California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LEGISLATION AND REGULATION COMMITTEE

Legislation Report

FOR ACTION

Action Item 1 – The Legislation and Regulation Committee (committee) recommends that the board support Assembly Bill 320.

Discussion: See the analysis provided in Attachment 1

Action Item 2 – The committee recommends that the board support Assembly Bill 1826.

Discussion: See the analysis provided in Attachment 2

Action Item 3 – The committee recommends that the board consider Assembly Bill 1957 without a recommendation from the Committee.

Discussion: See the analysis provided in Attachment 3. The bill was amended on April 1, 2004 to shift the mandates to the Department of Health Services and staff is recommending the board take no position based on those amendments.

Action Item 4 – The committee recommended that the board support Assembly Bill 1960 if it is amended based on a prior version of the bill. The prior version of the bill was deleted and new amendments requiring the board to license pharmacy benefits managers (among many other provisions) were adopted on April 12, 2004. Based on these amendments, staff is recommending that the board adopt an oppose position.

Discussion: See the analysis provided in Attachment 4

Action Item 5 – The committee recommends that the board consider Assembly Bill 2125 without a recommendation from the Committee.

Discussion: See the analysis provided in Attachment 5

Action Item 6 – The committee recommends that the board oppose Assembly Bill 2184 unless it is amended.

Discussion: See the analysis provided in Attachment 6

Action Item 7 – The committee recommends that the board support Assembly Bill 2660.

Discussion: See the analysis provided in Attachment 7

Action Item 8 – The committee recommends that the board support Assembly Bill 2682 if it is amended.

Discussion: See the analysis provided in Attachment 8

Action Item 9 – The committee recommends that the board consider Senate Bill 1149 without a recommendation from the Committee.

Discussion: See the analysis provided in Attachment 9

Action Item 10 – The committee recommends that the board support Senate Bill 1159.

Discussion: See the analysis provided in Attachment 10

Action Item 11 – The committee recommends that the board consider Senate Bill 1333 without a recommendation from the Committee.

Discussion: See the analysis provided in Attachment 11

Action Item 12 – The committee recommends that the board support Senate Bill 1427.

Discussion: See the analysis provided in Attachment 12

Action Item 13 – The committee recommends that the board oppose Senate Bill 1728 unless it is amended.

Discussion: SB 1728 was amended on April 12, 2004 to resolve the committee's opposition. Staff recommends that the board take no position on the amended bill as it is restricted to the Department of Fish and Game.

Action Item 14 – The committee recommends that the board support Senate Bill 1735.

Discussion: See the analysis provided in Attachment 13

NO ACTION

Board Sponsored Legislation

Senate Bill 1307 (Figueroa)

This bill is sponsored by the board to improve the licensing of wholesalers and the safety of wholesale transactions. The board approved draft legislation at its January 2004 meeting with the following principal elements:

Require pedigrees on all wholesale transactions effective January 1, 2007.
Restrict the wholesale transactions that can be made by a pharmacy.

Establish per occurrence cite and fine authority for specified wholesale violations.
Create a designation for closed pharmacy.
Require wholesalers to post a $100,000 surety bond to secure fines and penalties.
Require all non-resident wholesalers to be licensed by the board.
Prohibit the common ownership of a wholesaler and a closed pharmacy.

Staff and the author have been in active discussions with wholesale industry representatives and have conceptual agreement on the major issues. Industry representatives have focused on extending the implementation date for the pedigree requirement and eliminating the prohibition on common ownership of a wholesaler and a closed pharmacy. This bill was amended to allow the board to extend implementation of the pedigree requirement for up to one year if needed to allow full implementation of an RFID system for pedigrees. This timeline matches the expected rollout of the RFID system in the drug wholesale industry. There is conceptual agreement to replace the ownership prohibition with strict transaction restrictions for closed pharmacies and stiffer penalties for their violation. These provisions will be supplemented by provisions requiring wholesalers to perform reasonable "due diligence" to ensure that their closed pharmacy customers are engaged in legitimate business.

See Attachment 14 for the text of SB 1307.

Senate Bill 1913 (Business and Professions Committee)

This bill contains numerous provisions sponsored by the board to make technical and non-controversial changes to pharmacy law.

See Attachment 15 for the board sponsored provisions of SB 1913.

Status of Bills with a Board Position

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."
Board Position: **Support**
Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medi-Cal fraud.
Board Position: **Support**
Status: Senate Rules Committee

AB 1363 (Berg) Establishes requirements for needle exchange programs.
Board Position: **Support**
Status: Dead

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy. Board Position: **Support**
Status: Dead

SB 393 (Aanestad) Permits "tech check tech" in hospitals.
Board Position: **Support**
Status: Dead

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.
Board Position: **Oppose**
Status: Dead

Quarterly Status Report on Committee Goals for 2003-04

For your information, an update of the Committee's progress in accomplishing its strategic objectives is attached to this report (Attachment 16).

Meeting Summary for March 30, 2004

For your information the summary for the March 30, 2004 meeting of the Legislation and Regulation Committee meeting is attached to this report (Attachment 17).

Attachment 1

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 320 **VERSION: AS AMENDED MARCH 16, 2004**

AUTHOR: CORREA **SPONSOR: AUTHOR**

RECOMMENDED POSITION: SUPPORT

SUBJECT: GAG CLAUSES

Existing Law:

Permits the board to take enforcement action against a licensee for unprofessional conduct or other violations of the Pharmacy Law.

This Bill:

1) Prohibits a licensee of a board, bureau or program within the Department of Consumer Affairs (DCA) or an entity acting on behalf of a licensee from including a provision in a civil settlement that prohibits the other party from contacting, filing a complaint with, or cooperating with the DCA, or a board, bureau, or program. (B&P 143.5)

2) Prohibits a licensee of a board, bureau, or program within the DCA from including a provision in a settlement for a civil action that requires the other party to withdraw a complaint from the DCA, or a board, bureau, or program. (B&P 143.5)

3) Declares that such provisions (i.e., "gag clauses") to be void as against public policy. (B&P 143.5)

4) Specifies that a licensee who includes or permits a "gag clause" to be included in a settlement agreement is subject to disciplinary action by a board, bureau, or program. (B&P 143.5)

Comment:

1) Author's Intent. According to the author, current law allows licensees to use regulatory gag clauses to keep their misconduct secret and avoid appropriate oversight to the detriment of the public: "Even when such conduct is brought to the attention of the regulator through a third party, gag clauses can delay investigation and discipline by months because investigators must spend additional time and money trying to void such clauses and convince injured parties to cooperate. This bill will help ensure that regulatory agencies have unrestricted access to the information they need to effectively enforce the law and protect the public. It will also safeguard a consumer's right to inform their government when they are harmed or treated unprofessionally without jeopardizing their right to seek civil redress." The full extent to which gag clauses are used by DCA licensees is unknown because they are, by definition, secret.

2) Medical Board. According to a preliminary investigation recently released by MBC, such gag clauses have stymied a number of investigations, many of which involved

allegations of sexual misconduct. The most common result of such clauses seems to be delay: cases can be slowed by several months or even years because of fear on the part of patients who sometimes require a court order before they will cooperate. The legal burden of overcoming gag clauses can also add thousands of dollars in additional legal costs for the state.

3) Gag Clauses. This bill is intended to close a loophole in current law that allows a licensee under the supervision of DCA to prohibit a consumer who settles a civil suit from also filing a complaint or otherwise cooperating with a regulator. Such an agreement is known as a regulatory "gag clause." A regulatory gag clause requires a plaintiff to agree, as a condition of a malpractice or misconduct settlement with the licensee, to the inclusion of a provision prohibiting the plaintiff from contacting or cooperating with the defendant's regulator (or requiring the plaintiff to withdraw a pending complaint before that regulator.)

As an example, under current law, a physician who settles a malpractice complaint with an injured patient might require, as a condition of receiving the settlement payment, that the consumer not report the malpractice to the Medical Board of California (MBC) or otherwise speak regarding the case, even if the patient is contacted by DCA investigators or private attorneys who are looking into separate complaints against the physician.

4) Attorneys. This bill is modeled on an existing statute that prohibits attorneys from including such clauses in legal malpractice settlements, and is in line with a number of court decisions that describe a compelling public interest in voiding regulatory gag clauses so that the regulator can best protect the public from harm.

5) Support and Opposition.

Support:

California Public Interest Research Group
Center for Public Interest Law
Consumer Attorneys of California
Consumers for Auto Reliability and Safety
Consumers Union
California Medical Board

Opposition:

None on file.

6) History.

2004
Mar. 16 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B. & P.
Mar. 1 In committee: Hearing postponed by committee.
Feb. 17 Referred to Coms. on B. & P. and JUD.
Jan. 28 In Senate. Read first time. To Com. on RLS. for assignment.
Jan. 26 Read third time, passed, and to Senate. (Ayes 76. Noes 0. Page 4359.)
Jan. 22 From committee: Do pass. (Ayes 23. Noes 0.) (January 21). Read second time. To third reading.
Jan. 13 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 12. Noes 0.) (January 13).
2003

May 8 Re-referred to Com. on B. & P.
May 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
May 6 In committee: Hearing postponed by committee.
Apr. 29 In committee: Hearing postponed by committee.
Apr. 23 Re-referred to Com. on B. & P.
Apr. 22 Re-referred to Com. on B. & P. From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Apr. 21 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Feb. 18 Referred to Com. on B. & P.
Feb. 11 From printer. May be heard in committee March 13.
Feb. 7 Read first time. To print.

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AMENDED IN SENATE MARCH 16, 2004

AMENDED IN ASSEMBLY MAY 7, 2003

AMENDED IN ASSEMBLY APRIL 22, 2003

AMENDED IN ASSEMBLY APRIL 21, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 320

Introduced by Assembly Member Correa
(Coauthors: Assembly Members Bermudez, Shirley Horton, Koretz, Leno, Reyes, Vargas, and Wyland)

February 7, 2003

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

LEGISLATIVE COUNSEL'S DIGEST

AB 320, as amended, Correa. Professions and vocations: licensees: settlement agreements.

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

This bill would prohibit a licensee ~~of a profession or vocation~~, *or an entity acting on behalf of a licensee, which licensee is* regulated by the Department of Consumer Affairs or various boards, bureaus, or programs from including, or permitting to be included, a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board, bureau, or program.

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

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

1 SECTION 1. Section 143.5 is added to the Business and
2 Professions Code, to read:
3 143.5. (a) ~~A~~ *No* licensee ~~of a profession or vocation~~, *and no*
4 *entity acting on behalf of a licensee, which licensee is* regulated by
5 a board, bureau, or program within the Department of Consumer
6 Affairs, shall ~~not~~ include or permit to be included a provision in
7 an agreement to settle a civil dispute, whether the agreement is
8 made before or after the commencement of a civil action, that
9 prohibits the other party in that dispute from contacting, filing a
10 complaint with, or cooperating with the department, board,
11 bureau, or program or that requires the other party to withdraw a
12 complaint from the department, board, bureau, or program. A
13 provision of that nature is void as against public policy, and any
14 licensee who includes or permits to be included a provision of that
15 nature in a settlement agreement is subject to disciplinary action
16 by the board, bureau, or program.
17 (b) As used in this section, ''board'' shall have the same
18 meaning as defined in Section 22, and ''licensee'' means a person
19 that has been granted a license, as that term ~~in~~ *is* defined in Section
20 23.7.

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Attachment 2

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1826 **VERSION: AS AMENDED MARCH 18, 2004**

AUTHOR: BOGH **SPONSOR: RIVERSIDE COUNTY DA**

RECOMMENDED POSITION: SUPPORT

SUBJECT: FRAUDULENT USE OF A LICENSE

Existing Law:

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

2) Prohibits the acquisition and use of another individual's "personal identifying information" without their consent (identity theft). (Penal Code 530)

3) Establishes penalties of up to one year in jail and a fine of up to $10,000 for identity theft. (Penal Code 530.5)

4) Establishes a penalty of up to 50 days in jail and/or a fine of up to $5,000 for impersonating a pharmacist. (B&P 4322)

5) Permits licensing boards to establish citation and fine punishments for unlicensed activity. (B&P 148)

This Bill:

1) Adds a professional license number to the definition of "personal identifying information." (Penal Code 530.5)

Comment:

1) Author's Intent. The author has introduced this bill to create significant penalties for the theft and misuse of a professional or occupational license number. The bill was motivated by a case where the Medical Board of California received a consumer complaint regarding an individual who was falsely impersonating a licensed psychotherapist and charging patients for services. The Medical Board referred the case to the Riverside County District Attorney who sought to prosecute the individual under existing identity theft statutes. However, these statutes do not address the theft of a professional or occupational license. Subsequently, the Riverside County District Attorney has received a similar case from the Contractors State License Board.

2) Unlicensed Activity. There are existing penalties that a board may use to prosecute unlicensed activity. Most commonly, boards may issue citations and fines for up to $5,000 for unlicensed activity. In addition the Pharmacy Law (B&P Code Section 4322) of up to 50 days in jail and/or a fine of up to $5,000 for impersonating a licensee.

Unlicensed activity of this sort is one of the most serious violations of any licensing act. The principal purpose of any licensing act is to ensure public protection by requiring

demonstrated competence prior to entering practice. Individuals who falsely represent themselves as being licensed present a direct threat to public safety and undermine the public's confidence in the affected profession or occupation.

3) History.

Mar. 22	Re-referred to Com. on PUB. S.
Mar. 18	From committee chair, with author's amendments: Amend, and re-refer to Com. on PUB. S. Read second time and amended.
Mar. 15	In committee: Hearing postponed by committee.
Feb. 2	Referred to Com. on PUB. S.
Jan. 21	From printer. May be heard in committee February 20.
Jan. 20	Read first time. To print.

AMENDED IN ASSEMBLY MARCH 18, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1826

Introduced by Assembly Member Bogh

January 20, 2004

An act to amend Section 530.5 of the Penal Code, relating to professional and trade licenses.

LEGISLATIVE COUNSEL'S DIGEST

AB 1826, as amended, Bogh. Professional and trade licenses.

Existing law provides that every person who obtains personal identifying information of another person, and uses that information for any unlawful purpose, including to obtain, or attempt to obtain, credit, goods, services, or medical information in the name of the other person without the consent of that person, is guilty of a public offense punishable by either imprisonment in a county jail not to exceed one year, a fine not to exceed $1,000, or both that imprisonment and fine, or by imprisonment in the state prison, a fine not to exceed $10,000, or both that imprisonment and fine.

This bill would ~~provide that it is a public offense punishable by either imprisonment in a county jail for a period not to exceed one year, a fine not exceeding $1,000, or by both that imprisonment and fine, or by imprisonment in the state prison for 2, 3, or 4 years, a fine not exceeding $10,000, or by both that imprisonment and fine, to obtain the~~ *expand the definition of personal identifying information to include a* professional or trade license number, as defined~~, of another person and to use it for any unlawful purpose, including to obtain credit, goods, services, or medical information, or to provide, or to attempt to provide~~

~~professional services in the name of that person without his or her consent~~.

