. The department shall mail the program participant an identification card no later than seven days after eligibility has been determined.

(g) For applications submitted through a pharmacy, the department may issue a participant identification number for eligible applicants to the pharmacy for immediate access to the California Discount Prescription Drug Program.

(h) Any program participant that has been determined to be eligible shall be enrolled for 12 months~~, which ever occurs first~~ or until the program participant notifies the department of an intent to end enrollment.

(i) The department shall notify a program participant of termination of enrollment 30 days prior to the termination.~~A program participant shall remain enrolled in the program until the participant notifies the department that the participant no longer meets the eligibility criteria.~~

(j) A person shall be required to apply pursuant to this section for each 12-month period of eligibility.

130521. (a) The department may conduct an outreach program to inform California residents of their opportunity to participate in the program. The department shall coordinate outreach activities with the California Department of Aging and other state and local agencies, and nonprofit organizations that serve residents who may be eligible for the program. No outreach material shall contain the name or likeness of a drug.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about the program. The name of the organization sponsoring the materials shall in no way appear on the material but shall be reported to the public and the Legislature as otherwise provided by law.

130522. (a) A drug dispensed pursuant to prescription, including a drug dispensed without charge to the consumer, shall be accompanied by the California Discount Prescription Drug Program participation information in a manner approved by the department and as permitted by law.

(b) The information shall include advice to consult a health care provider or pharmacist about access to drugs at lower prices.

(c) The requirements of this section may be met by the distribution of a separate information form that is approved by, or produced and distributed by, the department.

Chapter 4. Pharmaceutical Manufacturer Patient Assistance Programs

130530. (a) The department shall encourage a participating manufacturer to maintain those private discount drug programs that are comparable to or more extensive than those provided prior to the enactment of this division. To the extent possible, the department shall encourage a participating manufacturer to simplify the application and eligibility processes for its private discount drug program.

(b) The department shall execute agreements with drug manufacturers and other private patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

(c) The department shall develop a system to provide a program participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer or other private patient assistance program.

(d) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the California Discount Prescription Drug Program.

(e) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(f) The California Discount Prescription Drug Program card issued pursuant to this division shall serve as a single point of entry for drugs available pursuant to subdivision (a), and shall meet all legal requirements for a health benefit card.

Chapter 5. Administration

130540. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130541. To implement the program, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. Drug rebate contracts negotiated by a third party shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or program participants.

130542. (a) The department shall deposit all payments the department receives pursuant to this division into the California Discount Prescription Drug Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, the fund is hereby continuously appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to this division and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General

Fund. The fund shall also contain any interest accrued on moneys in the fund.

130543. (a) (1) The director may adopt regulations as are necessary for the initial implementation of this division. The adoption, amendment, repeal, or readoption of a regulation authorized by this section is deemed to be necessary for the immediate preservation of the public peace, health and safety, or general welfare, for purposes of Sections 11346.1 and 11349.6 of the Government Code, and the department is hereby exempted from the requirement that it describe specific facts showing the need for immediate action.

(b) As an alternative to the adoption of regulations pursuant to subdivision (a), and notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division, in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action, provided that no bulletin or other similar instructions shall remain in effect after July 31, 2007. It is the intent that regulations adopted pursuant to this subdivision shall be in place on or before July 31, 2007.

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

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AMENDED IN ASSEMBLY APRIL 17, 2006

AMENDED IN ASSEMBLY MARCH 28, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

Assembly Joint Resolution No. 40

Introduced by Assembly Members Chan and Berg
(Coauthors: Assembly Members Cohn, Lieu, ~~and Mullin~~ *Mullin, Arambula, Baca, Bass, Bermudez, Calderon, Canciamilla, Chavez, Chu, Coto, Daucher, De La Torre, Dymally, Evans, Frommer, Garcia, Goldberg, Hancock, Shirley Horton, Jones, Karnette, Koretz, Laird, Leno, Levine, Lieber, Liu, Matthews, Montanez, Negrete McLeod, Oropeza, Parra, Pavley, Ridley-Thomas, Ruskin, Torrico, Umberg, Vargas, and Yee*)

January 19, 2006

Assembly Joint Resolution No. 40—Relative to Medicare prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AJR 40, as amended, Chan. Medicare prescription drugs.

This measure would memorialize the United States Congress and President to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005."

Fiscal committee: no.

WHEREAS, The United States Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) in 2003; and

WHEREAS, The MMA promised a voluntary prescription drug benefit, known as Medicare Part D, to all Medicare beneficiaries; and

WHEREAS, At the insistence of Congress and the President of the United States, Part D is administered by multiple private insurance companies offering dozens of different plans in every state; and

WHEREAS, In California alone, Medicare beneficiaries who wish to enroll in Part D must choose from 47 different stand-alone Medicare prescription drug plans and many more Medicare Advantage plans; and

WHEREAS, On October 15, 2005, Medicare prescription drug plan sponsors began aggressively marketing their plans to seniors and persons with disabilities; and

WHEREAS, On November 15, 2005, Medicare beneficiaries throughout the country began enrolling in the new Medicare Part D prescription drug plans; and

WHEREAS, As of December 2005, only 1 million of the approximately 21 million Medicare beneficiaries throughout the country who are eligible for voluntary enrollment in Part D had enrolled; and

WHEREAS, In addition only a small percentage of the millions of low-income beneficiaries eligible for federal subsidies have enrolled in Part D; and

WHEREAS, Federal law currently requires the initial open enrollment period to end on May 15, 2006, after, which Medicare beneficiaries will be subject to substantial permanent financial penalties for "late enrollment"; and

WHEREAS, The structure of Part D and the need to choose from among dozens of plans are causing confusion and consternation among seniors; and

WHEREAS, There have not been enough independent counselors available to help guide seniors through the myriad options; and

WHEREAS, Seniors who currently have retiree health care coverage, including prescription drug coverage, are at risk of losing both their existing health and drug coverage if they inadvertently enroll in Medicare Part D; and

WHEREAS, The federal government should not penalize seniors for being confused, but should work to provide Medicare

beneficiaries the time and opportunity to make the best choice about their prescription drug coverage; and

WHEREAS, Legislation has been introduced in the Congress, H.R. No. 3861, "The Medicare Informed Choice Act of 2005", that extends the deadline for enrollment in Medicare Part D until December 31, 2006, permits Medicare beneficiaries to change plans once in 2006 if they have made a poor selection, and protects those with retiree health benefits who may not be aware that purchasing Medicare drug coverage could cost them their retiree benefits; now, therefore, be it

Resolved by the Assembly and the Senate of the State of California, jointly, That the Legislature of the State of California memorializes the Congress and the President of the United States to enact H.R. No. 3861, "The Medicare Informed Choice Act of 2005" to give our nation's disabled and senior citizens who are Medicare beneficiaries the time to make an informed decision and protect them from losing their retiree health benefits; and be it further

Resolved, That the Chief Clerk of the Assembly transmit copies of this resolution to the President of the United States and to all Member of the Congress of the United States.

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AMENDED IN ASSEMBLY APRIL 19, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

Assembly Joint Resolution No. 49

Introduced by Assembly Member Nation

March 29, 2006

Assembly Joint Resolution No. 49—Relative to pharmaceutical advertisements.

LEGISLATIVE COUNSEL'S DIGEST

AJR 49, as amended, Nation. Direct-to-consumer prescription drug advertisements.

This measure would request that the United States Food and Drug Administration aggressively monitor and regulate direct-to-consumer advertising of prescription drugs by pharmaceutical companies, and would memorialize the President and the Congress to ban that advertising.

Fiscal committee: no.

1 WHEREAS, The United States is one of just a few countries
2 that allow pharmaceutical companies to advertise prescription
3 drugs; and
4 WHEREAS, Direct-to-consumer prescription drug advertising
5 is a category of promotional information about specific drug
6 treatments that is provided directly to consumers by or on behalf
7 of drug companies; and
8 WHEREAS, Direct-to-consumer prescription drug advertising
9 is not necessary in order for pharmaceutical companies to sell
10 their products; and

WHEREAS, Since pharmaceutical companies have been allowed to broadcast advertisements that mention a prescription drug by name without disclosing all of the risks of that medication, consumer demand for prescription medications has increased, resulting in a corresponding increase in the cost of prescriptions and of health care delivery; and

WHEREAS, While the pharmaceutical community has tried to convince the public, Congress, and the United States Food and Drug Administration (hereafter the FDA) that direct-to-consumer prescription drug advertisements are educational~~,~~ rather than promotional, the actual goal of the advertisements is not to educate the public, but rather to ensure that patients walk out of their doctors' offices with a prescription for a particular brand of prescription drug~~,~~ rather than with a prescription for a competitor's product or some other form of therapy that better suits the patient; and

WHEREAS, Physicians are under increasing pressure from patients who suspect that Heath Maintenance Organization formularies restrict physicians from prescribing the best prescription drugs; and

WHEREAS, Direct-to-consumer advertising of prescription drugs forces physicians to spend valuable time defending the reason that an advertised drug is unnecessary or detrimental to the patient's health; and

WHEREAS, If a physician declines to issue a prescription for a drug that a patient has seen advertised, the patient may turn to other sources to obtain the drug, including the Internet; and

WHEREAS, According to the United States General Accounting Office, the investigational arm of Congress, pharmaceutical manufacturers spent $1.1 billion in 1997 on direct-to-consumer prescription drug advertising, which increased to $2.7 billion in 2001, with expenditures increasing by double digits every year; and

WHEREAS, Numerous studies have linked the increased direct-to-consumer prescription drug advertising to the exponential growth in prescription drug expenditures; and

WHEREAS, In 1997, the FDA relaxed restrictions on the content of direct-to-consumer prescription drug advertising, withdrawing the prior requirement of a summary of side-effect and adverse reaction information and replacing it with a

requirement for a statement about "major risks" but not "all risks," which made television and radio advertisements about prescription drugs more practicable; now, therefore, be it

Resolved by the Assembly and the Senate of the State of California, jointly, That the United States Food and Drug Administration is requested to aggressively monitor and regulate direct-to-consumer advertising of prescription drugs by pharmaceutical companies, pending action by the President and the Congress of the United States to ~~limit, ban, or place increased restrictions on that~~ *ban that type of* advertising; and be it further

Resolved, That the President and the Congress of the United States are memorialized to ban direct-to-consumer advertising of prescription drugs by pharmaceutical companies; and be it further

Resolved, That the Chief clerk of the Assembly transmit copies of this resolution to the President of the United States, to the Speaker of the House of Representatives, to the Majority Leader of the Senate, to each Senator and Representative from California in the Congress of the United States, to the Secretary of the United States Department of Health and Human Services, and to the Director of the United States Food and Drug Administration.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1305 **VERSION: AMENDED MARCH 29, 2006**

AUTHOR: FIGUEROA **SPONSOR: AUTHOR**

RECOMMENDED POSITION:

SUBJECT: THE MEDICAL WASTE MANAGEMENT ACT

Existing Law:

1) Defines "sharps waste" as waste generated by a household that includes a hypodermic needle, syringe, or lancet. (Public Resources Code 40190.5)

Related Law Law:

1) Allows counties and cities to establish a Disease Prevention Demonstration Project (DPDP), that allows certified pharmacies to sell of up to 10 hypodermic needles to individuals over 18 years of age without a prescription. Pharmacies that participate in a DPDP are required to provide one or more of the following options for the safe disposal of hypodermic needle:

i. Have an onsite safe hypodermic needle and syringe collection and disposal program.

ii. Furnish or make available for purchase mail-back sharps disposal containers authorized by the United States Postal Service that meet applicable state and federal requirements, and provide tracking forms to verify destruction at a certified disposal facility.

iii. Furnish or make available for purchase personal sharps disposal containers that meet state and federal standards for disposal of medical waste.

