CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 57 | **VERSION: AS AMENDED MARCH 10, 2003**

AUTHOR: BATES | **SPONSOR: NONE**

RECOMMENDED POSITION: NONE | **SUBJECT: MDMA**

Existing Law:

1) Categorizes controlled substances into five schedules based on the risk of addiction and the existence of generally accepted medical use. (H&S 11054-11058)

2) Provides penalties up to and including incarceration in state prison for violations of laws relating to Schedule II controlled substances.

This Bill:

Categorizes MDMA (ecstasy) as a Schedule II controlled substance. (H&S 11055)

Comment:

1) Author's Intent. Existing federal law classifies MDMA as a Schedule I controlled substance. However, state law does not classify MDMA as a controlled substance and law enforcement cannot charge MDMA violations under state law.

2) Classification of Controlled Substances. Federal law spells out the criteria used to place substances in the appropriate schedule by the Attorney General of the United States. Those criteria are excerpted below:

a. Its actual or relative potential for abuse.
b. Scientific evidence of its pharmacological effect, if known.
c. The state of current scientific knowledge regarding the drug or other substance.
d. Its history and current pattern of abuse.
e. The scope, duration, and significance of abuse.
f. What, if any, risk there is to the public health.
g. Its psychic or physiological dependence liability.
h. Whether the substance is an immediate precursor of a substance already controlled under this subchapter.

Federal law provides added specific guidance on the placement of drugs into the five schedules, as follows:

Schedule I. -

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.

- There is a lack of accepted safety for use of the drug or other substance under medical supervision.

Schedule II. -
- The drug or other substance has a high potential for abuse.
- The drug or other substance has a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions.
- Abuse of the drug or other substances may lead to severe psychological or physical dependence.

Schedule III. -
- The drug or other substance has a potential for abuse less than the drugs or other substances in schedules I and II.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to moderate or low physical dependence or high psychological dependence.

Schedule IV. -
- The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule III.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

J. **Schedule V. -**
- The drug or other substance has a low potential for abuse relative to the drugs or other substances in schedule IV.
- The drug or other substance has a currently accepted medical use in treatment in the United States.
- Abuse of the drug or other substance may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

2) State Law. California has its own controlled substance schedules which largely mirror the federal schedules. However, states can and do sometimes place substances into higher schedules (e.g., move from Schedule III to Schedule II) independent of federal action. It is unclear whether scheduling a drug at a lower schedule than specified in federal law is permissible. The question has been referred to board counsel.

3) Medical Use. This bill makes Ecstasy a Schedule II controlled substance. One of the factors to be considered in determining whether a drug should be classified as Schedule II is whether the drug or substance has a currently accepted medical use in treatment in the United States. Recently, the Federal Drug Administration (FDA) approved limited chemical trials of Ecstasy for the treatment of post-traumatic stress disorder.

4) MDMA. According to the United States Department of Justice Drug Enforcement Agency, MDMA is a close structural analog of amphetamine and methamphetamine. MDMA has both stimulant and hallucinogenic effects in humans. In the 1970's, MDMA was documented to produce permanent damage to serotonin pathways in the brains of rats and monkeys. Short-term, high-dose use of MDMA has produced incidences of

an amphetamine-like psychosis and, in some cases, severe hyperthermia which was unresponsive to medical intervention leading to death.

The subjective effects of MDMA in humans include a heightened sense of awareness as well as a feeling of increased empathy or emotional closeness to others. The production of MDMA in clandestine laboratories; its increasing abuse among young people; and evidence of adverse health effects, including brain damage, to emergency scheduling of MDMA into C1 of the Controlled Substance Act in 1985.

MDMA is usually taken orally in doses ranging from 50 to 150 mg. Doses of MDMA are often "piggy-backed" on each other in a series over just a few hours, leading to severe over-heating and cardiac emergencies which require medical intervention.

5) Analogs. Existing law applies the same penalties to drugs that are unscheduled "analogs" of drugs listed in the controlled substances schedules (H&S 11401). Ecstasy is unscheduled but has a chemical composition similar to methamphetamine, which is a Schedule II controlled substance. California courts have held that Ecstasy is an "analog" of methamphetamine, and offenses involving Ecstasy may be prosecuted as if it were methamphetamine. This bill would not affect the available penalties for the unlawful possession, possession for sale, and sale of Ecstasy. The penalties would be the same as those currently being imposed under the "analog" statute.

6) History.

2003

Mar. 11 Re-referred to Com. on APPR.
Feb. 27 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 0.) (February 25).
Jan. 13 Referred to Com. on PUB. S.

2002

Dec. 9 Read first time.
Dec. 6 From printer. May be heard in committee January 5.
Dec. 5 Introduced. To print.

7) Support and Opposition

Support

Committee on Moral Concerns
County of San Diego
Los Angeles County District Attorney's Office
Peace Officers Research Association of California

Opposition

California Attorneys for Criminal Justice

AMENDED IN ASSEMBLY MARCH 10, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 57

Introduced by Assembly Member Bates
(Coauthors: Assembly Members Benoit, Daucher, Haynes, La Suer, Matthews, Maze, Mountjoy, Pacheco, Plescia, Runner, Vargas, and Wyland)
(Coauthors: Senators Ashburn, Denham, Knight, and Morrow)

December 5, 2002

An act to amend Section 11055 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 57, as amended, Bates. Controlled substances: Ecstasy (MDMA; XTC).

Existing law classifies controlled substances into 5 schedules and places the greatest restrictions and penalties on the use of those substances placed in Schedule I, including prohibiting the prescribing of any Schedule I controlled substance and requiring the prescription for any Schedule II controlled substance to be prepared in triplicate, as specified. The drug 3,4-Methylenedioxymethamphetamine, also known as MDMA, XTC, or Ecstasy, is a psychoactive drug possessing stimulant and hallucinogenic properties that is not classified within any of the schedules under the state controlled substances law, but is classified as a Schedule I drug under the federal controlled substances law.

This bill would classify the drug 3,4-Methylenedioxymethamphetamine within Schedule II of the state

controlled substances law. By expanding the scope of existing Schedule II crimes to also apply to this drug, this bill would impose a state-mandated local program upon local governments.

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

This bill would provide that 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:

SECTION 1. Section 11055 of the Health and Safety Code is amended to read:

11055. (a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Apomorphine.

(H) Codeine.

(I) Ethylmorphine.

(J) Hydrocodone.

(K) Hydromorphone.

(L) Metopon.

(M) Morphine.

(N) Oxycodone.
(O) Oxymorphone.
(P) Thebaine.
(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.
(3) Opium poppy and poppy straw.
(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.
(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).
(6) Cocaine, except as specified in Section 11054.
(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.
(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:
(1) Alfentanyl.
(2) Alphaprodine.
(3) Anileridine.
(4) Bezitramide.
(5) Bulk dextropropoxyphene (nondosage forms).
(6) Dihydrocodeine.
(7) Diphenoxylate.
(8) Fentanyl.
(9) Isomethadone.
(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).
(11) Levomethorphan.
(12) Levorphanol.
(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) 3,4-Methylenedioxymethamphetamine, including any trade name for that substance.

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital.
(2) Pentobarbital.
(3) Phencyclidines, including the following:
(A) 1-(1-phenylcyclohexyl) piperidine (PCP).
(B) 1-(1-phenylcyclohexyl) morpholine (PCM).
(C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph.

The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted, submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.
(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

~~(A) Phenylacetone.~~ *Phenylacetone.* Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):
(A) 1-phenylcyclohexylamine.
(B) 1-piperidinocyclohexane carbonitrile (PCC).

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 103 **VERSION: AS AMENDED MARCH 5, 2003**

AUTHOR: REYES **SPONSOR: NONE**

RECOMMENDED POSITION: OPPOSE

SUBJECT: DRUG MARKETING

Existing Law:

1) Requires pharmacists, pharmacies, and wholesalers to be licensed by the board.

2) Requires pharmaceutical manufacturers to be licensed by the Food and Drug Administration (FDA) or the Department of Health Services (DHS).

This Bill:

1) Requires pharmaceutical manufacturers and wholesale distributors to report the value of gifts provided to health professionals (identified by name) to the board annually beginning January 1, 2005. (B&P 4168)

2) Requires that the report of gifts be made in a manner specified by the board. (B&P 4168)

3) Requires the board to file a report with the Legislature annually, on or before March 1, 2006 regarding the data submitted. (B&P 4168)

4) Requires pharmaceutical manufacturing companies to designate a responsible party to the board. (B&P 4168)

5) Prohibits the board from disclosing any information designated by the manufacturer as a "trade secret." (B&P 4168)

6) Exempts the following gifts from the reporting requirement (B&P 4168):

a. Drug samples.
b. Reasonable compensation/reimbursement of expenses for participation in a clinical trial.
c. Gifts of less than $25.

7) Provides for a civil penalty of $10,000 per occurrence for each violation of this bill. (B&P 4168)

8) Defines "pharmaceutical manufacturing company" as an entity engaged in the production, preparation, propagation, compounding, conversion or processing of dangerous drugs. Further defines "pharmaceutical manufacturing company" as an

entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs. (B&P 4168)

Comment:

1) Author's Intent. The author is attempting to address the linkage between drug manufacturer marketing activity and prescribing behavior. The author cites both a Kaiser Family Foundation study that indicates 62% of doctors are accepting gifts from drug manufacturers and a study published in the Journal of the American Medical Association that found linkages between such marketing activity and prescriber behavior. The bill adopts a sunshine approach to reducing the influence of drug marketing on prescribing behavior. The bill is modeled on California's Political Reform Act that requires the reporting and publication of any gifts received by elected officials and other decision makers in state government. The author's office expects that the public sharing of this information will reduce the number and value of gifts doctors accept from drug manufacturers. The author notes that the Department of Health and Human Services, Office of the Inspector General is reviewing drug marketing practices in light of federal laws relating to kickbacks and is expected to issue an opinion in April. That opinion may eliminate the need for this bill.

2) Reporting Requirement. The bill requires the board make an annual report to the Legislature regarding the data submitted by drug manufacturers. However, the legislation does not specify the content or purpose of such a report. Publishing this gift information on a website and the publication of periodic analytic and statistical reports may be more effective in furthering the author's objective.

3) Trade Secret. The bill prohibits the board from disclosing any information reported to the board that is designated as a "trade secret" by the manufacturer. However, no definition of what constitutes a "trade secret" is provided. Absent such a definition it is possible for manufacturers to designate all data reported as a "trade secret" and render any reporting requirement meaningless.

4) $25. The bill specifies that gifts of less than $25 need not be reported to the board. However, the bill makes no provision for increasing that dollar value over time (either by indexing the amount to the CPI or allowing the board to increase the amount by regulation). Without a means to increase the dollar value of that exemption over time, the effect of inflation will be to require reporting of small gifts intended to be exempted by the bill.

5) Civil Penalty. The bill specifies that a civil penalty of up to $10,000 per violation may be imposed. A civil penalty requires engaging board counsel (the Attorney General's office) to seek such a penalty in court. Providing the board with the ability to issue a similar penalty via citation and fine would be more efficient and significantly less costly to the board.

6) Definitions. The definition of pharmaceutical manufacturer provided in the bill includes activities routinely performed by pharmacies and other board licensees, including wholesalers. For example, pharmacies generally do not engage in the sort of marketing practices described in this bill, but would be subject to its provisions.

7) Devices. The bill applies to marketing of dangerous drugs but not dangerous devices. The rationale for this exclusion is unclear at this time.

8) Fees. The bill would impose significant additional costs to the board but does not provide for the assessment of a fee to cover those expenses. The bill requires pharmaceutical manufacturers to report but the board does not license manufacturers at this time. The absence of such a license will complicate any effort to collect fees

from the manufacturers to support this program. This program may be better located with the Food and Drug Branch of the Department of Health Services which does have regulatory authority over manufacturers.

9) Related Legislation. Assemblyman Paul Koretz has introduced AB 1437 with similar provisions that assigns the responsibility for this new program to the Department of Health Services.

10) History.

Jan. 27	Referred to Coms. on HEALTH and B. & P.
Jan. 13	From printer. May be heard in committee February 12. Read first time.
Jan. 10	Introduced. To print.

AMENDED IN ASSEMBLY MARCH 5, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 103

Introduced by Assembly ~~Member~~ *Members* Reyes *and Koretz*
(Coauthors: Assembly Members Hancock and Lieber)
(Coauthors: Senators Chesbro, Romero, and Soto)

January 10, 2003

An act to add Section 4168 to the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 103, as amended, Reyes. Pharmaceuticals: marketing activities.

Existing law, the Pharmacy Law, regulates wholesalers and manufacturers of dangerous drugs and makes the California State Board of Pharmacy responsible for administering and enforcing the provisions of that law. Under the Pharmacy Law, all revenue collected by the board is deposited into the Pharmacy Board Contingent Fund. The Pharmacy Law makes a violation of its provisions punishable as a crime.

This bill would require a pharmaceutical manufacturing company, as defined, to annually disclose to the board *certain information regarding the* economic benefits the company provides in connection with its marketing activities*, including disclosing the names of the recipients of any benefits and the value, nature, and purpose of the benefits.* The bill would also require the board to report annually to the Governor and the Legislature regarding these disclosures.

The bill would impose a civil penalty of $10,000 for the violation of its disclosure requirements and would specify that awards obtained by the board be deposited into the Pharmacy Board Contingent Fund.

The bill by specifying an additional requirement under the Pharmacy Law, the violation of which is punishable as a criminal offense, would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. Section 4168 is added to the Business and
2 Professions Code, to read:
3 4168. (a) On or before January 1 of each year, a
4 pharmaceutical manufacturing company shall disclose to the
5 board the *recipient name and* value, nature, and purpose of any
6 gift, fee, payment, subsidy, or other economic benefit it provided
7 directly or through its pharmaceutical marketers *or wholesale*
8 *distributors* in connection with detailing, promotional, or other
9 marketing activities to a physician, hospital, nursing home,
10 pharmacist, health benefit plan administrator, or any other person
11 in California authorized to prescribe, dispense, or purchase
12 dangerous drugs in this state. Disclosure shall be made on a form
13 and in a manner prescribed by the board. The initial disclosure
14 shall be made on or before January 1, 2005, for the period
15 beginning on July 1, 2003, and ending June 30, 2004. The board
16 shall report to the Governor and the Legislature on or before March
17 1 of each year, commencing in 2006, the information disclosed to
18 it pursuant to this section.
19 (b) A pharmaceutical manufacturing company shall also
20 disclose to the board, on or before October 1, 2004, and annually
21 thereafter, the name and address of the individual responsible for
22 the company's compliance with the provisions of this section.

(c) The board shall not disclose information identified as a trade secret by the pharmaceutical marketing company in its disclosure.

(d) The following shall be exempt from disclosure:

(1) A complimentary sample of a dangerous drug intended to be furnished to a patient.

(2) The payment of reasonable compensation and reimbursement of expenses in connection with a clinical trial.

(3) Any gift, fee, payment, subsidy, or other economic benefit having a value of less than twenty-five dollars ($25).

~~(4) A scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking conference of a national, regional, or specialty medical or other professional association, if the recipient of the scholarship or other support is selected by the association.~~

(e) A civil penalty in the amount of ten thousand dollars ($10,000) may be assessed for each violation of this section. Each failure to disclose constitutes a separate violation of this section for which the civil penalty may be assessed. The prevailing plaintiff in the action shall be awarded costs and reasonable attorney's fees in addition to the civil penalty. If the board is the prevailing plaintiff, the civil penalty, costs, and attorney's fees shall be deposited into the Pharmacy Board Contingent Fund.

(f) The following definitions apply for purposes of this section:

(1) ''Clinical trial'' means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(2) ''Pharmaceutical manufacturing company'' means an entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly, or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and chemical synthesis ''Pharmaceutical manufacturing company'' also means an entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of dangerous drugs.

(3) ''Pharmaceutical marketer'' means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing,

promotional activities, or other marketing of a dangerous drug in this state to a physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase a dangerous drug. ~~The term does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a dangerous drug.~~

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

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ASSEMBLY BILL No. 1437

Introduced by Assembly Member Koretz

February 21, 2003

An act to add Article 6 (commencing with Section 110424.8) to Chapter 4 of Part 5 of Division 104 of the Health and Safety Code, and to add Section 14105.37 to the Welfare and Institutions Code, relating to drug marketing practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 1437, as introduced, Koretz. Drug marketing practices.

Existing law, the Sherman Food, Drug, and Cosmetic Law, contains various provisions regarding the packaging, labeling, and advertising of food, drugs, and cosmetics. A violation of any of these provisions is punishable as a misdemeanor.

This bill would make it unlawful, under that law, for any person to engage in inappropriate marketing of any drug or device used in the treatment of life-threatening chronic conditions to physicians or other medical providers.

This bill would also require every pharmaceutical manufacturing company to disclose to the State Department of Health Services the value, nature, and purpose of any gift, fee, payment, subsidy, or other economic benefit provided in connection with certain drug marketing activities, with certain exceptions.

This bill would create a new crime, thereby imposing a state-mandated local program.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including

prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on a Medi-Cal list of contract drugs, and obtains best price rebates from drug manufacturers.

This bill would require the department, during each negotiation with a manufacturer regarding the purchase price of a drug or drugs used to treat a life-threatening condition, to require the manufacturer to disclose the aggregate marketing costs for the drug or drugs that are the subject to the negotiation.