Because this bill would ~~create a new crime,~~ *change the definition of a crime and require local agencies to perform additional services,* this 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.~~

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 530.5 of the Penal Code is amended to read:

530.5. (a) Every person who willfully obtains personal identifying information, as defined in subdivision (b), of another person, and uses that information for any unlawful purpose, including to obtain, or attempt to obtain, credit, goods, services, or medical information in the name of the other person without the consent of that person, is guilty of a public offense, and upon conviction therefor, shall be punished either by imprisonment in a county jail not to exceed one year, a fine not to exceed one thousand dollars ($1,000), or both that imprisonment and fine, or

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

(b) ''Personal identifying information,'' as used in this section, means the name, address, telephone number, health insurance identification number, taxpayer identification number, school identification number, state or federal driver's license number, or identification number, *professional or trade license number,* social security number, place of employment, employee identification number, mother's maiden name, demand deposit account number, savings account number, checking account number, PIN (personal identification number) or password, alien registration number, government passport number, date of birth, unique biometric data including fingerprint, facial scan identifiers, voice print, retina or iris image, or other unique physical representation, unique electronic data including identification number, address, or routing code, telecommunication identifying information or access device, information contained in a birth or death certificate, or credit card number of an individual person.

(c) In any case in which a person willfully obtains personal identifying information of another person, uses that information to commit a crime in addition to a violation of subdivision (a), and is convicted of that crime, the court records shall reflect that the person whose identity was falsely used to commit the crime did not commit the crime.

(d) Every person who, with the intent to defraud, acquires, transfers, or retains possession of the personal identifying information, as defined in subdivision (b), of another person is guilty of a public offense, and upon conviction therefor, shall be punished by imprisonment in a county jail not to exceed one year, or a fine not to exceed one thousand dollars ($1,000), or by both that imprisonment and fine.

(e) ~~Every person who willfully obtains the professional or trade license number issued by any state within the United States, or by the United States, as defined in subdivision (f), of another person, and uses that number for any unlawful purpose, including to obtain, or attempt to obtain credit, goods, services, or medical information, or to provide, or attempt to provide, professional services in the name of the person without the consent of that person, is guilty of a public offense, and upon conviction therefor, shall be punished either by imprisonment in a county jail for a~~

~~period not to exceed one year, a fine not to exceed one thousand dollars ($1,000), or both that imprisonment and fine, or by imprisonment in the state prison for two, three, or four years, a fine not to exceed ten thousand dollars ($10,000), or both that imprisonment and fine.~~

~~(f)~~ As used in this section, ''professional or trade license number'' means the unique number issued to a natural person by any *state or federal* governmental agency, board, organization, or ~~other~~ licensing authority required for the purpose of lawfully practicing a profession or trade.

~~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.~~

SEC. 2. 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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Attachment 3

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1957 **VERSION: AS AMENDED APRIL 1, 2004**

AUTHOR: FROMMER ET AL. **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NONE

SUBJECT: DRUG IMPORTATION

Existing Law:

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

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

This Bill:

1) Requires the Department of Health Services (department) to establish a Web site on or before July 1, 2005 that will facilitate the safe purchase of prescription drugs from Canadian pharmacies. (B&P 4430)

2) Requires this Web site to include price comparisons between typical pharmacy prices and Canadian pharmacy prices for the 50 most commonly prescribed drugs. (B&P 4430)

3) Requires this Web site to include links to "certified" Canadian pharmacies. (B&P 4430)

4) Establishes the requirements that must be met for the department to "certify" a Canadian pharmacy to include:

a. Verification of licensure by the appropriate Canadian province.
b. Compliance with the requirements that must be met by non-resident pharmacies.
c. Meets standards for safety, access and affordability established by the board.
d. Requires a prescription from the patient's personal physician.
e. Requires a patient medical history.
f. Requires a signed patient agreement.
g. Requires prescriptions to be mailed in original packaging.
h. Requires physical address and phone number for the pharmacy on the pharmacy Web site.

5) Requires the Department of General Services to review the purchasing of drugs by other state agencies and determine if significant cost savings would result from the purchase of Canadian drugs by these agencies. (Government Code 14892)

6) Permits the Department of General Services to purchase Canadian drugs if it can obtain appropriate waivers from federal law. (Government Code 14893)

Comment:

1) Author's Intent. The authors state, "California needs to take significant steps to remedy a situation that is literally forcing taxpayers to break the law in order to preserve their health and is recklessly driving health care costs up to unprecedented levels… Prescription drug costs continue to skyrocket, making life-saving drugs increasingly unaffordable for individuals, employers, local governments and the state. Individuals without health coverage and seniors, who require more medications on average than younger Californians, are especially hard hit. As a result, many Californians are forced to turn to Web sites that offer prescription drugs from Canadian pharmacies at deeply discounted prices…In 2002, United States consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15.3% over the previous year. Over the three prior years, prescription drug spending increased an average of 17.3% each year. On average, United States residents spend $654 on drugs, while a resident in Britain only pays $197, according to a recent *TIME* magazine article. For that reason, news reports estimate that more than a million Americans spent $800 million last year on prescription drugs from Canada, where drugs are, on average, 40% cheaper."

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

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

3) Price Controls. Consumers seek to purchase drugs from Canadian pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. [For your information, attached is a recent article from the journal *Health Affairs* describes the price control methods used in Canada.] ***Branded*** drugs can commonly be purchased from Canadian pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board is sympathetic to the difficulty of those without drug insurance have affording the drugs they need and the impact of drug pricing on the affordability of insurance coverage for those who have it.

Much of the public debate regarding the importation of drugs from Canada has focused on the safety of imported drugs. This debate on safety masks the more basic affordability problem that underlies importation. Consumers are seeking Canadian drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies. In this circumstance, importation is an indirect method of imposing price controls on drugs. Despite this reality, little if any consideration has been articulated regarding the establishment of direct price controls. While proposing direct price controls would be politically challenging, such a debate would present a more straightforward discussion regarding the cost of and accessibility to prescription drugs. The board is not advocating any

particular action in this respect, but rather encouraging a full and honest debate regarding the essential issue of drug pricing.

5) Minnesota. The Web site provisions of this bill largely duplicate existing efforts made by the state of Minnesota. As indicated above, the bill would require the department to expend additional resources to duplicate an existing web page. Linking to the Minnesota Rx Connect Web site would be a faster and less expensive approach to providing California consumers this information.

6) History.

Apr. 1	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 18	Referred to Coms. on HEALTH and B. & P.
Feb. 19	(Corrected February 17.)
Feb. 13	From printer. May be heard in committee March 14.
Feb. 12	Read first time. To print.

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AMENDED IN ASSEMBLY APRIL 1, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1957

Introduced by Assembly Members Frommer, Chu, Pavley, and Ridley-Thomas

February 12, 2004

~~An act to add Article 25 (commencing with Section 4430) to Chapter 9 of Division 2 of the Business and Professions Code, and to add~~ *An act to add* Sections 14982 and 14983 to the Government Code, *and to add Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code*, relating to prescription drugs~~, and making an appropriation therefor~~.

LEGISLATIVE COUNSEL'S DIGEST

AB 1957, as amended, Frommer. Prescription drugs.

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

~~Existing law establishes, within the Department of Consumer Affairs, the California State Board of Pharmacy, which has licensing, regulatory, and disciplinary functions relating to pharmacists, pharmacies, and prescription drugs and devices. Existing law requires the board to impose upon pharmacists and pharmacies fees to fund these functions. The fees are paid into the Pharmacy Board Contingent Fund which is continuously appropriated for the expenses of the board. Existing law provides for the registration and licensure of a nonresident~~

~~pharmacy and establishes the fee for an out-of-state drug distributor's license and annual renewal issued pursuant to those provisions.~~

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

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

This bill would require the ~~board~~ *department* to establish a Web site on or before July 1, 2005, to facilitate the safe purchase by California residents of prescription drugs at reduced prices. *It would require that the Web site establish electronic links to pharmacies that are located in Canada and that meet specified requirements.* The bill would require the *department's* Web site to include price comparisons of prescription drugs, including prices charged by licensed pharmacies in the state and Canadian pharmacies that provide mail order service to the United States ~~that meet certification requirements established under the bill~~ *and whose Web sites are linked to the department's.*

~~Because the bill would result in increased expenditures from funds that are continuously appropriated to the board by requiring the board to establish a Web site and administer the certification of Canadian pharmacies under the bill, the bill would make an appropriation.~~

Existing law authorizes the Department of General Services to administer a coordinated prescription drug bulk purchasing program under which the department may enter into contracts on a bid or negotiated basis with manufacturers and suppliers of single-source or multisource drugs and obtain from them discounts, rebates, and refunds as permissible under federal law. Existing law requires certain state agencies to participate in the program and authorizes any other state, local, and public agency governmental entity to elect to participate in the program.

This bill would require the department to review state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from Canadian sources. The bill would require the department to report to the Legislature and recommend options to facilitate prescription drug importation. The bill would authorize the department to establish pilot programs under which purchases of prescription drugs from Canada would be made at reduced prices for purposes of state departments and agencies.

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

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

~~SECTION 1. Article 25 (commencing with Section 4430) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:~~

~~Article 25. Prescription Drugs~~

~~4430. (a) The board shall establish a Web site on or before July 1, 2005, that will facilitate the safe purchase by California residents of prescription drugs at reduced prices.~~

~~(b) (1) The Web site shall include price comparisons of the 50 most commonly prescribed brand name prescription drugs, including typical prices charged by licensed pharmacies in the state and by certified Canadian pharmacies that provide mail order service to the United States.~~

~~(2) (A) The Web site shall establish electronic links to certified Canadian pharmacies.~~

~~(B) The Web site may establish electronic links to other appropriate Web sites to allow California residents to safely purchase prescription drugs at reduced prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.~~

~~(c) For purposes of this section, ''certified Canadian pharmacy'' means a pharmacy that is located in Canada and meets all of the following requirements as determined by the board:~~

~~(1) Is licensed by the province in which it is located.~~

~~(2) Complies with all of the requirements of a nonresident pharmacy as specified in Section 4112.~~

~~(3) Meets the safety, access, and affordability standards established by the board for a certified Canadian pharmacy. These standards established by the board shall require, at a minimum, that only a Canadian pharmacy that complies with all of the following may be certified:~~

~~(A) Requires a prescription from a patient's personal physician.~~

~~(B) Requires a patient medical history.~~

~~(C) Requires a signed patient agreement.~~

~~(D) Ships prescriptions in tamper proof original manufacturer containers to individuals in the United States.~~

~~(E) Includes a physical address and pharmacy license number on its company Web site.~~

~~SEC. 2.~~

SECTION 1. Section 14982 is added to the Government Code, to read:

14982. (a) The department shall coordinate a review of state departments and agencies that purchase prescription drugs to determine which state programs may save significant state funds by purchasing from Canadian sources. State departments to be reviewed shall include, but not be limited to, all of the following:

(1) The State Department of Health Services.

(2) The Managed Risk Medical Insurance Board.

(3) The Department of General Services.

(4) The California Public Employees' Retirement System (CalPERS).

(b) The department shall report its findings based on the review required under subdivision (a) to the Legislature and shall recommend options to the Legislature, including conducting pilot programs, to facilitate prescription drug importation. The recommendations shall include a determination of the need to seek any federal approvals or waivers.

~~SEC. 3.~~

SEC. 2. Section 14983 is added to the Government Code, to read:

14983. (a) The department may establish pilot programs under which purchases of prescription drugs from Canada are

made at reduced prices for purposes of state departments and agencies.

(b) As a condition of implementing any pilot program under this section, the department shall seek and obtain all appropriate federal waivers and approvals necessary for the implementation of that pilot program.

SEC. 3. Article 5 (commencing with Section 110242) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. Prescription Drug Web Site

110242. (a) The department shall establish a Web site on or before July 1, 2005, that will facilitate the safe purchase by California residents of prescription drugs at reduced prices.

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

(2) (A) The Web site shall establish electronic links to pharmacies that are located in Canada and that meet the following requirements:

(i) Are licensed by the province in which they are located.

(ii) Comply with the requirements of a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, as determined to be appropriate by the department.

(iii) Require a prescription from a patient's personal physician.

(iv) Require a patient medical history.

(v) Require a signed patient agreement.

(vi) Ship prescription drugs in tamper proof original manufacturer containers to individuals in the United States.

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

(viii) Sell only prescription drugs that have been approved for sale in Canada by the Therapeutic Products Directorate of Health Canada.

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

(B) The Web site may establish electronic links to other appropriate Web sites to allow California residents to safely purchase prescription drugs at affordable prices, including links to Web sites of health plans and health insurers regarding their prescription drug formularies.

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Attachment 4

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 1960 **VERSION: AS AMENDED APRIL 12, 2004**

AUTHOR: PAVLEY **SPONSOR: CALIFORNIA LABOR FEDERATION**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PHARMACY BENEFIT MANAGERS

Existing Law:

Provides for the regulation of HMOs and the benefits they provide by the Department of Managed Health Care.

This Bill:

1) Defines "labeler" as any person who repackages prescription drugs for later sale and who has a labeler code issued by the Food and Drug Administration (FDA). (B&P 4130)

2) Defines "pharmacy benefits management" as the purchase of prescription drugs on behalf of an entity that provides a healthcare benefit or any of the following activities:

a. Mail order pharmacy services.
b. Claims processing.
c. Obtaining and administering rebate agreements.
d. Therapeutic intervention and generic substitution programs.
e. Disease management programs.