(H&S 121285)

This Bill:

1) Defines "home-generated sharps waste" as hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications derived from a household, including a multifamily residence or household.
(H&S 117671 Added)

2) Excludes “home-generated sharps waste” from the definition of medical waste.
(H&S 117700 Amended)

3) Prohibits a person on or after January 1, 2008, from knowingly placing home-generated sharps waste in any of the following containers:

i. Any container used for the collection of solid waste, recyclable materials, or greenwaste.

ii. Any container used for the commercial collection of solid waste or recyclable materials from business establishments.

iii. Any roll-off container used for the collection of solid waste, construction, and demolition debris, greenwaste, or other recyclable materials. (H&S 118286 Added)

4) Requires on or after January 1, 2008, home-generated sharps waste to be transported only in a sharps container, or other approved containers, and to only be managed at any of the following:

i. A household hazardous waste facility.
ii. A home-generated sharps consolidation point.
iii. A medical waste generator's facility.
iv. A facility, through the use of a medical waste mail-back container, approved by the Department of Health Services.

(H&S 118286)

Comment:

1) Author's Intent. The author's intent is to close a loophole in current law that allows home-generated needles to be legally placed in solid waste and recycling containers where they present substantial risks to workers and the general public. Currently fifty percent of counties accept sharps at their county waste disposal sites; often times the collection of sharps at the sites is funded through waste collection or utility tax funds. The author is looking for a solution to this problem that may include manufacturers taking back used sharps that have been paid for by health insurance.

2) Problems as Currently Written. There are a couple problems with the bill. The first problem is the bill is unenforceable. The bill would prohibit people from disposing of sharps in "garbage cans," green waste or recycling collection containers. Much like the disposable battery law that recently took effect on January 1, 2006 that would prohibit a person from disposing of batteries in their household waste; there is no reasonable way for a city or county to monitor peoples disposal habits and enforce the law.

The second problem with the bill is in the absence of funding from government or industry, the bill could prove costly to people who use sharps. The bill does not specify how sharps will move from an individual's home to an approved facility or who is responsible for providing approved sharps containers. It is conceivable that a sharps user could be responsible for both the costs of the sharps containers as well as transport of the sharps. Finding a source of funding for disposal other than sharps users will likely result in a higher rate of compliance with the law.

3) Previous Legislation.

SB 1159 (Chapter 608, Statutes of 2004) allows counties and cities to establish a Disease Prevention Demonstration Project (DPDP), that allows certified pharmacies to sell of up to 10 hypodermic needles to individuals over 18 years of age without a prescription. The measure also requires participating pharmacies to provide one of three options for the safe disposal of hypodermic needles.

SB 1362 (Chapter 157, Statutes of 2004) established the Safe Needle Disposal Act of 2004, allows, but does not mandate cities and counties to authorize household hazardous waste (HHW) collection facilities to operate as home-generated sharps consolidation points. Additionally, the measure defined "sharps waste" in Public Resources Code section 40190.5.

SB 372 (Chapter 877, Statutes of 1995) authorized, but did not mandate 1) a medical waste generator to accept home-generated sharps waste for consolidation with its own medical wastes and 2) an enforcement agency to approve a location as a point of consolidation for the collection of home-generated sharps waste, which would be required to be transported and treated as medical waste.

4) Support & Opposition.

Support: Alameda County Board of Supervisors
Alameda County Health Care Services Agency
Alameda County Environmental Health
Alameda County Health Care for the Homeless Program
Alameda County Sharps Coalition
California Hepatitis C Task Force
California Refuse Removal Council
California State Association of Counties
League of California Cities, Planning and Conservation League
Royal Medical Inc United Pharmacy
Sharps Compliance, Inc.
Sierra Club California
Solid Waste Association of North America
Waste Management

Concerned: American Diabetes Association
California Hospital Association
Contra Costa Health Services

5) History.

2006

Apr. 18	Set for hearing April 24.
Apr. 17	Hearing postponed by committee.
Apr. 3	Set, first hearing. Hearing canceled at the request of author. Set for hearing April 17.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 20	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 13	Set for hearing April 3.
Feb. 22	To Com. on E.Q.
Feb. 17	From print. May be acted upon on or after March 19.
Feb. 16	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN SENATE MARCH 29, 2006

AMENDED IN SENATE MARCH 20, 2006

SENATE BILL No. 1305

Introduced by Senator Figueroa

February 16, 2006

An act to *amend Section 117700 of, and to* add Sections 117671 and 118286 to, the Health and Safety Code, relating to medical waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 1305, as amended, Figueroa. ~~Medical waste.~~ *The Medical Waste Management Act.*

The existing Medical Waste Management Act, administered by the State Department of Health Services, regulates the management and handling of medical waste, as defined. ~~The act is enforced by the department and local enforcement agencies.~~ *Under existing law, certain items, such as household waste, are specifically excluded from the definition of medical waste.*

This bill would also exclude home-generated sharps waste, as defined, from the definition of medical waste.

Existing law permits a registered medical waste generator, if specified conditions are met, to accept home-generated sharps waste to be consolidated with the facility's medical waste stream.

Existing law also permits a household hazardous waste collection facility, if specified conditions are met, to operate a home-generated sharps consolidation point, and permits the department to approve other home-generated sharps consolidation points.

This bill would specifically define home-generated sharps waste.

This bill would, on or after January 1, 2008, prohibit a person from knowingly placing home-generated sharps waste in certain types of

containers, provide that home-generated sharps waste shall be transported only in a sharps container, as defined in the act, or other container approved by the department or local enforcement agency, and provide that this waste shall only be managed at specified locations consistent with existing law.

~~Since a violation of an order enforcing the Medical Waste Management Act is a misdemeanor, 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.~~

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

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

1 SECTION 1. Section 117671 is added to the Health and
2 Safety Code, to read:
3 117671. "Home-generated sharps waste" means hypodermic
4 needles, pen needles, intravenous needles, lancets, and other
5 devices that are used to penetrate the skin for the delivery of
6 medications derived from a household, including a multifamily
7 residence or household.
8 *SEC. 2. Section 117700 of the Health and Safety Code is*
9 *amended to read:*
10 117700. Medical waste does not include any of the following:
11 (a) Waste generated in food processing or biotechnology that
12 does not contain an infectious agent as defined in Section
13 117675.
14 (b) Waste generated in biotechnology that does not contain
15 human blood or blood products or animal blood or blood
16 products suspected of being contaminated with infectious agents
17 known to be communicable to humans.
18 (c) Urine, feces, saliva, sputum, nasal secretions, sweat, tears,
19 or vomitus, unless it contains fluid blood, as provided in
20 subdivision (d) of Section 117635.

(d) Waste which is not biohazardous, such as paper towels, paper products, articles containing nonfluid blood, and other medical solid waste products commonly found in the facilities of medical waste generators.

(e) Hazardous waste, radioactive waste, or household waste, *including, but not limited to, home-generated sharps waste, as defined in Section 117671.*

(f) Waste generated from normal and legal veterinarian, agricultural, and animal livestock management practices on a farm or ranch.

~~SEC. 2.~~

SEC. 3. Section 118286 is added to the Health and Safety Code, to read:

118286. (a) On or after January 1, 2008, no person shall knowingly place home-generated sharps waste in any of the following containers:

(1) Any container used for the collection of solid waste, recyclable materials, or greenwaste.

(2) Any container used for the commercial collection of solid waste or recyclable materials from business establishments.

(3) Any roll-off container used for the collection of solid waste, construction, and demolition debris, greenwaste, or other recyclable materials.

(b) On or after January 1, 2008, home-generated sharps waste shall be transported only in a sharps container, or other containers approved by the enforcement agency, and shall only be managed at any of the following:

(1) A household hazardous waste facility pursuant to Section 25218.13.

(2) A "home-generated sharps consolidation point" as defined in subdivision (b) of Section 117904.

(3) A medical waste generator's facility pursuant to Section 118147.

(4) A facility through the use of a medical waste mail-back container approved by the department pursuant to subdivision (b) of Section 118245.

~~SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or~~

~~infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1430 | **VERSION: AMENDED APRIL 17, 2006**

AUTHOR: ALQUIST | **SPONSOR: HEALTH OFFICERS ASSOCIATION OF CALIFORNIA**

RECOMMENDED POSITION:

SUBJECT: THE LOCAL PANDEMIC AND EMERGENCY HEALTH PREPAREDNESS ACT OF 2006

Existing Law:

Gives county health officers broad powers to prevent the spread of a communicable disease once a case appears in her or his jurisdiction.

This Bill:

States that the Legislature intends to adopt the Local Pandemic and Emergency Health Preparedness Act of 2006 to establish a mechanism by which local health officers and providers can mobilize and take appropriate actions in the event of a public health emergency and crisis.

Comment:

1) Author's Intent. The author's intent is to expand the authority of local health officers to act rapidly in the event of an emergency such as, pandemic influenza outbreak or a bioterrorism attack.