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:

SECTION 1. Article 6 (commencing with Section 110424.8) is added to Chapter 4 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 6. Drug Marketing Practices

110424.8. (a) It is unlawful for any person to engage in inappropriate marketing of any drug or device used in the treatment of life-threatening chronic conditions to physicians or other medical providers.

(b) For purposes of this section, ‘‘inappropriate marketing’’ means any action intended to entice a physician or other medical provider to employ a drug or device in the treatment of a patient by offering any of the following:

(1) Cash payments to physicians of any kind.

(2) Gifts to physicians that are not directly related to the benefit of the patient or the practice of the physician related to the drug or device.

(3) Travel, meals, or lodging for the physician unless they are associated with legitimate physician education.

(4) Any payment or subsidy for other cost that is not directly related to the benefit of the patient or the practice of the physician related to the drug or device.

(c) For purposes of this section, ‘‘life-threatening chronic condition’’ means a condition or disease that requires specialized medical care over a prolonged period of time and will result in death within five years without an appropriate drug regimen.

110424.85. (a) Every pharmaceutical manufacturing company shall disclose to the department, on a quarterly basis, the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician, hospital, nursing facility, pharmacist, health benefit plan administrator or any other person in California authorized to prescribe, dispense, or purchase prescription drugs in this state. Disclosure shall be made on a form and in a manner prescribed by the department.

(b) Each company subject to the requirements of subdivision (a) shall also disclose to the department annually the name and address of the individual responsible for compliance with that subdivision.

(c) The department shall keep confidential all trade secret information disclosed to the department pursuant to subdivision (a). The disclosure form prescribed by the department shall permit the company to identify any information that is a trade secret.

(d) The following shall be exempt from disclosure:

(1) Free samples of prescription drugs intended to be distributed to patients.

(2) The payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials. As used in this paragraph, ‘‘clinical trial’’ means an approved clinical trial conducted in connection with a research study designed to answer specific questions about vaccines, new therapies, or new ways of using known treatments.

(3) Any gift, fee, payment, subsidy, or other economic benefit the value of which is less than twenty-five dollars ($25).

(4) Scholarship or other support for medical students, residents, and fellows to attend a significant educational, scientific, or policymaking conference of a national, regional, or

specialty medical or other professional association if the recipient of the scholarship or other support is selected by the association.

(e) As used in this section:

(1) ‘‘Pharmaceutical marketer’’ means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs in the state to any physician, hospital, nursing home, pharmacist, health benefit plan administrator, or any other person authorized to prescribe, dispense, or purchase prescription drugs. The term does not include a wholesale drug distributor or the distributor’s representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(2) ‘‘Pharmaceutical manufacturing company’’ means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a wholesale drug distributor or pharmacist.

SEC. 2. Section 14105.37 is added to the Welfare and Institutions Code, to read:

14105.37. During each negotiation with a manufacturer regarding the purchase of a drug or drugs that are used to treat a life-threatening condition, the department shall require the manufacturer to disclose the aggregate marketing costs for the drug or drugs that are the subject of that negotiation. The department shall keep this data confidential, although the department, on an annual basis and without identifying any manufacturer in any way, shall provide aggregate marketing cost information to the relevant committees in both houses of the Legislature and to the Legislative Analyst.

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 186 **VERSION: AS INTRODUCED**

AUTHOR: CORREA **SPONSOR: CA OPTOMETRIC ASSOCIATION**

RECOMMENDED POSITION: NONE

SUBJECT: OPTOMETRISTS

Existing Law:

1) Permits optometrists to prescribe "therapeutic pharmaceutical agents" for the treatment of many eye diseases. (B&P 3041)

2) Defines optometrists as prescribers. (B&P 4170, Health & Safety Code 11150)

3) Specifies who may request and/or receive drug samples. (B&P 4061)

This Bill:

1) Adds optometrists to the list of persons who may receive shipments of dangerous drugs or dangerous devices without a prescriptions. (B&P 4059)

2) Permits physical therapists to furnish dangerous devices upon the prescription of an optometrist. (B&P 4059)

3) Adds optometrists to the list of prescribers of controlled substances. (B&P 4060)

4) Permits optometrists to request and receive drug samples. (B&P 4061)

Comment:

1) Author's Intent. To make a number of technical changes to pharmacy law to reflect the recently expanded scope of practice provided to optometrists. The changes would permit optometrists to order and receive drug samples, order and maintain drug stock (including controlled substances) in their offices and would eliminate a problem in current law that permits optometrists to prescribe controlled substances but does not allow patients to possess controlled substances prescribed by an optometrist.

2) Scope of Practice. Therapeutically certified optometrists have the authority to prescribe both topical and oral medications for the treatment of certain types of eye disease and ocular injuries. The drugs available to optometrists include controlled substances.

3) Physical Therapists? The bill permits optometrists to authorize the furnishing of a device by a physical therapist. It is unclear at this time what devices optometrists may prescribe that would be furnished by a physical therapist.

4) History.

Jan. 28	From printer. May be heard in committee February 27.
Jan. 27	Read first time. To print.

ASSEMBLY BILL No. 186

Introduced by Assembly Member Correa

January 27, 2003

An act to amend Sections 4059, 4060, and 4061 of the Business and Professions Code, relating to optometrists.

LEGISLATIVE COUNSEL'S DIGEST

AB 186, as introduced, Correa. Optometrists: dangerous drugs and devices.

Existing law, the Pharmacy Law, authorizes a manufacturer, wholesaler, or pharmacy to furnish a dangerous drug or dangerous device to a physician, dentist, podiatrist, and veterinarian without a prescription when accompanied by sale and purchase records. Existing law also permits these persons to possess a controlled substance when in properly labeled stocked containers, and also authorizes the distribution of a dangerous drug or device as a complimentary sample only upon the written request of these persons.

This bill would include optometrists in these provisions.

Existing law authorizes a pharmacist to furnish topical pharmaceutical agents to an optometrist.

The bill would instead authorize a pharmacist to furnish therapeutic pharmaceutical agents to an optometrist.

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

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

SECTION 1. Section 4059 of the Business and Professions Code is amended to read:

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

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

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

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

manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist or may furnish ~~topical~~ *therapeutic* pharmaceutical agents authorized for use pursuant to ~~paragraph (5) of~~ subdivision ~~(a)~~ *(c)* of Section 3041 to an optometrist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

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

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

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

(i) This section shall become operative on July 1, 2001.

SEC. 2. Section 4060 of the Business and Professions Code is amended to read:

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

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

SEC. 3. Section 4061 of the Business and Professions Code is amended to read:

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

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

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 261 **VERSION: AS INTRODUCED**

AUTHOR: MADDOX **SPONSOR: AUTHOR**

RECOMMENDED POSITION: SUPPORT

SUBJECT: BACKROOM CLINICS

Existing Law:

1) Prohibits the dispensing or furnishing of dangerous drugs or dangerous devices without a license. (Health & Safety Code 11352.1)

2) Imposes a misdemeanor penalty and/or $5,000 fine for the unlicensed dispensing or furnishing of dangerous drugs or dangerous devices. (Health & Safety Code 11352.1)

3) Permits local health officers to issue immediate cease and desist orders against those dispensing or furnishing dangerous drugs or dangerous devices without a license. (Health & Safety Code 101070)

This Bill:

Increases the penalty for unlicensed dispensing of dangerous drugs or dangerous devices to include the option of felony prosecution.

Comment:

1) Author's Intent. According to the author, "Drug smugglers running black market pharmaceutical rings are taking advantage of recent immigrants looking to purchase the same medicines they used at home. These medicines are smuggled into California and often fail to meet the Federal Drug Administration's (FDA) quality control standards. They regularly lack warnings and proper dosage, and are frequently sold at exorbitant prices. The deaths of two toddlers have been linked to black market medicine rings. This bill will help rid the community of unlicensed doctors and pharmacists by increasing the penalty from a misdemeanor to an alternate felony/misdemeanor for the sale or distribution of illegal pharmaceutical medicines."

2) Wobbler. This bill establishes a "wobbler" penalty for the unlicensed distribution of dangerous drugs or dangerous devices. A wobbler gives prosecutors the option of charging the case as either a misdemeanor or a felony. Wobblers are created to address crimes that have the potential to vary substantially in the severity of the offense

or to address individuals who are repeatedly prosecuted for the same offense. This wobbler provision was included in the legislation that originally established this offense, but the penalty was reduced to a misdemeanor in the Senate Public Safety Committee.

3) Prior Legislation. The board supported similar legislation (AB 394) which failed passage last year.

4) History.

03/18/03	From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 0.) (March 11).
02/11/03	Referred to Com. on PUB. S.
02/05/03	From printer. May be heard in committee March 7.
02/04/03	Read first time. To print.

5) Support & Opposition.

Support

California Peace Officers' Association
California Police Chiefs' Association

Opposition

American Civil Liberties Union
California Attorneys for Criminal Justice

ASSEMBLY BILL No. 261

Introduced by Assembly Member Maddox

February 4, 2003

An act to amend Sections 11352.1 and 101070 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 261, as introduced, Maddox. Controlled substances: dispensing or furnishing without a license.

(1) Existing law provides that any person who knowingly and unlawfully dispenses or furnishes a dangerous drug or dangerous device, or who knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device, without a license to dispense or furnish these products, is guilty of a misdemeanor, punishable as specified.

This bill would instead make a violation of the above provision a misdemeanor or a felony. By providing for the prosecution of the offense as a felony with its attendant prosecutorial costs, this bill would impose a state-mandated local program.

(2) Existing law authorizes a local health officer who determines that a person within his or her jurisdiction is unlawfully dispensing or furnishing specified drugs requiring a prescription, a dangerous drug or device, or a controlled drug, to take specified action, including the immediate closure of a business upon a reasonable suspicion that the business poses an immediate threat to the public health, welfare, or safety, as defined.

This bill would declare that nothing in that provision shall be construed to diminish the authority of local law enforcement to enforce

any criminal law relating to the unlawful dispensing or furnishing of controlled substances.

(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:

SECTION 1. Section 11352.1 of the Health and Safety Code is amended to read:

11352.1. (a) The Legislature hereby declares that the dispensing and furnishing of prescription drugs, controlled substances, and dangerous drugs or dangerous devices without a license poses a significant threat to the health, safety, and welfare of all persons residing in the state. It is the intent of the Legislature in enacting this provision to enhance the penalties attached to this illicit and dangerous conduct.

(b) Notwithstanding Section 4321 of the Business and Professions Code, and in addition to any other penalties provided by law, any person who knowingly and unlawfully dispenses or furnishes a dangerous drug or dangerous device, or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code, or who knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code without a license to dispense or furnish these products, shall be guilty of a misdemeanor *or a felony.* Upon the first conviction, each violation shall be punishable by imprisonment in a county jail not to exceed one year *or by imprisonment in the state prison*, or by a fine not to exceed five thousand dollars ($5,000), or by both that fine and imprisonment. Upon a second or subsequent conviction, each violation shall be punishable by imprisonment in a county jail not

to exceed one year *or by imprisonment in the state prison*, or by a fine not to exceed ten thousand dollars ($10,000), or by both that fine and imprisonment.

SEC. 2. Section 101070 of the Health and Safety Code is amended to read:

101070. (a) (1) The Legislature hereby finds and declares that the dispensing or furnishing of drugs requiring a prescription pursuant to Section ~~11470~~ *111470*, a controlled substance as defined in Section 4021 of the Business and Professions Code, or a dangerous drug or a dangerous device as defined in Section 4022 of the Business and Professions Code, without a license poses a significant threat to the public health, safety, and welfare of all residents of the state. In recent years, the public has become increasingly exposed to a proliferation of persons who engage in these illegal or dangerous acts.

(2) The Legislature further finds and declares that extraordinary measures are needed to control this burgeoning problem. Therefore, the occasional enlistment of local health officers in regulatory and enforcement functions normally reserved to the state is appropriate and necessary in order to protect the health, safety, and welfare of all persons of this state.

(3) Notwithstanding the foregoing, nothing contained in this section shall be construed as limiting or supplanting the authority of the state agencies charged with the regulation of the practice of pharmacy.

(b) Whenever a local health officer determines that there exists in his or her jurisdiction any person who, without a license, is dispensing or furnishing drugs requiring a prescription pursuant to Section 111470, a controlled substance as defined in Section 4021 of the Business and Professions Code, or a dangerous drug or a dangerous device as defined in Section 4022 of the Business and Professions Code, the local health officer may take action against ~~such~~ *that* person. This action shall include, but not be limited to:

(1) Receiving and investigating complaints from the public, from other licensees or from health care facilities that a person is engaging in any or all of the activity set forth in this subdivision. In conducting any investigation pursuant to this paragraph, the local health officer shall have the assistance of, and be accompanied by, a licensed pharmacist. The local health officer shall provide the Board of Pharmacy, and any other state agency

charged with jurisdiction over the activity set forth in this subdivision, with a copy of all complaints received pursuant to this paragraph.

(2) Issuing an order to the person to immediately cease and desist from the unlawful activity described in this subdivision, after confirming that the person is engaging in any or all of the activity set forth in this subdivision, and determining that the person has not been convicted of engaging in that activity pursuant to Section 11352.1 or any other applicable provision of law. In issuing the order, the local health officer shall notify the person that the activity is illegal in the State of California. In the event the local health officer determines that any or all of the items described in this subdivision must be confiscated, in addition to the cease and desist order, the local health officer shall enlist the aid of local law enforcement to execute confiscation of those items.

(3) Order the closure of the business, if any, operated, managed, or owned by the person after confirming that the person is engaging in any or all of the activity set forth in this subdivision, and determining whether the person has previously been convicted of engaging in that activity pursuant to Section 11352.1 or any other applicable provision of law. If the public health officer has a reasonable suspicion that the operation of a business poses an immediate threat to public health, welfare, or safety, the business may be ordered closed immediately while the hearing described in subdivision (c) is pending. Immediate danger to the public health, welfare, or safety includes, but is not limited to, evidence that the person is providing, selling, or distributing drugs that require a prescription, or dangerous drugs, devices, or controlled substances without a license. In the event that the local health officer determines that any or all of the items described in this subdivision must be confiscated in addition to the closure of the business, that officer shall enlist the aid of local law enforcement to execute the confiscation of those items.

(c) (1) Any person engaging in any or all of the activity described in subdivision (b) whose business is closed as a result of action by local health officer pursuant to subdivision (b) shall be entitled to a hearing to show cause why the closure was unwarranted.

(2) Whenever a local health officer orders the closure of a business pursuant to subdivision (b), the local health officer shall

immediately issue to the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section, and informing the owner of the right to a hearing, if requested, to show cause why the business should not be closed.

(3) A written request for a hearing shall be submitted by the person to the local health officer within 15 calendar days of closure. A failure to request a hearing within 15 calendar days of closure shall be deemed a waiver of the right to a hearing.

(4) The hearing shall be held within 15 calendar days of the receipt of a request for a hearing; however, when circumstances warrant, the hearing officer may order a hearing at any reasonable time within this 15-day period to expedite the hearing process. Upon written request of the person, the hearing officer may postpone any hearing date, if circumstances warrant the postponement.

(5) The hearing officer shall issue a written notice of decision to the person within five working days following the hearing. In the event the hearing officer determines that the closure was warranted, the notice shall specify the acts or omissions with which the person is charged, and shall state that the business shall remain closed permanently. Evidence that the person engaged in any or all of the activity set forth in subdivision (b) shall constitute prima facie evidence that permanent closure is warranted. Any business still operating shall close immediately upon receipt of the written decision ordering closure.

(d) Nothing in this section shall be construed to diminish the authority of local law enforcement to enforce any criminal law relating to the unlawful dispensing or furnishing of controlled substances, including, but not limited to, Section 11352.1.

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 521 | **VERSION: AS INTRODUCED**

AUTHOR: DIAZ | **SPONSOR: CA ONGRESS OF SENIORS & SENIOR LEGISLATURE**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: DRUG INFORMATION

Existing Law:

1) Requires pharmacists to provide oral consultation to each patient with a new prescription or when deemed necessary in the pharmacist's professional judgment. (16CCR1707.2)

2) Requires pharmacists to inform the patient, either orally or in writing, of the harmful effects of a drug when those effects impairs the ability to drive a vehicle or when taken in conjunction with alcohol. (B&P 4074)

This Bill:

Requires pharmacists to provide a large-print informational insert for each prescription drug if the drug poses a substantial risk of harm if taken in combination with alcohol or other medications. (B&P 4074.5)

Comment:

1) Author's Intent. This bill is sponsored by the California Congress of Seniors and the California Senior Legislature. The bill has been introduced to reduce adverse medication interactions by providing patients with more information about their medications. The author notes that this problem is particularly significant in older populations who use more prescription drugs which increases the likelihood of interactions with other prescription drugs and over-the-counter drugs.

2) Drafting Concerns. The bill requires pharmacists to provide printed material informing patients about interactions with alcohol or other drugs (both over-the-counter and prescription drugs). Existing law (section 4074) requires pharmacists to inform patients (either verbally or in writing) of drug interactions with alcohol or that may impair the patient's ability to drive. This requirement should be modified to eliminate a reference to interactions with alcohol since the new section requires providing the written material specifically for alcohol interactions. Attached are proposed amendments that will address this duplication.

3) History.

Feb. 27 Referred to Com. on HEALTH.
Feb. 19 From printer. May be heard in committee March 21.

Feb. 18 Read first time. To print.