(B&P 4130)

2) Defines "pharmacy benefits manager" (PBM) as an entity that performs "pharmacy benefits management" as defined. (B&P 4130)

3) Exempts health care service plans or health insurers if they perform pharmacy benefits management directly, or through a subsidiary, exclusively for their enrollees or insureds. (B&P 4130)

4) Requires pharmacy benefits managers to register with the Board of Pharmacy (board). (B&P 4131)

5) Requires the board to adopt regulations specifying the documents that must be submitted as part of a PBM application. (B&P 4131)

6) Requires the board to adopt regulations to establish the fee for PBM registration. (B&P 4131)

7) Requires the board to adopt regulations to establish the grounds for denial of a PBM registration. (B&P 4131)

8) Requires PBMs to disclose to the purchaser or prospective purchaser the following:

a. the amount of all rebate revenues.
b. the nature, type and amounts of all other revenues that the PBM receives from each pharmaceutical manufacturer or labeler. (B&P 4132)

9) Requires the PBM to disclose the following information in writing within 30 days of the request and no less than once per year if requested:

a. the aggregate amount of all rebates and other retrospective utilization discounts received, directly or indirectly, by the PBM from pharmaceutical manufacturers.
b. the amounts of rebates or other retrospective utilization discounts received, directly or indirectly, by the PBM from pharmaceutical manufacturers for a specific list of drugs.
c. the nature, type and amount of all other revenue received by the PBM, directly or indirectly, from pharmaceutical manufacturers for services provided to the pharmaceutical manufacturers.
d. any prescription drug utilization information requested by the purchaser. (B&P 4132)

10) Requires purchasers requesting information to sign a confidentiality agreement with the PBM regarding any proprietary information disclosed to the purchaser. (B&P 4132)

11) Requires PBMs to disclose formularies to the public upon request. (B&P 4132)

12) Requires PBMs to disclose the members of any pharmacy and therapeutics committee, the credentials of committee members, and relationships between the members and pharmaceutical manufacturers. (B&P 4132)

13) Requires all PBM contracts to contain the following elements:

a. the rebate and revenue information required to be disclosed per item 9 above.
b. the disclosure of utilization information to parties other than the purchasers.
c. the administrative or other fees charged to the purchaser by the PBM.
d. factors that trigger an audit of the PBM.
e. revenues, rebates, or discounts received by the PBM from entities other than pharmaceutical manufacturers.
f. bulk purchase arrangements between PBMs with mail order pharmacies and pharmaceutical manufacturers.
g. the formulary development process. (B&P 4132)

14) Prohibits the PBM from limiting or excluding coverage for a drug if the PBM has previously approved the drug and the patient's provider continues to prescribe the drug. (B&P 4134)

15) Requires PBMs to have an expeditious process for authorizing coverage for non-formulary drugs. Requires PBMs to disclose this process to the public and prescribers. (B&P 4135)

16) Requires PBMs to provide a written explanation for denying coverage for a non-formulary drug. (B&P 4135)

17) Requires PBMs to make the following information available to both the public and a purchaser:

a. the drug formulary.
b. records developed by the pharmacy and therapeutics committee used in building a formulary.
c. arrangements with prescribers used to increase formulary compliance. (B&P 4131)

Comment:

1) Author's Intent. According to the author, prescription drug prices in this country are set through a complicated process of rebates and other secret special deals that may or may not result in large purchasers, such as the state of California, getting the best price possible. It is imperative that we open up this process, bringing a critical level of transparency to the system to ensure that the Legislature knows that the state and other large purchasers, such as businesses, are getting maximum value for each dollar spent.

2) PBM Task Force. The board convened a task force on PBM regulation in 2003. The task force conducted a thorough evaluation of PBM practices to determine whether establishing state regulation of PBMs was necessary. The task force was unable to identify a clear need for regulation of PBMs. The task force was unable to define an existing or potential consumer harm that could be remedied by the regulation of PBMs. The areas of greatest potential concern, as expressed by participants, were related to the business and contractual relationships between PBMs and their clients (health plans, employers, trust funds, etc.) that would be best resolved by those parties in their negotiations.

3) Incomplete Registration Proposal. The bill proposes the registration of PBMs by the board. However, there is no clear objective for that registration process. Without clear direction regarding the purpose of this registration program it would be difficult for the board to develop an adequate registration program. This clear purpose is particularly necessary given the lack of definition in the bill regarding the registration program.

The bill generally requires the board to develop regulations on the documentation required for registration, establish a fee for the program, and develop grounds for denial of a registration. Without a specific purpose for the licensing program, it would be difficult for the board to develop the grounds for denial. The proposal is also incomplete in that it does not provide for the expiration and/or renewal of a PBM registration. Under this bill, PBMs would be granted a registration that would be valid indefinitely. Licenses are uniformly time limited to provide ongoing accountability of the licensing program to the board and renewal fees fund the ongoing regulatory program associated with that license.

4) Definition of PBM. The definition of a PBM appears to be more inclusive than the author intends. As drafted, this definition would require an entity that engages in any of the specified activities is a PBM. That list of activities includes mail service pharmacy, retail network management, formulary development, and generic substitution. Therefore, any pharmacy that mails a prescription to a patient, a chain pharmacy managing a retail pharmacy network, a hospital developing a formulary, and a pharmacy that engages in therapeutic substitution would be engaging in pharmacy benefits management and would have to obtain a PBM registration from the board. Ironically, an HMO or health insurer that has a full service PBM operation serving its enrollees would be exempt from registration as a PBM. This definitional problem is fundamental, but could be resolved with much greater precision if a clear purpose for the registration program were articulated.

5) Duplicate Provisions. The bill duplicates a number of provisions of existing law relating to the continuity of drug coverage, disclosure of formularies, and the denial of registration.

Continuity of Care: The bill generally requires the continuing coverage of a drug previously approved by the PBM for an ongoing course of therapy. A virtually identical provision exists in current law (H&S Code 1367.22). The existing provision is also more appropriately located than the proposed provision in this bill. Under existing law, the

licensed health care service plan is obligated to provide medically necessary services and bears ultimate responsibility for the benefits provided. The only potential application of this provision beyond current law would be to restrict the actions of a self-insured health plan indirectly through the PBM. The state generally is excluded from regulating the provision of benefits by such self-insured plans under ERISA which is referenced below.

Formulary Disclosure: The bill requires, in two separate and duplicative provisions, the PBM to disclose the formulary to the public. An existing provision of current law requires the disclosure of a formulary by a health care service plan (H&S 1367.20) that is virtually identical to both provisions in this bill. The only potential application of this provision beyond current law would be to restrict the actions of a self-insured health plan indirectly through the PBM. The state generally is excluded from regulating the provision of benefits by such self-insured plans under ERISA which is referenced below.

Denial of Registration: The bill requires the board to develop criteria for denying registration of a PBM. Existing law (B&P 480) establishes the basis for boards and bureaus at the Department of Consumer Affairs to deny an application for license or registration. Enacting a parallel system for denying PBM applications would be complex and is potentially inconsistent with existing law on denying applications. Such inconsistency would be fatal to any proposed regulations.

6) Resources. The bill does provide for a fee to be charged as set by the board. However, because there is no provision for a renewal fee or expiration of the license, the initial fee will be required to be quite high to fund both the issuance and ongoing regulation of PBMs. The board does not have adequate staff resources (both in terms of available staff time and requisite expertise) to implement this program at this time. The earliest date that such resources are possibly available is July 1, 2005 assuming that the 2005-06 Budget Act included the appropriations required to implement the bill. The current Administration has made it clear that new program funding is not likely to be provided.

7) Sunrise. Existing law (B&P 473.6) requires that new licensing programs are subject to a "sunrise" review by the Joint Committee on Boards, Commissions and Consumer Protection (formerly the Joint Legislative Sunset Review Committee). Under this statute the new program proposal must be subject to a comprehensive report establishing the need for the licensing program. That report then is considered during the annual sunset review hearings. If the committee finds that the necessity for licensure has been demonstrated, then the proposal is placed in a bill for consideration by the Legislature. If not, the proposal does not move forward. This bill would be required to be subjected to the sunrise process. That process will extend beyond the current legislative session.

8) ERISA. As this bill affects the provision of a healthcare benefit, it may be subject to pre-emption by ERISA. ERISA is a federal statute governing the provision of employment benefits and its provisions can result in state regulation of benefits being invalidated. Pre-emption issues with ERISA are complex and this legislation should be reviewed by an individual with expertise in ERISA pre-emption case law to determine if it is likely to be overturned by a federal court.

9) History.

Apr. 12	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended. Re-referred to Com. on HEALTH.
Mar. 18	Referred to Coms. on HEALTH and B. & P.
Feb. 19	(Corrected February 17.)
Feb. 13	From printer. May be heard in committee March 14.
Feb. 12	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 12, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 1960

Introduced by Assembly Members Pavley and Frommer
(Coauthors: Assembly Members Chu, and Ridley-Thomas)

February 12, 2004

An act to add Article 8 (commencing with Section 4130) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy benefits management.

LEGISLATIVE COUNSEL'S DIGEST

AB 1960, as amended, Pavley. Pharmacy benefits management.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes it responsible for the regulation and licensure of persons engaged in pharmacy practices relating to the furnishing of dangerous drugs, as defined. Under existing law, a violation of the provisions of the Pharmacy Law is a crime.

This bill would define the term ''pharmacy benefits management'' as ~~negotiating the purchase of dangerous drugs on behalf of specified entities and administering or managing the prescription drug benefit programs of those entities~~, *among other things, the procurement of prescription drugs at a negotiated rate for dispensation within this state*. The bill would also define the term ''pharmacy benefits manager'' as an entity that performs pharmacy benefits management. The bill would ~~impose on that entity a fiduciary duty to the person employing or contracting with the entity~~ *require pharmacy benefits managers to register with the California State Board of Pharmacy, and would require that board to set specified standards for the registration*

thereof. The bill would further require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers with regard to revenues and its drug formularies, upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs.

Because the bill would specify an additional requirement under the Pharmacy Law, a violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

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

SECTION 1. Article 8 (commencing with Section 4130) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 8. Pharmacy Benefits Management

~~4130. "Pharmacy benefits management" means negotiating the purchase of dangerous drugs on behalf of an entity that provides health care services, including a health care service plan or a health insurer, or an entity that purchases those services and administering or managing the prescription drug benefit program provided or purchased by those entities. The administration or management of a prescription drug benefit program includes all of the following:~~

~~(a) Providing mail pharmacy services.~~

~~(b) Claims processing, managing a retail network, and paying claims to a pharmacy for dangerous drugs dispensed to an enrollee or insured.~~

~~(c) Rebate contracting and administering the rebates.~~

~~(d) Therapeutic intervention and generic substitution programs.~~

~~(e) Disease management programs.~~

~~4131. A "pharmacy benefits manager" means an entity that performs pharmacy benefits management and includes a person or entity acting for a pharmacy benefits manager in a contractual or employment relationship in the performance of pharmacy benefits management.~~

~~4132. A pharmacy benefits manager owes a fiduciary duty to the person who contracts with, or employs, the pharmacy benefits manager.~~

4130. For purposes of this article, the following definitions shall apply:

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

(b) "Pharmacy benefits management" is the procurement of prescription drugs at a negotiated rate for dispensation within this state, the administration or management of prescription drug benefits, or the provision of any of the following services with regard to the administration of the following pharmacy benefits:

(1) Mail service pharmacy.

(2) Claims processing, retail network management, and payment of claims to pharmacies for prescription drugs.

(3) Clinical formulary development and management services.

(4) Rebate contracting and administration.

(5) Certain patient compliance, therapeutic intervention, and generic substitution programs.

(6) Disease management programs involving prescription drug utilization.

(c) "Pharmacy benefits manager" is any person who performs pharmacy benefits management. The term does not include a health care service plan or health insurer if the health care service plan or health insurer offers or provides pharmacy benefits management services or administration through an affiliate, subsidiary, or other related entity, and if those services or administration are offered or provided only to enrollees, subscribers, or insureds who are also covered by health benefits

offered or provided by that health care service plan or health insurer.

4131. (a) A person may not engage in pharmacy benefits management in the state unless the person registers with the board.

(b) An applicant for registration shall do all of the following:

(1) Submit to the board an application on the form that the board provides.

(2) Submit the documents that the board requires.

(3) Pay to the board a fee set by the board.

(c) The board shall register each applicant that meets the standards of this section.

(d) The board shall set standards for the denial of registration.

4132. (a) A pharmacy benefits manager shall disclose to the purchaser or prospective purchaser, on request, the amount of all rebate revenues and the nature, type, and amounts of all other revenues that the pharmacy benefits manager receives from each pharmaceutical manufacturer or labeler with whom the pharmacy benefits manager has a contract. The pharmacy benefits manager shall disclose in writing all of the following:

(1) The aggregate amount, and for a specified list of drugs, the specific amount, of all rebates and other retrospective utilization discounts received by the pharmacy benefits manager directly or indirectly from each pharmaceutical manufacturer or labeler that are earned in connection with the dispensing of prescription drugs to individuals benefiting from the pharmacy benefits manager services.

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

(3) Any prescription drug utilization information requested by the purchaser.

(b) A pharmacy benefits manager shall provide the information described in paragraphs (1), (2), and (3) of subdivision (a) within 30 days of receipt of the request. If requested, the information shall be provided no less than once each year.

(c) Except for utilization information, a pharmacy benefits manager need not make the disclosures required in subdivision (a) unless and until the purchaser or prospective purchaser agrees in writing to maintain as confidential any information that the pharmacy benefits manager reasonably considers proprietary. That agreement may provide for equitable and legal remedies in the event of a violation of the agreement. Proprietary information includes trade secrets, and information on pricing, costs, revenues, taxes, market share, negotiating strategies, customers and personnel held by a pharmacy benefits manager and used for its business purposes.

(d) Every pharmacy benefits manager that maintains one or more drug formularies shall provide to members of the public, upon request, a copy of the most current list of prescription drugs on the formulary of the manager by major therapeutic category, with an indication of whether any drugs on the list are preferred over other listed drugs. If the pharmacy benefits manager maintains more than one formulary, the manager shall notify the requester that a choice of formulary lists is available.

(e) A pharmacy benefits manager shall disclose the membership of any pharmacy and therapeutics committee, the credentials of committee members, and any relationships between committee members and drug manufacturers.

4133. A pharmacy benefits manager may not execute a contract for the provision of pharmacy benefits management services that fails to address the following items:

(a) The amount of the total revenues, rebates, and discounts identified in paragraphs (1) and (2) of subdivision (a) of Section 4132 that shall be passed on to the purchaser.

(b) The disclosure or sale of enrollee utilization data by the pharmacy benefits manager to any person or entity other than the purchaser or prospective purchaser.

(c) Any administrative or other fees charged by the pharmacy benefits manager to the purchaser or prospective purchaser.

(d) Factors that trigger an audit of the contract for pharmacy benefits management services.

(e) Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers.

(f) Bulk purchase arrangements between pharmacy benefits managers with mail-order pharmacies and drug manufacturers.

(g) The process for development of formularies and notification of changes to formularies, provided that the pharmacy benefits manager meets the requirements of Sections 4134 and 4135.

4134. A pharmacy benefits manager may not limit or exclude coverage for a drug for an enrollee if the drug previously had been approved for coverage by the pharmacy benefits manager for a medical condition of the individual consumer and the prescribing provider continues to prescribe the drug for the medical condition, provided that the drug is appropriately prescribed and is considered safe and effective for treating the consumer's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the manager that is medically appropriate for the consumer, nor shall this section be construed to prohibit generic drug substitutions as authorized by Section 4073. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription to treat a medical condition of a consumer pursuant to subdivision (a) of Section 4059.

4135. (a) A pharmacy benefits manager shall maintain an expeditious process by which prescribing providers may obtain authorization for a medically necessary nonformulary prescription drug. On or before July 1, 2005, every pharmacy benefits manager shall make public on request a description of its process, including timelines, for responding to authorization requests for nonformulary drugs. Each pharmacy benefits manager shall provide a written description of its most current process, including timelines, to each purchaser and, on request, to prescribing providers. For purposes of this section, a prescribing provider shall include a provider authorized to write a prescription to treat a medical condition of an enrollee pursuant to subdivision (a) of Section 4040.

(b) Any pharmacy benefits manager that disapproves a request made pursuant to subdivision (a) by a prescribing provider to obtain authorization for a nonformulary drug shall provide the reasons for the disapproval in a notice provided to the purchaser.

(c) The process described in subdivision (a) by which prescribing providers may obtain authorization for medically

necessary nonformulary drugs does not apply to a nonformulary drug that has been prescribed for an enrollee in conformity with Section 4134.