2) Amended on April 17, 2006: SB 1430 was amended on April 17, 2006 to replace the substantive proposed changes to law with Legislative intent. The author anticipate the bill will be amended again to replace the intent language with substantive changes that will enact the Local Pandemic and Emergency Health Preparedness Act of 2006. A copy of the April 17 and March 28, 2006 version the bill are attached for your information.

3) History.

2006

Apr. 17	Read second time. Amended. Re-referred to Com. on RLS.
Apr. 12	Set for hearing April 25 in JUD. pending receipt.
Apr. 6	From committee: Do pass as amended, but first amend, and re-refer to Com. on RLS. (Ayes 8. Noes 0. Page 3481.)
Mar. 28	From committee with author's amendments. Read second time. Amended. Re-referred to committee.

Mar. 24	Hearing postponed by committee. Set for hearing April 5.
Mar. 10	Set for hearing March 29.
Mar. 2	To Com. on HEALTH.
Feb. 23	From print. May be acted upon on or after March 25.
Feb. 22	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 17, 2006

AMENDED IN SENATE MARCH 28, 2006

SENATE BILL No. 1430

Introduced by Senator Alquist

February 22, 2006

An act ~~to amend Section 56.10 of the Civil Code, to amend Section 8659 of the Government Code, and to amend Section 100106 of, and to add Sections 101080.1, 101080.2, and 120176 to, the Health and Safety Code,~~ relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1430, as amended, Alquist. The Local Pandemic and Emergency Health Preparedness Act of 2006.

Existing law authorizes the Director of Health Services and local health officers to issue orders to enforce various public health and safety requirements. Existing law also authorizes local peace officers to enforce orders of the State Department of Health Services and of local health officers issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease and authorizes the Director of Health Services and the local health officer to consider whether a request for enforcement assistance would necessitate advising regarding measures to be taken to prevent infection of enforcement officers when requesting assistance in enforcement of their orders.

This bill would enact the Local Pandemic and Emergency Health Preparedness Act of 2006, and state the intent of the Legislature to adopt this act in order to establish a mechanism by which local health officers and providers can mobilize and take appropriate actions in the event of a public health emergency and crisis.

~~(1) Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor.~~

~~This bill would authorize a provider of health care or a health care service plan to disclose the medical information to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events, and the conduct of public health surveillance, public health investigations, and public health interventions.~~

~~(2) Existing law provides any physician or surgeon, hospital, pharmacist, nurse, or dentist immunity from liability for any injury sustained by any person by reason of services rendered during any state of war emergency, state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency.~~

~~This bill would include within this immunity any health care provider, as defined to include, among others, podiatrists, psychologists, chiropractors, and marriage and family therapists.~~

~~(3) Existing law authorizes the Director of Health Services and local health officers to issue orders to enforce various health and safety requirements. Existing law also authorizes local peace officers to enforce the orders of the State Department of Health Services and of local health officers issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease and authorizes the state director and the local health officer to consider whether a request for enforcement assistance would necessitate advising regarding measures to be taken to prevent infection of enforcement officers when requesting assistance in enforcement of their orders.~~

~~This bill would require the State Department of Health Services to annually report to the Legislature on the number of instances when the department requests enforcement assistance from local peace officers under these provisions.~~

~~This bill would also authorize a local health officer, in the event of potential human exposures to biological, chemical, toxic, or radiological agents that may spread to others and require immediate action, to issue an order, which shall be in effect for a period not longer than 2 hours, to first responders for the purposes of immediately isolating exposed individuals. The bill would authorize the local health officer, if he or she determines within the 2-hour period, that decontamination or continued isolation of an exposed individual is necessary to protect the public health, to require that the exposed individual remain isolated for a reasonable period of time necessary to protect the public health, or to undergo decontamination, or both. The bill would make a violation of an order issued pursuant to those provisions a misdemeanor, punishable by a fine of up to $1,000, or imprisonment in the county jail for a period of up to 90 days, or both.~~

~~(4) Existing law authorizes, in the event of a release, spill, escape, or entry of hazardous waste or medical waste that meets certain requirements, the Director of Health Services to declare a health emergency and the local health officer to declare a county health emergency in the county or any area thereof affected by the threat to the public health. Whenever a local health emergency is declared by a local health officer pursuant to these provisions, the local health emergency is prohibited from remaining in effect for a period in excess of 7 days unless it has been ratified by the board of supervisors, as specified.~~

~~This bill would also authorize the director to declare a health emergency and the local health officer to declare a county health emergency in the county or any affected area whenever there is a presence or threat of the introduction of any contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent.~~

~~(5) Existing law requires each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the State Department of Health Services, or any other contagious, infectious, or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, to take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases. Violation of this provision is a misdemeanor.~~

~~This bill would require each health officer to take reasonable measures as may be necessary to prevent the occurrence and spread of human disease or adverse health conditions caused by any serious or life-threatening contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent.~~

~~This bill would also require, during an outbreak of a communicable disease, or upon the imminent threat of a communicable disease outbreak, or epidemic that threatens the public's health, all health care providers, health clinics, health care service plans, pharmacies, and their suppliers, distributors, and other for-profit and nonprofit entities to disclose inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products requested by a local health official for use in the prevention of, or may be implicated in the transmission of, communicable disease to the local health officer.~~

~~By changing the definition of a crime and by increasing the duties of local officers, this bill would impose a state-mandated local program.~~

~~(6) 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.~~

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

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

1 SECTION 1. This act shall be known, and may be cited as the
2 Local Pandemic and Emergency Health Preparedness Act of
3 2006.
4 *SEC. 2. It is the intent of the Legislature to adopt the Local*
5 *Pandemic and Emergency Health Preparedness Act of 2006 to*
6 *establish a mechanism by which local health officers and*
7 *providers can mobilize and take appropriate actions in the event*
8 *of a public health emergency and crisis.*

1 ~~SEC. 2. Section 56.10 of the Civil Code is amended to read:~~
2
3
4 **All matter omitted in this version of the bill**
5 **appears in the bill as amended in the**
6 **Senate, March 28, 2006. (JR11)**
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AMENDED IN SENATE MARCH 28, 2006

SENATE BILL No. 1430

Introduced by Senator Alquist

February 22, 2006

An act to amend Section ~~100106 of~~ *56.10 of the Civil Code, to amend Section 8659 of the Government Code, and to amend Section 100106 of, and to add Sections 101080.1, 101080.2, and 120176 to,* the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 1430, as amended, Alquist. ~~Public health.~~ *The Local Pandemic and Emergency Health Preparedness Act of 2006.*

~~Existing~~

(1) Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor.

This bill would authorize a provider of health care or a health care service plan to disclose the medical information to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events, and the conduct of public health

surveillance, public health investigations, and public health interventions.

(2) Existing law provides any physician or surgeon, hospital, pharmacist, nurse, or dentist immunity from liability for any injury sustained by any person by reason of services rendered during any state of war emergency, state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency.

This bill would include within this immunity any health care provider, as defined to include, among others, podiatrists, psychologists, chiropractors, and marriage and family therapists.

(3) Existing law authorizes the Director of Health Services and local health officers to issue orders to enforce various health and safety requirements. Existing law also authorizes local peace officers to enforce the orders of the State Department of Health Services and of local health officers issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease and authorizes the state director and the local health officer to consider whether a request for enforcement assistance would necessitate advising regarding measures to be taken to prevent infection of enforcement officers when requesting assistance in enforcement of their orders.

This bill would require the State Department of Health Services to annually report to the Legislature on the number of instances when the department requests enforcement assistance from local peace officers under these provisions.

This bill would also authorize a local health officer, in the event of potential human exposures to biological, chemical, toxic, or radiological agents that may spread to others and require immediate action, to issue an order, which shall be in effect for a period not longer than 2 hours, to first responders for the purposes of immediately isolating exposed individuals. The bill would authorize the local health officer, if he or she determines within the 2-hour period, that decontamination or continued isolation of an exposed individual is necessary to protect the public health, to require that the exposed individual remain isolated for a reasonable period of time necessary to protect the public health, or to undergo decontamination, or both. The bill would make a violation of an order issued pursuant to those provisions a misdemeanor, punishable by a fine of up to $1,000, or imprisonment in the county jail for a period of up to 90 days, or both.

(4) Existing law authorizes, in the event of a release, spill, escape, or entry of hazardous waste or medical waste that meets certain requirements, the Director of Health Services to declare a health emergency and the local health officer to declare a county health emergency in the county or any area thereof affected by the threat to the public health. Whenever a local health emergency is declared by a local health officer pursuant to these provisions, the local health emergency is prohibited from remaining in effect for a period in excess of 7 days unless it has been ratified by the board of supervisors, as specified.

This bill would also authorize the director to declare a health emergency and the local health officer to declare a county health emergency in the county or any affected area whenever there is a presence or threat of the introduction of any contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent.

(5) Existing law requires each health officer knowing or having reason to believe that any case of the diseases made reportable by regulation of the State Department of Health Services, or any other contagious, infectious, or communicable disease exists, or has recently existed, within the territory under his or her jurisdiction, to take measures as may be necessary to prevent the spread of the disease or occurrence of additional cases. Violation of this provision is a misdemeanor.

This bill would require each health officer to take reasonable measures as may be necessary to prevent the occurrence and spread of human disease or adverse health conditions caused by any serious or life threatening contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent.

This bill would also require, during an outbreak of a communicable disease, or upon the imminent threat of a communicable disease outbreak, or epidemic that threatens the public's health, all health care providers, health clinics, health care service plans, pharmacies, and their suppliers, distributors, and other for-profit and nonprofit entities to disclose inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products requested by a local health official for use in the prevention of, or may be implicated in the transmission of, communicable disease to the local health officer.

By changing the definition of a crime and by increasing the duties of local officers, this bill would impose a state-mandated local program.

(6) 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.

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

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

1 *SECTION 1. This act shall be known, and may be cited as*
2 *The Local Pandemic and Emergency Health Preparedness Act of*
3 *2006.*
4 *SEC. 2. Section 56.10 of the Civil Code is amended to read:*
5 56.10. (a) No provider of health care, health care service
6 plan, or contractor shall disclose medical information regarding a
7 patient of the provider of health care or an enrollee or subscriber
8 of a health care service plan without first obtaining an
9 authorization, except as provided in subdivision (b) or (c).
10 (b) A provider of health care, a health care service plan, or a
11 contractor shall disclose medical information if the disclosure is
12 compelled by any of the following:
13 (1) By a court pursuant to an order of that court.
14 (2) By a board, commission, or administrative agency for
15 purposes of adjudication pursuant to its lawful authority.
16 (3) By a party to a proceeding before a court or administrative
17 agency pursuant to a subpoena, subpoena duces tecum, notice to
18 appear served pursuant to Section 1987 of the Code of Civil
19 Procedure, or any provision authorizing discovery in a
20 proceeding before a court or administrative agency.
21 (4) By a board, commission, or administrative agency pursuant
22 to an investigative subpoena issued under Article 2 (commencing

with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title 2 of the Government Code.