ASSEMBLY BILL No. 521

Introduced by Assembly Member Diaz

February 18, 2003

An act to add Section 4074.5 to the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 521, as introduced, Diaz. Prescription drug warnings.

Existing law, the Pharmacy Law, requires a pharmacist to inform a patient, orally or in writing, of certain information about the harmful effects of a prescription drug taken in combination with alcohol. Existing law makes the violation of the Pharmacy Law a crime.

This bill would additionally require a pharmacist to include a large-print informational insert with each drug dispensed by prescription informing the patient when the drug poses a substantial risk of harm if taken in combination with alcohol or other medication.

Because a violation of this requirement would be punishable as a crime, the bill would impose a state-mandated local program.

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

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

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

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

SECTION 1. Section 4074.5 is added to the Business and Professions Code, to read:

4074.5. A pharmacist shall include a large-print informational insert with each drug dispersed by prescription informing the patient when the drug poses a substantial risk of harm to the person consuming the drug if taken in combination with alcohol or other medications, including both prescription and nonprescription drugs.

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

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 746 **VERSION: AS INTRODUCED**

AUTHOR: MATTHEWS **SPONSOR: NONE**

RECOMMENDED POSITION: SUPPORT

SUBJECT: MEDI-CAL FRAUD

Existing Law:

1) Permits the board to revoke licenses. (B&P 4300)

2) Requires the board to take disciplinary action for unprofessional conduct. (B&P 4301)

3) Defines unprofessional conduct to include both:

- The commission of any act involving moral turpitude, dishonesty, **fraud**, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

- The cash settlement of a violation of the Medi-Cal program.

(B&P 4301)

This Bill:

Requires health professional licensing boards (including the Board of Pharmacy) to revoke a license if the licensee is convicted of more than one charge of Medi-Cal fraud. (B&P 490.7)

Comment:

1) Author's Intent. The author introduced this legislation to address the ongoing fraud problem in the Medi-Cal program. The board already prosecutes cases against pharmacists and pharmacies that engage in Medi-Cal fraud. The Pharmacy Law already defines any type of fraud as unprofessional conduct which may result in professional discipline.

2) History.

Mar. 3 Referred to Com. on B. & P.
Feb. 20 From printer. May be heard in committee March 22.
Feb. 19 Read first time. To print.

ASSEMBLY BILL No. 746

Introduced by Assembly Member Matthews

February 19, 2003

An act to add Section 490.7 to the Business and Professions Code, relating to the healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 746, as introduced, Matthews. Medical fraud: revocation of professional licenses.

Existing law establishes the State Department of Consumer Affairs, which is comprised of various boards, including, but not limited to, the Dental Board of California, the Medical Board of California, the State Board of Optometry, the California State Board of Pharmacy, and the Board of Psychology, among others, which each issue licenses.

Existing law authorizes a board to suspend or revoke a license if the licensee has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the license was issued.

Existing law provides for the Medi-Cal program, pursuant to which medical benefits are provided to public assistance recipients and certain other low-income persons. Under existing law, the Director of Health Services is required to suspend the participation in the Medi-Cal program by a provider of services for conviction of any felony or any misdemeanor involving fraud, among other things.

This bill would require a board to revoke a license if the licensee has more than one conviction for any felony or misdemeanor involving fraud committed by the licensee in his or her capacity as a provider of services under the Medi-Cal program.

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

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

SECTION 1. Section 490.7 is added to the Business and Professions Code, to read:

490.7. A board shall revoke a license, pursuant to Section 490, if the licensee is licensed pursuant to Division 2 (commencing with Section 500) and has more than one conviction of any felony or misdemeanor involving fraud committed by the licensee in his or her capacity as a provider of services under the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000), or Chapter 8 (commencing with Section 14200), of Part 3 of Division 9 of the Welfare and Institutions Code.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1196 **VERSION: AS INTRODUCED**

AUTHOR: MONTANEZ **SPONSOR: CA. COALITION OF NURSE PRACTITIONERS**

RECOMMENDED POSITION: NONE

SUBJECT: NURSE PRACTITIONERS

Existing Law:

1) Permits nurse practitioners to write prescriptions for Schedules III-V controlled substances under a protocol agreement with a physician. Schedule III controlled substances may only be prescribed under a patient specific protocol. (B&P 2836.1)

2) Permits physician assistants to write prescriptions for Schedule II-V controlled substances under a patient specific protocol agreement with a physician. (B&P 3502.1)

This Bill:

1) Permits nurse practitioners to prescribe Schedule II controlled substances under a patient specific protocol and after completing six months of training in ordering drugs under the supervision of a physician and completing a course in the pharmacology of the drugs to be prescribed. (B&P 2836.1)

2) Requires the nurse practitioner to notify the Board of Registered Nursing of the completion of the required training. (B&P 2836.1)

3) Requires the Board of Registered Nursing to issue a number to the nurse practitioner to be included on any prescription issued by the nurse practitioner. (B&P 2836.1)

4) Requires the Board of Registered Nursing to provide a list of these numbers to the Board of Pharmacy on request. (B&P 2836.1)

Comment:

1) Author's Intent. The author is seeking to improve patient access to appropriate drug treatment by granting nurse practitioners the authority to order Schedule II controlled substances for their patients. This would establish parity with physician assistants and nurse-midwives and provide the over 6,000 nurse practitioners with the authority to order controlled substance with an important patient care tool.

2) Physician Assistants. Physician assistants have had Schedule II privileges since they were permitted to order medications by SB 1642 of 1994.

3) History

Feb. 24	Read first time.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 21	Introduced. To print.

ASSEMBLY BILL No. 1196

Introduced by Assembly Member Montanez

February 21, 2003

An act to amend Section 2836.1 of the Business and Professions Code, relating to nurse practitioners.

LEGISLATIVE COUNSEL'S DIGEST

AB 1196, as introduced, Montanez. Nurse practitioners: prescriptions.

Existing law, the Nursing Practice Act, licenses and regulates nurse practitioners and authorizes a nurse practitioner to furnish drugs or devices that are classified as Schedule III to Schedule V controlled substances under the California Uniform Controlled Substance Act, subject to certain conditions. Existing law makes a violation of the act a misdemeanor.

This bill would expand these provisions to include drugs or devices that are classified as Schedule II controlled substances under the California Uniform Controlled Substances Act. The bill would establish additional requirements for a nurse practitioner who is authorized to furnish drugs or devices, including registering with the United States Drug Enforcement Administration. The bill would require the Board of Registered Nursing to certify and issue a nurse practitioner a number that the nurse practitioner must document on all prescriptions he or she transmits.

By increasing the scope of the Nursing Practice Act, the violation of which is a misdemeanor, this bill creates a new crime.

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:

SECTION 1. Section 2836.1 of the Business and Professions Code is amended to read:

2836.1. Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and his or her supervising physician and surgeon under any of the following circumstances:

(1) When furnished or ordered incidental to the provision of family planning services.

(2) When furnished or ordered incidental to the provision of routine health care or prenatal care.

(3) When rendered to essentially healthy persons.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or his or her designee.

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

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to

require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f) *(1)* Drugs or devices furnished or ordered by a nurse practitioner may include Schedule ~~III~~ *II* through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure. ~~When~~

(2) When Schedule *II or* III controlled substances, as defined in ~~Section~~ *Sections 11055 and* 11056*, respectively,* of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g) *(1) The furnishing or ordering of drugs or devices by a nurse practitioner is conditional on the board issuing the nurse practitioner a number after he or she has successfully completed the requirements of paragraph (2). The nurse practitioner shall include that number on all his or her transmittals of orders for drugs or devices. The board shall maintain a list of the nurse practitioners it has certified pursuant to this section and the number it has issued to each nurse practitioner. The board shall make the list available to the California State Board of Pharmacy upon its request. A nurse practitioner who is authorized to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.*

(2) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed (1) at least six month's physician and surgeon-supervised experience in the furnishing or ordering of drugs or devices and (2) a course in

pharmacology covering the drugs or devices to be furnished or ordered under this section. The board shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term ‘‘furnishing’’ in this section, in health facilities defined in subdivisions (b), (c), (d), (e), and (i) of Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) ‘‘Drug order’’ or ‘‘order’’ for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to ‘‘prescription’’ in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

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

O

CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1363 **VERSION: AS INTRODUCED**

AUTHOR: BERG **SPONSOR: COUNTY HEALTH OFFICERS ASSN**

RECOMMENDED POSITION: SUPPORT

SUBJECT: HYPODERMICS

Existing Law:

1) Specifies that public entities and their agents or employees shall not be subject to criminal prosecution for operating a needle exchange program authorized by a public entity pursuant to a declaration of a local health emergency. (H&S 11364.7)

2) Requires that hypodermic needles and syringes be sold only by a pharmacy, dentist, veterinarian, podiatrist or by the holder of a hypodermic needle and syringe license issued by the board. (B&P 4142)

3) Requires the distribution of hypodermic needles and syringes to be regulated by the Board of Pharmacy. (B&P 4140)

4) Requires a prescription to obtain a hypodermic needle or syringe. (B&P 4142)

5) Exempts hypodermic needles and syringes for the administration of insulin and adrenaline from the prescription requirement. (B&P 4145)

6) Exempts hypodermic needles and syringes for use in animals from the prescription requirement. (B&P 4145)

7) Exempts hypodermic needles and syringes for industrial use from the prescription requirement. (B&P 4144)

8) Defines hypodermic needles and syringes used with illicit drugs as drug paraphernalia. (H & S 11014.5)

9) Imposes misdemeanor penalties for the unlawful sale of drug paraphernalia. (H & S 11364.7)

This Bill:

1) Repeals the prescription requirement for hypodermic needles and syringes. (B&P 4145)

2) Permits needle exchange programs operated by local governments to furnish needles and syringes without a prescription and without a permit from the board. (B&P 4145)

3) Requires cities or counties operating needle exchange programs to do so only under the following circumstances:

a. Consultation with the state Department of Health Services.
b. Development of operating procedures by the local health officer for the exchange of hypodermic needles and syringes.
c. Development of a database relating to the exchange needles.
d. Provision of community outreach and preventive education to reduce exposure to HIV infection and blood-borne hepatitis.
e. Demonstrate effort to secure treatment for drug addiction for participants.
f. Involvement of the community in the development of the project.
g. Involvement of local public safety officials in the development of the project. (H&S 121346)

4) Requires assessment of exchange project results. (H&S 121346)

Comment:

1) Author's Intent. The author is seeking to increase the availability of clean needles and syringes to reduce the transmission of blood-borne diseases such as hepatitis and HIV. The bill accomplishes this by both removing the prescription requirement for needles and syringes and broadening the law permitting clean needle exchange programs operated by local governments.

2) Past Legislation. Assembly Bill 136 (Chapter 762, Statutes of 1999) removed potential criminal prosecution for clean needle exchange programs operated by public entities or the agents of public entities. Legislation in that same session that exempted needles distributed in a clean needle program operated by a public entity from the prescription requirement was rejected by the Governor.

3) Senate Bill 1785. In 2002, Senator John Vasconcellos introduced Senate Bill 1785 which eliminated the prescription requirement for needles and syringes and instead required that they only be sold by a pharmacist. The bill also limited the quantity sold to 30 needles per purchase. That bill was supported by the board and vetoed by the Governor. The veto message is provided below:

> To the Members of the California State Senate:
>
> I am returning Senate Bill 1785 without my signature.
>
> SB 1785 would authorize pharmacists and physicians to furnish hypodermic needles or syringes for human use without a prescription. In addition, persons who are 18 years of age or older would be able to possess up to 30 hypodermic needles or syringes.
>
> I am committed to the underlying goal of the bill which is to reduce the transmission of HIV and hepatitis C among injection drug users, and I am proud of the progress we have made in combating these two diseases. California spends $93.2 million on education and prevention programs and I have added millions of dollars in the Office of AIDS for behavioral and early intervention, programs for high-risk youth, communities of color and HIV prevention evaluation. I have strongly supported our new HIV reporting system which will reveal trends in HIV transmission and assist in targeting HIV education, prevention and care efforts. I have

signed legislation that already makes hypodermic needles and syringes available from authorized, legally sanctioned syringe exchange programs located throughout California.

In Spring 2000, the Department of Health Services appointed the Hepatitis C Working Group, comprised of key stakeholders from the public and private sectors. The Working Group developed the first-ever hepatitis C strategic plan for California. In August 2000, I signed SB 1256 (Polanco) which allocated $1.5 million for hepatitis C outreach and education.

I worked hard with the author of the legislation I signed in 1999 to bring law enforcement and health officials together on a bill that would decriminalize supervised needle exchange programs. This bill undermines the key elements that won my support for that legislation:

* It eliminates the requirement for a one-for-one exchange of syringes, which is the standard of practice in authorized needle exchange programs.
* By eliminating the one-on-one exchange, this bill eliminates the ability to focus aggressive intervention efforts toward getting drug addicts into treatment.
* It eliminates the requirement that needle exchange programs be conducted with local government approval, ongoing oversight and as the result of a declared health emergency.

Additionally, this bill could potentially increase the amount of contaminated needles and syringes in parks, beaches and other public areas. This would place the non-injection drug using population at greater risk for HIV, hepatitis C, and other blood-borne diseases. While I appreciate the author's hard work and dedication to this issue, I cannot sign this measure.

The board supported SB 1785.

4) Related Legislation. Senate Bill 774 (Vasconcellos) has been introduced in this session that is substantially the same as Senate Bill 1785 referenced above.

5) History.

Feb. 24	Read first time.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 21	Introduced. To print.

ASSEMBLY BILL No. 1363

Introduced by Assembly Member Berg

February 21, 2003

An act to repeal and add Section 4145 of the Business and Professions Code, and to add Chapter 16 (commencing with Section 121345) to Part 4 of Division 105 of the Health and Safety Code, relating to AIDS.

LEGISLATIVE COUNSEL'S DIGEST

AB 1363, as introduced, Berg. AIDS: clean needle and syringe exchange program.

Existing law authorizes pharmacists and physicians to furnish hypodermic needles and syringes without a prescription or permit for human use in the administration of insulin or adrenaline if certain conditions are met.

Existing law prohibits any public entity, and its agents or employees, from being subject to criminal prosecution for distribution of hypodermic needles or syringes to participants in clean needle and syringe exchange projects authorized by the public entity pursuant to a declaration of a local emergency due to the existence of a critical local public health crisis.

This bill would authorize cities, counties, or cities and counties to develop clean needle and syringe exchange projects that contain prescribed components, and would authorize pharmacists, physicians, and certain persons authorized under those projects to furnish hypodermic needles and syringes without a prescription or permit.

This bill would require that a participating county, city, or city and county assess the project using certain criteria, and submit a progress report that takes into consideration data from the assessment to the

Director of Health Services, the Governor, and the chairpersons of both health committees of the Legislature.

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

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

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

(a) The rapidly spreading acquired immune deficiency syndrome (AIDS) epidemic, and the more recent spread of blood-borne hepatitis, pose an unprecedented public health crisis in California, and threaten, in one way or another, the life and health of every Californian.

(b) Injection drug users are the second largest group at risk of becoming infected with the human immunodeficiency virus (HIV) and developing AIDS, and they are the primary source of heterosexual, female, and perinatal transmission in California, the United States, and Europe.

(c) According to the Office of AIDS, injection drug use has emerged as one of the most prevalent risk factors for new AIDS cases in California.

(d) Studies indicate that the lack of sterile needles available on the streets, and the existence of laws restricting needle availability promote needle sharing, and consequently the spread of HIV among injection drug users. The sharing of contaminated needles is the primary means of HIV transmission within the injection drug user population.

(e) Most injection drug users use a variety of drugs, mainly heroin, cocaine, and amphetamines. Because amphetamine- and cocaine-injecting drug users inject more frequently than heroin users, their risk for HIV infection is higher.

SEC. 2. Section 4145 of the Business and Professions Code is repealed.

~~4145. Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use in the administration of insulin or adrenaline; a pharmacist or veterinarian may, without a prescription or license, furnish hypodermic needles and syringes for use on poultry or animals;~~

~~and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use in the administration of insulin or adrenaline, or from a pharmacist, veterinarian, or licenseholder, for use on poultry or animals; if all of the following requirements are met:~~

~~(a) No needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.~~

~~(b) The furnisher, at the time furnishing occurs, makes a record of the furnishing in the manner required by Section 4146.~~

SEC. 3. Section 4145 is added to the Business and Professions Code, to read:

4145. (a) Notwithstanding any other provision of law, the following persons may, without a prescription or permit, furnish a hypodermic needle or syringe if all the requirements in subdivision (c) are met:

(1) A pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use in the administration of insulin or adrenaline.

(2) A pharmacist or veterinarian may, without a prescription or permit, furnish hypodermic needles and syringes for use on poultry or animals.

(3) A pharmacist, physician, or other person designated under the operating procedures developed pursuant to paragraph (1) of subdivision (b) of Section 121346 of the Health and Safety Code may, without a prescription or permit, furnish hypodermic needles and syringes when operating a clean needle and syringe exchange project and any person may, without a prescription or a permit, obtain hypodermic needles and syringes from a program established pursuant to Chapter 16 (commencing with Section 121345) of Part 4 of Division 105 of the Health and Safety Code.

(b) Any person may, without a prescription or permit, obtain hypodermic needles and syringes from a pharmacist or physician for human use in the administration of insulin or adrenaline, or from a pharmacist, veterinarian, or permitholder for use on poultry or animals if all the requirements in subdivision (c) are met.