(d) Every pharmacy benefits manager shall maintain all of the following information, which shall be made available to the purchaser or the public upon request:

(1) The complete drug formulary or formularies of the plan, if the plan maintains a formulary, including a list of the prescription drugs on the formulary of the plan by major therapeutic category with an indication of whether any drugs are preferred over other drugs.

(2) Records developed by the pharmacy and therapeutic committee of the plan, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefits management companies, used to guide the drugs prescribed for the enrollees of the plan, that fully describe the reasoning behind formulary decisions.

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

(e) Nonformulary prescription drugs shall include any drug for which an individual's copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation.

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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Attachment 5

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2125 **VERSION: AS INTRODUCED**

AUTHOR: LEVINE **SPONSOR: SENIOR LEGISLATURE**

RECOMMENDED POSITION: NONE

SUBJECT: PRESCRIBING PRACTICES

Existing Law:

Requires pharmacists to include a diagnosis on the prescription label if the patient requests it. (B&P 4076)

This Bill:

1) Requires physicians to include write the patient's diagnosis on each prescription unless the patient objects. (B&P 2242.2)
2) Requires pharmacists to include the patient's diagnosis on each prescription label unless the patient objects. (B&P 4076)

Comment:

1) Author's Intent. The author intends to increase patient compliance with prescribed drug therapy. Compliance is particularly important among older persons taking numerous medications. Without indications on the label of each prescription, it is difficult for many patients to know which drug is taken for which condition. This is particularly so for those whose care is entrusted to a caregiver or family member.

2) Compliance. Patient compliance with drug therapy is a substantial problem in the health care system. In studies of patient behavior, only about half of patients who leave a physician's office with a prescription take the drug as directed. The most common reason given for noncompliance is forgetfulness, which may be more appropriately described as denial of illness; having to take a drug is a constant reminder of illness. Compliance is worse with chronic diseases requiring complex, long-term treatment. Older persons may take several drugs; the regimen may be complex and hard to remember and to follow, thereby increasing the likelihood of an adverse drug interaction According to an estimate from the Office of the U.S. Inspector General, noncompliance results in 125,000 deaths from cardiovascular disease each year. If patients took their drugs as directed, up to 23% of nursing home admissions, 10% of hospital admissions, many physician visits, many diagnostic tests, and many unnecessary treatments could be avoided.

3) History.

Mar. 18 Referred to Com. on HEALTH.
Feb. 19 From printer. May be heard in committee March 20.
Feb. 18 Read first time. To print.

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ASSEMBLY BILL No. 2125

Introduced by Assembly Member Levine

February 18, 2004

An act to amend Section 4076 of, and to add Section 2242.2 to, the Business and Professions Code, relating to the healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2125, as introduced, Levine. Prescriptions: requisite information.

Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Under the act, a physician and surgeon is generally required to examine a patient prior to prescribing, dispensing, or furnishing a dangerous drug to him or her. The act makes a failure to comply with this requirement unprofessional conduct. Under the act, the board through its Division of Medical Quality, is required to take disciplinary action against a physician and surgeon for unprofessional conduct, which includes a violation of the act's regulatory provisions. The act also makes a violation of those provisions punishable as a crime. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacy practices by the California State Board of Pharmacy. Under that law, a pharmacist is required to include specified information on the container label before dispensing a prescription including, if requested by the patient, the condition for which the drug was prescribed.

This bill would require a physician and surgeon, unless directed otherwise by the patient, to indicate the patient's diagnosis on each prescription. The bill would also require a pharmacist to include this

information on the container's label, unless directed otherwise by the patient.

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

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

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

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

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

SECTION 1. Section 2242.2 is added to the Business and Professions Code, to read:

2242.2. A physician and surgeon shall indicate the patient's diagnosis on each prescription that he or she issues for a dangerous drug, unless the patient directs the physician and surgeon not to include this information on his or her prescription.

SEC. 2. 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, *unless the patient directs the pharmacist not to include this information on the label*.

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

aforementioned information or the information is otherwise readily available at the time of drug administration.

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

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

SEC. 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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Attachment 6

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2184 **VERSION: AS INTRODUCED**

AUTHOR: PLESCIA **SPONSOR: CARDINAL HEALTH**

RECOMMENDED POSITION: OPPOSE UNLESS AMENDED

SUBJECT: AUTOMATED DISPENSING DEVICES

Existing Law:

1) Permits licensed health care facilities to employ an automated drug delivery system to provide drugs to patients before the next scheduled delivery by a pharmacy or for no more than 72 hours. (H&S 1261.6)

2) Permits the use of automated drug delivery systems in non-profit clinics licensed by the board under specified circumstances. (B&P 4186)

This Bill:

1) Permits the board to license an automated drug delivery system (ADDS) if the system is operated by a pharmacy in either a skilled nursing facility or an intermediate care facility. (B&P 4119.1)

2) Specifies that drugs stored in the ADDS are part of the pharmacy's inventory and shall be considered to be dispensed from the pharmacy when removed from the ADDS. (B&P 4119.1)

3) Requires the board to, in consultation with the Department of Health Services (DHS), set a "reasonable" fee for issuing a license to an ADDS and that fee shall include the costs of enforcement related to the ADDS. (B&P 4119.1)

4) Permits the board to establish an agreement with DHS to share ADDS fee revenue and to have DHS provide inspection of the ADDS devices licensed by the board. (B&P 4119.1)

5) Requires the ADDS device to be under the supervision of a pharmacist who need not be physically present. (B&P 4119.1)

6) Requires that drugs removed from the ADDS must be in "properly labeled units of administration." (H&S 1261.6)

7) Requires that a pharmacist approves each order prior to the drug being removed from the ADDS. (H&S 1261.6)

8) Requires the pharmacy holding the ADDS license to control access to the ADDS. (H&S 1261.6)

9) Requires user access to the ADDS to be controlled and tracked using either a password or biosensor. (H&S 1261.6)

Comment:

1) Author's Intent. The sponsor is seeking to expand the use of automated dispensing devices in skilled nursing and intermediate care environments. In addition, the sponsor is seeking to obtain formal recognition of these devices by the Board of Pharmacy to satisfy DEA requirements for issuing DEA registration numbers that would allow the devices to contain controlled substances.

2) Automated Dispensing. Current law permits skilled nursing and intermediate care facilities to employ automated dispensing devices for limited purposes. The law requires that drugs from the devices may only be used to provide drugs to a patient until those drugs can be provided by the pharmacy. The law requires that orders for drugs dispensed from the device must be evaluated by a pharmacist. The devices may also be used as emergency pharmaceutical supply containers that are also permitted by existing law. The devices are not licensed by the board.

3) Regulatory Model. The bill would permit replacement of a substantial amount of pharmacy services provided to patients in these settings with a tele-pharmacy model. In this instance, tele-pharmacy would be implemented through automated devices that are owned and operated by an existing pharmacy. As such, the devices would require a formal process to license, certify or approve them as proposed in the bill. At present, the board does not have a mechanism for issuing such a license and tying it to an underlying pharmacy license.

The bill, as introduced, has a number of structural problems that would require substantial staff time to correct. The bill authorizes full scope tele-pharmacy in these two care settings and the board does not have an appropriate regulatory model for this activity. Numerous issues would remain to be resolved. Such as:

> Does each device require its own pharmacist-in-charge (PIC) or can the PIC of the underlying pharmacy act as PIC for each of the devices licensed through that pharmacy?
> If so, is there a limit on the number of devices that can be supervised by a pharmacy and any individual PIC?
> If a violation occurs with one of the devices, does that violation and any attendant enforcement action go on record against the underlying pharmacy?
> If a license for one of the devices were revoked what action if any would apply to other devices operated by the pharmacy and the underlying pharmacy itself?

These are just few issues that would need to be resolved to effectively implement such a regulatory model and these (and many other) details are not adequately addressed in the current draft of the legislation.

4) Dual Jurisdiction. The bill proposes a sharing of jurisdiction over the automated dispensing devices between the board and the Department of Health Services (DHS). If the devices are to be licensed by the board the enforcement authority should be exercised by the board alone. DHS should continue to exercise its authority over the licensed care facilities, but as a pharmacy, the devices should be the responsibility of the board.

5) Definitions. The bill refers to these dispensing devices providing "pharmacy services" but the bill does not define that term. The bill also does not clearly define the process by which pharmacists review drug orders prior to dispensing (i.e., does the pharmacist approve the initial order and all subsequent doses administered are automatically released, or does the pharmacist have to individually release each dose? The bill

indicates that the device need not be located in the pharmacy to provide services to a licensed facility but it does not require that the device be located in the licensed facility.

6) Prior Legislation. In 2001 the board sponsored legislation (Assembly Bill 809) which proposed a general model for licensing remote pharmacies and allow tele-pharmacy to be generally available in California. That legislation received substantial opposition and eventually was amended to allow that model to be employed in non-profit clinics. The bill was signed by the Governor. A copy of that legislation (as introduced) is attached for your reference.

7) History.

Mar. 18 Referred to Coms. on HEALTH and B. & P.
Feb. 19 From printer. May be heard in committee March 20.
Feb. 18 Read first time. To print.

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ASSEMBLY BILL No. 2184

Introduced by Assembly Member Plescia

February 18, 2004

An act to add Section 4119.1 to the Business and Professions Code, and to amend Sections 1261.5 and 1261.6 of the Health and Safety Code, relating to health facilities, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2184, as introduced, Plescia. Health facilities: pharmacy services: automated drug delivery systems.

Existing law provides for the licensing and regulation by the State Department of Health Services of health facilities, including skilled nursing facilities and intermediate care facilities.

The Pharmacy Law, which provides for the licensing and regulation of the practice of pharmacy, is under the jurisdiction of the California State Board of Pharmacy. The Pharmacy Law prescribes requirements for the dispensing of drugs. Under existing law, anyone who knowingly violates the Pharmacy Law is guilty of a misdemeanor.

Existing law authorizes a pharmacy to furnish dangerous drugs or dangerous devices to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container that is maintained within the facility in accordance with regulations of the department. Existing law establishes circumstances under which drugs may be removed from an automated drug delivery system at a skilled nursing facility or intermediate care facility. Existing law defines an automated drug delivery system as a mechanical system that performs operations and activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs.

This bill would provide that a pharmacy may provide services to a skilled nursing facility or intermediate care facility through the use of an automated drug delivery system that meets certain requirements and the automated drug delivery system need not be located at the same location as the pharmacy. The bill would require that this automated drug delivery system be under the supervision of a licensed pharmacist, would not require that the pharmacist be physically present at the site, and would permit the pharmacist to supervise the system electronically. Because the bill would specify additional requirements under the Pharmacy Law and health facility laws, a violation of which is a crime, the bill would impose a state-mandated local program.

Existing law requires the board to collect licensing fees and penalties and fines, which are paid into the State Treasury and credited to the Pharmacy Board Contingent Fund. This fund is a continuously appropriated fund that is used to pay the expenses, and for the use, of the board.

This bill would require, that the board issue a separate license, permit, or other authorization to the pharmacy to permit the storage of drugs in the automated drug delivery system at the address of a facility and would authorize the board to establish fees to reimburse activities associated with this authorization. Because this bill would increase the moneys credited to and expended from the continuously appropriated Pharmacy Board Contingent Fund, it would make an appropriation.

The bill would also correct an erroneous cross-reference.

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: yes. Fiscal committee: yes. State-mandated local program: yes.

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

1 SECTION 1. Section 4119.1 is added to the Business and
2 Professions Code, to read:
3 4119.1. (a) A pharmacy may provide pharmacy services to a
4 health facility licensed pursuant to subdivision (c), (d), or both, of
5 Section 1250 of the Health and Safety Code, through the use of an

automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) To permit the storage of drugs in the automated drug delivery system at a facility, the board shall issue a separate license, permit, or other authorization to the pharmacy providing pharmacy services using an automated drug delivery system for the address at the facility, and for each automated drug delivery system if more than one is operating in different locations in the facility.

(2) The board, in consultation with the State Department of Health Services if appropriate for purposes of paragraph (3), shall establish a reasonable fee for processing and issuing a license, permit, or other authorization under this subdivision, as well as for enforcing the requirements of this section and subdivision (f) of Section 1261.6 of the Health and Safety Code, including applicable inspections.

(3) The board, pursuant to an agreement, may provide for the inspection of automated drug delivery systems at health facilities by the State Department of Health Services and provide for the transfer of a portion of the proceeds of fee amounts to the State Department of Health Services to reimburse those inspection costs.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

SEC. 2. Section 1261.5 of the Health and Safety Code is amended to read:

1261.5. (a) The number of oral dosage form or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c) or (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container, pursuant to Section ~~4035~~ *4119* of the Business and Professions Code, shall be limited to 24. The State Department of Health Services may limit the number of doses of each drug available to

not more than four doses of any separate drug dosage form in each emergency supply.

(b) Any limitations established pursuant to subdivision (a) on the number and quantity of oral dosage or suppository form drugs provided by a pharmacy to a health facility licensed pursuant to subdivision (c), (d), or both (c) and (d), of Section 1250 for storage in a secured emergency supplies container shall not apply to an automated drug delivery system, as defined in Section 1261.6, when a pharmacist controls access to the drugs. This subdivision shall become operative on July 1, 1999.

SEC. 3. Section 1261.6 of the Health and Safety Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the system for administration to a patient.

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

(4) User access to the system shall be controlled and tracked using an identification or password system or biosensor.

(5) The system shall make a complete and accurate record of all users accessing the system and all drugs removed from the system.

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets or drawers, or similar technology, the

stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

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

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

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

~~(g)~~

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

~~(h)~~

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

~~(i)~~

(j) This section shall become operative on July 1, 1999.

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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Attachment 7

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2660 **VERSION: AS AMENDED APRIL 12, 2004**

AUTHOR: LENO **SPONSOR: KAISER PERMANENTE**

RECOMMENDED POSITION: SUPPORT

SUBJECT: PHARMACIST DEA REGISTRATION

Existing Law:

1) Specifies those practitioners authorized to sign a prescription for a dangerous drug or dangerous device. (B&P 4040)

2) Permits pharmacists to initiate or adjust the drug regimen of a patient under a protocol. (B&P 4052)

3) Prohibits the possession of a controlled substance except when possessed pursuant to a prescription. (B&P 4060)

4) Specifies the contents of the label affixed to dispensed prescriptions including the name of the practitioner ordering the drug or device. (B&P 4076)

5) Specifies those practitioners who may prescribe controlled substances. (H&S 11150)

This Bill:

1) Permits pharmacists to sign orders for dangerous drugs when initiating or adjusting drug regimens under protocol. (B&P 4040)

2) Requires pharmacists to obtain a DEA registration number if they are authorized to initiate or adjust drug therapy under protocol. (B&P 4052)

3) Permits the possession of a controlled substance dispensed pursuant to a drug order signed by a pharmacist. (B&P 4060)

4) Requires a prescription label to include the name of the practitioner, including a pharmacist, who ordered the drug. (B&P 4076)

5) Clarifies existing law to permit pharmacists initiating and adjusting drug regimen under protocol are permitted to own a pharmacy. (B&P 4111))

6) Permits pharmacists to order controlled substances pursuant to a protocol. (H&S 11150

Comment:

1) Author's Intent. The author and sponsor are seeking to ensure that pharmacists working under protocol can obtain DEA registration numbers that are required to order

controlled substances. The sponsor reports that the DEA has refused to issue DEA registration numbers to pharmacists because state law is not sufficiently clear in granting authority to pharmacists to order controlled substances. The sponsor also indicated a desire to allow pharmacists to order and receive drug samples for use when exercising their authority to initiate or adjust drug regimens.