(5) By an arbitrator or arbitration panel, when arbitration is lawfully requested by either party, pursuant to a subpoena duces tecum issued under Section 1282.6 of the Code of Civil Procedure, or any other provision authorizing discovery in a proceeding before an arbitrator or arbitration panel.

(6) By a search warrant lawfully issued to a governmental law enforcement agency.

(7) By the patient or the patient's representative pursuant to Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code.

(8) By a coroner, when requested in the course of an investigation by the coroner's office for the purpose of identifying the decedent or locating next of kin, or when investigating deaths that may involve public health concerns, organ or tissue donation, child abuse, elder abuse, suicides, poisonings, accidents, sudden infant death, suspicious deaths, unknown deaths, or criminal deaths, or when otherwise authorized by the decedent's representative. Medical information requested by the coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation and shall be disclosed to the coroner without delay upon request.

(9) When otherwise specifically required by law.

(c) A provider of health care or a health care service plan may disclose medical information as follows:

(1) The information may be disclosed to providers of health care, health care service plans, contractors, or other health care professionals or facilities for purposes of diagnosis or treatment of the patient. This includes, in an emergency situation, the communication of patient information by radio transmission or other means between emergency medical personnel at the scene of an emergency, or in an emergency medical transport vehicle, and emergency medical personnel at a health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) The information may be disclosed to an insurer, employer, health care service plan, hospital service plan, employee benefit plan, governmental authority, contractor, or any other person or

entity responsible for paying for health care services rendered to the patient, to the extent necessary to allow responsibility for payment to be determined and payment to be made. If (A) the patient is, by reason of a comatose or other disabling medical condition, unable to consent to the disclosure of medical information and (B) no other arrangements have been made to pay for the health care services being rendered to the patient, the information may be disclosed to a governmental authority to the extent necessary to determine the patient's eligibility for, and to obtain, payment under a governmental program for health care services provided to the patient. The information may also be disclosed to another provider of health care or health care service plan as necessary to assist the other provider or health care service plan in obtaining payment for health care services rendered by that provider of health care or health care service plan to the patient.

(3) The information may be disclosed to any person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in paragraph (2). However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part.

(4) The information may be disclosed to organized committees and agents of professional societies or of medical staffs of licensed hospitals, licensed health care service plans, professional standards review organizations, independent medical review organizations and their selected reviewers, utilization and quality control peer review organizations as established by Congress in Public Law 97-248 in 1982, contractors, or persons or organizations insuring, responsible for, or defending professional liability that a provider may incur, if the committees, agents, health care service plans, organizations, reviewers, contractors, or persons are engaged in reviewing the competence or qualifications of health care professionals or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.

(5) The information in the possession of any provider of health care or health care service plan may be reviewed by any private or public body responsible for licensing or accrediting the

provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

(6) The information may be disclosed to the county coroner in the course of an investigation by the coroner's office when requested for all purposes not included in paragraph (8) of subdivision (b).

(7) The information may be disclosed to public agencies, clinical investigators, including investigators conducting epidemiologic studies, health care research organizations, and accredited public or private nonprofit educational or health care institutions for bona fide research purposes. However, no information so disclosed shall be further disclosed by the recipient in any way that would disclose the identity of any patient or be violative of this part.

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior written request and expense of the employer may disclose to the employee's employer that part of the information that:

(A) Is relevant in a lawsuit, arbitration, grievance, or other claim or challenge to which the employer and the employee are parties and in which the patient has placed in issue his or her medical history, mental or physical condition, or treatment, provided that information may only be used or disclosed in connection with that proceeding.

(B) Describes functional limitations of the patient that may entitle the patient to leave from work for medical reasons or limit the patient's fitness to perform his or her present employment, provided that no statement of medical cause is included in the information disclosed.

(9) Unless the provider of health care or health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was

created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

(10) The information may be disclosed to a health care service plan by providers of health care that contract with the health care service plan and may be transferred among providers of health care that contract with the health care service plan, for the purpose of administering the health care service plan. Medical information may not otherwise be disclosed by a health care service plan except in accordance with the provisions of this part.

(11) Nothing in this part shall prevent the disclosure by a provider of health care or a health care service plan to an insurance institution, agent, or support organization, subject to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code, of medical information if the insurance institution, agent, or support organization has complied with all requirements for obtaining the information pursuant to Article 6.6 (commencing with Section 791) of Part 2 of Division 1 of the Insurance Code.

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court investigator engaged in determining the need for an initial conservatorship or continuation of an existent conservatorship, if the patient is unable to give informed consent, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

(13) The information may be disclosed to an organ procurement organization or a tissue bank processing the tissue of a decedent for transplantation into the body of another person, but only with respect to the donating decedent, for the purpose of aiding the transplant. For the purpose of this paragraph, the terms "tissue bank" and "tissue" have the same meaning as defined in Section 1635 of the Health and Safety Code.

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, such as the voluntary reporting, either directly or indirectly, to the federal Food and

Drug Administration of adverse events related to drug products or medical device problems.

(15) Basic information, including the patient's name, city of residence, age, sex, and general condition, may be disclosed to a state or federally recognized disaster relief organization for the purpose of responding to disaster welfare inquiries.

(16) The information may be disclosed to a third party for purposes of encoding, encrypting, or otherwise anonymizing data. However, no information so disclosed shall be further disclosed by the recipient in any way that would be violative of this part, including the unauthorized manipulation of coded or encrypted medical information that reveals individually identifiable medical information.

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to any entity contracting with a health care service plan or the health care service plan's contractors to monitor or administer care of enrollees for a covered benefit, provided that the disease management services and care are authorized by a treating physician, or (B) to any disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code, provided that the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of any well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

(18) The information may be disclosed to a local health department for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.

(e) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no contractor or corporation and its subsidiaries and affiliates shall further disclose medical information regarding a patient of the provider of health care or an enrollee or subscriber of a health care service plan or insurer or self-insured employer received under this section to any person or entity that is not engaged in providing direct health care services to the patient or his or her provider of health care or health care service plan or insurer or self-insured employer.

SEC. 3. Section 8659 of the Government Code is amended to read:

8659. ~~Any physician or surgeon (whether licensed in this state or any other state), hospital, pharmacist, nurse, or dentist~~ *(a) Any health care provider* who renders services during any state of war emergency, a state of emergency, or a local emergency at the express or implied request of any responsible state or local official or agency shall have no liability for any injury sustained by any person by reason of such services, regardless of how or under what circumstances or by what cause such injuries are sustained; provided, however, that the immunity herein granted shall not apply in the event of a willful act or omission.

(b) "Health care provider" means any of the following:

(1) A health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

(2) A clinic licensed pursuant to Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code.

(3) A home health agency licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code.

(4) A physician and surgeon licensed pursuant to Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code or pursuant to the Osteopathic Act.

(5) A podiatrist licensed pursuant to Article 22 (commencing with Section 2460) of Chapter 5 of Division 2 of the Business and Professions Code.

(6) A dentist licensed pursuant to Chapter 4 (commencing with Section 1600) of Division 2 of the Business and Professions Code.

(7) A psychologist licensed pursuant to Chapter 6.6 (commencing with Section 2900) of Division 2 of the Business and Professions Code.

(8) An optometrist licensed pursuant to Chapter 7 (commencing with Section 3000) of Division 2 of the Business and Professions Code.

(9) A chiropractor licensed pursuant to the Chiropractic Initiative Act.

(10) A marriage and family therapist licensed pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code.

(11) A clinical social worker licensed pursuant to Chapter 14 (commencing with Section 4900) of Division 2 of the Business and Professions Code.

(12) A physical therapist licensed pursuant to Chapter 5.7 (commencing with Section 2600) of Division 2 of the Business and Professions Code.

~~SECTION 1.~~

SEC. 4. Section 100106 of the Health and Safety Code is amended to read:

100106. (a) Pursuant to Section 11158 of the Government Code, the sheriff of each county, or city and county, may enforce within the county, or the city and county, all orders of the State Department of Health Services issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease. Every peace officer of every political subdivision of the county, or city and county, may enforce within the area subject to his or her jurisdiction all orders of the State Department of Health Services issued for the purpose of preventing the spread of any contagious, infectious, or communicable disease. This section is not a limitation on the

authority of peace officers or public officers to enforce orders of the State Department of Health Services. When deciding whether to request this assistance in enforcement of its orders, the State Department of Health Services may consider whether it would be necessary to advise the enforcement agency of any measures that should be taken to prevent infection of the enforcement officers.

(b) The State Department of Health Services shall report annually to the Legislature on the number of instances when the department requests the enforcement assistance described in this section.

SEC. 5. Section 101080.1 is added to the Health and Safety Code, to read:

101080.1. (a) Whenever there is a presence or threat of the introduction of any contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent, the director may declare a health emergency and the local health officer may declare a local emergency in the county or any area thereof affected by the threat to the public health. Whenever a local emergency is declared by a local health officer pursuant to this section, the local emergency shall not remain in effect for a period in excess of seven days unless it has been ratified by the board of supervisors. Thereafter the board of supervisors shall review, at least every 14 days until the local emergency is terminated, the need for continuing the local emergency and shall proclaim the termination of the local health emergency at the earliest possible date that conditions warrant the termination.

(b) After a declaration of a local emergency pursuant to this section, the director or local health officer may do both of the following:

(1) Provide information related to the emergency, or any necessary portions thereof, to the state or local agencies responding to the local emergency or county local emergency or to medical and other professional personnel treating victims of the local emergency.

(2) Sample, analyze, or otherwise determine the identifying and other technical information relating to the local emergency as necessary to respond to or abate the county health emergency and protect the public health.

SEC. 6. Section 101080.2 is added to the Health and Safety Code, to read:

101080.2. (a) In the event of potential human exposures to biological, chemical, toxic, or radiological agents that may spread to others and require immediate action, including, but not limited to, decontamination, the local health officer may issue an order to first responders for the purpose of immediately isolating exposed individuals. An order issued pursuant to this section shall not be in effect for a period longer than two hours. If within the two-hour period the local health officer determines that decontamination or continued isolation of an exposed individual is necessary to protect the public health, the local health officer may require that the exposed individuals remain isolated for a reasonable period of time necessary to protect the public health, or undergo decontamination, or both.