(c) (1) No needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(2) The furnisher, at the time the furnishing occurs, shall make a record of the furnishing in the manner required by Section 4146.

SEC. 4. Chapter 16 (commencing with Section 121345) is added to Part 4 of Division 105 of the Health and Safety Code, to read:

CHAPTER 16. CLEAN NEEDLE AND SYRINGE EXCHANGE PROGRAM

121345. (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to attempt to reduce the spread of HIV infection and blood-borne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange program pursuant to this chapter in any city and county, county, or city upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121346.

121346. (a) A city and county, or a county, or a city with or without a health department that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Health Services, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and blood-borne hepatitis infection among injection drug users. Providers and users of an exchange project authorized by the

county, city, or city and county shall not be subject to criminal prosecution for possession of syringes or needles during participation in an exchange project.

(b) Each project shall include, but not be limited to, all of the following:

(1) The development of a set of operating procedures by the local health officer for the furnishing and exchange of hypodermic needles and syringes for injection drug users and the approval of the operating procedures by the county, city, or city and county.

(2) The development of a data base and collection of data relating to the furnishing and replacement of clean hypodermic needles and syringes to injection drug users by persons designated in the operating procedures developed pursuant to paragraph (1). The data collected pursuant to this paragraph shall be reported to the department annually commencing two years after the inception of the project.

(3) The provision of community outreach and preventive education that is culturally sensitive and linguistically appropriate to reduce project participants' exposure to HIV infection and blood-borne hepatitis.

(4) A demonstrated effort to secure treatment for drug addiction for participants upon their request.

(5) The involvement of the community in the development of the project.

(6) The involvement of local public safety officials in the development of the project.

(7) Accessibility of the project to the target population while being sensitive to community concerns.

(8) Appropriate levels of staff expertise in working with injection drug users and adequate staff training in providing community referrals, needle hygiene, and safety precautions.

(9) Enhanced treatment capacity, insofar as possible, for injection drug users.

(10) Preferential acceptance, insofar as possible, of HIV-infected drug users into drug treatment programs.

(c) The projects authorized pursuant to this chapter shall be part of a network of voluntary and confidential HIV services, where available, including, but not limited to, all of the following:

(1) Anonymous HIV antibody testing and counseling.

(2) Hepatitis screening, counseling, and vaccination.

(3) Notwithstanding Section 121015, voluntary, anonymous, or confidential partner notification.

(4) Early intervention and ongoing primary medical care followup for infected persons and their partners.

(5) Social services to support families of HIV-infected drug users.

(d) Components of the projects authorized pursuant to this chapter shall be assessed as to their effectiveness by the participating city and county, county, or city. Assessment shall include, but not be limited to, the following measures, where they are available:

(1) The incidence of HIV among the subject population.

(2) Needle exchange rates.

(3) Level of drug use.

(4) Level of needle sharing.

(5) Use of condoms.

(6) Availability of needle exchange programs in the jurisdiction.

(7) Program participation rates.

(8) The number of participants referred for treatment.

(9) The status of treatment and recovery of those entering substance abuse treatment programs.

(10) Referrals for HIV, sexually transmitted diseases, and hepatitis screening and treatment.

(11) Referrals for, or provision of, primary medical care.

(e) All components of the projects authorized pursuant to this chapter shall be voluntary. Where persons are provided services as a part of a project, including, but not limited to, antibody testing, counseling, or medical or social services, those provisions of law governing the confidentiality and anonymity of that information shall apply. All information obtained in the course of implementing a project that personally identifies any person to whom needle furnishing and exchange services are provided shall remain confidential and shall not be released to any person or agency not participating in the project without the person's written consent.

(f) A city and county, county, or city with or without a health department initiating a clean needle and syringe exchange project, shall submit a progress report two years from the project's inception. The report shall take into consideration available data

on factors listed in subdivision (d). The report shall be submitted to the director, the Governor, and the chairpersons of both health committees of the Legislature.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1460 **VERSION: AS INTRODUCED**

AUTHOR: NATION **SPONSOR: CPHA**

RECOMMENDED POSITION: SUPPORT

SUBJECT: LABORATORY DIRECTORS

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

This Bill:

Permits a pharmacist to become a laboratory director based on his/her pharmacist license. (B&P 1209)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor indicates that amendments are forthcoming that reflect this intent. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available. Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) History.

Feb. 24	Read first time.
Feb. 23	From printer. May be heard in committee March 25.
Feb. 21	Introduced. To print.

ASSEMBLY BILL No. 1460

Introduced by Assembly Member Nation

February 21, 2003

An act to amend Sections 1209 and 4052.1 of the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 1460, as introduced, Nation. Clinical laboratory directors.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists. Under that law, a pharmacist is authorized to perform routine patient assessment procedures that are defined, in part, by reference to regulations adopted by a federal agency. Existing law also provides for the regulation of clinical laboratories and specifies the qualifications required to serve as a laboratory director. Under existing law, the violation of these provisions is punishable as a crime.

This bill would reflect the change of name of the federal agency that adopted those particular regulations. The bill would also authorize a pharmacist to be a laboratory director of a clinical laboratory that provides routine patient assessment procedures under designated conditions. Because the bill would specify these conditions, the violation of which would be punishable as 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:

SECTION 1. Section 1209 of the Business and Professions Code is amended to read:

1209. (a) *(1)* As used in this chapter, ''laboratory director'' means any person who is a duly licensed physician and surgeon, or is licensed to direct a clinical laboratory under this chapter and who substantially meets the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory. The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, he or she shall remain responsible for ensuring that all those duties and responsibilities are properly performed.

(2) A pharmacist may be a laboratory director of a clinical laboratory that provides routine patient assessment procedures if the clinical laboratory has received a certificate of waiver under CLIA and the regulations adopted pursuant to it by the federal Centers for Medicare and Medicaid Services, and the pharmacist has completed a training program on the duties and responsibilities of a laboratory director.

(b) (1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to assure compliance with this act and CLIA. He or she shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.

(2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which he or she has been found by the laboratory director to be competent to perform and report.

(c) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.

(d) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:

(1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.

(2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.

(3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.

(e) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.

(1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

(A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.

(B) Monitoring the recording and reporting of test results.

(C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(D) Direct observation of performance of instrument maintenance and function checks.

(E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(F) Assessment of problem solving skills.

(2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimens. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.

(f) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:

(1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high quality service.

(2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.

As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.

(g) Subdivision (f) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.

SEC. 2. Section 4052.1 of the Business and Professions Code is amended to read:

4052.1. *(a)* Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, ''routine patient assessment procedures'' means *either of the following*: ~~(a) procedures~~

(1) Procedures that a patient could, with or without a prescription, perform for himself or herself~~, or (b) clinical~~.

(2) Clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal ~~Health Care Financing Administration~~ *Centers for Medicare and Medicaid Services*, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. ~~A~~

(b) A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

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: SB 151 **VERSION: AS INTRODUCED**

AUTHOR: BURTON **SPONSOR: CMA, AM CANCER SOCIETY, COMPASSION IN DYING**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TRIPLICATE PRESCRIPTIONS

Existing Law:

1) Establishes the Controlled Substance Review and Evaluation System (CURES) as a pilot project to electronically monitor the dispensing of Schedule II controlled substances in outpatient pharmacies. (H&S 11165)

2) Requires pharmacies to electronically report dispensing data on all Schedule II prescriptions to the Department of Justice on a monthly basis. (California Code of Regulations, Title 16, Section 1715.5)

3) Sunsets the CURES pilot project on January 1, 2008. (H&S 11165)

4) Requires that prescriptions for Schedule II controlled substances to be written on three-part (triplicate) forms issued by the Department of Justice. (H&S 11164)

5) Permits prescribers to use ordinary prescription forms for Schedule II controlled substance if the patient has a terminal illness. (H&S 11159.2)

This Bill:

1) Repeals the triplicate requirement for Schedule II controlled substances.

2) Makes the CURES program permanent.

Comment:

1) Author's Intent. Medical research has consistently documented that prescription pads issued by law enforcement deters physician prescribing for pain due to physician fears about law enforcement oversight. California has an electronic monitoring system for Schedule II prescriptions that provides a more effective monitoring system than the carbon copy system adopted in the 1940s.

Pain is an issue that everyone understands and wishes to avoid. According to proponents, patients in California experiencing severe pain have a 50-50 chance of having their pain treated appropriately. One of the major reasons for this unfortunate fact is that the State of California is one of only three states in the nation that require a

special, serialized prescription pad issued by the State Department of Justice in order for physicians to prescribe Schedule II drugs.

2) Prior Legislation. In 2000, the board sponsored AB 2018 (Thomson) which proposed to repeal the triplicate and make CURES permanent. AB 2018 was defeated in that form, but ultimately passed and was signed by Governor Davis in an alternate form that reduced the administrative hassles associated with the triplicate prescriptions. In 2001, Senator Johannessen introduced SB 1000 to make CURES permanent and repeal the triplicate in an early form. The bill was ultimately amended to state legislative intent to repeal the triplicate and to make further administrative changes to the CURES program. This bill was supported by the board and vetoed by the Governor. In 2002, the board sponsored AB 2655 (Matthews) to extend the CURES program and to allow practitioners to access patient information in the CURES system. That bill was signed by the Governor and took effect on January 1, 2003.

3) Board Policy. The board has had a long standing policy of supporting the treatment of pain and supportive of repealing the triplicate requirement in California. The board spearheaded the development of CURES as an electronic replacement for the triplicate monitoring system. The board provided start up funding for CURES and funding for the first 5 years of operation through a $1.3 million appropriation from the Pharmacy Board Contingent Fund.

4) History.

Mar. 10	Set for hearing March 26.
Feb. 25	To Coms. on H. & H.S. and PUB. S.
Feb. 11	From print. May be acted upon on or after March 12.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 151

Introduced by Senator Burton

February 7, 2003

An act to amend Sections 11164, 11165, 11165.1, 11167, and 11167.5 of, and to repeal Sections 11161, 11162.5, and 11169 of, the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 151, as introduced, Burton. Controlled substances: Schedule II.

Existing law provides that no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense such a prescription unless it complies with specified requirements, one of which is that prescriptions for Schedule II controlled substances shall be prepared in triplicate. Existing law also provides for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances pursuant to the Controlled Substance Utilization Review and Evaluation System (CURES) program, as specified. The CURES program is scheduled to become inoperative on July 1, 2008, and repealed on January 1, 2009.

This bill would eliminate the triplicate prescription requirement for Schedule II controlled substances. The bill would require prescribers of Schedule II controlled substances to meet the same prescription requirements imposed with respect to other prescribable controlled substances. The bill would also provide for the indefinite continuation of the CURES program by deleting its repeal date. The bill would make conforming changes to related provisions.

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

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

SECTION 1. Section 11161 of the Health and Safety Code is repealed.

~~11161. (a) Prescription blanks shall be issued by the Department of Justice in serially numbered groups of not more than 100 forms each in triplicate unless a practitioner orally, electronically, or in writing requests a larger amount, and shall be furnished to any practitioner authorized to write a prescription for controlled substances classified in Schedule II. The Department of Justice may charge a fee for the prescription blanks sufficient to reimburse the department for the actual costs associated with the preparation, processing, and filing of any forms issued pursuant to this section. The prescription blanks shall not be transferable. Any person possessing a triplicate prescription blank otherwise than as provided in this section is guilty of a misdemeanor.~~

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

~~(c) The order provided by subdivision (b) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the~~

~~burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender all triplicate prescription blanks with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.~~

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

~~(e) If the practitioner has not moved to vacate the order issued under subdivision (b) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (b) shall be vacated.~~

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

SEC. 2. Section 11162.5 of the Health and Safety Code is repealed.

~~11162.5. (a) Every person who counterfeits a prescription blank purporting to be an official prescription blank prepared and issued pursuant to Section 11161, or knowingly possesses more than three such counterfeited prescription blanks, shall be punished by imprisonment in the state prison or by imprisonment in the county jail for not more than one year.~~

~~(b) Every person who knowingly possesses three or fewer counterfeited prescription blanks purporting to be official prescription blanks prepared and issued pursuant to Section 11161, shall be guilty of a misdemeanor punishable by imprisonment in~~

~~the county jail not exceeding six months, or by a fine not exceeding one thousand dollars ($1,000), or by both.~~

SEC. 3. Section 11164 of the Health and Safety Code is amended to read:

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

(a) ~~The signature on each prescription for a controlled substance classified in Schedule II shall be wholly written in ink or indelible pencil in the handwriting of the prescriber upon the official prescription form issued by the Department of Justice. Each prescription shall be prepared in triplicate, signed by the prescriber, and shall contain, either typewritten or handwritten by the prescriber or his or her employee, the date, name, and address of the person for whom the controlled substance is prescribed, the name, quantity, and strength of the controlled substance prescribed, directions for use, and the address, category of professional licensure, and the federal controlled substance registration number of the prescriber. The original and duplicate of the prescription shall be delivered to the pharmacist filling the prescription. The duplicate shall be retained by the pharmacist and the original, properly endorsed by the pharmacist with the name and address of the pharmacy, the pharmacy's state license number, the date the prescription was filled and the signature of the pharmacist, shall be transmitted to the Department of Justice at the end of the month in which the prescription was filled. Upon receipt of an incompletely prepared official prescription form of the Department of Justice, the pharmacist may enter on the face of the prescription the address of the patient. A pharmacist may fill a prescription for a controlled substance classified in Schedule II containing an error or errors, if the pharmacist notifies the prescriber of the error or errors and the prescriber approves any correction. The prescriber shall fax or mail a corrected prescription to the pharmacist within seven days of the prescription being dispensed.~~

~~(b)~~ Each prescription for a controlled substance classified in Schedule *II*, III, IV, or V, except as authorized by subdivision ~~(c)~~ *(b)*, shall be subject to the following requirements:

(1) The prescription shall be signed and dated by the prescriber and shall contain the name of the person for whom the controlled substance is prescribed, the name and quantity of the controlled substance prescribed, and directions for use. With respect to prescriptions for controlled substances classified in Schedules *II*, III and IV, the signature, date, and information required by this paragraph shall be wholly written in ink or indelible pencil in the handwriting of the prescriber.

(2) In addition, the prescription shall contain the name, address, telephone number, category of professional licensure, and federal controlled substance registration number of the prescriber. The information required by this paragraph shall be either preprinted upon the prescription blank, typewritten, rubber stamped, or printed by hand. Notwithstanding any provision in this section, the prescriber's address, telephone number, category of professional licensure, or federal controlled substances registration number need not appear on the prescription if that information is readily retrievable in the pharmacy.

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

~~(c)~~

(b) Any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be reduced to writing by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. The date of issue of the prescription and all the information required for a written prescription by subdivision ~~(b)~~ *(a)* shall be included in the written record of the prescription. The pharmacist need not reduce to writing the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient if that information is readily retrievable in the pharmacy. Pursuant to authorization of the prescriber, any employee of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in

Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the employee of the prescriber transmitting the prescription.

~~(d)~~

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

~~(e)~~

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

~~(f) In addition to the prescriber's record required by Section 11190, any practitioner dispensing a controlled substance classified in Schedule II in accordance with subdivision (b) of Section 11158 shall prepare a written record thereof on the official forms issued by the Department of Justice, pursuant to Section 11161, and shall transmit the original to the Department of Justice in accordance with any rules that the department may adopt for completion and transmittal of the forms.~~

SEC. 4. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, and the Osteopathic Medical Board of California Contingent Fund, establish the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II controlled substances by all practitioners authorized to prescribe or dispense these controlled substances. CURES shall be implemented as a pilot project, commencing on July 1, 1997, to be administered concurrently with the existing triplicate prescription process, to examine the comparative efficiencies between the two systems.

(b) The CURES pilot project shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to

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

~~(c) This section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 5. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner ~~eligible to obtain triplicate prescription forms pursuant to Section 11161~~ *authorized to write a prescription for controlled substances classified in Schedule II* or a pharmacist may make a written request for, and the Department of Justice may release to that practitioner or pharmacist, the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(2) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(b) In order to prevent the inappropriate, improper, or illegal use of Schedule II controlled substances, the Department of Justice may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(c) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical

Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

~~(d) This section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute that is enacted before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 6. Section 11167 of the Health and Safety Code is amended to read:

11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a Schedule II controlled substance may be dispensed on an oral, written, or electronic data transmission order, subject to all of the following requirements:

(a) The order contains all information required by subdivision (a) of Section 11164.

(b) Any written order is signed and dated by the prescriber in indelible pencil or ink, and the pharmacy reduces any oral or electronic data transmission order to writing prior to actually dispensing the controlled substance.