2) Other Legislation. The board has proposed amendments to Section 4076 in the annual omnibus bill that are substantially the same as those proposed in this bill. This duplication should be resolved by removing the provision from one of the bills. This would avoid the logistical difficulty involved in having such similar amendments in two bills.

5) History.

Apr. 12	Re-referred to Com. on B. & P.
Apr. 12	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Mar. 31	From committee: Do pass, and re-refer to Com. on B. & P. with recommendation: To Consent Calendar. Re-referred. (Ayes 16. Noes 0.) (March 30). (Corrected April 2.)
Mar. 30	Re-referred to Com. on HEALTH.
Mar. 26	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 18	Referred to Coms. on HEALTH and B. & P.
Feb. 22	From printer. May be heard in committee March 23.
Feb. 20	Read first time. To print.

AMENDED IN ASSEMBLY APRIL 12, 2004

AMENDED IN ASSEMBLY MARCH 26, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL No. 2660

Introduced by Assembly Member Leno

February 20, 2004

An act to amend Sections 4040, 4052, 4060, 4076, and 4111 of the Business and Professions Code, and to amend Section 11150 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 2660, as amended, Leno. Prescriptions: issuance by a pharmacist.

Existing law, the Uniform Controlled Substances Act, authorizes a pharmacist in specified circumstances to write or issue a prescription. The Pharmacy Law, which provides for the licensure and regulation by the California State Board of Pharmacy of pharmacy practices, defines a prescription, in part, as being issued by designated healing arts practitioners, not including a pharmacist. The Pharmacy Law prohibits the board from issuing a pharmacy license to, or renewing a pharmacy license of, specified persons, including those who are authorized to write a prescription. A knowing violation of the Pharmacy Law is a misdemeanor offense.

This bill would revise the definition of ''prescription'' to include a drug order issued by a pharmacist pursuant to specified conditions. The bill would also specify that the board is not precluded from issuing or

renewing a license for a pharmacy owned or owned and operated by a pharmacist who is authorized to issue a specified drug order.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which would be a crime, it would impose a state-mandated local program.

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

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

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

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

SECTION 1. Section 4040 of the Business and Professions Code is amended to read:

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

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

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

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

(C) The date of issue.

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

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

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, or physician assistant who issues a drug order pursuant to Section 2746.51, 2836.1, or 3502.1, respectively, or the pharmacist who issues a drug order pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(2) Issued by a physician, dentist, optometrist, podiatrist, or veterinarian or, if a drug order is issued pursuant to Section 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse practitioner, or physician assistant licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 by a pharmacist licensed in this state.

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

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

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

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

SEC. 2. 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~~ *individual patient's treating prescriber*, 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 *treating* 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 *treating* 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 *treating* 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) (A) Furnish emergency contraception drug therapy in accordance with either of the following:

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

(ii) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American College of Obstetricians and Gynecologists, the California Pharmacist Association, and other appropriate entities. Both the board and the Medical Board of California shall have authority to ensure compliance with this clause, and both boards are specifically charged with the enforcement of this provision with respect to their respective licensees. Nothing in this clause shall be construed to expand the authority of a pharmacist to prescribe any prescription medication.

(B) Prior to performing a procedure authorized under this paragraph, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(C) A pharmacist, pharmacist's employer, or pharmacist's agent may not directly charge a patient separate consultation fee for emergency contraception drug therapy services initiated pursuant to this paragraph, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this subparagraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency

contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. The provisions of this subparagraph shall cease to be operative for dedicated emergency contraception drugs when these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(D) A pharmacist may not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this paragraph.

(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) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

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

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

SEC. 3. 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, a physician assistant pursuant to Section 3502.1, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, 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. 4. Section 4076 of the Business and Professions Code is amended to read:

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

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade

name or the commonly used name or the principal active ingredients.

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

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

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

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

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

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

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

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

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

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

SEC. 5. Section 4111 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

SEC. 6. Section 11150 of the Health and Safety Code is amended to read:

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1

(commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

SEC. 7. 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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Attachment 8

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2682 **VERSION: AS INTRODUCED**

AUTHOR: NEGRETE MCLEOD **SPONSOR: JAM PHARMACEUTICALS**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: WHOLESALERS

Existing Law:

1) Requires wholesalers to be licensed by the board. (B&P 4160)

2) Requires out-of-state distributors shipping drugs into California to be licensed. (B&P 4161)

3) Exempts out-of-state distributors shipping drugs only to licensed wholesalers in California from being licensed by California. (B&P 4161)

This Bill:

1) Requires the board to adopt regulations governing the wholesaling of dangerous drugs and devices by anyone who is not a manufacturer or an "authorized distributor." (B&P 4160.1)

2) Requires that the regulations required above incorporate the same requirements established by the Prescription Drug Marketing Act (PDMA) and regulations adopted pursuant to the PDMA. (B&P 4160.1)

3) Requires all out-of-state wholesalers shipping dangerous drugs or dangerous devices into to be licensed by the California Board of Pharmacy. (B&P 4161.1)

Comment:

1) Author's Intent. As of this writing, staff has not been able to contact the author's office. However, discussions with the bill's sponsor indicated similar concerns to those expressed by the board regarding the weaknesses in the existing wholesale distribution chain. An updated analysis will be provided at the hearing if staff can make contact with the author's office.

2) Board of Pharmacy Legislation. The board is sponsoring Senate Bill 1307 (Figueroa) which also requires all non-resident wholesalers to be licensed by the board and will be amended to take a range of other actions relating to the licensure and regulation of wholesalers including:

a. Require a pedigree for all drug transactions as of January 1, 2007.
b. Require all wholesalers to obtain a $100,000 bond to secure administrative fines and penalties.
c. Prohibit pharmacies from acting as a wholesaler.

d. Increase fines for violations related to counterfeit drugs and key documentation requirements.

This legislation is the result of several years work by the board's enforcement committee on curbing counterfeits and drug diversion. Similar provisions are included in recommendations from the FDA and NABP.

3) Problems in Wholesaling. A great deal of attention has been focused of late on weaknesses in the current wholesale market. Both the Washington Post and the Wall Street Journal have devoted attention to the wholesale market and how current regulations make it vulnerable to counterfeit drugs. In addition, both the NABP (new model law) and the FDA (Task Force on Counterfeit Drugs) have made substantial recommendations on how to improve regulation in this area.

4) Regulations. The bill requires the board to regulate all wholesalers and to adopt regulations that mirror those included in the PDMA and related federal regulations. If the intent is to essentially incorporate all of the PDMA rules in California law, that could be done more easily by taking that action directly in the bill. Requiring the board to adopt regulations delays the process by at least one year, if not longer given the complexity of such regulations.

5) Suggested Amendments. The bill should be amended to reflect the board's proposal. That proposal has been developed in a long and considered process and represents the board's judgment regarding the best approach to solve these problems in California.

6) History.

Mar. 18	Referred to Coms. on HEALTH and B. & P.
Feb. 22	From printer. May be heard in committee March 23.
Feb. 20	Read first time. To print.

ASSEMBLY BILL No. 2682

Introduced by Assembly Member Negrete McLeod

February 20, 2004

An act to amend Section 4161 of, and to add Sections 4160.1 and 4161.1 to, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 2682, as introduced, Negrete McLeod. Pharmacy: out-of-state wholesalers.

The Pharmacy Act provides for licensing and regulation of wholesalers of prescription drugs and devices by the California State Board of Pharmacy. Existing law requires out-of-state wholesalers of prescription drugs and devices selling or distributing those drugs and devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board, unless they sell or distribute only through a licensed wholesaler. A violation of the Pharmacy Act is a crime.

This bill would require the board to adopt regulations governing any person engaged in the wholesale distribution of a dangerous drug or device and who is not the manufacturer or an authorized distributor of record of the dangerous drug or device, which regulations shall implement the same federal regulatory provisions applicable to wholesalers engaged in interstate commerce. The bill would require all out-of-state wholesalers selling or distributing prescription drugs or devices in this state to obtain an out-of-state dangerous drugs and devices distributor's license from the board. Because this bill would require additional persons to pay existing fees to the board to obtain a

license, it would result in the deposit of additional revenue in the Pharmacy Board Contingent Fund, a continuously appropriated fund, and would thereby make an appropriation.

Because a violation of the Pharmacy Act is a crime, the bill would impose a state-mandated local program by revising the definition of a 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: yes. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. Section 4160.1 is added to the Business and Professions Code, to read:

4160.1. Notwithstanding any other provision of law, the board shall adopt regulations governing any person engaged in the wholesale distribution of a dangerous drug or device and who is not the manufacturer or an authorized distributor of record of the dangerous drug or device. The regulations adopted by the board shall implement the same regulatory provisions applicable to wholesalers engaged in interstate commerce pursuant to the federal Prescription Drug Marketing Act (21 U.S.C. Sec. 353(e)) and the regulations adopted pursuant thereto, as contained in 21 C.F.R. Part 205, as amended from time to time.

SEC. 2. Section 4161 of the Business and Professions Code is amended to read:

4161. (a) No person shall act as an out-of-state manufacturer ~~or wholesaler~~ of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. ~~Persons~~ *Manufacturers* not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer ~~or wholesaler~~ or have an

out-of-state dangerous drug or dangerous device distributor's license.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license *pursuant to this section* shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer ~~or wholesaler~~ pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer ~~or wholesaler~~.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer ~~or wholesaler~~ pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.

SEC. 3. Section 4161.1 is added to the Business and Professions Code, to read:

4161.1. (a) No person shall act as an out-of-state wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. This provision shall apply to any person, other than the manufacturer of a dangerous drug or device, who is engaged in the wholesale distribution of dangerous drugs or devices and who may be licensed by the state pursuant to 21 U.S.C. Sec. 353(e)(2)(A) and regulations adopted by the United States Secretary of Health and Human Services pursuant to 21 C.F.R. Part 205, and shall apply regardless of whether the out-of-state wholesaler maintains an office or any other facility in this state.

(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license pursuant to this section shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.

(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state wholesaler.

(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state wholesaler pursuant to this section to serve as any evidence that the out-of-state wholesaler is doing business within this state.

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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Attachment 9

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1149 **VERSION: AS AMENDED APRIL 1, 2004**

AUTHOR: ORTIZ **SPONSOR: AUTHOR**

RECOMMENDED POSITION: NONE

SUBJECT: IMPORTATION

Existing Law:

1) Requires pharmacies operating in California (including non-resident pharmacies) to be licensed by the board. (B&P 4110)

2) Prohibits the importation of prescription drugs except by a manufacturer.

This Bill:

1) Finds that prescription drugs are an essential part of health care delivery but that due to their high cost, many Californians face difficulty accessing the medications they need.

2) Finds that licensed Canadian pharmacies generally meet safety standards for the acquisition, and dispensing of prescription drugs that are as stringent as those in California.

3) Requires the Board to develop and disseminate information, including through an interactive website, identifies Canadian pharmacies that have established that they meet recognized standards for the safe acquisition, shipment, handling, and dispensing of prescription drugs to persons in California. (B&P 4001.2)

4) Provides that a Canadian pharmacy that meets recognized standards for the safe acquisition, handling, and dispensing of drugs shall mean a pharmacy which is located in Canada and which meets all of the following requirements:

a. Is licensed in the province in which it is located;
b. Is accredited or eligible for accreditation by the Internet and Mail Order Pharmacy Accreditation Commission and/or a member of the Canadian International Pharmacy Association; and
c. Meets the requirements for licensure as a California pharmacy if it were located in California.
d. Does not require its customers to sign a waiver of liability.

(B&P 4001.2)

5) Requires the Board to collect, publish, and post on the interactive website it creates, information concerning out-of-country suppliers of prescription drugs that have been found to have violated recognized standards for the safe shipment, handling, and processing of prescription drugs. (B&P 4001.3)

6) Provides that in carrying out the latter duty, the Board may rely on information made available by regulatory and law enforcement bodies and is not required to conduct its own surveillance activities or investigation. (B&P 4001.3)

7) Repeals its provisions on January 1, 2008.

Comment:

1) Author's Intent. The author's intent is to provide an additional means for consumers in California, particularly seniors, persons with disabilities, and low-income residents, to access affordable prescription drugs. According to the author, drugs are in indispensable component of health care delivery, yet millions of Californians face barriers to accessing the drugs they need to maintain their health due to their rising cost.

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

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

3) Price Controls. Consumers seek to purchase drugs from Canadian pharmacies to save money. Drug prices are lower in Canada because the Canadian government has a system to control drug prices. [For your information, attached is a recent article from the journal *Health Affairs* describes the price control methods used in Canada.] ***Branded*** drugs can commonly be purchased from Canadian pharmacies at substantial discounts. However, US prices are generally lower for ***generic*** drugs.

4) Affordability. The board is sympathetic to the difficulty of those without drug insurance have affording the drugs they need and the impact of drug pricing on the affordability of insurance coverage for those who have it.

Much of the public debate regarding the importation of drugs from Canada has focused on the safety of imported drugs. This debate on safety masks the more basic affordability problem that underlies importation. Consumers are seeking Canadian drugs because of lower prices not because of problems with drug availability or because of the convenience of the Canadian pharmacies. In this circumstance, importation is an indirect method of imposing price controls on drugs. Despite this reality, little if any consideration has been articulated regarding the establishment of direct price controls. While proposing direct price controls would be politically challenging, such a debate would present a more straightforward discussion regarding the cost of and accessibility to prescription drugs. The board is not advocating any particular action in this respect, but rather encouraging a full and honest debate regarding the essential issue of drug pricing.

5) Approved Pharmacies. The bill requires the board to list on its web site Canadian pharmacies that are licensed in Canada, is accredited by the Internet and Mail Order Pharmacy Accreditation Commission, and would meet the requirements for licensure

as a non-resident pharmacy. California law requires that pharmacies (both resident and non-resident) to be licensed by the board to protect the consumer. Those licenses are issued for a fixed term to help ensure ongoing compliance with California law and are subject to the full spectrum of enforcement actions for violations of California law.

It would be untenable for the board to issue any official approval or listing of a Canadian pharmacy other than a full pharmacy license. The license mechanism provides the board with both the financial and legal resources required to conduct a license issuance process that would be absent in the "certification" process proposed by this bill. In addition, the board would have no ability to take enforcement action against the "certification" should a "certified" pharmacy fall out of compliance with the certification standards or violate California law.

6) Licensing Foreign Locations. It is unclear if the board has the requisite legal authority to issue a license to a pharmacy located in Canada. The licensure of non-resident pharmacies is premised on the relative consistency of pharmacy standards among the different states in the US and the ability of the appropriate licensing agency in each of those states to be the primary enforcer of those standards. The board does not currently have the knowledge and expertise to judge the nature and extent of pharmacy regulation by either the Canadian national government or the relevant provincial governments. The board would have to acquire that knowledge and expertise before making a judgment whether it is appropriate to license a Canadian pharmacy as a non-resident pharmacy.