(b) A violation of an order issued pursuant to subdivision (a) is a misdemeanor, punishable by a fine of up to one thousand dollars ($1000), or by imprisonment in the county jail for a period of up to 90 days, or by both.

SEC. 7. Section 120176 is added to the Health and Safety Code, to read:

120176. (a) In order to prevent human disease or adverse health conditions in the territory in his or her jurisdiction caused by any serious or life threatening contagious, infectious, or communicable disease, chemical agent, noncommunicable biologic agent, toxin, or radioactive agent, each health officer shall take reasonable measures as may be necessary to prevent the occurrence and spread of the disease or adverse health conditions.

(b) During an outbreak of communicable disease, or upon the imminent threat of communicable disease outbreak or epidemic that threatens the public's health, all health care providers, clinics, health care service plans, pharmacies, their suppliers, distributors, and other for-profit and nonprofit entities shall disclose inventories of critical medical supplies, equipment, pharmaceuticals, vaccines, or other products requested by a local health officer that may be used for the prevention of or may be implicated in the transmission of communicable disease to the local health officer. The local health officer shall keep this proprietary information confidential.

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.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1683 **VERSION: INTRODUCED**

AUTHOR: SCOTT **SPONSOR: CALPRIG**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL INFORMATION: CLINICAL TRIAL DATA

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Pharmaceutical Drug Right-to-Know Act. (B&P 30650 Added)

2) Defines the following terms: adverse events, clinical trial, comparator drug, completion date, Initiation date, pharmaceutical company, pharmaceutical drug, principal sponsors, purposes of the trial, outcomes of the trial, outcomes to be tested, and trial funding sources. (B&P 130651 Added)

3) Requires any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state to make publicly available every new and ongoing clinical trial and every completed clinical trial, that the company conducts or sponsors for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state.

Requires clinical trial information includes, but not limited to, all of the following:

- The name of the trial.
- Commercial and chemical name of all pharmaceutical drugs to be tested, including comparator drugs.
- Dosages to be tested for each drug, including dosages of comparator drugs.
- Initiation date and expected completion date of the trial.
- Purposes of the trial, including the medical condition or conditions to be studied.
- Outcomes to be tested, including all time points at which outcome data will be measured.
- Trial funding sources.
- Number of participants to be enrolled.
- A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

- Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.
- Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.
- Any other information required for clinical trial registration by section 113 of the federal Food and Drug Administration Modernization Act of 1997.

(B&P 130652 & 130653 Added)

4) Requires any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available an explanation of noncompletion for any clinical trial that the manufacturer initiates but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state.

Required noncompletion informaiton includes, but not limited to, all of the following:

- The list of information required in B&P 130652.
- Reasons for termination of the trial.
- Number of patients enrolled in the trial on the termination date.
- Frequency, severity, and nature of all adverse events experienced by trial participants.
- If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.
- How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

(B&P 130654 Added)

5) Requires that pharmaceutical companies post the information required in sections 130652, 130653 & 130654, on www.clinicaltrials.gov a Web Site administered by the National Institutes of Health. The measure also establishes dates by which pharmaceutical companies would be required to post clinical trial information. (B&P 130655 Added)

6) Requires that on or before February 1 of each year beginning February 1, 2008, each company subject to measure submit a report to the Attorney General certifying that it is in compliance with this measure and that the information submitted is accurate and complete.

(B&P 130655 Added)

7) Specifies that pharmaceutical companies that fail to meet all of the requirements of the measure would be deemed a violation of the law and liable for a civil penalty of ____ dollars ($____) per violation. (B&P 130659 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the federal government to take action to warn the public about potentially dangerous drugs.

2) ClinicalTrials.gov. The National Institutes of Health (NIH) developed the Web Site ClinicalTrials.gov in collaboration with the Food and Drug Administration (FDA), as a result of the FDA Modernization Act, which was passed into law in November 1997. The Web Site offers up-to-date information for locating federally and privately supported clinical trials for a wide

range of diseases and conditions. ClinicalTrials.gov currently contains approximately 27,200 clinical studies sponsored by NIH, other federal agencies, and private industry. Studies listed in the database are conducted in all 50 States and in over 120 countries. ClinicalTrials.gov receives over 8 million page views per month and hosts approximately 20,000 visitors daily.

3) Drugmaker's Clinical Trial Internet Portal. In September 2005, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) launched an Internet search portal to provide patients and doctors information on ongoing and completed clinical trials for medications that have been approved for marketing. The search engine establishes links to information posted on pharmaceutical company-owned Web Sites and other commercial or government sponsored Web Sites containing information provided by pharmaceutical companies. Clinical trail results are published within one year after a medication is approved, or for post-approvals, within one year of trial completion. (IFPMA members include the European Federation of Pharmaceutical Industries and Associations, the Japanese Pharmaceutical Manufacturers Associations, and the Pharmaceutical Research and Manufacturers of America.)

4) Other Legislation. AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved. This bill has been in the Senate Health Committee since June 2005.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.) SB 380 died in the Assembly last year.

5) History.

2006

Apr. 6	Set for hearing April 19.
Mar. 9	To Com. on HEALTH.
Feb. 27	Read first time.
Feb. 25	From print. May be acted upon on or after March 27.
Feb. 24	Introduced. To Com. on RLS. for assignment. To print.

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SENATE BILL No. 1683

Introduced by Senator Scott

February 24, 2006

An act to add Division 112.6 (commencing with Section 130650) to the Health and Safety Code, relating to pharmaceutical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 1683, as introduced, Scott. Pharmaceutical information: clinical trial data.

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

This bill would require a pharmaceutical company that sells, delivers, offers for sale, or gives away pharmaceutical drugs within the state to make publicly available every new and ongoing clinical trial, the results of every completed clinical trial, an explanation of noncompletion for any uncompleted clinical trial that the company conducts or sponsors. The bill would authorize the Director of Health Services to adopt additional reporting requirements and would require each subject company to submit an annual report to the Attorney General that certifies that the company is in compliance with the provisions of the bill. The bill would make violation of its provisions subject to a civil penalty of $_____.

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

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

1 SECTION 1. (a) The Legislature finds and declares all of the
2 following:

(1) Recent scandals involving Vioxx, Celebrex, Paxil, and other medications have demonstrated a need for the state to better protect California consumers taking pharmaceutical products.

(2) In some of these scandals, including Vioxx and Paxil, the manufacturers of the drugs had access to clinical trial data demonstrating serious potential adverse side effects or lack of effectiveness, but the manufacturers did not share the data with the general public.

(3) The absence of this information hurts consumers both financially and physically. Research by the federal Food and Drug Administration estimates that Vioxx alone may have caused up to 140,000 cases of coronary heart disease in the United States.

(4) Articles and editorials in leading medical journals and newspapers have highlighted problems with clinical trial reporting beyond outright data suppression, including: the use of a comparison drug at a dosage that is too low to be effective, making the study drug appear superior; the choice of a comparison drug dosage that is too high, making the study drug appear less toxic; the publication of data only from preferential endpoints; the publication of the same data in multiple articles to increase the data's impact; and the use of ghostwriters paid indirectly or directly by the study sponsor to give the sponsor control over the publication's message.

(5) By making sure that all clinical studies on pharmaceutical drugs see the light of day and that the information necessary to understand and critique the studies is available, doctors and other medical professionals will be better equipped to make sound decisions about medicines and patients will be better informed about potential dangers of certain medicines.

(b) It is the intent of the Legislature in enacting this act to require pharmaceutical drug companies to make public the results of all clinical trials conducted on their drugs if those drugs are made available to California consumers.

SEC. 2. Division 112.6 (commencing with Section 130650) is added to the Health and Safety Code, to read:

DIVISION 112.6. PHARMACEUTICAL DRUG RIGHT-TO-KNOW ACT

130650. This division shall be known, and may be cited as the "Pharmaceutical Drug Right-to-Know Act."

130651. For purposes of this chapter, the following definitions shall apply:

(a) "Adverse events" means any negative health outcome occurring in a clinical trial subject during the course of the clinical trial.

(b) "Clinical trial" means a clinical investigation as defined by the federal Food and Drug Administration that involves any experiment to test the safety or efficacy of a drug or biological product with one or more human subjects.

(c) "Comparator drug" means an investigational or marketed drug or placebo against which a new drug is being tested and compared.

(d) "Completion date" means the date of the last patient visit necessary for completion of the trial or the date of the first publication of any data from the clinical trial, whichever is first.

(e) "Initiation date" means date of enrollment for the first patient in a clinical trial.

(f) "Pharmaceutical company" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of pharmaceutical drugs, either directly or indirectly, by means of chemical synthesis or by a combination of extraction and chemical synthesis. "Pharmaceutical company" also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of pharmaceutical drugs. "Pharmaceutical company" also includes a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a pharmaceutical drug in this state on behalf of a pharmaceutical company.

(g) "Pharmaceutical drug" means any drug which is approved by the federal Food and Drug Administration and commercially available in the state.

(h) "Principal sponsors" means the entity ultimately responsible for funding the trial, the entity ultimately responsible for designing the trial protocol, and the entity who owns the data generated by the trial.

(i) "Purposes of the trial" means the hypotheses that the trial is testing, including, but not limited to, all of the following:

(1) The drug's effectiveness in treating a specific illness or condition. In this case, the illness or condition shall be named, and what type of effect is being sought shall be specified.

(2) The drug's safety when used to treat a specific illness or condition. In this case, the illness or condition shall be named.

(3) The relative effectiveness or relative safety of the drug in treating a specific illness or condition as compared to another drug. In this case, the illness or condition shall be named, and the effect or adverse events to be compared shall be specified.

(j) "Outcomes of the trial" means the specific measurements that were taken to evaluate the effects the drug and any comparator drug had on trial participants.

(k) "Outcomes to be tested" means the specific measurements that will be taken to evaluate the effects the drug and any comparator drug have on trial participants.

(*l*) "Trial funding sources" means the name of and financial contribution amount for each organization, corporation, individual, or other entity that provides any funding for the clinical trial.

130652. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, every new and ongoing clinical trial that the company conducts or sponsors for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for registration shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs to be tested, including comparator drugs, if any.