~~(c) The prescriber provides a triplicate prescription, completed as provided by subdivision (a) of Section 11164, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.~~

~~(d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Bureau of Narcotic Enforcement in writing within 144 hours of the prescriber's failure to do so and shall make and retain a written, readily retrievable record of the prescription, including the date and method of notification of the Bureau of Narcotic Enforcement.~~

SEC. 7. Section 11167.5 of the Health and Safety Code is amended to read:

11167.5. (a) An order for a controlled substance classified in Schedule II in a licensed skilled nursing facility, an intermediate care facility, or a licensed home health agency providing hospice care may be dispensed upon an oral or electronically transmitted prescription. Prior to filling the prescription, the pharmacist shall reduce it to writing in ink or indelible pencil in the handwriting of the pharmacist upon an official prescription form issued by the

Department of Justice for that purpose. The prescriptions shall ~~be prepared in triplicate and shall~~ contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed facility or home health agency providing hospice care in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, and federal controlled substance registration number of the prescriber. ~~The duplicate shall be retained by the pharmacist, and the triplicate shall be forwarded to the prescriber by the end of the month in which the prescription was issued.~~ The ~~original~~ *prescription* shall be properly endorsed by the pharmacist with the pharmacy's state license number, the signature of the pharmacist, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed facility or home health agency providing hospice care and shall be forwarded by the pharmacist to the Department of Justice at the end of the month in which the prescription was filled. A skilled nursing facility, intermediate care facility, or licensed home health agency providing hospice care shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) For the purposes of this section, ''hospice care'' means interdisciplinary health care which is designed to alleviate the physical, emotional, social, and spiritual discomforts of an individual who is experiencing the last phases of a terminal disease and to provide supportive care for the primary care person and the family of the patient under hospice care.

SEC. 8. Section 11169 of the Health and Safety Code is repealed.

~~11169. When codeine, or dihydrocodeinone or tincture opii camphorata (paregoric) is not combined with other medicinal ingredients, it shall be prescribed on the official triplicate blanks.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 250 **VERSION: AS INTRODUCED**

AUTHOR: BATTIN SPONSOR: AUTHOR

RECOMMENDED POSITION: SUPPORT

SUBJECT: CHILD ABUSE REPORTING

Existing Law:

1) Defines any licensed health professional (including pharmacists) as a mandated reporter of suspected child abuse. (Penal Code 11165.7)

2) Requires mandated reporters to report any observed or reasonably suspected incidences of child abuse or neglect encountered in the scope of their professional duties. (Penal Code 11166)

3) Specifies that failure to report is punishable by 6 months in jail or a $1,000 fine, or both. (Penal Code 11166.5)

This Bill:

Requires licensing boards to revoke the license of any licensee who fails to report child abuse. (Penal Code 11166)

Comment:

1) Author's Intent. The author is responding to a number of cases in his district where health practitioners have failed to report suspected child abuse. The author believes that such a failure to report justifies the revocation of a professional license.

2) Mandated Reporters. As health care practitioners, pharmacists do have a legal obligation to report suspected child abuse or neglect to the appropriate local authority. However, most pharmacists are not in positions where they are likely to encounter evidence of child abuse or neglect. Board staff does not recall any complaints related to a failure to report suspected child abuse.

3) History.

Feb. 25	To Coms. on H. & H.S. and PUB. S.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 250

Introduced by Senator Battin

February 18, 2003

An act to amend Sections 11165.7 and 11166 of the Penal Code, relating to mandated reporters.

LEGISLATIVE COUNSEL'S DIGEST

SB 250, as introduced, Battin. Mandated reporters.

Existing law, the Child Abuse and Neglect Reporting Act (CANRA), requires a mandated reporter, as defined, to report whenever he or she, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or neglect. Failure to report an incident is a crime punishable by imprisonment in a county jail for a period of 6 months, a fine of up to $1,000, or by both that imprisonment and fine.

This bill would add receptionists or administrative employees of a hospital or health facility, as defined, to the list of individuals who are mandated reporters. This bill would also provide that if a person issued a license or certificate to engage in a profession or occupation, the members of which are required to make reports pursuant to this section, fails to report an incident of known or reasonably suspected child abuse or neglect, as required, the failure to report is grounds for revocation of his or her license or certificate. Because this bill would require employees of local agencies to perform a higher level of service and change the definition of 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, including the creation of a State Mandates Claims Fund to pay the costs of mandates that do not exceed $1,000,000 statewide and other procedures for claims whose statewide costs exceed $1,000,000.

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: yes.

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

SECTION 1. Section 11165.7 of the Penal Code is amended to read:

11165.7. (a) As used in this article, ‘‘mandated reporter’’ is defined as any of the following:

(1) A teacher.

(2) An instructional aide.

(3) A teacher’s aide or teacher’s assistant employed by any public or private school.

(4) A classified employee of any public school.

(5) An administrative officer or supervisor of child welfare and attendance, or a certificated pupil personnel employee of any public or private school.

(6) An administrator of a public or private day camp.

(7) An administrator or employee of a public or private youth center, youth recreation program, or youth organization.

(8) An administrator or employee of a public or private organization whose duties require direct contact and supervision of children.

(9) Any employee of a county office of education or the California Department of Education, whose duties bring the employee into contact with children on a regular basis.

(10) A licensee, an administrator, or an employee of a licensed community care or child day care facility.

(11) A headstart teacher.

(12) A licensing worker or licensing evaluator employed by a licensing agency as defined in Section 11165.11.

(13) A public assistance worker.

(14) An employee of a child care institution, including, but not limited to, foster parents, group home personnel, and personnel of residential care facilities.

(15) A social worker, probation officer, or parole officer.

(16) An employee of a school district police or security department.

(17) Any person who is an administrator or presenter of, or a counselor in, a child abuse prevention program in any public or private school.

(18) A district attorney investigator, inspector, or local child support agency caseworker unless the investigator, inspector, or caseworker is working with an attorney appointed pursuant to Section 317 of the Welfare and Institutions Code to represent a minor.

(19) A peace officer, as defined in Chapter 4.5 (commencing with Section 830) of Title 3 of Part 2, who is not otherwise described in this section.

(20) A firefighter, except for volunteer firefighters.

(21) A physician, surgeon, psychiatrist, psychologist, dentist, resident, intern, podiatrist, chiropractor, licensed nurse, dental hygienist, optometrist, marriage, family and child counselor, clinical social worker, or any other person who is currently licensed under Division 2 (commencing with Section 500) of the Business and Professions Code.

(22) Any emergency medical technician I or II, paramedic, or other person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(23) A psychological assistant registered pursuant to Section 2913 of the Business and Professions Code.

(24) A marriage, family and child therapist trainee, as defined in subdivision (c) of Section 4980.03 of the Business and Professions Code.

(25) An unlicensed marriage, family, and child therapist intern registered under Section 4980.44 of the Business and Professions Code.

(26) A state or county public health employee who treats a minor for venereal disease or any other condition.

(27) A coroner.

(28) A medical examiner, or any other person who performs autopsies.

(29) A commercial film and photographic print processor, as specified in subdivision (e) of Section 11166. As used in this article, ''commercial film and photographic print processor'' means any person who develops exposed photographic film into negatives, slides, or prints, or who makes prints from negatives or slides, for compensation. The term includes any employee of such a person; it does not include a person who develops film or makes prints for a public agency.

(30) A child visitation monitor. As used in this article, ''child visitation monitor'' means any person who, for financial compensation, acts as monitor of a visit between a child and any other person when the monitoring of that visit has been ordered by a court of law.

(31) An animal control officer or humane society officer. For the purposes of this article, the following terms have the following meanings:

(A) ''Animal control officer'' means any person employed by a city, county, or city and county for the purpose of enforcing animal control laws or regulations.

(B) ''Humane society officer'' means any person appointed or employed by a public or private entity as a humane officer who is qualified pursuant to Section 14502 or 14503 of the Corporations Code.

(32) A clergy member, as specified in subdivision (c) of Section 11166. As used in this article, ''clergy member'' means a priest, minister, rabbi, religious practitioner, or similar functionary of a church, temple, or recognized denomination or organization.

(33) Any custodian of records of a clergy member, as specified in this section and subdivision (c) of Section 11166.

(34) Any employee of any police department, county sheriff's department, county probation department, or county welfare department.

(35) An employee or volunteer of a Court Appointed Special Advocate program, as defined in Rule 1424 of the Rules of Court.

(36) Any receptionist or administrative employee of a hospital or health facility as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

(b) Volunteers of public or private organizations whose duties require direct contact and supervision of children are encouraged to obtain training in the identification and reporting of child abuse.

(c) Training in the duties imposed by this article shall include training in child abuse identification and training in child abuse reporting. As part of that training, school districts shall provide to all employees being trained a written copy of the reporting requirements and a written disclosure of the employees' confidentiality rights.

(d) School districts that do not train their employees specified in subdivision (a) in the duties of mandated reporters under the child abuse reporting laws shall report to the State Department of Education the reasons why this training is not provided.

(e) The absence of training shall not excuse a mandated reporter from the duties imposed by this article.

SEC. 2. Section 11166 of the Penal Code is amended to read:

11166. (a) Except as provided in subdivision (c), a mandated reporter shall make a report to an agency specified in Section 11165.9 whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or neglect. The mandated reporter shall make a report to the agency immediately or as soon as is practicably possible by telephone, and the mandated reporter shall prepare and send a written report thereof within 36 hours of receiving the information concerning the incident. The mandated reporter may include with the report any nonprivileged documentary evidence the mandated reporter possesses relating to the incident.

(1) For the purposes of this article, ''reasonable suspicion'' means that it is objectively reasonable for a person to entertain a suspicion, based upon facts that could cause a reasonable person in a like position, drawing, when appropriate, on his or her training and experience, to suspect child abuse or neglect. For the purpose of this article, the pregnancy of a minor does not, in and of itself, constitute a basis for a reasonable suspicion of sexual abuse.

(2) The agency shall be notified and a report shall be prepared and sent even if the child has expired, regardless of whether or not the possible abuse was a factor contributing to the death, and even if suspected child abuse was discovered during an autopsy.

(3) A report made by a mandated reporter pursuant to this section shall be known as a mandated report.

(b) *(1)* Any mandated reporter who fails to report an incident of known or reasonably suspected child abuse or neglect as required by this section is guilty of a misdemeanor punishable by up to six months confinement in a county jail or by a fine of one thousand dollars ($1,000) or by both that fine and punishment.

(2) In addition, if a person issued a license or certificate to engage in a profession or occupation, the members of which are required to make reports pursuant to this section fails to report an incident of known or reasonably suspected child abuse or neglect, as required, the failure to report is grounds for revocation of that license or certificate.

(c) (1) A clergy member who acquires knowledge or a reasonable suspicion of child abuse or neglect during a penitential communication is not subject to subdivision (a). For the purposes of this subdivision, ‘‘penitential communication’’ means a communication, intended to be in confidence, including, but not limited to, a sacramental confession, made to a clergy member who, in the course of the discipline or practice of his or her church, denomination, or organization, is authorized or accustomed to hear those communications, and under the discipline, tenets, customs, or practices of his or her church, denomination, or organization, has a duty to keep those communications secret.

(2) Nothing in this subdivision shall be construed to modify or limit a clergy member’s duty to report known or suspected child abuse or neglect when the clergy member is acting in some other capacity that would otherwise make the clergy member a mandated reporter.

(3) (A) On or before January 1, 2004, a clergy member or any custodian of records for the clergy member may report to an agency specified in Section 11165.9 that the clergy member or any custodian of records for the clergy member, prior to January 1, 1997, in his or her professional capacity or within the scope of his or her employment, other than during a penitential communication, acquired knowledge or had a reasonable

suspicion that a child had been the victim of sexual abuse that the clergy member or any custodian of records for the clergy member did not previously report the abuse to an agency specified in Section 11165.9. The provisions of Section 11172 shall apply to all reports made pursuant to this paragraph.

(B) This paragraph shall apply even if the victim of the known or suspected abuse has reached the age of majority by the time the required report is made.

(C) The local law enforcement agency shall have jurisdiction to investigate any report of child abuse made pursuant to this paragraph even if the report is made after the victim has reached the age of majority.

(d) Any commercial film and photographic print processor who has knowledge of or observes, within the scope of his or her professional capacity or employment, any film, photograph, videotape, negative, or slide depicting a child under the age of 16 years engaged in an act of sexual conduct, shall report the instance of suspected child abuse to the law enforcement agency having jurisdiction over the case immediately, or as soon as practically possible, by telephone, and shall prepare and send a written report of it with a copy of the film, photograph, videotape, negative, or slide attached within 36 hours of receiving the information concerning the incident. As used in this subdivision, ‘‘sexual conduct’’ means any of the following:

(1) Sexual intercourse, including genital-genital, oral-genital, anal-genital, or oral-anal, whether between persons of the same or opposite sex or between humans and animals.

(2) Penetration of the vagina or rectum by any object.

(3) Masturbation for the purpose of sexual stimulation of the viewer.

(4) Sadomasochistic abuse for the purpose of sexual stimulation of the viewer.

(5) Exhibition of the genitals, pubic, or rectal areas of any person for the purpose of sexual stimulation of the viewer.

(e) Any other person who has knowledge of or observes a child whom he or she knows or reasonably suspects has been a victim of child abuse or neglect may report the known or suspected instance of child abuse or neglect to an agency specified in Section 11165.9.

(f) When two or more persons, who are required to report, jointly have knowledge of a known or suspected instance of child abuse or neglect, and when there is agreement among them, the telephone report may be made by a member of the team selected by mutual agreement and a single report may be made and signed by the selected member of the reporting team. Any member who has knowledge that the member designated to report has failed to do so shall thereafter make the report.

(g) (1) The reporting duties under this section are individual, and no supervisor or administrator may impede or inhibit the reporting duties, and no person making a report shall be subject to any sanction for making the report. However, internal procedures to facilitate reporting and apprise supervisors and administrators of reports may be established provided that they are not inconsistent with this article.

(2) The internal procedures shall not require any employee required to make reports pursuant to this article to disclose his or her identity to the employer.

(3) Reporting the information regarding a case of possible child abuse or neglect to an employer, supervisor, school principal, school counselor, coworker, or other person shall not be a substitute for making a mandated report to an agency specified in Section 11165.9.

(h) A county probation or welfare department shall immediately, or as soon as practically possible, report by telephone, fax, or electronic transmission to the law enforcement agency having jurisdiction over the case, to the agency given the responsibility for investigation of cases under Section 300 of the Welfare and Institutions Code, and to the district attorney's office every known or suspected instance of child abuse or neglect, as defined in Section 11165.6, except acts or omissions coming within subdivision (b) of Section 11165.2, or reports made pursuant to Section 11165.13 based on risk to a child which relates solely to the inability of the parent to provide the child with regular care due to the parent's substance abuse, which shall be reported only to the county welfare or probation department. A county probation or welfare department also shall send, fax, or electronically transmit a written report thereof within 36 hours of receiving the information concerning the incident to any agency to which it makes a telephone report under this subdivision.

(i) A law enforcement agency shall immediately, or as soon as practically possible, report by telephone to the agency given responsibility for investigation of cases under Section 300 of the Welfare and Institutions Code and to the district attorney's office every known or suspected instance of child abuse or neglect reported to it, except acts or omissions coming within subdivision (b) of Section 11165.2, which shall be reported only to the county welfare or probation department. A law enforcement agency shall report to the county welfare or probation department every known or suspected instance of child abuse or neglect reported to it which is alleged to have occurred as a result of the action of a person responsible for the child's welfare, or as the result of the failure of a person responsible for the child's welfare to adequately protect the minor from abuse when the person responsible for the child's welfare knew or reasonably should have known that the minor was in danger of abuse. A law enforcement agency also shall send, fax, or electronically transmit a written report thereof within 36 hours of receiving the information concerning the incident to any agency to which it makes a telephone report under this subdivision.

SEC. 3. 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, notwithstanding Section 17610 of the Government Code, 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. If the statewide cost of the claim for reimbursement does not exceed one million dollars ($1,000,000), reimbursement shall be made from the State Mandates Claims Fund.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 292 **VERSION: AS INTRODUCED**

AUTHOR: SPEIER **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NONE

SUBJECT: PRESCRIPTION LABELS

Existing Law:

1) Requires the following elements on a prescription label:

a. drug name.
b. directions for the use of the drug.
c. name of the patient or patients.
d. name of the prescriber
e. date of issue.
f. name and address of the pharmacy
g. prescription number
h. strength of the drug
i. quantity of the drug
j. expiration date

2) Requires pharmacists to consult with the patient on any new prescription. (16CCR1707.2)

This Bill:

Requires each prescription label to include a color image of the pill dispensed. (B&P 4076)

Comment:

1) Author's Intent. The author introduced this bill in response to the continuing problem of medication errors. The bill proposes the color image of the pill as an additional check for both the pharmacist dispensing the medication and the patient taking the medication. The bill was introduced to stimulate discussion about how to decrease the incidence of wrong drug medication errors. The author indicates that one major chain currently includes a black and white image of the pill on the receipt for a prescription and that existing Oregon regulations require either an image or a written description of the pill on the prescription label. The author has not determined what the start-up costs would be to implement the bill's requirements.

2) Other Forms. The bill only contemplates drugs delivered in tablet or capsule form. A provision for exempting other forms or addressing the imaging of other forms of drugs (inhalants, injectables, eye drops, etc.) needs to be included.

3) History.

Mar. 6	To Com. on B. & P.
Feb. 20	From print. May be acted upon on or after March 22.
Feb. 19	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 292

Introduced by Senator Speier

February 19, 2003

An act to amend Section 4076 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 292, as introduced, Speier. Pharmacy: prescription labels.

Under the Pharmacy Law, a pharmacist is required to dispense a prescription in a container that is correctly labeled. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

This bill would require the label to have a color image of the tablet or capsule of the drug. Because a knowing violation of the bill would be a misdemeanor, it would impose a state-mandated local program.

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

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

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

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

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

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

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

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

(3) The name of the patient or patients.

(4) The name of the prescriber and, if applicable, the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, or the physician assistant who functions pursuant to Section 3502.1.

(5) The date of issue.

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

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

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

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

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

(11) A color image of the tablet or capsule.