7) Resources. The bill requires the board to take on a number of additional responsibilities for which it does not have the resources. The certification program would have to be developed from scratch as a new quasi-licensing program and the collection and regular update of prescription drug pricing information would be an entirely new activity. Drug pricing is notoriously variable based on the purchaser and the timing of the purchase, and the board would have to develop a methodology for establishing actual market prices. Both of these activities would require additional staff. Given the board's existing challenges meeting existing statutory obligations because of recent staff and budgetary cutbacks, additional personnel would be required. It is unlikely that such additional resources would be provided in the present fiscal environment.

8) Minnesota. The Web site provisions of this bill largely duplicate existing efforts made by the state of Minnesota. As indicated above, the bill would require the board to expend additional resources to duplicate an existing web page. Linking to the Minnesota Rx Connect Web site would be a faster and less expensive approach to providing California consumers this information.

Suggested Amendments: The bill should be amended to refer patients to pharmacies approved by Minnesota or other states currently operating Web sites directing patients to Canadian pharmacies. The bill should also be amended to require permission or waiver from the federal government prior to instituting this program.

9) Support and Opposition.

Support:

AIDS Healthcare Foundation
California Alliance for Retired Americans
California Health Advocates
California Labor Federation, AFL-CIO
California Nurses Association
Congress of California Seniors
Consumer Federation of California

Consumers Union
Foundation for Taxpayer and Consumer Rights
Gray Panthers California
Health Access California
Older Women's League of California
Senior Action Network
Service Employees International Union

Oppose:

BIOCOM
Bristol-Myers Squibb Company
California Chamber of Commerce
Pharmaceutical Research and Manufacturers of America

10) History.

Apr. 1	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 22	Hearing postponed by committee. Set for hearing April 12.
Mar. 16	Read second time. Amended. Re-referred to Com. on B. & P.
Mar. 15	From committee: Do pass as amended, but first amend, and re-refer to Com. on B. & P. (Ayes 8. Noes 2. Page 3060.)
Mar. 11	Set for hearing March 22 in B. & P. pending receipt.
Mar. 4	Withdrawn from committee. Re-referred to Coms. on H. & H.S. and B. & P.
Mar. 3	Withdrawn from committee. Re-referred to Com. on RLS.
Mar. 1	Set for hearing March 10 in H. & H. S. pending receipt.
Mar. 1	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Feb. 17	To Com. on B. & P.
Jan. 27	From print. May be acted upon on or after February 26.
Jan. 26	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 1, 2004

AMENDED IN SENATE MARCH 16, 2004

AMENDED IN SENATE MARCH 1, 2004

SENATE BILL No. 1149

Introduced by Senator Ortiz

January 26, 2004

An act to add *and repeal* Sections 4001.2 and 4001.3 ~~to~~ *of* the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1149, as amended, Ortiz. Dangerous drugs: Canadian pharmacies: foreign suppliers.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy and makes it responsible for licensing and regulating pharmacy practices, including the furnishing of dangerous drugs, as defined.

This bill would require the board to develop and disseminate information identifying pharmacies in Canada that meet recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs to California residents. The bill would also require the board to collect, publish, and post on an Internet Web site information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have violated safe shipment, handling, and processing standards. *The bill would repeal its provisions on January 1, 2008.*

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 all of the following:

(a) Prescription medications are an essential part of health care delivery and have contributed to increasing the life expectancy of patients and treating their diseases and conditions.

(b) Despite this, due to the high cost of prescription medications, many Californians, especially elderly, disabled, and low-income persons, face difficulty accessing the medications they need to maintain their health.

(c) As one means of accessing affordable prescription medications, increasing numbers of Californians are purchasing prescription medications from foreign countries, in many cases through an Internet Web site.

(d) California consumers currently have few ways of determining which outlets and suppliers of prescription medications in foreign countries are safe and reliable, particularly those offering their products through an Internet Web site.

(e) Canadian pharmacies that are licensed by the provinces in which they are located generally meet safety standards for the acquisition, distribution, and dispensing of prescription medications that are as stringent as those in California.

(f) In order to help ensure access to prescription medications, there is a need to provide consumers with information about safe and reliable Canadian pharmacies and about fraudulent and unsafe suppliers or outlets of prescription medications whose practices may potentially harm consumers, and there is a need to assist consumers in making informed choices for obtaining prescription medications for their health care needs.

SEC. 2. Section 4001.2 is added to the Business and Professions Code, to read:

4001.2. (a) The board shall develop and disseminate information identifying Canadian pharmacies that have established that they meet recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs to persons in California. As part of this requirement, the board shall establish an interactive Internet Web site that links consumers to, or provides information about, Canadian pharmacies that the board has determined meet recognized

standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs to persons in California.

(b) For the purposes of this section, a Canadian pharmacy that meets recognized standards for the safe acquisition, shipment, handling, and dispensing of dangerous drugs means a pharmacy that is located in Canada and meets all of the following requirements:

(1) Is licensed by the province in which it is located.

(2) Is accredited or eligible for accreditation by the Internet and Mail Order Pharmacy Accreditation Commission or is a member of the Canadian International Pharmacy Association.

(3) Meets the requirements for licensure by the board as a pharmacy.

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

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

SEC. 3. Section 4001.3 is added to the Business and Professions Code, to read:

4001.3. (a) The board shall collect, publish, and post on an Internet Web site created pursuant to Section 4001.2, information concerning suppliers of dangerous drugs that are located and operating outside of the United States that have been found to have violated recognized standards for the safe shipment, handling, and processing of dangerous drugs.

(b) In carrying out this section, the board may rely on information made available by regulatory and law enforcement bodies, including, but not limited to, the federal Food and Drug Administration, the United States Customs Service, prescription drug regulatory bodies of foreign countries, the Attorney General, the United States Department of Justice, the boards of pharmacy of other states, and the National Association of Boards of Pharmacy.

(c) The board is not required to conduct surveillance activities or its own investigations in order to carry out the requirements of this section, but is authorized to engage in those activities to the extent its resources permit.

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

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Attachment 10

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1159 **VERSION: AS AMENDED MARCH 16, 2004**

AUTHOR: VASCONCELLOS **SPONSOR: DRUG POLICY ALLIANCE**

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 prescription requirement for hypodermic needles and syringes (needles) if:

a. The patient is known to the furnisher and has a legitimate medical need for the needles; or,
b. The patient is over 18 years of age and the pharmacy is part of a demonstration project. (B&P 4145)

2) Restricts the number of needles that may be provided by a pharmacy participating in a demonstration project to 10 in any single transaction. (B&P 4145)

3) Repeals the logbook requirement for furnishing needles. (B&P 4146)

4) Exempts needles obtained legitimately from the definition of drug paraphernalia. (H&S 11364)

5) Establishes the requirements of a demonstration project, from January 1, 2005 to December 31, 2008, to evaluate the impact of allowing the furnishing of needles without a prescription.

6) Requires pharmacies participating in the demonstration project to:

a. register with the local health department.
b. provide patients with information on local drug treament options, local testing options for HIV and hepatitis C, and local options for safe needle disposal.
c. store needles in a location only accessible to authorized pharmacy personnel.
d. provide either onsite needle disposal or mail back sharps disposal containers. (H&S 121285)

7) Prohibits the disposal of a needle on a playground, beach, park, or school. (B&P 4147)

8) Establishes a penalty of up to six months in jail and/or a fine of $200 - $2,000 for disposing of a needle on a playground, beach, park, or school. (B&P 4147)

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) New York Model. In May 2000, the New York State Legislature enacted Chapter 56 of the Laws of 2000, creating the Expanded Syringe Access Demonstration Program (ESAP), with the purpose of reducing the transmission of blood-borne diseases, including HIV and Hepatitis C. SB 1159 is nearly identical to the New York law, allowing for the sale or furnishing of up to 10 syringes per transaction to persons 18 years of age or older without a prescription if the pharmacy is registered with the local health department.

The New York Academy of Medicine, in consultation with the AIDS Advisory Council, evaluated the effects of the New York law and published the results of that evaluation in 2003. The evaluation found that:

- Needle sharing among injection drug users has slightly declined since ESAP's inception.
- More and more pharmacies and drug users are participating in the program, though greater awareness is needed.
- Discarded needles or syringes have not been found in higher quantities on the street as a result of this program.
- No increases in drug-related criminal arrests have occurred since this program began.
- No increases in drug use or drug injections have been observed since ESAP began.

The Academy's report concluded that the program has great potential to prevent transmission of blood-borne diseases without any detrimental effects on syringe disposal, drug use or crime. Furthermore, the report recommended that the ESAP law

be adopted on a permanent basis. Governor Pataki recently extended the program, which was set to expire on March 31, 2003, through September 2007.

3) 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.

In 2003, Senator John Vasconcellos introduced Senate Bill 774 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 board supported SB 774. It is unknown at this time what position the new Governor may take o this legislation.

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 allow the furnishing of needles by a the holder of a hypodermic permit to persons with a demonstrated medical need . However, the furnishing of needles without demonstrated medical need would have to occur in 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) Needles and Disease Transmission. California is one of five states that prohibit the sale of sterile syringes without a prescription. Sharing dirty syringes is linked to 20% of all AIDS cases in California. The link between injection drug use and HIV is particularly strong for women and people of color. In California, 37% of cumulative AIDS cases among women, 24.3% of cases among African American men and women and 22.4% of cases among Latinas are directly attributable to syringe sharing. Additionally, as of 2001, an estimated 600,000 Californians were infected with hepatitis C, with an additional 5,000 new infections each year attributable to dirty syringes.

6) History

Mar. 31	Set for hearing April 19.
Mar. 16	Read second time. Amended. Re-referred to Com. on ENV. QUAL.
Mar. 15	From committee: Do pass as amended, but first amend, and re-refer to Com. on ENV. QUAL. (Ayes 8. Noes 2. Page 3060.)
Mar. 1	Set for hearing March 10.
Feb. 17	To Coms. on H. & H.S. and ENV. QUAL.
Feb. 3	From print. May be acted upon on or after March 4.
Feb. 2	Introduced. Read first time. To Com. on RLS. for assignment. To print.

7) Support and Opposition

Support:

Drug Alliance Policy Network (main sponsor)
AIDS Healthcare Foundation (co-sponsor)
American Liver Foundation, San Diego Area Chapter (co-sponsor)
California Medical Association (co-sponsor)
California Nurses Association (co-sponsor)
Health Officers Association of California (co-sponsor)
San Francisco AIDS Foundation (co-sponsor)
Southern California HIV Advocacy Coalition (co-sponsor)
United Food & Commercial Workers International Union (co-sponsor)
Walgreens (co-sponsor)

California Retailers Association (co-sponsor)
AIDS Project Los Angeles
Alameda County Board of Supervisors
County Health Executives Association of California
California National Organization for Women
California Opioid Maintenance Providers
California Pharmacists Association
California Society of Addiction Medicine
County Alcohol and Drug Program Administrators Association of California
Sierra Club

Oppose:

California Narcotic Officers' Association
Capitol Resource Institute

AMENDED IN SENATE MARCH 16, 2004

SENATE BILL No. 1159

Introduced by Senator Vasconcellos
(Principal coauthors: Assembly Members Berg and Nation)
(Coauthors: Assembly Members Goldberg, Hancock, Jerome Horton, Laird, and Levine)

February 2, 2004

An act to amend ~~Section 4145~~ *Sections 4145 and 4147* of, and to repeal Section 4146 of, the Business and Professions Code, to amend Section 11364 of, and to add Chapter 13.5 (commencing with Section 121285) to Part 4 of Division 105 of, the Health and Safety Code, and to amend Sections 41770 and 41900 of, and to add Section 41803 to, the Public Resources Code, relating to hypodermic needles and syringes.

LEGISLATIVE COUNSEL'S DIGEST

SB 1159, as amended, 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, until December 31, 2008, to sell or furnish 10 or fewer hypodermic needles or syringes to a person for human use without a prescription if the pharmacy is registered with a local health department in the Disease Prevention Demonstration Project, which would be created by the bill to evaluate the long-term desirability of allowing licensed pharmacies to sell or

furnish nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

The bill would require local health departments to register pharmacies in the program and to cooperate with the Office of AIDS of the State Department of Health Services, thereby imposing a state-mandated local program. The bill would require the Office of AIDS of the State Department of Health Services, in conjunction with an advisory panel, to evaluate the effects of allowing the sale of hypodermic needles or syringes without prescription, and would require a report to be submitted to the Governor and the Legislature by January 15, 2008, subject to funding being available from federal or private sources. The demonstration program would terminate on December 31, 2008.

Alternatively, the bill would also authorize the sale or furnishing of hypodermic needles or syringes to a person for human use without a prescription if the person is known to the furnisher and has previously provided the furnisher with a prescription or other proof of a legitimate medical need.

The bill would make it unlawful to discard or dispose a hypodermic needle or syringe upon the grounds of a playground, beach, park, or any public or private elementary, vocational, junior high, or high school. The bill would make a knowing violation of this prohibition a crime, thereby imposing a state-mandated local program.

(2) Existing law requires a pharmacist to keep detailed records of nonprescription sales of hypodermic needles and syringes.

This bill would delete that requirement.

(3) Existing law prohibits the possession and sale of drug paraphernalia.

This bill, until December 31, 2008, would authorize a person to possess 10 or fewer hypodermic needles or syringes if acquired through an authorized source.

(4) Existing law requires a county or regional agency to prepare an integrated waste management plan based on submissions from cities and the county that includes a program element for the safe collection, recycling, treatment, and disposal of hazardous waste generated by households that should be separated from the solid waste stream.

This bill would authorize, as part of the update of the household waste element described above, a program to be identified for the safe collection, recycling, treatment, and disposal of household sharps

waste, defined to mean hypodermic needles, syringes, and lancets. The bill would enact other related provisions.

~~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, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to these statutory provisions.~~

(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, 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 4145 of the Business and Professions Code is amended to read:

4145. (a) 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, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(2) For the period commencing January 1, 2005, and ending December 31, 2008, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered for the Disease Prevention Demonstration Project pursuant to Chapter 16 (commencing with Section 121350) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

(b) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that 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.

SEC. 2. Section 4146 of the Business and Professions Code is repealed.

SEC. 3. *Section 4147 of the Business and Professions Code is amended to read:*

4147. *(a) For the 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 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 is unlawful to discard or dispose of a hypodermic needle or syringe upon the grounds of a playground, beach, 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

of 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) does 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. 4. 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 hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) For the period commencing January 1, 2005, and ending December 31, 2008, subdivision (a) shall not apply to the possession solely for personal use of 10 or fewer hypodermic needles or syringes if acquired from an authorized source.