(c) Dosages to be tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation date and expected completion date of the trial.

(e) Purposes of the trial, including the medical condition or conditions to be studied.

(f) Outcomes to be tested, including all time points at which outcome data will be measured.

(g) Trial funding sources.

(h) Number of participants to be enrolled.

(i) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(j) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(k) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(*l*) Any other information required for clinical trial registration by section 113 of the federal Food and Drug Administration Modernization Act of 1997.

130653. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, the results of every completed clinical trial that the company has conducted or sponsored for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information necessary to meet this requirement shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs, if any.

(c) Dosages tested for each drug, including dosages of comparator drugs, if any.

(d) Initiation and completion dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Outcomes of the trial including all time points at which outcome data were measured.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients completing the trial.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender, race, age, preexisting health conditions, and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(*l*) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity, and nature of all adverse events experienced by trial participants, including participants that did not complete the trial.

(o) If any of the data from the study were published in any form, for each of these publications.

(p) If any of the data from the study were published, the name and employer of each author of the study, including "ghostwriters."

(q) Any financial interest the principal researchers of the study have in the drugs tested or compared in the trial and in the principal sponsors of the trial.

(r) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130654. Any pharmaceutical company that sells, delivers, offers for sale, or gives away any pharmaceutical drug within this state shall make publicly available, in accordance with Section 130655, an explanation of noncompletion for any clinical trial that the manufacturer initiates but does not complete for every pharmaceutical drug that the company sells, delivers, offers for sale, or gives away in this state. Information required for an explanation of noncompletion shall include, but not be limited to, all of the following:

(a) The name of the trial.

(b) Commercial and chemical name of all pharmaceutical drugs tested, including comparator drugs.

(c) Dosages tested for each drug including dosages of comparator drugs, if any.

(d) Initiation and termination dates of the trial.

(e) Purposes of the trial, including the medical condition or conditions studied.

(f) Reasons for termination of the trial.

(g) Trial funding sources.

(h) Number of patients initially enrolled in the trial.

(i) Number of patients enrolled in the trial on the termination date.

(j) A list of all specific characteristics used to include and exclude people as trial participants, such as gender race, age, and preexisting health conditions and an explanation of why each characteristic was used to include or exclude patients.

(k) Names and contact information for principal sponsors of the trial. Contact information shall include at least a telephone number, mailing address, and email address for public inquiry.

(*l*) Names and contact information for principal researchers of the trial. Contact information shall include at least a telephone number, mailing address, and e-mail address for public inquiry.

(m) Frequency, severity, and nature of all adverse events experienced by trial participants.

(n) If the study involved a comparison of two or more pharmaceutical drugs, all information regarding the relative efficacy of each drug and the relative frequency, severity and nature of all adverse events experienced by trial participants, including participants that did not complete the trial, for each drug.

(o) How the information regarding adverse events to the study drug is reflected in the package insert for the drug, including direct quotations from the package insert.

130655. The information required pursuant to Sections 130652, 130653, and 130654 shall be submitted for inclusion on www.clinicaltrials.gov, the Web site administered by the National Institutes of Health pursuant to section 113 of the federal Food and Drug Administration Modernization Act of 1997, or its successor Web site subject, to all of the following conditions:

(a) For clinical trials with a trial initiation date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov no later than 21 days after the trial's initiation. For ongoing clinical trials with a trial initiation date

before January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130652 to www.clinicaltrials.gov on or before January 22, 2007.

(b) For clinical trials with a trial completion date on or after January 1, 2007, the sponsor of the trial shall submit the information required pursuant to Section 130653 to www.clinicaltrials.gov on or before 90 days from when the pharmaceutical drug is first sold, delivered, or offered for sale, or given away in the state. The publication information required in subdivisions (o) and (p) of Section 130653 shall be updated promptly whenever data from the trial have been included in a new publication. If the trial was registered when it was initiated, any differences between the information reported at that time and the information being submitted upon completion shall be highlighted and explained.

(c) For clinical trials with a noncompletion date on or after January 1, 2007, the sponsor of the trial shall submit the information required by Section 130654 to www.clinicaltrials.gov no later than 21 days after the trial's noncompletion. For clinical trials with a trial noncompletion date before January 1, 2007, the sponsor of the trial shall submit the required information to www.clinicaltrials.gov on or before January 22, 2007.

130657. All information submitted pursuant to this division shall be in plain English to the maximum extent possible, with the goal of being readily understandable by a person who is not a medical professional.

130658. The Director of Health Services may adopt additional reporting requirements and rules for the implementation of this division.

130659. On or before February 1 of each year beginning February 1, 2008, each company subject to this division shall submit a report to the Attorney General certifying that it is in compliance with this section and that the information submitted is accurate and complete.

130660. Failure by a pharmaceutical company to meet all of the requirements of this division shall be deemed a violation of the law and the pharmaceutical company shall be liable for a civil penalty of ____ dollars ($____) per violation. Each clinical trial registration required by, and each clinical trial results disclosure

1 required that does not fully comply with, this division shall be
2 considered a separate violation for which the pharmaceutical
3 company is liable. Additionally, each day of each violation shall
4 be considered a separate violation for which the pharmaceutical
5 company is liable.

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2005

Watch Bills

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AMENDED IN SENATE JUNE 15, 2005

AMENDED IN SENATE JUNE 6, 2005

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 26, 2005

AMENDED IN ASSEMBLY APRIL 12, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 651

Introduced by Assembly Members ~~Levine and Berg~~ *Berg and Levine*
(Coauthors: Assembly Members Bass, Canciamilla, Chu, Dymally, Goldberg, Koretz, Laird, Leno, and Wolk)
(Coauthors: Senators Kuehl, Lowenthal, and Romero)

February 17, 2005

An act to add Chapter 3.95 (commencing with Section 7195) to Part 1 of Division 7 of the Health and Safety Code, relating to death.

LEGISLATIVE COUNSEL'S DIGEST

AB 651, as amended, ~~Levine~~ *Berg*. California Compassionate Choices Act.

Existing law authorizes an adult to give an individual health care instruction and to appoint an attorney to make health care decisions for that individual in the event of his or her incapacity pursuant to a power of attorney for health care.

This bill would enact the California Compassionate Choices Act, which would authorize an adult who meets certain qualifications, and who has been determined by his or her attending physician to be suffering from a terminal disease, as defined, to make a request for

medication for the purpose of ending his or her life in a humane and dignified manner. The bill would establish procedures for making these requests.

This bill would further provide that no provision in a contract, will, or other agreement, or in a health care service plan contract, policy of disability insurance, or health benefit plan contract, shall be valid to the extent it would affect whether a person may make or rescind a request for medication for the purpose of ending his or her life in a humane and dignified manner. The bill would prohibit the sale, procurement, or issuance of any life, health, or accident insurance or annuity policy, or the rate charged for any policy, from being conditioned upon or affected by the request. The bill would require that nothing in its provisions be construed to authorize ending a patient's life by lethal injection, mercy killing, or active euthanasia, and would provide that action taken in accordance with the act shall not constitute suicide or homicide.

This bill would provide immunity from civil or criminal liability or professional disciplinary action for participating in good faith compliance with the act. The bill would provide that no health care provider is under any duty to participate in providing to a qualified patient medication to end that patient's life and would authorize a general acute care hospital to prohibit a licensed physician from carrying out a patient's request under this act on the premises of the hospital if the hospital has notified the licensed physician of its policy regarding this act.

This bill would require the State Department of Health Services to adopt regulations regarding the collection of information to determine the use of and compliance with the act, and would require the department to annually review a sample of certain records and make a statistical report of the information collected.

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

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

1 SECTION 1. Chapter 3.95 (commencing with Section 7195)
2 is added to Part 1 of Division 7 of the Health and Safety Code, to
3 read:

Chapter 3.95. California Compassionate Choices Act

Article 1. General Provisions

7195. (a) The Legislature believes that dying patients should have choices throughout the continuum of palliative care and that much must be done to improve access to hospice care and pain management. Hospice and effective palliative care successfully assist many thousands of terminally ill patients to die with dignity and without pain, and the Legislature hopes that all patients considering the procedures available under this chapter will properly consider other options, including hospice care and effective pain management. The Legislature finds that medical studies have shown that between 5 and 10 percent of dying patients experience severe pain and suffering that cannot be palliated by the best hospice or comfort care. The Legislature finds that in response to the Death with Dignity Act in the State of Oregon, that the referrals to hospice increased significantly. In addition, doctors significantly increased the use of morphine and other strong pain medications, thus improving the end-of-life care for more dying patients.

(b) (1) It is the intent of the Legislature that the personal and autonomous choice of dying patients regarding the time and manner of their death provided under this chapter be viewed as but one of several end-of-life options for dying patients.

(2) It is the intent of the Legislature that this chapter be strictly construed and not expanded in any manner. The restrictions and safeguards in the provisions of this chapter are based on the intent of the Legislature to balance the personal and autonomous choice of dying patients regarding the time and manner of their death and the Legislature's goal of providing safeguards to ensure that there are not instances of a coerced, unwanted, or early death by a vulnerable dying patient.

(3) The Legislature finds and declares that historically persons with disabilities have been subject to discrimination in the provision of medical care and have been treated by some as though their lives were less valuable or worthy of maintenance than those without disabilities. The Legislature finds that this discriminatory conduct is both illegal and reprehensible.

(4) It is the intent of the Legislature that a disability or age alone are not reason for a patient to be a qualified patient as defined in subdivision (*l*) of Section 7195.1. Any disabled individual or elderly person, and any physician who is the attending physician to these individuals, must strictly comply with all of the provisions of this chapter. Strict and rigorous attention must be evidenced in distinguishing chronic conditions, which are not eligible conditions under this chapter, and terminal illnesses, which are eligible, as described in this chapter.

7195.1. For purposes of this chapter the following definitions shall apply:

(a) "Adult" means an individual who is 18 years of age or older.

(b) "Attending physician" means the physician who has primary responsibility for the care of the patient and for treatment of the patient's terminal disease.

(c) "Capable" means that in the opinion of the patient's attending physician or consulting physician, a patient has the ability to make and communicate health care decisions to health care providers, including communication through persons familiar with the patient's manner of communicating if those persons are available. Incapable means that the patient does not have the mental capacity to make and understand decisions about his or her medical care.

(d) "Consulting physician" means a physician, other than the attending physician, who is qualified by specialty or experience to make a professional diagnosis and prognosis regarding the patient's disease.