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

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

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 393 **VERSION: AS INTRODUCED**

AUTHOR: AANESTEAD **SPONSOR: CSHP**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in a field of study directly related to the duties of a pharmacy technician.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.
d. Has 1500 hours of experience as a pharmacy clerk.

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128)

2) Requires hospitals implementing TCT to do the following:

a. conduct ongoing training for technicians specified by the board in regulations.
b. conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. remove any technician in TCT programs whose accuracy rate falls below 99.9 percent.
d. possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO).

e. be inspected by the Board of Pharmacy.
f. establish a program using pharmacists to provide clinical services.
(B&P 4128)

3) Permits the board to adopt other rules related to TCT. (B&P 4128)

4) Requires the board to adopt rules specifying the criteria for TCT training programs. (B&P 4128)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128)

6) Requires that data and records for TCT programs be retained for three years. (B&P 4128)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy (attached) and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

3) Regulations. The bill requires the board to adopt regulations specifying the criteria for TCT training programs. Such a requirement would both add workload for the board and delay implementation of TCT for at least one year due to the timeframes required in the rulemaking process. Placing these criteria in statute using the training programs developed by Cedars-Sinai and Long Beach Memorial as a guide would both save board resources and speed implementation of TCT.

> **Suggested Amendment #1 - The bill should be amended to remove the requirement for the board to adopt these criteria by regulation and the criteria should be added to the bill.**

4) Records. The bill requires that TCT data and records be retained in the hospital for at least three years.

> **Suggested Amendment #3 – The bill should be amended to require that the records are readily retrievable by the pharmacy. This is the same standard applied to other pharmacy records.**

5) History.

Mar. 6 To Com. on B. & P.

Feb. 21 From print. May be acted upon on or after March 23.
Feb. 20 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 393

Introduced by Senator Aanestad

February 20, 2003

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 393, as introduced, Aanestad. Pharmacists: in-patient pharmacy technician services.

Existing law, the Pharmacy Law, authorizes the California State Board of Pharmacy to regulate, license, register, and discipline pharmacists and pharmacy technicians. Existing law authorizes a pharmacy technician working in an inpatient hospital or a correctional facility to perform nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist.

This bill would authorize a general acute care hospital to implement and operate a program using specially trained pharmacy technicians to check the work of other pharmacy technicians who have filled floor and ward stock and unit dose distribution systems for patients whose pharmacy prescriptions have been previously reviewed by a licensed pharmacist. The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. Because violations of this bill would be 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. State-mandated local program: yes.

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

SECTION 1. The Legislature finds and declares that:

(a) Pharmacists have emerged as critical members of a medical team by providing services such as patient education, drug therapy monitoring, and pharmacokinetic consultations. Pharmacists often work side by side with physicians and nurses, and participate in medical rounds. Pharmacists play an integral role in ensuring a safe medication use process. Through interpretation, evaluation, and clarification of orders, pharmacists ensure the absence of drug allergies, interactions, duplications, and the optimal selection of dose, dosage form, frequency, route, and duration of therapy.

(b) There currently exists a shortage of pharmacists in the State, and this shortage has the potential to cause harm to patients because hospitals lack sufficient staffing to fully take advantage of clinical pharmacy programs that have been shown to reduce the number of medication errors in hospitals and improve patient outcomes.

(c) Studies authorized by the California State Board of Pharmacy, and conducted under the direction of the University of California, San Francisco, at major California hospitals, have established that certain non-discretionary functions currently performed by pharmacists in the hospital setting can safely be performed by properly trained pharmacy technicians. Specifically, allowing properly trained pharmacy technicians to check certain tasks performed by other pharmacy technicians is a safe and efficient use of staff, and frees pharmacists to provide the more important and skilled clinical pharmacy services that are critical to quality patient care and the reduction of medication errors.

(d) Pharmacists are substantially over-qualified for performing these non-discretionary in-patient checking functions, and current rules that require pharmacists to perform these functions

unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain non-discretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. In-Patient Pharmacy Technician Services

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts an ongoing training program pursuant to criteria the board, by regulation, has adopted for training pharmacy technicians. This criteria shall include both didactic and practical elements. Prior to adopting these regulations, the board shall approve a hospital's request to implement a pharmacy technician program if it is satisfied that the hospital has an adequate training program and meets the other requirements of this section.

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months

for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is re-qualified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians pursuant to this section. The board shall adopt regulations establishing the criteria described in paragraph (1) of subdivision (a).

(c) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

(d) Data and records required by this section shall be retained in each participating hospital for at least three years.

(e) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

(f) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be limited to the holder of the pharmacy permit and the pharmacist-in-charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician Certifying Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

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: SB 490 **VERSION: AS INTRODUCED**

AUTHOR: ALPERT **SPONSOR: PUBLIC HEALTH INSTITUTE**

RECOMMENDED POSITION: NONE

SUBJECT: EMERGENCY CONTRACEPTION

Existing Law:

1) Permits pharmacists to dispense emergency contraception without a prescription if a protocol is established with a prescriber. (B&P 4052)

2) Requires that pharmacists to complete a training program in emergency contraception before dispensing emergency contraception without a prescription. (B&P 4052)

3) Requires pharmacists dispensing emergency contraception without a prescription to furnish the patient with a standard fact sheet on emergency contraception developed by the board. (B&P 4052)

This Bill:

Provides that a pharmacist may dispense emergency contraception either under a protocol with a physician or pursuant to a protocol developed by the board. (B&P 4052)

Comment:

1) Author's Intent. The author intends to further expand access to emergency contraception therapy. Two years after the passage of SB 1169 permitted pharmacists to dispense emergency contraception under protocol, there are still 12 counties where no pharmacist is dispensing emergency contraception under protocol and 85% of the protocols established are with prescribers affiliated with Planned Parenthood. Physicians are citing liability concerns when refusing to establish such a protocol with pharmacists. The establishment of a statewide protocol would eliminate this barrier to access. New Mexico has such a statewide protocol in place. The author anticipates amending the bill to assure broad participation in the protocol development process by physician organizations.

2) Emergency Contraception. Emergency contraception (EC) drug therapy, commonly referred to as the "morning after pill" are hormone pills that when taken within 72 hours of unprotected intercourse, reduce the chance of a woman becoming

pregnant by about 75 percent. The hormones are regular birth control pills containing estrogen and progestin, taken in two doses. In California and Washington, there is also available an EC pill known as "Plan B" made from synthetic progestin. The EC pills provide a short, high burst of hormone exposure that disrupts the hormone patterns essential for pregnancy. The EC pills reduce the hormone release from the ovary and the development of the uterine lining is disturbed, the disruptions are temporary, however, lasting only a few days. Depending on the time during the menstrual cycle when the EC pills are taken, they prevent pregnancy by inhibiting or delaying ovulation, or altering the lining of the uterus thereby inhibiting implantation of a fertilized egg. The EC pills can also prevent sperm from fertilizing an egg. EC pills do not cause an abortion. Because implantation occurs five to seven days after fertilization, EC pills work before implantation and not after a woman is already pregnant.

3) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation.

4) Related Legislation. Senator Jackie Speier introduced Senate Bill 545 in the current legislative session which prohibits pharmacists from charging a consultation fee for emergency contraception that exceeds the dispensing fee provided by Medi-Cal.

5) New Mexico. New Mexico has adopted a statewide protocol for pharmacists dispensing emergency contraception as proposed by this bill. That protocol was developed by the state board of pharmacy in conjunction with the state medical board and the state nursing board. A copy of that protocol is attached for your reference.

6) History.

Mar. 13	Set for hearing April 2.
Mar. 13	To Coms. on H. & H.S. and B. & P.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 20	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 490

Introduced by Senator Alpert

February 20, 2003

An act to amend Section 4052 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 490, as introduced, Alpert. Pharmacy: prescriptions.

Existing law regulates the practice of pharmacy by the California State Board of Pharmacy. Under existing law, a pharmacist may not, in general, furnish a dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. However, existing law authorizes a pharmacist to initiate emergency contraception drug therapy in accordance with standardized protocols developed by the pharmacist and an authorized prescriber acting within his or her scope of practice.

This bill would also authorize a pharmacist to initiate emergency contraception drug therapy in accordance with a standardized procedure or protocol approved by the board.

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

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

SECTION 1. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the

patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with ~~standardized~~ *either of the following:*

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. ~~Prior~~

(B) A standardized procedure or protocol approved by the board.

Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 506 **VERSION: AS INTRODUCED**

AUTHOR: SHER **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NONE

SUBJECT: ANIMAL DRUGS

Existing Law:

1) Permits the board to issue a license to a wholesaler as a veterinary food-animal drug retailer (vet retailer). (B&P 4053)

2) Permits vet retailers to dispense veterinary prescriptions for food animals directly to the client without a pharmacist. (B&P 4053)

3) Requires vet retailers to have a qualified exemptee on the premises when dispensing food animal drugs. (B&P 4053)

4) Specifies the training required for vet retailer exemptees. (16CCR1780.1)

This Bill:

Prohibits vet retailers from dispensing injectable or oral antibiotics. (B&P 4053)

Comment:

1) Author's Intent. The author introduced this bill to address the issue of the extensive use of antibiotics in food-animals and how these practices contribute to antibiotic resistance. The bill is in a very early form and the author expects substantial amendments focusing on how to improve the handling and dispensing of drugs by veterinary food-animal drug retailers. As written, the bill would require that antibiotics for food-animals be labeled and distributed by either a pharmacy or a veterinarian instead of a veterinary food-animal drug retailer.

2) Antibiotic Resistance. According to the Food and Drug Administration (FDA), disease-causing microbes that have become resistant to drug therapy are an increasing public health problem. Tuberculosis, gonorrhea, malaria, and childhood ear infections are just a few of the diseases that have become hard to treat with antibiotic drugs. The increase in antibiotic resistance is due largely to the increasing use of antibiotics. The FDA also notes the following:

- Though food-producing animals are given antibiotic drugs for important therapeutic, disease prevention or production reasons, these drugs have the

downside of potentially causing microbes to become resistant to drugs used to treat human illness, ultimately making some human sicknesses harder to treat.

- About 70 percent of bacteria that cause infections in hospitals are resistant to at least one of the drugs most commonly used to treat infections.

- Some organisms are resistant to all approved antibiotics and must be treated with experimental and potentially toxic drugs.
- Some research has shown that antibiotics are given to patients more often than guidelines set by federal and other healthcare organizations recommend.

3) History.

Mar. 6	To Com. on B. & P.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 20	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 506

Introduced by Senator Sher

February 20, 2003

An act to amend Section 4053 of the Business and Professions Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 506, as introduced, Sher. Veterinary food-animal drug retailers.

The Pharmacy Law makes it unlawful for any person other than a pharmacist to compound or dispense a dangerous drug or device, or to compound or dispense a prescription. Existing law provides exemptions from this prohibition for specified persons, including a veterinary food-animal drug retailer under certain circumstances.

This bill would prohibit a veterinary food-animal drug retailer from applying for an exemption to distribute oral or injectable antibiotics.

Because violations of this bill would be 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. State-mandated local program: yes.

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

SECTION 1. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a manufacturer, veterinary food-animal drug retailer, or wholesaler if the board shall find that sufficient, qualified supervision is employed by the manufacturer, veterinary food-animal drug retailer, or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) An individual employed by a manufacturer, veterinary food-animal drug retailer, or wholesaler may apply for an exemption from Section 4051. In order to obtain and maintain that exemption, the individual shall meet the following requirements:

(1) He or she shall be a high school graduate or possess a general education development equivalent.

(2) He or she shall have a minimum of one year of paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of state and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of state and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.

(4) The board may, by regulation, require training programs to include additional material.

(5) The board may, by regulation, require training programs to include additional material.

(6) The board shall not issue a certificate of exemption until the applicant provides proof of completion of the required training to the board.

(c) The manufacturer, veterinary food-animal drug retailer, or wholesaler shall not operate without a pharmacist or an individual in possession of a certificate of exemption on its premises.

(d) Only a pharmacist or an individual in possession of a certificate of exemption shall prepare and affix the label to veterinary food-animal drugs.

(e) Notwithstanding any other provision of law, a veterinary food-animal drug retailer may not apply for an exemption to distribute injectable or oral antibiotics.

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

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 545 **VERSION: AS INTRODUCED**

AUTHOR: SPEIER **SPONSOR: AM. COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS**

RECOMMENDED POSITION: NONE

SUBJECT: EMERGENCY CONTRACEPTION

Existing Law:

1) Permits pharmacists to dispense emergency contraception without a prescription if a protocol is established with a prescriber. (B&P 4052)

2) Requires that pharmacists complete a training program in emergency contraception before dispensing emergency contraception without a prescription. (B&P 4052)

3) Requires pharmacists dispensing emergency contraception without a prescription to furnish the patient with a standard fact sheet on emergency contraception developed by the board. (B&P 4052)

This Bill:

1) States legislative intent that women not be discriminated against when receiving emergency contraception and should not be treated differently than other classes of patients receiving services in a pharmacy.

2) Eliminates the requirement that pharmacists receive additional training before dispensing emergency contraception without a prescription. (B&P 4052)

3) Prohibits pharmacists from charging a separate consultation fee for dispensing emergency contraception that exceeds the dispensing fee charged for Medi-Cal. (B&P 4052)

4) Clarifies existing law to indicate that dispensing emergency contraception without a prescription does not require consultation above the general consultation required under board regulations. (B&P 4052)

5) Clarifies existing law to indicate that dispensing emergency contraception without a prescription does not require record keeping in excess of those required by existing board regulations. (B&P 4052)

6) Requires pharmacies participating in the Medi-Cal program to offer emergency contraception. (B&P 4427)

Comment:

1) Author's Intent. The author introduced this bill to assure the broadest possible access to emergency contraception. The sponsor believes that the charging of additional "consultation" fees to emergency contraception patients poses a barrier to access to emergency contraception for those patients who do not have a drug benefit covering emergency contraception. The sponsor characterizes this practice as discriminatory and contends that emergency contraception therapy does not require a consultation beyond that required for any new prescription.

2) Emergency Contraception. Emergency contraception (EC) drug therapy, commonly referred to as the "morning after pill" are hormone pills that when taken within 72 hours of unprotected intercourse, reduce the chance of a woman becoming pregnant by about 75 percent. The hormones are regular birth control pills containing estrogen and progestin, taken in two doses. In California and Washington, there is also available an EC pill known as "Plan B" made from synthetic progestin. The EC pills provide a short, high burst of hormone exposure that disrupts the hormone patterns essential for pregnancy. The EC pills reduce the hormone release from the ovary and the development of the uterine lining is disturbed, the disruptions are temporary, however, lasting only a few days. Depending on the time during the menstrual cycle when the EC pills are taken, they prevent pregnancy by inhibiting or delaying ovulation, or altering the lining of the uterus thereby inhibiting implantation of a fertilized egg. The EC pills can also prevent sperm from fertilizing an egg. EC pills do not cause an abortion. Because implantation occurs five to seven days after fertilization, EC pills work before implantation and not after a woman is already pregnant.

3) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation.

4) Related Legislation. Senator Dede Alpert introduced Senate Bill 490 in the current legislative session which permits pharmacists to dispense emergency contraception without a prescription according to a protocol approved by the board.

5) History.

Mar. 13	To Coms. on B. & P. and RLS.
Feb. 21	From print. May be acted upon on or after March 23.
Feb. 20	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 545

Introduced by Senator Speier

February 20, 2003

An act to amend Section 4052 of, and to add Section 4427 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

SB 545, as introduced, Speier. Emergency contraception drug therapy.

Existing Law, the Pharmacy Law, provides for the licensing and regulation of the practice of pharmacy under the jurisdiction of the California State Board of Pharmacy. Existing law requires a pharmacist to provide consultation when furnishing drugs, with certain exceptions, and the board has set forth specific requirements applicable to the provision of consultation and the maintenance of patient medication records. Existing law authorizes a pharmacist, in addition to other functions, to initiate emergency contraception drug therapy if the pharmacist has completed a training program on emergency contraception and certain other conditions are met.

This bill would remove this training requirement. The bill would also state that the provisions authorizing the initiation of emergency contraception drug therapy do not impose a duty on a pharmacist to provide consultation different from or to maintain patient medication records that differ from that which is generally required by the board's regulations. The bill would, however, require a pharmacist to ask questions necessary to determine a patient's eligibility for the therapy. The bill would also prohibit a pharmacist from charging a separate consultation fee for the initiation of emergency contraception drug therapy.

Existing law provides for the Medi-Cal program, administered by the State Department of Health Services, under which qualified low-income persons are provided with health care services, including prescription benefits. Under existing law, the department pays participating pharmacists a discounted price for drugs on the Medi-Cal drug formulary.

This bill would require a pharmacy that participates in the Medi-Cal program to offer the initiation of emergency contraception drug therapy. The bill would prohibit a pharmacist initiating emergency contraception drug therapy from charging a dispensing fee in excess of the dispensing fee charged to Medi-Cal patients.

Existing law makes it a misdemeanor to knowingly violate the Pharmacy Law. All other violations of that law are infractions unless otherwise indicated.

Because this bill would create new prohibitions on pharmacists, the violation of which would be a crime, the bill would impose a state-mandated local program.