~~SEC. 4.~~

SEC. 5. Chapter 13.5 (commencing with Section 121285) is added to Part 4 of Division 105 of the Health and Safety Code, to read:

CHAPTER 13.5. DISEASE PREVENTION DEMONSTRATION PROJECT

121285. (a) The Disease Prevention Demonstration Project, a collaboration between pharmacies and local and state health officials, is hereby authorized for the purpose of evaluating the long-term desirability of allowing licensed pharmacists to furnish

or sell nonprescription hypodermic needles or syringes to prevent the spread of blood-borne pathogens, including HIV and hepatitis C.

(b) The Office of AIDS shall, subject to the availability of federal or private funds for these purposes, evaluate the effects of allowing pharmacists to furnish or sell a limited number of hypodermic needles or syringes without prescription, and provide a report to the Governor and the Legislature on or before January 15, 2008. The report shall include, but need not be limited to, the effect of nonprescription hypodermic needle or syringe sale on all of the following:

(1) Hypodermic needle or syringe sharing practice among those who inject illegal drugs.

(2) Rates of disease infection caused by hypodermic needle or syringe sharing.

(3) Needlestick injuries to law enforcement officers and waste management employees.

(4) Drug crime or other crime in the vicinity of pharmacies.

(5) Safe or unsafe discard of used hypodermic needles or syringes.

(6) Rates of injection of illegal drugs.

(c) The Office of AIDS, subject to the availability of federal or private funds for this purpose, shall convene an uncompensated advisory panel comprised of all of the following: two or more specialists in the control of infectious diseases; one or more representatives of the California State Board of Pharmacy; one or more representatives of independent pharmacies; one or more representatives of chain pharmacy owners; one or more representatives of law enforcement executives, such as police chiefs and sheriffs; one or more representatives of rank and file law enforcement officers; a specialist in hazardous waste management from the State Department of Health Services; one or more representatives of rank and file waste haulers; one or more representatives of the waste management industry; and one or more representatives of local health officers.

(d) Local health departments shall be responsible for all of the following:

(1) Maintaining a list of all pharmacies within the local health department's jurisdiction that have registered under the Disease Prevention Demonstration Project.

(2) Providing pharmacies with written information that can be reproduced that is to be provided in writing or orally by the pharmacy at the time of furnishing or sale of nonprescription hypodermic needles or syringes, including all of the following:

(A) Local options for accessing drug treatment.

(B) Local options for accessing testing and treatment for HIV and hepatitis C.

(C) Local options for safe disposal of sharps waste, including, if available, the locations of authorized needle exchange programs, home-generated sharps consolidation points as defined in Section 117904, or medical waste generators for disposal pursuant to Section 118147.

(3) Cooperating with the Office of AIDS in the collection and analysis of data relative to the evaluation of the Disease Prevention Demonstration Project, as needed.

(e) In order to furnish or sell nonprescription hypodermic needles or syringes as part of the Disease Prevention Demonstration Project, a pharmacy shall do all of the following:

(1) Register with the local health department by providing a contact name and related information, and certifying that it will provide, at the time of furnishing or sale of hypodermic needles or syringes, written information or verbal counseling on all of the following:

(A) Local options for accessing drug treatment.

(B) Local options for accessing testing and treatment for HIV and hepatitis C.

(C) Local options for safe disposal of sharps waste, including, if available, the locations of authorized needle exchange programs, home-generated sharps consolidation points as defined in Section 117904, or medical waste generators for disposal pursuant to Section 118147.

(2) Store hypodermic needles and syringes so that they are available only to authorized personnel, and not openly available to customers.

(3) In order to provide for the safe disposal of hypodermic needles and syringes, a registered pharmacy shall provide one or more of the following options:

(A) An onsite safe hypodermic needle and syringe collection and disposal program.

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

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

(f) As used in this chapter, ''sharps waste'' means hypodermic needles, syringes, and lancets.

~~SEC. 5.~~

SEC. 6. Section 41770 of the Public Resources Code is amended to read:

41770. (a) Except as provided in subdivision (d), each countywide or regional agency integrated waste management plan, and the elements thereof, shall be reviewed, revised, if necessary, and submitted to the board every five years in accordance with the schedule set forth under Chapter 7 (commencing with Section 41800).

(b) Any revisions to a countywide or regional agency integrated waste management plan, and the elements thereof, shall use a waste disposal characterization method that the board shall develop for the use of the city, county, city and county, or regional agency. The city, county, city and county, or regional agency shall conduct waste disposal characterization studies, as prescribed by the board, if it fails to meet the diversion requirements of Section 41780, at the time of the five-year revision of the source reduction and recycling element.

(c) The board may review and revise its regulations governing the contents of revised source reduction and recycling elements to reduce duplications in one or more components of these revised elements.

(d) On and after January 1, 2005, when a county or regional agency revises its countywide or regional integrated waste management plan and its elements, the city and county household hazardous waste elements may be updated to include a program for the safe collection, treatment, and disposal of sharps waste generated by households. As used in this subdivision, ''sharps waste'' means hypodermic needles, syringes, and lancets.

~~SEC. 6.~~

SEC. 7. Section 41803 is added to the Public Resources Code, to read:

41803. In addition to the provisions of Section 41802, any household hazardous waste plan submitted to the board after January 1, 2005, may include a program for the safe collection, treatment, and disposal of sharps waste generated by households that may include the following:

(a) The designation of authorized locations such as household hazardous waste collection facilities, designated hospitals and clinics, and fire stations, that will accept sharps waste.

(b) Efforts by the local agency to inform and encourage the public to return sharps waste to designated collection locations.

(c) Efforts by the local agency to inform and encourage the public to subscribe to mail-back programs authorized by the United States Postal Service.

(d) Expenditures for the safe collection, treatment, and disposal of sharps waste, consideration of the feasibility of offering low-cost mail-back programs for senior and low-income households.

As used in this section, ''sharps waste'' means hypodermic needles, syringes, and lancets.

~~SEC. 7.~~

SEC. 8. Section 41900 of the Public Resources Code is amended to read:

41900. Each city and county shall demonstrate a funding source, or sources, available to pay for preparing, adopting, and implementing the element or plan, as required by this part, including fees imposed pursuant to Section 41901. Plans submitted after January 1, 2005, may also include the identification of funding sources for the collection, treatment, and disposal of sharps waste generated by households. As used in this section, "sharps waste'' means hypodermic needles, syringes, and lancets.

~~SEC. 8. Notwithstanding Section 17610 of the Government Code, if the Commission on State Mandates determines that this act contains 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.~~

SEC. 9. 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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Attachment 11

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1333 **VERSION: AS AMENDED MARCH 16, 2004**

AUTHOR: PERATA **SPONSOR: AIDS HEALTHCARE FOUNDATION**

RECOMMENDED POSITION: NONE

SUBJECT: IMPORTATION BY PHARMACIES

Existing Law:

1) Establishes the Medi-Cal program, which is administered by the State Department of Health Services (DHS), under which qualified low-income persons receive health care services, including prescription drugs.

2) Establishes the AIDS Drug Assistance Program (ADAP) to provide drug treatments to persons infected with the human immunodeficiency virus (HIV).

This Bill:

1) Allows DHS to reimburse pharmacies for drugs that are dispensed to Medi-Cal or ADAP beneficiaries that are purchased from a Canadian pharmacy.

2) Provides that the reimbursement rate paid to a pharmacy for a Canadian drug dispensed to a beneficiary shall be up to an undefined percentage below the otherwise applicable rate, but may not be more than 50 percent of the difference between the cost of acquiring the drug from a Canadian pharmacy and the wholesale price the pharmacy would have otherwise paid to a pharmaceutical wholesaler.

3) Provides that a drug shall not be eligible for the reimbursement rate provided by the bill if the drug price, after rebates from the manufacturer, is the same or lower than the lowest available Canadian price for the drug.

4) Provides that in order for a pharmacy to be reimbursed for a drug that it has acquired from a Canadian pharmacy, the Canadian pharmacy shall meet the requirements for a nonresident pharmacy as defined, and comply with all applicable Canadian licensing and registration requirements.

5) Provides that a pharmacy shall not be subject to any adverse action under state law solely because the pharmacy acted in accordance with the provisions of the bill.

Comment:

1) Author's Intent. The author's intent in introducing SB 1333 is to provide an additional means of controlling drug expenditures in the Medi-Cal and ADAP, to help mitigate the need for substantial cuts in the two programs. According to information prepared for the author's office, national health care spending has increased 7 - 9 percent each year since 2000 and that 16 percent of the increase has been caused by prescription drug spending. According to the author, while the Medi-Cal federal and state

supplemental rebate programs have helped limit individual drug prices, overall drug spending in the program has increased by 55 percent over the past three fiscal years. The ADAP program continues to grow as well and is currently budgeted at $212 million. The Governor's proposed 2004-05 budget proposes to cap enrollment in ADAP as a means of controlling growth in the program.

2) Immunity Clause. The bill prohibits the board, or any other state entity, from taking action against a pharmacy for importing Canadian drugs for these two programs based on California law. This state immunity clause effectively sanctions the importation of Canadian drugs for patients in these two programs if they are imported from licensed Canadian pharmacies. The language would not prohibit any entity from taking action against the pharmacy based on federal law. The board can take action against a pharmacy based on violations of federal law relating to dangerous drugs, controlled substances, or federal law relating to pharmacy (B&P 4301 (j) & (o)). The author's intent seems to be to prohibit state agencies from taking enforcement action against pharmacies for importing Canadian drugs for these programs, but the language may require some refinement to accomplish that objective.

3) Appropriate Drugs. Some drugs used in both the Medi-Cal and the ADAP programs are not well suited to mail service pharmacy. Most notably, this would include any injectable drugs. The author may want to consider restricting Canadian importation to those drugs well suited to delivery by mail.

4) Pricing. Pressure to allow importation of drugs from Canada is growing because of the high price of many prescription drugs in the United States. According to various sources, comparable drugs in Canada sell for 40 percent less than in the US on average, and can sometimes sell for 50 - 70 percent less because the Canadian government limits what drug companies can charge for prescription drugs.

5) Federal Law. The Federal Food, Drug, and Cosmetic Act (FDCA), currently makes it illegal to import drugs into the US that are not FDA-approved or manufactured and labeled in accordance with provisions of the Act. The Act also makes it illegal for any person other than the original manufacturer of a drug to reimport it back into the US, even it otherwise complies with the FDCA.

In 2000, Congress passed the Medicine Equity and Drug Safety Act to permit importation of prescription drugs by commercial importers. The Act added a new section to the FDCA allow drug wholesalers and pharmacists to import drugs in limited circumstances, but only if the Secretary of Health and Human Services (HHS) certifies to Congress that importation will pose no additional risk to the public's health and safety and will result in a significant reduction in the cost of covered products. Both the current and previous Secretaries have refused to make this certification. However, Secretary Thompson recently testified to a Congressional committee that he would support allowing drugs to be reimported from Canada if Congress puts strict conditions on the practice.

6) Personal Importation. The FDA has adopted a personal importation policy which permits individuals and physicians to import up to a three-month supply of drugs for treatment of a patient's condition for which effective treatment may not be available domestically, which do not present an unreasonable risk, and for which there is no intent to market to US residents. In practice, the FDA generally has not prosecuted individuals who are importing drugs for their own use.

7) Support and Opposition

Support:

AIDS Healthcare Foundation (sponsor)

American Federation of State, County, & Municipal Employees
California Alliance for Retired Americans
California Nurses Association
Consumer Federation of California
Consumers Union
Health Access California
Jericho
Older Women's League of California
Senior Action Network
Service Employees International Union
United Nurses Association of California/Union of Health Care Professionals
Western Center on Law and Poverty

Oppose:

BIOCOM
Bristol-Myers Squibb Company
California Chamber of Commerce
California Healthcare Institute
Pfizer, Inc.
Pharmaceutical Research and Manufacturers of America
60 Plus Association

8) History.

Mar. 26 Set for hearing April 19.
Mar. 25 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 2. Page 3153.) Re-referred to Com. on APPR.
Mar. 16 From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 15 Art. IV, Sec. 8(a), of Constitution dispensed with. Joint Rule 55 suspended.
Mar. 11 Set for hearing March 24.
Mar. 4 To Com. on H. & H.S.
Feb. 19 From print. May be acted upon on or after March 20.
Feb. 18 Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN SENATE MARCH 16, 2004

SENATE BILL No. 1333

Introduced by Senator Perata

February 18, 2004

An act to add Section ~~14105.32~~ *120956* to the Health and Safety Code, ~~relating to Medi-Cal.~~ *and to add Section 14105.75 to the Welfare and Institutions Code, relating to prescription drugs.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1333, as amended, Perata. ~~Medi-Cal: drug contracts: lowest price~~ *Prescription drug reimbursement: pharmacy purchases from Canadian sources: Medi-Cal: AIDS Drug Assistance program.*

~~Existing~~

(1) Existing law establishes the Medi-Cal program, which is administered by the State Department of Health Services and under which qualified low-income persons receive health care services, including prescription drugs. Existing law authorizes the department to enter into contracts with manufacturers of drugs on a bid or nonbid basis and requires the department to maintain a list of those drugs for which contracts have been executed. Existing law requires that contracts executed pursuant to this provision be for the manufacturer's best price. Existing law defines ''best price'' as the negotiated price, or the manufacturer's lowest price available to any class of trade organization or entity, including, but not limited to, wholesalers, retailers, hospitals, repackagers, providers, or governmental entities within the United States, that contracts with a manufacturer for a specified price for drugs, inclusive of cash discounts, free goods, volume discounts, rebates, and on- or off-invoice discounts or credits.

~~This bill would require, notwithstanding any other provision of law, that the department negotiate contracts with drug manufacturers for purposes of the Medi-Cal program that result in drug prices that are the same as or less than the lowest price given to any federal, state, or local government.~~

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

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

This bill would authorize, notwithstanding any other provision of law, the department to reimburse a pharmacy that provides to a Medi-Cal beneficiary a prescription drug that was purchased from a Canadian pharmacy. This bill would provide that reimbursement for that prescription drug may be in an amount up to an established percentage less than the most recent allowable drug product price, not to exceed 50% of the difference between the purchase price from the Canadian pharmacy and the purchase price the pharmacy would have paid to a pharmaceutical wholesaler.

(2) Existing law requires the Director of Health Services, to the extent that state and federal funds are appropriated in the Budget Act for this purpose, to establish a program, known as the AIDS Drug Assistance program (ADAP) to provide drug treatments to persons infected with human immunodeficiency virus (HIV). Existing law requires the director to establish a rate structure for reimbursement for the cost of each drug included in the program and requires that the rates be established at not less than the actual cost of the drug. Existing law requires the director to develop, maintain, and update a list of drugs provided under the program and authorizes the director to purchase a listed drug directly from the manufacturer and negotiate the most favorable bulk price for that drug.

This bill would authorize, notwithstanding any other provision of law, the department to reimburse, in the same manner described in (2) above, a pharmacy that has provided to a person eligible for benefits under ADAP a prescription drug that was purchased from a Canadian pharmacy.