(e) "Counseling" means a consultation between a state licensed psychiatrist or psychologist and a patient for the purpose of determining whether the patient is suffering from a psychiatric or psychological disorder, or depression causing impaired judgment.

(f) "Health care provider" means a person licensed, certified, or otherwise authorized or permitted by the law of this state to administer health care in the ordinary course of business or practice of a profession, and includes a licensed health care facility.

(g) *(1)* "Health care facility" means any health facility described in Section 1250.

(2) "Hospice" means a comprehensive, interdisciplinary program of medical and socially supportive care delivered to patients with a terminal disease in order to palliate their symptoms and pain since the patient's condition is no longer amenable to curative therapies and for whom the primary therapeutic goal is comfort and dignity at the end of life.

(h) "Informed decision" means a decision, made by a qualified patient, to request and obtain a prescription to end his or her life in a humane and dignified manner, that is not based on coercion by the patient's next of kin or any other third parties, is based on an appreciation of the relevant facts, and is made after being fully informed by the attending physician of all of the following:

(1) His or her medical diagnosis.

(2) His or her prognosis.

(3) The potential risk associated with taking the medication to be prescribed.

(4) The probable result of taking the medication to be prescribed.

(5) The feasible alternatives, as provided in paragraph (5) of subdivision (b) of Section 7196, including, but not limited to, comfort care, hospice care, and pain control.

(i) "Medically confirmed" means the medical opinion of the attending physician has been confirmed by a consulting physician who has examined the patient and the patient's relevant medical records.

(j) "Patient" means a person who is under the care of a physician.

(k) "Physician" means a doctor of medicine or osteopathy licensed to practice medicine by the Medical Board of California.

(l) "Qualified patient" means a capable adult who is a resident of California and has satisfied the requirements of this chapter in order to obtain a prescription for medication to end his or her life in a humane and dignified manner.

(m) "Resident" means a person who has lived in a principal place of residence in the State of California for six months or more.

(n) "Terminal disease" means an incurable and irreversible disease that has been medically confirmed and will, within reasonable medical judgment, produce death within six months.

7195.3. An adult who is capable, is a resident of California, has been determined by the attending physician and a consulting physician to be suffering from a terminal disease, and who has voluntarily expressed his or her wish to obtain life-ending medication to his or her attending physician shall, in addition to the other requirements of this chapter, make a written request for medication for the purpose of ending his or her life in a humane and dignified manner in accordance with this chapter in order to be eligible for qualification under this chapter.

7195.5. (a) A valid written request for medication under this chapter shall be in substantially the form prescribed by Section 7199, signed and dated by the patient and witnessed by at least two individuals who, in the presence of the patient, attest that to the best of their knowledge and belief the patient is capable, acting voluntarily, and is not being coerced to sign the request.

(b) ~~One~~ *Both* of the witnesses shall be a person who is not any of the following:

(1) A relative of the patient by blood, marriage, or adoption.

(2) A person who at the time the request is signed would be entitled to any portion of the estate of the qualified patient upon death under any will or by operation of law.

(3) An owner, operator, or employee of a health care facility where the qualified patient is receiving medical treatment or is a resident.

(c) The patient's attending physician at the time the request is signed shall not be a witness.

Article 2. Safeguards

7196. Upon being voluntarily informed by a qualified patient that the patient wishes to receive medication for the purpose of ending his or her life in a humane and dignified manner in accordance with this chapter, the attending physician shall do all of the following:

(a) Make the initial determination of whether a patient has a terminal disease, is capable, and has made the request voluntarily.

(b) Inform the patient of all of the following:

(1) His or her medical diagnosis.

(2) His or her prognosis.

(3) The potential risks associated with taking the medication to be prescribed.

(4) The probable result of taking the medication to be prescribed.

(5) The feasible alternatives, including, but not limited to, comfort care, hospice care, and pain control. This disclosure must be provided in writing to the patient, and shall include, but not be limited to, contact information about locally based providers of comfort and hospice care.

(c) Refer the patient to a consulting physician for medical confirmation of the diagnosis, and for a determination that the patient is capable and acting voluntarily.

(d) Refer the patient for counseling if appropriate pursuant to Section 7196.2.

(e) Request that the patient notify next of kin.

(f) Inform the patient that he or she has an opportunity to rescind the request at any time and in any manner, and offer the patient an opportunity to rescind at the end of the 15-day waiting period described in Section 7196.5.

(g) Verify, immediately prior to writing the prescription for medication under this chapter, that the patient is making an informed decision.

(h) Fulfill the medical record documentation requirements of Section 7196.8.

(i) Ensure that all appropriate steps are carried out in accordance with this chapter prior to writing a prescription for medication to enable a qualified patient to end his or her life in a humane and dignified manner.

7196.1. Before a patient is qualified under this chapter, a consulting physician shall examine the patient and his or her relevant medical records and shall, in writing, confirm, the attending physician's diagnosis and that the patient is suffering from a terminal disease and verify that the patient is capable, is acting voluntarily, and has made an informed decision.

7196.2. If, in the opinion of the attending physician or the consulting physician, a patient may be suffering from a psychiatric or psychological disorder that impairs judgment or from depression or medication that impairs judgment, *or the patient is not a hospice patient,* the attending physician or consulting physician shall require the patient to undergo

counseling as specified in subdivision (e) of Section 7195.1. In this case, no medication to end the patient's life in a humane and dignified manner shall be prescribed unless the patient first undergoes the requisite *consultation or* counseling and until the person performing the counseling determines that the patient is not suffering from a psychiatric or psychological disorder that impairs judgment, or from impaired judgment caused by depression or medication.

7196.3. No person shall receive a prescription for medication to end his or her life in a humane and dignified manner unless he or she has made an informed decision as defined in subdivision (h) of Section 7195. Immediately prior to writing a prescription for medication in accordance with this chapter, the attending physician shall verify that the patient is making an informed decision.

7196.4. The attending physician shall ask the patient to notify the patient's next of kin of his or her request for medication pursuant to this chapter. A patient who declines or is unable to notify next of kin shall not have his or her request denied for that reason.

7196.5. In order to receive a prescription for medication to end his or her life in a humane and dignified manner, a qualified patient shall have made an oral request and a written request, and reiterate the oral request to his or her attending physician no less than 15 days after making the initial oral request. At the time the qualified patient makes his or her second oral request, the attending physician shall offer the patient an opportunity to rescind the request.

7196.6. A patient may rescind his or her request at any time and in any manner without regard to his or her mental state. No prescription for medication under this chapter may be written without the attending physician offering the qualified patient an opportunity to rescind the request.

7196.7. No less than 15 days shall elapse between the patient's initial oral request and the writing of a prescription under this chapter. No less than 48 hours shall elapse between the patient's written request and the writing of a prescription under this chapter.

7196.8. The following shall be documented or filed in the patient's medical record:

(a) All oral requests by a patient for medication to end his or her life in a humane and dignified manner.

(b) All written requests by a patient for medication to end his or her life in a humane and dignified manner.

(c) The attending physician's diagnosis and prognosis, and his or her determination that the patient is capable, acting voluntarily, and has made an informed decision.

(d) The consulting physician's diagnosis and prognosis, and his or her verification that the patient is capable, acting voluntarily, and has made an informed decision.

(e) A report of the outcome and determinations made during counseling, if performed.

(f) The attending physician's offer to the patient to rescind his or her request at the time of the patient's second oral request pursuant to Section 7196.5.

(g) The attending physician's discussion with the patient of feasible alternatives, including, but not limited to, hospice care, comfort care, and pain control.

(h) A note by the attending physician indicating that all the requirements of this chapter have been met and indicating the steps taken to carry out the request, including a notation of the medication prescribed.

7196.9. Only requests made by California residents under this chapter shall be granted.

7197.1. (a) The department shall adopt regulations regarding requirements for the collection of information to determine the use of and compliance with this chapter. The information collected shall not be a public record and shall not be made available for inspection by the public.

(b) The department shall generate and make available to the public an annual statistical report of information collected pursuant to subdivision (a).

(c) The department shall annually review a sample of records maintained pursuant to this chapter.

7197.3. (a) No provision in a contract, will, or other agreement, whether written or oral, to the extent the provision would affect whether a person may make or rescind a request for medication to end his or her life in a humane and dignified manner, shall be valid.

(b) No obligation owing under any contract in existence on or before January 1, 2006, shall be conditioned or affected by the making or rescinding of a request by a person for medication to end his or her life in a humane and dignified manner.

(c) No health care service plan contract, as defined in subdivision (r) of Section 1345, shall be conditioned upon or affected by the making or rescinding of a request by a person for medication to end his or her life in a humane and dignified manner. Any such contract provision shall be invalid.

(d) No provision of a policy of disability insurance or a health benefit plan contract that provides coverage for hospital, medical, or surgical expenses pursuant to Part 2 (commencing with Section 10110) of Division 2 of the Insurance Code shall be conditioned upon or affected by the making or rescinding of a request by a person to end his or her life in a humane and dignified manner. Any such policy provision shall be invalid.

7197.5. The sale, procurement, or issuance of any life, health, or accident insurance or annuity policy or the rate charged for any policy shall not be conditioned upon or affected by the making or rescinding of a request by a person for medication to end his or her life in a humane and dignified manner. A qualified patient's act of ingesting medication to end his or her life in a humane and dignified manner in accordance with this chapter shall not have an effect upon a life, health, or accident insurance or annuity policy.

7197.7. Nothing in this chapter shall be construed to authorize a physician or any other person to end a patient's life by lethal injection, mercy killing, or active euthanasia. The patient must self-administer the medication provided under this chapter. Actions taken in accordance with this chapter shall not, for any purpose, constitute suicide, assisted suicide, mercy killing, or homicide, under the law.

Article 3. Immunities and Liabilities

7198. Except as provided in Section 7198.5:

(a) Notwithstanding any other provision of law, no person shall be subject to civil or criminal liability or professional disciplinary action for participating in good faith compliance with this chapter. This includes being present when a qualified

patient takes the prescribed medication to end his or her life in a humane and dignified manner.

(b) No professional organization or association, or heath care provider, may subject a person to censure, discipline, suspension, loss of license, loss of privileges, loss of membership, or other penalty for participating or refusing to participate in good faith compliance with this chapter.

(c) No request by a patient for or provision by an attending physician of medication in good faith compliance with this chapter shall constitute neglect for any purpose of law or provide the sole basis for the appointment of a guardian or conservator.