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

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

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. It is the intent of the Legislature to ensure
2 equality of access to pharmaceuticals for the women of California.
3 In ensuring that access, the Legislature intends to eliminate
4 discriminatory practices relating to emergency contraception,
5 which treat women differently from other classes of patients who
6 receive their prescriptions through pharmacies.
7 SEC. 2. Section 4052 of the Business and Professions Code
8 is amended to read:
9 4052. (a) Notwithstanding any other provision of law, a
10 pharmacist may:
11 (1) Furnish a reasonable quantity of compounded medication
12 to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

(A) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(B) Ordering drug therapy-related laboratory tests.

(C) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(D) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(5) (A) Perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance, as applicable, with policies, procedures, or protocols of that facility, the home health agency, the licensed clinic, the health care service plan, or that physician, in accordance with subparagraph (C):

(i) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(ii) Ordering drug therapy-related laboratory tests.

(iii) Administering drugs and biologicals by injection pursuant to a prescriber's order (the administration of immunizations under the supervision of a prescriber may also be performed outside of a licensed health care facility).

(iv) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the

patient's prescriber for the individual patient, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this clause within 24 hours.

(B) A patient's prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(C) The policies, procedures, or protocols referred to in this paragraph shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and, at a minimum, meet all of the following requirements:

(i) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(ii) Require that the medical records of the patient be available to both the patient's prescriber and the pharmacist.

(iii) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(iv) Except for procedures or functions provided by a health care facility, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

(8) Initiate emergency contraception drug therapy in accordance with standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice. ~~Prior to performing any procedure authorized under this paragraph, a pharmacist shall have completed a training program on emergency contraception, which includes, but is not limited to, conduct of sensitive communications, quality assurance, referral to additional services, and documentation.~~ *A pharmacist may not charge a separate consultation fee to a patient for emergency contraception drug therapy that is initiated pursuant to this section, and may not charge a dispensing fee that is in excess of the dispensing fee charged to Medi-Cal patients for the initiation of emergency contraception drug therapy pursuant to this section.*

This paragraph does not impose a duty on a pharmacist to do any of the following:

(A) Provide a consultation different from that required pursuant to Section 1707.2 of Title 16 of the California Code of Regulations, except that a pharmacist shall ask questions necessary to determine patient eligibility for the initiation of emergency contraception drug therapy.

(B) Maintain patient medication records that differ from the requirements specified in Section 1707.1 of Title 16 of the California Code of Regulations.

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (A) successfully completed clinical residency training or (B) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized factsheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using

the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 3. Section 4427 is added to the Business and Professions Code, to read:

4427. As a condition for the participation of a pharmacy in the Medi-Cal program pursuant to Chapter 7 (commencing with Section 14000) of Division 9 of the Welfare and Institutions Code, the pharmacy shall offer as a service the initiation of emergency contraception drug therapy.

SEC. 4. 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: SB 774 **VERSION: AS INTRODUCED**

AUTHOR: VASCONCELLOS **SPONSOR: AUTHOR**

RECOMMENDED POSITION: SUPPORT

SUBJECT: HYPODERMIC NEEDLES

Existing Law:

1) Requires the distribution of hypodermic needles and syringes to be regulated by the Board of Pharmacy. (B&P 4140)

2) Requires a prescription to obtain a hypodermic needle or syringe. (B&P 4142)

3) Exempts hypodermic needles and syringes for the administration of insulin and adrenaline from the prescription requirement. (B&P 4145)

4) Exempts hypodermic needles and syringes for use in animals from the prescription requirement. (B&P 4145)

5) Exempts hypodermic needles and syringes for industrial use from the prescription requirement. (B&P 4144)

6) Defines hypodermic needles and syringes used with illicit drugs as drug paraphernalia. (Health & Safety Code 11014.5)

7) Imposes misdemeanor penalties for the unlawful sale of drug paraphernalia. (Health & Safety Code 11364.7)

This Bill:

1) Repeals the requirement for a prescription to purchase hypodermic needles and syringes at retail. (B&P 4142)

2) Permits individuals who are 18 years of age or older to purchase up to 30 hypodermic needles and syringes in a single transaction. (B&P 4142)

3) Requires pharmacies that sell hypodermic needles to restrict access to the needles to pharmacy personnel only. (B&P 4142)

4) Requires pharmacies that sell needles to provide purchasers with information regarding the safe disposal of the needles and penalties for disposing of them on a playground or school grounds. (B&P 4142.4)

5) Requires pharmacies selling needles to provide purchasers with information regarding drug addiction, availability of addiction treatment programs, and a telephone number to call for assistance and information regarding blood borne diseases. (B&P 4142.4)

6) Requires pharmacies selling needles to provide onsite needle disposal programs. (B&P 4142.6)

7) Repeals the requirement for sellers of needles to maintain a record of needle sales. (B&P 4146)

8) Requires pharmacies selling needles to report the number of needles sold per month and the number of transactions involving needles to the local public health officer monthly. (B& 4142.2)

9) Prohibits the disposal of needles at a playground or on school grounds subject to a fine up to $2,000 or imprisonment for up to 6 months. (B&P 4147)

10) Exempts possession of up to 30 needles from drug paraphernalia crimes. (H&S 11364)

11) Requires local public health officers to be available to pharmacies to consult regarding policies for sale of needles, review consumer education and treatment materials provided by pharmacies, needle disposal policies, and coordinate needle sales by pharmacies with existing local treatment programs. (B&P 4142)

Comment:

1) Author's Intent. The author seeks to increase access to hypodermic needles and syringes. The author points out numerous studies establishing the link between HIV transmission and intravenous drug use. These same studies indicate that the use of sterile syringes greatly reduces the transmission of HIV and other diseases among intravenous drug users. A bulletin supported by the U.S. Department of Health and Human Services called for the use of a new, sterile syringe for each injection by drug users. A coalition of health organizations including the American Medical Association, National Association of Boards of Pharmacy, and the American Pharmaceutical Association recommends that states take action to make clean needles and syringes available to intravenous drug users.

2) Previous Legislation. Assembly Bill 136 (Chapter 762, Statutes of 1999) removed potential criminal prosecution for clean needle exchange programs operated by public entities or the agents of public entities. Legislation in that same session that exempted needles distributed in a clean needle program operated by a public entity from the prescription requirement was rejected by the Governor.

Assembly Bill 1292 of 2001 proposed repealing the regulation of needles by the board. That bill was amended to a form substantially similar to this legislation. The bill was supported by the board subject to inclusion of amendments to resolve technical issues and repealing the requirement to issue a hypodermic permit. The bill was not taken to a hearing at the request of the author.

In 2002, Senator John Vasconcellos introduced Senate Bill 1785 which eliminated the prescription requirement for needles and syringes and instead required that they only be sold by a pharmacist. The bill also limited the quantity sold to 30 needles per purchase. That bill was supported by the board and vetoed by the Governor. The

veto message is provided below:

> To the Members of the California State Senate:
>
> I am returning Senate Bill 1785 without my signature.
>
> SB 1785 would authorize pharmacists and physicians to furnish hypodermic needles or syringes for human use without a prescription. In addition, persons who are 18 years of age or older would be able to possess up to 30 hypodermic needles or syringes.
>
> I am committed to the underlying goal of the bill which is to reduce the transmission of HIV and hepatitis C among injection drug users, and I am proud of the progress we have made in combating these two diseases. California spends $93.2 million on education and prevention programs and I have added millions of dollars in the Office of AIDS for behavioral and early intervention, programs for high-risk youth, communities of color and HIV prevention evaluation. I have strongly supported our new HIV reporting system which will reveal trends in HIV transmission and assist in targeting HIV education, prevention and care efforts. I have signed legislation that already makes hypodermic needles and syringes available from authorized, legally sanctioned syringe exchange programs located throughout California.
>
> In Spring 2000, the Department of Health Services appointed the Hepatitis C Working Group, comprised of key stakeholders from the public and private sectors. The Working Group developed the first-ever hepatitis C strategic plan for California. In August 2000, I signed SB 1256 (Polanco) which allocated $1.5 million for hepatitis C outreach and education.
>
> I worked hard with the author of the legislation I signed in 1999 to bring law enforcement and health officials together on a bill that would decriminalize supervised needle exchange programs. This bill undermines the key elements that won my support for that legislation:
>
> * It eliminates the requirement for a one-for-one exchange of syringes, which is the standard of practice in authorized needle exchange programs.
> * By eliminating the one-on-one exchange, this bill eliminates the ability to focus aggressive intervention efforts toward getting drug addicts into treatment.
> * It eliminates the requirement that needle exchange programs be conducted with local government approval, ongoing oversight and as the result of a declared health emergency.
>
> Additionally, this bill could potentially increase the amount of contaminated needles and syringes in parks, beaches and other public areas. This would place the non-injection drug using population at greater risk for HIV, hepatitis C, and other blood-borne diseases. While I appreciate the author's hard work and dedication to this issue, I cannot sign this measure.

The board supported SB 1785.

3) Related Legislation. Assembly Bill 1363 (Berg) also repeals the prescription requirement and establishes more detailed authority for government operated needle exchange programs.

4) Hypodermic Permits. Currently any entity furnishing needles at retail must have either a pharmacy or hypodermic permit from the board. This bill would alter that and require all needles furnished for human use to be distributed by a pharmacy. Hypodermic permits would still be required to furnish needles for animal use (existing law exempts needles furnished for industrial use and this bill retains that exemption).

5) History

Mar. 13	To Coms. on H. & H.S. and RLS.
Feb. 24	Read first time.
Feb. 22	From print. May be acted upon on or after March 24.
Feb. 21	Introduced. To Com. on RLS. for assignment. To print.

SENATE BILL No. 774

Introduced by Senator Vasconcellos

February 21, 2003

An act to amend Sections 4140, 4142, 4145, and 4147 of, to add Sections 4142.2, 4142.4, 4142.6, and 4142.8 to, and to repeal Section 4146 of, the Business and Professions Code, and to amend Sections 11364 and 11364.5 of the Health and Safety Code, relating to hypodermic needles and syringes.

LEGISLATIVE COUNSEL'S DIGEST

SB 774, as introduced, Vasconcellos. Hypodermic needles and syringes.

(1) Existing law regulates the sale, possession, and disposal of hypodermic needles and syringes. Under existing law, a prescription is required to purchase a hypodermic needle or syringe for human use, except to administer adrenaline or insulin.

This bill would authorize a licensed pharmacist to sell hypodermic needles or syringes to a person without a prescription under specified conditions.

(2) Existing law requires a person to properly establish his or her identity in order to purchase a needle or syringe. Existing law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes.

This bill would delete both the identity requirement and the requirement that a pharmacist keep detailed records of nonprescription sales of hypodermic needles and syringes.

(3) Existing law prohibits the possession and sale of drug paraphernalia.

This bill would authorize a person to possess up to 30 hypodermic needles or syringes if acquired through an authorized source.

(4) Existing law prohibits the disposal of hypodermic needles and syringes in certain cases.

This bill would increase the criminal penalty for improper disposal of hypodermic needles and syringes in certain cases, thereby imposing a state-mandated local program.

(5) 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:

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

(a) Injection drug use is linked to 19 percent of all AIDS cases and one-half of all hepatitis C cases in California. Injection drug users become infected and transmit diseases such as HIV and hepatitis C to others by sharing blood-contaminated syringes.

(b) The lifetime cost of treating one person with AIDS is estimated to be over one hundred ninety-five thousand dollars ($195,000).

(c) According to the California Department of Health Services, 500,000 to 600,000 Californians are estimated to have contracted hepatitis C, a disease for which there is no known cure.

(d) The United States Public Health Service and the Centers for Disease Control and Prevention recommend that injection drug users who cannot or will not stop injecting drugs use a sterile needle for every injection as a public health measure to limit blood-borne disease transmission.

(e) Current California law requiring a prescription for the purchase of syringes and restricting the possession of syringes presents a formidable obstacle to disease prevention and threatens public safety. California is only one of six states that requires a prescription to purchase a syringe.

(f) Legislation to permit the pharmacy-based sale of sterile syringes without a prescription would reduce new cases of HIV,

hepatitis C, and other blood-borne diseases and would ultimately save California millions of dollars in medical costs.

SEC. 2. This act shall be known and may be cited as the Syringe Pharmacy Sale and Disease Prevention Act.

SEC. 3. Section 4140 of the Business and Professions Code is amended to read:

4140. ~~No~~ *A* person ~~shall~~ *may not* possess or have under his or her control ~~any~~ *a* hypodermic needle or syringe except when acquired in accordance with this article.

SEC. 4. Section 4142 of the Business and Professions Code is amended to read:

4142. *(a)* Except as otherwise provided by this article, ~~no~~ *a* hypodermic needle or syringe *for human use* shall *not* be sold at retail ~~except upon the prescription of a physician, dentist, veterinarian, or podiatrist.~~ *unless it is sold in a licensed pharmacy by either a pharmacist or a person licensed by the board to sell or furnish hypodermic needles or syringes.*

(b) A person who is 18 years of age or older may purchase for personal use pursuant to subdivision (a) up to 30 hypodermic needles or syringes per transaction without a prescription.

SEC. 5. Section 4142.2 is added to the Business and Professions Code, to read:

4142.2. A licensed pharmacy that sells nonprescription hypodermic needles and syringes at retail for human use shall do the following:

(a) Notify the local health officer, as defined in Chapter 1 (commencing with Section 101000) of Part 3 of Division 101 of the Health and Safety Code, that the pharmacy will be selling hypodermic needles and syringes without prescriptions.

(b) Store hypodermic needles and syringes so that they are available only to authorized personnel, and not openly available to customers.

(c) Report the number of syringes sold per month and the number of sales transactions for syringes and needles sold without a prescription per month to the local health officer.

SEC. 6. Section 4142.4 is added to the Business and Professions Code, to read:

4142.4. At the time of each purchase of nonprescription hypodermic needles and syringes at retail for human use, a

licensed pharmacy that sells those items shall provide a purchaser the following information:

(a) Information regarding the safe disposal of hypodermic needles and syringes that includes a notice of the penalties provided in Section 4147 for the improper disposal of hypodermic needles and syringes on playgrounds, public beaches, public parks, or school grounds.

(b) Public health information about the prevention, testing, and treatment of substance abuse, including a telephone number to call for assistance, and information on the transmission of blood-borne diseases, including information about the prevention, testing, and treatment of HIV and hepatitis C.

SEC. 7. Section 4142.6 is added to the Business and Professions Code, to read:

4142.6. A licensed pharmacy that sells nonprescription hypodermic needles and syringes at retail for human use shall provide one or more of the following safe syringe disposal programs:

(a) An onsite safe syringe disposal program.

(b) Make available for purchase mail-back sharps disposal packages that include postage paid, return packaging that is authorized by the United States Postal Service, a sharps container that meets applicable state and federal requirements, and tracking forms to verify destruction at a certified disposal facility.

(c) Make available for purchase or furnish personal sharps disposal containers and refer purchasers of nonprescription hypodermic needles and syringes to locally authorized, home-generated sharps consolidation points as defined in Section 117904 of the Health and Safety Code or to locally registered medical waste generators that accept home-generated medical sharps waste for disposal pursuant to Section 118147 of the Health and Safety Code.

SEC. 8. Section 4142.8 is added to the Business and Professions Code, to read:

4142.8. In order to maximize the public health benefits and public acceptance of the provisions of this article, the local health officer shall be available to do all of the following:

(a) Consult with pharmacies in establishing policies to sell hypodermic needles and syringes without a prescription.

(b) Review the appropriateness of information a licensed pharmacy is required to provide under Section 4142.4.

(c) Advise pharmacies, as necessary, on the options available within their jurisdiction for the disposal of used hypodermic needles and syringes that have been sold pursuant to this article.

(d) To the extent feasible, assist in coordinating activities authorized or required by this section with existing local programs directed at HIV, hepatitis C, and substance abuse treatment and prevention.

SEC. 9. Section 4145 of the Business and Professions Code is amended to read:

4145. Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use ~~in the administration of insulin or adrenaline~~; a pharmacist or veterinarian may, without a prescription or license, furnish hypodermic needles and syringes for use on poultry or animals; and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use ~~in the administration of insulin or adrenaline~~, or from a pharmacist, veterinarian, or licenseholder, for use on poultry or animals~~; if all of the following requirements are met:~~

~~(a) No needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.~~

~~(b) The furnisher, at the time furnishing occurs, makes a record of the furnishing in the manner required by Section 4146~~.

SEC. 10. Section 4146 of the Business and Professions Code is repealed.

~~4146. Any furnishing of a hypodermic syringe or hypodermic needle without a prescription shall, at the time of furnishing, be recorded in a book by the furnisher. The record of furnishing shall consist of the date and hour of the furnishing, the type or kind, size, and quantity of syringe or needle furnished, the purpose and use for which the needle or syringe was obtained, the signature of the furnisher, and the signature and address of the person to whom the needle or syringe was furnished. The record book shall be available for inspection by any authorized officer of the law.~~

SEC. 11. Section 4147 of the Business and Professions Code is amended to read:

4147. *(a) For purposes of this section, "playground" means any park or outdoor recreational area specifically designed to be used by children that has play equipment installed, or any similar facility located on public or private school grounds or on city or county parks.*

(b) Any hypodermic needle or syringe that is to be disposed of, shall be contained, treated, and disposed of, pursuant to Part 14 (commencing with Section 117600) of Division 104 of the Health and Safety Code.

(c) It shall be unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, a public beach, a public park, or any public or private elementary, vocational, junior high, or high school.

(d) A person who knowingly violates subdivision (c) is guilty of a misdemeanor, and upon conviction shall be punished by a fine or not less than two hundred dollars ($200) and not more than two thousand dollars ($2,000), or by imprisonment of up to six months, or by both that fine and imprisonment.

(e) Subdivision (c) shall not apply to the containment, treatment, and disposal of medical sharps waste from medical care or first aid services rendered on school grounds, nor to the containment, treatment, and disposal of hypodermic needles or syringes used for instructional or educational purposes on school grounds.

SEC. 12. Section 11364 of the Health and Safety Code is amended to read:

11364. *(a)* It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e), or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance which is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to the possession solely for personal use of supplies of up to 30 hypodermic needles or syringes acquired from authorized sources, including, but not limited to, pharmacies, hospitals, and public health clinics.

SEC. 13. Section 11364.5 of the Health and Safety Code is amended to read:

11364.5. (a) Except as authorized by law, ~~no~~ *a* person shall *not* maintain or operate ~~any~~ *a* place of business in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away unless such drug paraphernalia is completely and wholly kept, displayed or offered within a separate room or enclosure to which persons under the age of 18 years not accompanied by a parent or legal guardian are excluded. Each entrance to such a room or enclosure shall be signposted in reasonably visible and legible words to the effect that drug paraphernalia is kept, displayed or offered in such room or enclosure and that minors, unless accompanied by a parent or legal guardian, are excluded.

(b) Except as authorized by law, no owner, manager, proprietor or other person in charge of any room or enclosure, within any place of business, in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away shall permit or allow any person under the age of 18 years to enter, be in, remain in or visit such room or enclosure unless such minor person is accompanied by one of his or her parents or by his or her legal guardian.

(c) Unless authorized by law, no person under the age of 18 years shall enter, be in, remain in or visit any room or enclosure in any place of business in which drug paraphernalia is kept, displayed or offered in any manner, sold, furnished, transferred or given away unless accompanied by one of his or her parents or by his or her legal guardian.

(d) As used in this section, ‘‘drug paraphernalia’’ means all equipment, products, and materials of any kind which are intended for use or designed for use, in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance. ‘‘Drug paraphernalia’’ includes, but is not limited to, all of the following:

(1) Kits intended for use or designed for use in planting, propagating, cultivating, growing or harvesting of any species of

plant which is a controlled substance or from which a controlled substance can be derived.

(2) Kits intended for use or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

(3) Isomerization devices intended for use or designed for use in increasing the potency of any species of plant which is a controlled substance.

(4) Testing equipment intended for use or designed for use in identifying, or in analyzing the strength, effectiveness or purity of controlled substances.

(5) Scales and balances intended for use or designed for use in weighing or measuring controlled substances.

(6) Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose, and lactose, intended for use or designed for use in cutting controlled substances.

(7) Separation gins and sifters intended for use or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, marijuana.

(8) Blenders, bowls, containers, spoons, and mixing devices intended for use or designed for use in compounding controlled substances.

(9) Capsules, balloons, envelopes, and other containers intended for use or designed for use in packaging small quantities of controlled substances.

(10) Containers and other objects intended for use or designed for use in storing or concealing controlled substances.

(11) Hypodermic syringes, needles, and other objects intended for use or designed for use in parenterally injecting controlled substances into the human body.

(12) Objects intended for use or designed for use in ingesting, inhaling, or otherwise introducing marijuana, cocaine, hashish, or hashish oil into the human body, such as the following:

(A) Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes with or without screens, permanent screens, hashish heads, or punctured metal bowls.

(B) Water pipes.

(C) Carburetion tubes and devices.

(D) Smoking and carburetion masks.

(E) Roach clips, meaning objects used to hold burning material, such as a marijuana cigarette that has become too small or too short to be held in the hand.

(F) Miniature cocaine spoons, and cocaine vials.

(G) Chamber pipes.

(H) Carburetor pipes.

(I) Electric pipes.

(J) Air-driven pipes.

(K) Chillums.

(L) Bongs.

(M) Ice pipes or chillers.

(e) In determining whether an object is drug paraphernalia, a court or other authority may consider, in addition to all other logically relevant factors, the following:

(1) Statements by an owner or by anyone in control of the object concerning its use.

(2) Prior convictions, if any, of an owner, or of anyone in control of the object, under any state or federal law relating to any controlled substance.

(3) Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons whom he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this section. The innocence of an owner, or of anyone in control of the object, as to a direct violation of this section shall not prevent a finding that the object is intended for use, or designed for use, as drug paraphernalia.

(4) Instructions, oral or written, provided with the object concerning its use.

(5) Descriptive materials, accompanying the object which explain or depict its use.

(6) National and local advertising concerning its use.

(7) The manner in which the object is displayed for sale.

(8) Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor or dealer of tobacco products.

(9) The existence and scope of legitimate uses for the object in the community.

(10) Expert testimony concerning its use.

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

(1) Any pharmacist or other authorized person who sells or furnishes drug paraphernalia described in paragraph (11) of subdivision (d) upon the prescription of a physician, dentist, podiatrist or veterinarian *or who sells hypodermic needles or syringes without a prescription pursuant to Section 4142 or 4145 of the Business and Professions Code*.

(2) Any physician, dentist, podiatrist or veterinarian who furnishes or prescribes drug paraphernalia described in paragraph (11) of subdivision (d) to his or her patients.

(3) Any manufacturer, wholesaler or retailer licensed by the California State Board of Pharmacy to sell or transfer drug paraphernalia described in paragraph (11) of subdivision (d).

(g) Notwithstanding any other provision of law, including Section 11374, violation of this section shall not constitute a criminal offense, but operation of a business in violation of the provisions of this section shall be grounds for revocation or nonrenewal of any license, permit, or other entitlement previously issued by a city, county, or city and county for the privilege of engaging in such business and shall be grounds for denial of any future license, permit, or other entitlement authorizing the conduct of such business or any other business, if the business includes the sale of drug paraphernalia.

SEC. 14. The Legislative Analyst shall review the available literature evaluating the following programs in regards to their public acceptance, efficacy, and cost: the New York State Department of Health Expanded Syringe Access Demonstration Program (ESAP) safety insert recommendations on safe syringe disposal, the Rhode Island State Department of Public Health-sponsored syringe disposal programs (Sharps Smart), and the San Francisco Safe Needle Disposal Program (SFSNDP). The Legislative Analyst shall also review recent literature on syringe disposal programs to identify other effective programs. The Legislative Analyst shall identify the most effective options for implementing a program in California, the approximate cost of implementing a program statewide, and a potential funding stream to support a program. On or before December 1, 2003, the Legislative Analyst shall report his or her findings to the committees of both houses of the Legislature with subject matter jurisdiction over health or criminal justice matters.

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

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State of California Department of Consumer Affairs

Memorandum

To: Legislation and Regulation Committee Date: March 17, 2003

From: Paul Riches
Legislative Analyst

Subject: Veterinary Drugs

Senator Sheila Kuehl has introduced Senate Bill 175 to clarify the board's jurisdiction as it relates to "veterinary drugs." The board has jurisdiction over "dangerous drugs" as defined in Business and Professions Code 4022. That section explicitly exempts "veterinary drugs" from the definition of "dangerous drugs" and thus from the board's jurisdiction. Much of the confusion related to this issue revolves around the usage and definition of those terms.

The term "veterinary drug" has been used with a number of different meanings. Some believe it to be any drug prescribed by a veterinarian. However, many of the drugs prescribed by veterinarians are actually drugs approved for use in humans and other drugs are used by veterinarians that are specifically approved by the FDA for use in animals upon the prescription of a veterinarian. The board believes that the term "veterinary drug" to mean those drugs approved by the FDA for animal use and that the term "dangerous drug" means those drugs approved by the FDA for use in humans when prescribed by an appropriately licensed health professional. Under the board's interpretation, it currently has jurisdiction over drugs prescribed by veterinarians when they are drugs approved for use by humans (dangerous drugs) for use in animals. For example, veterinarians use many of the same antibiotics to treat infections that are used by physicians to treat humans. It does not have jurisdiction when veterinarians prescribe drugs approved for animal use.

It is also worth noting that veterinarians currently are not subject to the prescriber dispensing laws that apply to other prescribers (physicians, dentists, etc.). Board staff has proposed a number of technical amendments to the bill (a bill analysis and the text of the proposed amendments are attached for your reference) and the author has indicated that they will accept those amendments. These amendments include adding veterinarians to the prescriber dispensing statute.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 175 **VERSION: AS INTRODUCED**

AUTHOR: KUEHL **SPONSOR: CAL. VET MED ASSN**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: VETERINARY DRUGS

Existing Law:

1) Defines "dangerous drugs" as those drugs for human use that require a prescription. (B&P 4022)

2) Excludes veterinary drugs from the definition of "dangerous drugs."

3) Excludes veterinarians from pharmacy law provisions relating to prescriber dispensing. (B&P 4170)

This Bill:

1) Redefines "dangerous drugs" to include veterinary drugs. (B&P 4022)

2) Includes veterinarians in existing prescriber dispensing statutes. (B&P 4170 et seq.)

Comment:

1) Author's Intent. The author introduced the bill to clarify existing law as it relates to the regulation of veterinary drugs by the Board of Pharmacy.

2) Veterinary Drugs. The Food and Drug Administration (FDA) approves drugs for veterinary use separately from those for human use. These drugs are approved for use in animals only upon a veterinarian's prescription. These drugs are excluded from the definition of "dangerous drugs" in Business and Professions Section 4022. The board is required to regulate dangerous drugs as defined in Section 4022 and cannot regulate a drug that does not meet the definition.

There are also a range of veterinary drugs approved for over-the-counter (OTC) sales that are chemically identical to human drugs available only by prescription. These drugs are commonly sold in pet and feed stores. The board is prohibited from regulating OTC drugs by Business and Professions Code Section 4057.

However, many drugs used in animals are drugs approved by the FDA for human use. These drugs (e.g., antibiotics, analgesics, etc) are dosed for animals but are the same drugs used to treat humans. These drugs are within the board's jurisdiction because they meet the definition of dangerous drugs in Section 4022.

As drafted, SB 175 would broaden the board's regulatory authority to include veterinary drugs and would subject veterinarians to board enforcement action. Existing law and board practice is to share jurisdiction over prescriber dispensing cases with the appropriate licensing board. The board is presently engaged in a discussion regarding the enforcement of prescriber dispensing laws with the Medical Board of California.

3) Statutory History. In 1980 the section of law defining "dangerous drugs" (now Section 4022) was completely rewritten. Prior to that change, the section listed specific drugs that were dangerous drugs and exempted certain veterinary drugs from that definition. However, the 1980 revisions established a blanket exemption for all veterinary drugs. This change was characterized at the time as a technical change to streamline the law and follow federally established drug designations in place of the specific listing in current law.

Existing law identifies veterinarians as prescribers (B&P 4024), but veterinarians are exempted from the statutes regulating prescriber dispensing (B&P 4170 et seq.) that establish the rules for prescribers who dispense drugs directly to their own patients. Among the requirements under the prescriber dispensing statutes is that prescribers must allow the patient to fill the prescription at a pharmacy of their choosing. That requirement does not currently apply to veterinarians.

4) Amendments. Board staff has been engaged in discussions with the Veterinary Medical Board on this issue in recent months. Attached are amendments to the bill proposed by staff. These amendments address several technical drafting issues and clarify the meaning of "good faith medical examination" in the board's citation and fine authority relating to internet dispensing to include the definition of that phrase adopted by the Veterinary Medical Board.

5) History.

Mar. 13	Set for hearing March 24.
Feb. 25	To Com. on B. & P.
Feb. 13	From print. May be acted upon on or after March 15.
Feb. 12	Introduced. Read first time. To Com. on RLS. for assignment. To print.

Board of Pharmacy
Proposed Amendments to SB 175 (Kuehl)
As Introduced

SECTION 1. Section 4022 of the Business and Professions Code is amended to read:
4022. "Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:
(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.
(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006.

SEC. 2. Section 4067 of the Business and Professions Code is amended to read:
4067. (a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal , or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.
(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.
(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).
(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.
(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.
(f) For the purposes of this section “good faith prior examination” includes both the requirement for a physician and surgeon under Section 2242 of the Business and Professions Code and the requirement for a veterinary medical doctor under Title 16, Section 2032.1 of the California Code of Regulations.

SEC. 3. Section 4170 of the Business and Professions Code is amended to read:
4170. (a) No prescriber shall dispense drugs or dangerous devices to patients in his or her office or place of practice unless all of the following conditions are met:

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

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

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

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

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

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

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

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

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

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

SEC. 4. Section 4171 of the Business and Professions Code is amended to read:

4171. (a) Section 4170 shall not prohibit the furnishing of a limited quantity of samples by a prescriber, if the prescriber dispenses the samples to the patient in the package provided by the manufacturer, no charge is made to the patient therefor, and an appropriate record is entered in the patient's chart.

(b) Section 4170 shall not apply to clinics, as defined in subdivision (a) of Section 1204 or subdivision (b) or (c) of Section 1206 of the Health and Safety Code, ~~to veterinarians furnishing drugs for the treatment of animals,~~ to programs licensed pursuant to Sections 11876, 11877, and 11877.5 of the Health and Safety Code, or to a prescriber dispensing parenteral chemotherapeutic agents, biologicals, or delivery systems used in the treatment of cancer.

SEC. 5 ~~4.~~ Section 4175 of the Business and Professions Code is amended to read:

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

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

State of California Department of Consumer Affairs

Memorandum

To: Legislation and Regulation Committee Date: March 19, 2003

From: Paul Riches
Legislative Analyst

Subject: Omnibus Provision

Below is suggested language for inclusion in the annual omnibus measure. Staff is suggesting this language to reduce workload associated with providing license verifications to interested parties. By allowing license verifications from the board's to be accepted by those needing to verify licensure, fewer verification requests will be submitted to board staff. This is particularly of concern for wholesalers wishing to ship to newly licensed pharmacies.

Add Section 4106 to the Business and Professions Code.

4106. For purposes of license verification, a person may rely upon a printout from the board's web site, that includes the license issuance and expiration dates, of any board-issued license.

State of California Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee Date: March 17, 2003

From: Paul Riches
Legislative Analyst

Subject: Regulations Update

Recently Approved

Section 1717 (e) – Delivery of Medications
Summary: This regulation will eliminate the waiver process established by 1717(e). This waiver process permits pharmacies to depot drugs for delivery to patients at non-pharmacy locations. Instead, the regulation will permit pharmacies to depot drugs at any location where the patient receives health care services.
Status: Approved by OAL. Effective Date: March 12, 2003

Section 1720.4 – Foreign Graduates
Summary: This regulation will specify the procedure for foreign graduates who cannot obtain verifiable transcripts to become eligible to take the pharmacist license examination.
Status: Approved by OAL. Effective Date: March 13, 2003

Section 1745 – Partial Filling of Schedule II Prescriptions
Summary: This regulation will make the partial fill regulation consistent with recent statutory changes to Schedule II prescription requirements.
Status: Approved by OAL. Effective Date: March 12, 2003

Pending Regulations

Section 1732.05 – Continuing Education
Summary: This regulation will recognize continuing education credits approved by other California health professions licensing boards.
Status: Comment period closed December 16, 2002. The board approved the regulation at its January 2003 meeting. Subsequent to that meeting a 15 day notice was published to make a technical correction to the regulation. That comment period closes on March 28, 2003. Staff anticipates filing the regulation with the Office of Administrative Law shortly after the comment period closes.

Section 1751 – Sterile Compounding

Summary: This regulation will establish guidelines for the compounding of sterile drug products.
Status: The board held a regulation hearing on the regulation at the October 2002 board meeting. A subsequent workshop was held on a new draft at the December 2002 Licensing Committee meeting. Subsequent to that meeting and the January 2003 board meeting, staff withdrew the prior rulemaking and noticed a new regulation on the same subject matter that reflected the proposal made at the December 5, 2002 meeting. The notice of proposed action was published on February 21, 2003 and the comment period closes on April 7, 2003. The regulation will be considered by the board at the April 29, 2003 board meeting.

Section 1775 et seq. – Citation and Fine
Summary: The proposed regulation will permit the executive officer and/or the executive officer's designee to issue citations and fines. Consolidates related citation and fine regulations.
Status: The notice of proposed action was published on February 21, 2003 and the comment period closes on April 7, 2003. It is expected that the board will vote on the proposed regulation at the April 29, 2003 board meeting.

<u>Awaiting Notice</u>

Section 1707.5 – Hospital Central Fill
Summary: This regulation will permit central refill operations for hospitals.
Status: Conducted informational hearing at October 2002 board meeting.

Section 1709.1 - Pharmacist-in-Charge at Two Locations
Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.
Status: None

Section 1715 – Pharmacy Self Assessment
Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.
Status: None.

Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records
Summary: This regulation will make any needed changes to board regulations to conform to Assembly Bill 2240 and require that pharmacists confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. It will also repeal section 1717.2. The notice to consumers required by this section has been superseded by amendments to California law that substantially strengthened privacy protections.
Status: None

Section 1717.4 – Authentication of Electronic Prescriptions
Summary: This regulation will require pharmacists to authenticate electronic prescriptions.
Status: None

Section 1764 – Wholesaling
Summary: This regulation will impose dollar volume limits on wholesale drug transfers by pharmacies, impose dollar volume limits on transfers between wholesalers, and require pedigrees for drug shipments under specified circumstances.
Status: The Enforcement Committee conducted an informational hearing on this proposal at its December 2002 meeting.

Section 1793.3 – "Clerk-Typist" Ratio
Summary: This regulation will eliminate the clerk/typist ratio.
Status: None.