(d) No health care provider shall be under any duty, whether by contract, by statute, or by any other legal requirement to participate in the provision to a qualified patient of medication to end his or her life in a humane and dignified manner. If a health care provider is unable or unwilling to carry out a patient's request under this chapter, and the patient transfers his or her care to a new health care provider, the prior health care provider shall transfer, upon request, a copy of the patient's relevant medical records to the new health care provider.

(e) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250, may prohibit a licensed physician from carrying out a patient's request under this chapter on the premises of the hospital if the hospital has notified the licensed physician of its policy regarding this chapter.

7198.5. (a) Nothing in this chapter limits civil or criminal liability resulting from other negligent conduct or intentional misconduct by any person.

(b) The penalties in this chapter do not preclude criminal penalties applicable under other law for conduct that is inconsistent with this chapter.

Article 4. Severability

7198.9. Any section of this chapter that is held invalid as to any person or circumstance shall not affect the application of any other section of this chapter that can be given full effect without the invalid section or portion thereof.

Article 5. Form of the Request

7199. A request for a medication as authorized by this chapter shall be in substantially the following form:

REQUEST FOR MEDICATION
TO END MY LIFE IN A HUMANE AND DIGNIFIED MANNER

I, ____, am an adult of sound mind.

I am suffering from ____, which my attending physician has determined is a terminal disease which will, within reasonable medical judgment, likely lead to my death within six months, and which has been medically confirmed by a consulting physician.

I have been fully informed of my diagnosis, prognosis, the nature of the medication to be prescribed, and the potential associated risks, the expected result, and the feasible alternatives, including comfort care, hospice care, and pain control.

I request that my attending physician prescribe medication that will allow me to hasten the end of my life in a humane and dignified manner.

INITIAL ONE:

_____ I have informed my family of my decision and taken their opinions into consideration.

_____ I have decided not to inform my family of my decision.

_____ I have no family to inform of my decision.

I understand that I have the right to rescind this request at any time.

I understand the full import of this request, and I expect to die when I take the medication to be prescribed.

I make this request voluntarily and without reservation, and I accept full moral responsibility for my actions.

Signed: _____

Dated: _____

DECLARATION OF WITNESSES

We declare that the person signing this request:

(a) Is personally known to us or has provided proof of identity;

(b) Signed this request in our presence;

(c) Appears to be of sound mind and not under duress, fraud, or undue influence;

(d) Is not a patient for whom either of us is the attending physician.

_____ Witness 1/Date

_____ Witness 2/Date

NOTE: One witness shall not be a relative (by blood, marriage, or adoption) of the person signing this request, shall not be entitled to any portion of the person's estate upon death, and shall not own, operate, or be employed at a health care facility where the person is a patient or resident.

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Meeting Summary

Legislation and Regulation Committee
April 19, 2006

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MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: APRIL 19, 2006
DEPARTMENT OF CONSUMER AFFAIRS
FIRST FLOOR HEARING ROOM
1625 NORTH MARKET BLVD
10:00 A.M. – 12:00 P.M.

BOARD MEMBERS PRESENT:

JOHN JONES, CHAIR
KENNETH H. SCHELL, MEMBER
DAVE FONG, MEMBER
ANDREA ZINDER, MEMBER

BOARD STAFF PRESENT:

PATRICIA HARRIS
VIRGINIA HEROLD
JAN PEREZ

The meeting was convened at 10:00 a.m..

Legislation

The committee was provided with a list of bills and bill analysis, which it reviewed. While the discussion was lively at times, the board chose to take positions on only a few bill and directed staff to watch bills on which it took no position. The bills the committee discussed and the positions the committee recommended are as follows:

Board Sponsored Legislation

AB 595 (Negrete McLeod) Pharmacy: compounding of prescription drugs.
Status: Senate Floor.
This bill is sponsored by the board to establish standards for pharmacies that compound and to provide direction for regulations that will follow later this year. The board approved this legislative proposal at its January 2005 meeting.

AB 2408 (Negrete McLeod) Pharmacists, pharmacies, and nonresident pharmacies.
Status: Status: Assembly Appropriations Committee.
This bill is sponsored by the board and would update the definition of a pharmacy, nonresident pharmacy, and the professional practice of pharmacy. The board approved draft legislation at its February 2006 meeting.

SB 1475 (Senate Business and Professions and Economic Development Committee) Omnibus Bill.
Status: Senate Business, Professions And Economic Development Committee – Hearing April 24, 2006.
The board approved eight proposals for the omnibus legislation, however only three of the eight proposals are currently in the bill.

Approved Proposals in SB 1475
B&P 4104 Licensed Employee, Theft, Impairment: Pharmacy Procedures.
B&P 4162 Wholesalers Surety Bond Requirements.
B&P 4180-4182 and 4190-4192 Nonprofit or Free Clinics.

Approved Proposals NOT in SB 1475
B&P 4314 & 4315 Cite and Fine, Letter of Admonishment.
B&P 4084 Adulterated or Counterfeit Drug or Dangerous Device.
B&P 4160 Wholesaler License.
B&P 4127.1 Injectable Sterile Drug Products.
B&P 4073 Substitution of Generic Drug, Check off Box on Electronic Prescriptions.

SB 1476 (Figueroa) Board Sunset Extension Bill.
Status: Senate Business, Professions And Economic Development Committee – Hearing April 24, 2006
This bill will extend the board's sunset date two years, from 2008 to 2010. The board's sunset report to the Legislature will be due September 2008. Additionally the measure would repeal B&P section 4163.5, effectively moving the implementation date of electronic pedigree requirement from January 1, 2007 to January 1, 2008.

Bills of Interest

AB 2198 (Houston) Health care: controlled substances and dangerous drugs.
Status: Assembly Health Committee.
Committee Recommendation: None.

AB 2308 (Plescia) Ambulatory surgical centers: licensure.
Status: Assembly Health Committee - Hearing April 25, 2006.
Committee Recommendation: None.

AB 2583 (Nation) Dispensing prescription drugs and devices: refusal to dispense.
Status: Assembly Appropriations Committee.
Committee Recommendation: Oppose Unless Amended.
Proposed Amendments: (1) Specify in law the exact wording of the sign. (2) Require pharmacies, rather than the board, to print the sign. (3) Why is the sign needed if the point it for patients to get their medications due to protocol in B&P 733 (b)(3)(A)?

AB 2743 (Matthews) Pharmacists: ancillary personnel.
Status: Assembly Business and Professions Committee – Hearing April 25, 2006.
Committee Recommendation: No Position.

AB 2986 (Mullin) Controlled substances: prescription requirements.
Status: Assembly Public Safety Committee - Hearing April 18, 2006.
Committee Recommendation: No Position.

SB 1366 (Aanestad) Controlled substances.
Status: Assembly Public Safety Committee - Hearing April 25, 2006.
Committee Recommendation: Neutral.

2006 Watch Bills

AB 1908 (Karnette) Medi-Cal: pharmacy reimbursement.
Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2057 (Cogdill) Controlled substances.
Status: Assembly Appropriations Committee.

AB 2308 (Plescia) Ambulatory surgical centers: licensure.
Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2373 (Plescia) Automated drug delivery system.
Status: Assembly Business and Professions Committee.

AB 2730 (Nation) Medi-Cal: contract drug list: advertising.
Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2856 (Hancock) Informed consent: prescription medication off-label use.
Status: Assembly Health Committee - Hearing April 25, 2006.

AB 2877 (Frommer) Prescription drugs: importation: procurement.
Status: Assembly Business and Professions Committee.

AB 2911 (Nunez) California Discount Prescription Drug Program.
Status: Assembly Health Committee - Hearing April 25, 2006.

AJR 40 (Chan) Medicare Prescription Drugs.
Status: Senate.

AJR 49 (Nation) Direct-To-Consumer Prescription Drug Advertisements
Status: Assembly Health Committee - Hearing May 2, 2006.

SB 1305 (Figueroa) The Medical Waste Management Act.
Status: Senate Environmental Quality Committee – Hearing April 24, 2006.

SB 1430 (Alquist) The Local Pandemic and Emergency Health Preparedness Act of 2006.
Status: Senate Floor.

SB 1683 (Scott) Pharmaceutical information: clinical trial data.
Status: Senate Health Committee – Hearing April 25, 2006.

2005 Watch Bills

AB 651 (Berg) California Compassionate Choices Act.
Status: Senate Rules Committee.

AB 21 (Levine) Pharmacists: contraceptive devices.
Status: Senate Health Committee - Hearing Cancelled.

AB 71 (Chan) Pharmaceuticals: adverse drug reactions: Office of Ca. Drug Safety Watch.
Status: Senate Health Committee - Hearing Cancelled.

AB 75 (Frommer) Pharmaceutical assistance program.
Status: Senate Health Committee - Hearing Cancelled.

AB 225 (Negrete McLeod) Electronic prescription information.
Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

AB 283 (Koretz) Pseudoephedrine: retail sale.
Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

AB 657 (Karnette) Pharmacies: prescription containers.
Status: Senate Business, Professions, and Economic Development Committee - Hearing Cancelled.

SB 380 (Alquist) Drugs: adverse event reporting.
Status: Assembly Floor, failed passage. Reconsideration granted. Inactive file.

SB 592 (Aanestad) Acute care hospitals: inpatient pharmacy technician services.
Status: Assembly Health Committee - Failed passage in committee. Reconsideration granted.

Proposed Legislation

The committee approved a legislative proposal brought by MedImmune Inc. that would make a technical amendment to add biologics license applications to B&P Section 4162.5(a)(4); Submission of Surety Bond for the Issuance or Renewal of Nonresident Wholesaler License; Exemption.

Regulations Update

The committee discussed the comments the board received for 16 CCR section 1717(e) and to add 16 CCR section 1713 Prescription Drop Boxes and Automated Self-Use Delivery Device for Refill Prescriptions. The committee recommended minor changes to the proposed regulation. These changes will be presented to the board as an alternative to the language that was noticed on February 24, 2006.

The committee approved proposed changes to update the building code relating to pharmacies. The California Building Standards Commission (CBSC) had asked the board to review and update pharmacy building standards in the building code, in preparation of the CBSC adoption of the 2006 International Building Code and 2006 International Fire Code, the 2005 National Electrical Code, and 2006 Uniform Mechanical Code and Uniform Plumbing Code, in CCR, Title 24. The CBSC anticipates adopting the new standards in early 2008.

Adjournment

The committee adjourned at 12:00 p.m..