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 14105.32 is added to the Welfare and Institutions Code, to read:~~

~~14105.32. Notwithstanding any other provision of law, for purposes of this chapter the department shall negotiate contracts with the manufacturers of drugs that result in drug prices that are the same as or less than the lowest price given to any federal, state, or local government.~~

SECTION 1. Section 120956 is added to the Health and Safety Code, to read:

120956. (a) Notwithstanding any other provision of law, the department may reimburse a pharmacy that provides to a person eligible for benefits under this chapter a prescription drug that was purchased from a Canadian pharmacy, and shall reimburse that pharmacy for those prescription drugs pursuant to this section.

(b) The reimbursement rate for a prescription drug described in subdivision (a) may be up to, but not exceeding, ____ percent less than the most recent allowable drug product price, but in no case shall this reduced reimbursement rate be more than 50 percent of the difference between the purchase price from the Canadian pharmacy and the purchase price the pharmacy would have paid to a pharmaceutical wholesaler.

(c) Notwithstanding any other provision, a drug shall not be eligible for reimbursement under this section if the department finds that the drug price, after rebates from the drug's manufacturer, is the same as or lower than the lowest available Canadian price for the same drug.

(d) In order for a pharmacy to be reimbursed pursuant to this section, the Canadian pharmacy from which it purchases a prescription drug shall meet the requirements for a nonresident pharmacy as specified in Section 4112 of the Business and

Professions Code, as appropriate, and comply with all lawful directions and licensing and registration requirements of the applicable Canadian regulatory and licensing agency or agencies.

(e) A pharmacy shall not be subject to any adverse action under state law solely because the pharmacy acted in accordance with this section.

SEC. 2. Section 14105.75 is added to the Welfare and Institutions Code, to read:

14105.75. (a) Notwithstanding any other provision of law, the department may reimburse a pharmacy that provides a prescription drug that was purchased from a Canadian pharmacy to a Medi-Cal beneficiary, and shall reimburse that pharmacy for those prescription drugs pursuant to this section.

(b) The reimbursement rate for a prescription drug described in subdivision (a) may be up to, but not exceeding, ____ percent less than the most recent allowable drug product price, but in no case shall this reduced reimbursement rate be more than 50 percent of the difference between the purchase price from the Canadian pharmacy and the purchase price the pharmacy would have paid to a pharmaceutical wholesaler.

(c) Notwithstanding any other provision, a drug shall not be eligible for reimbursement under this section if the department finds that the drug price, after rebates from the drug's manufacturer, is the same as or lower than the lowest available Canadian price for the same drug.

(d) In order for a pharmacy to be reimbursed pursuant to this section, the Canadian pharmacy from which it purchases a prescription drug shall meet the requirements for a nonresident pharmacy as specified in Section 4112 of the Business and Professions Code, as appropriate, and comply with all lawful directions and licensing and registration requirements of the applicable Canadian regulatory and licensing agency or agencies.

(e) A pharmacy shall not be subject to any adverse action under state law solely because the pharmacy acted in accordance with this section.

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Attachment 12

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1427 **VERSION: AS INTRODUCED**

AUTHOR: ACKERMAN **SPONSOR: NONE**

RECOMMENDED POSITION: SUPPORT

SUBJECT: COUNTERFEIT DRUGS

Existing Law:

Establishes penalties for drug counterfeiting of up to 1 year in jail and/or a fine of up to $10,000. (H&S 111825)

This Bill:

1) Establishes that it is a felony to introduce counterfeit drugs into commerce if those drugs result in a death. (H&S 111827)

2) Specifies that in addition to imprisonment, those guilty of introducing counterfeits that result in death are responsible for restitution to the victims and disgorgement of their profits. (H&S 111827)

Comment:

1) Author's Intent. Staff has not been able to contact the author's office as of this writing. An updated analysis will be provided at the meeting if possible.

2) SB 1307. The board is sponsoring SB 1307 this year to improve the safety of the wholesale drug market. The board's bill focuses on establishing pedigree requirements and stiffer penalties (higher fines) for counterfeiting and wholesale violations. The provisions of this bill are compatible with the board's bill.

3) Problems With Counterfeits. The Food and Drug Administration (FDA) has stated in a recently published report, that it has seen "an increase in counterfeiting activities as well as increased sophistication in the methods used to introduce finished dosage form counterfeits into the otherwise legitimate U.S. drug distribution system. FDA counterfeit drug investigations have increased to over 20 per year since 2000, after averaging only 5 per year through the late 1990's. Increasingly, these investigations have involved well-organized criminal operations that seek to introduce finished drug products that may closely resemble legitimate drugs yet may contain only inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients, or be contaminated. Thus, drug counterfeiting poses real public health and safety concerns today, and may pose an even greater threat in the future if we fail to take preventative measures now. As counterfeiters continue to seek out new technologies to make deceptive products and introduce them into legitimate commerce, our systems for protecting patients must respond effectively."

4) History.

Mar. 4	To Com. on PUB. S.
Feb. 20	From print. May be acted upon on or after March 21.
Feb. 19	Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 1427

Introduced by Senator Ackerman

February 19, 2004

An act to add Section 111827 to the Health and Safety Code, relating to counterfeit drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1427, as introduced, Ackerman. Sherman Food, Drug, and Cosmetic Law: violations: counterfeit drugs.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the packaging, labeling, and advertising of food, drugs, and cosmetics. Existing law defines ''counterfeit'' with respect to a food, drug, device, or cosmetic, and makes it unlawful for any person to cause any food, drug, device, or cosmetic to be a counterfeit, or to sell, dispense, or hold for sale or dispense, the counterfeit food, drug, device, or cosmetic. A violation of these provisions is punishable as a misdemeanor.

This bill would provide, notwithstanding existing penalties, that any person who initially introduces into commerce a drug that is counterfeit is guilty of a felony, punishable by imprisonment in the state prison, if that action results in the death of a human being. By creating a new crime, the bill would impose a state-mandated local program. The bill would also provide that a person found guilty under the bill shall be subject to economic penalties, including restitution and disgorgement of the proceeds of the violation.

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 111827 is added to the Health and Safety Code, to read:

111827. (a) Notwithstanding Section 111825, or any other provision of law, any person who initially introduces into commerce a drug that is counterfeit is guilty of a felony, punishable by imprisonment in the state prison, if that action results in the death of a human being.

(b) In addition to imprisonment, any person found guilty under this section shall be responsible for economic penalties including, but not limited to, restitution to consumer victims, and disgorgement of any proceeds or other consideration obtained as a result of the violation.

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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Attachment 13

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1735 **VERSION: AS INTRODUCED**

AUTHOR: FIGUEROA **SPONSOR: AUTHOR**

RECOMMENDED POSITION: SUPPORT

SUBJECT: SPECIAL FUND AGENCIES

Existing Law:

1) Establishes the Pharmacy Board Contingent Fund to provide for the support of the Board of Pharmacy. (B&P 4406)

2) Establishes fees, payable to the Pharmacy Board Contingent Fund, for licensing activities undertaken by the board. (B&P 4400)

3) Requires revenue generated by board issued citations be deposited into the Pharmacy Board Contingent Fund. (B&P 125.9)

4) Requires all expenses of the board to be paid from revenue generated by the board. (B&P 4407)

5) Requires that any position in state government that is vacant for more than 6 months be eliminated. (Government 12439)

This Bill:

1) Exempts special fund agencies within the Department of Consumer Affairs (including the board) from the 6 month rule. (Government 12439.5)

2) Requires that any position lost to the 6 month rule prior to January 1, 2004 by special fund agencies at the Department of Consumer Affairs be restored. (Government 12439.5)

3) Requires the Department of Consumer Affairs to provide the legislature with any staff or appointment vacancy information requested within 30 days. (Government 12439.5)

4) Exempts agencies within the Department of Consumer Affairs from the hiring freeze established by Executive Order D-70-03. (Government 12439.5)

5) Exempts agencies within the Department of Consumer Affairs from the elimination of vacant positions as required by Executive Order D-71-03. (Government 12439.5)

Comment:

1) Author's Intent. The author seeks to minimize the impact of budget cutting efforts on consumer protection agencies that do not receive general fund revenue (i.e., tax revenue). Like the board, other boards and bureaus in the Department of Consumer

Affairs are funded by licensing fees that do not enter the state General Fund. Efforts needed to bring general fund revenue into balance with General Fund expenditures should not be applied to these special fund agencies. Savings realized by special fund agencies will not help reduce the General Fund deficit and will result in diminished consumer protection.

2) Board Impact. The board has lost 10 positions between the application of the 6 month rule and the elimination of vacant positions imposed by executive order. Furthermore, the board reduced its line item for board member reimbursement by $11,000 to comply with the reduction targets established by the prior administration. Passage of this bill would likely restore all these lost positions.

3) General Fund vs. Special Fund. Most state government services are financed through the state General Fund which receives general state revenue from various taxes (including income tax and sales tax). Services provided from the General Fund include Medi-Cal, K-12 education, higher education (i.e., CSU and UC), debt service, prisons, and social services programs. When budget figures are cited, they refer mostly to General Fund spending and revenue. The recent deficit crisis in California government is a deficit in the General Fund.

Many government services are provided by other sources of revenue that are directed to specific activities. The licensing boards within the Department of Consumer Affairs are good examples of special fund agencies. Their activities are solely funded through licensing fees and fines. These agencies receive no General Fund revenue and their spending is not figured in the budget deficit figures reported in the media.

4) History.

Apr. 1	Set for hearing April 19.
Mar. 31	Hearing postponed by committee.
Mar. 16	Set for hearing April 12.
Mar. 11	To Com. on B. & P.
Feb. 22	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. 1735

Introduced by Senators Figueroa and Aanestad
(Coauthor: Assembly Member Correa)

February 20, 2004

An act to add Sections 12439.5 and 16321 to the Government Code, relating to state offices.

LEGISLATIVE COUNSEL'S DIGEST

SB 1735, as introduced, Figueroa. Boards: Department of Consumer Affairs.

(1) Existing law provides for the establishment and funding of various boards under the jurisdiction of the Department of Consumer Affairs, and establishes the Division of Investigation in the department.

Existing law requires, with certain exceptions, the Controller to abolish any state position that is vacant for 6 monthly pay periods. The Director of Finance may authorize the reestablishment of any positions abolished by the Controller pursuant to these provisions under specified conditions.

This bill would exempt from the provisions requiring the abolishment of vacant positions any position on any board under the jurisdiction of the Department of Consumer Affairs that is funded solely from non-General Fund sources, or in the Division of Investigation in the department. It would provide that any position on a board under the jurisdiction of the department, or in the division, that was abolished pursuant to these provisions prior to January 1, 2004, shall be reestablished by the Director of Consumer Affairs to the extent that non-General Fund moneys are available for that purpose. It would also require the Director of Consumer Affairs to provide to the Legislature information on all staff and appointment vacancies for boards under the

jurisdiction of the department, and the division, within 30 days of receiving the Legislature's request for that information.

The bill would prohibit the Director of Finance from refusing to authorize the filling of a vacancy in any staff position on a board under the jurisdiction of that department or in the division unless the Director of Finance has made a finding based upon substantial evidence that there are insufficient non-General Fund resources to fill the position.

(2) Pursuant to existing law, the civil administration of the laws of the state is vested in the Governor, who is required to supervise the official conduct of all executive and ministerial officers and to see that all offices are filled and their duties performed.

This bill would specify that the provisions of specified executive orders of the Governor with respect to the hiring of state employees shall not apply to any board under the jurisdiction of the Department of Consumer Affairs nor to the Division of Investigation within the department.

(3) Existing law provides that moneys may be loaned from one state fund or account to other state funds or accounts, subject to specified conditions.

This bill would prohibit non-General Fund moneys deposited in any fund supporting a board under the jurisdiction of the Department of Consumer Affairs from being loaned to, or being used to secure a loan to, the General Fund. It would require the Director of Finance to provide a schedule for all loans of funds supporting boards under the jurisdiction of the Department of Consumer Affairs to the General Fund, which are required to be repaid in full.

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 12439.5 is added to the Government Code, to read:

12439.5. (a) Section 12439 shall not apply to any position on any board under the jurisdiction of the Department of Consumer Affairs that is funded solely from non-General Fund sources, or to the Division of Investigation within the department.

(b) (1) Any position on a board, or in the division, described in subdivision (a) that was abolished pursuant to Section 12439

prior to January 1, 2004, shall be reestablished to the extent that non-General Fund moneys are available for that purpose.

(2) The Director of Finance may not refuse to reestablish a position abolished as described in paragraph (1) or pursuant to his or her own action, or to authorize the filling of a vacancy in any staff position, on a board, or in the division, described in subdivision (a) unless the director has made a finding based upon substantial evidence that there are insufficient non-General Fund resources to fill the position.

(c) The Director of Consumer Affairs shall provide to the Legislature information on all staff and appointment vacancies for boards, and the division, described in subdivision (a), within 30 days of receiving the Legislature's request for that information.

(d) The provisions of Executive Order D-70-03 and Executive Order D-71-03 shall not apply to any board under the jurisdiction of the Department of Consumer Affairs, nor to the Division of Investigation within the department.

SEC. 2. Section 16321 is added to the Government Code, to read:

16321. (a) Notwithstanding any other provision of law, no non-General Fund moneys deposited in any fund or account supporting a board under the jurisdiction of the Department of Consumer Affairs may be loaned to, or used to secure a loan to, the General Fund.

(b) The Director of Finance shall provide a schedule for all loans of funds supporting boards under the jurisdiction of the Department of Consumer Affairs to the General Fund, which are required to be repaid in full.

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Attachment 14

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AMENDED IN SENATE APRIL 1, 2004

SENATE BILL No. 1307

Introduced by Senator Figueroa

February 17, 2004

An act to amend Sections ~~4160, 4163, 4164, 4165, and 4166 of, to repeal Section 4162 of, and to repeal and add Section 4161 of, the~~ *4043, 4160, 4164, 4165, 4166, and 4400 of, to amend, repeal, and add Section 4163 of, to add Sections 4021.5, 4034, 4126.5, 4163.5, and 4168 to, to add and repeal Section 4169 of, and to repeal and add Sections 4161 and 4162 of, the* Business and Professions Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 1307, as amended, Figueroa. Wholesalers and manufacturers of dangerous drugs and devices.

(1) Existing law, the Pharmacy Law, provides for the licensing and regulation of wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law makes ~~the~~ *a* violation of *the* Pharmacy Law a crime. ~~Existing~~

This bill, on and after January 1, 2007, would require a pedigree, as defined, to accompany each distribution of a dangerous drug, except that the California State Board of Pharmacy is authorized to the extend the compliance date to January 1, 2008, under specified circumstances. It would, on and after that date, prohibit a wholesaler or pharmacy from selling, trading, or transferring a dangerous drug or device without a pedigree, and would prohibit a wholesaler or pharmacy from acquiring a dangerous drug or device without receiving a pedigree.

(2) Existing law prohibits a person *from* acting as a wholesaler of dangerous drugs or devices without a license.

This bill would require dangerous drugs or dangerous devices to be acquired from a person authorized by law to possess or furnish them. The bill would exempt a licensed drug manufacturer that only ~~ship~~ *ships* drugs of its own manufacture from the provisions governing wholesalers, except for the prohibition against furnishing dangerous drugs or devices to an unauthorized person.

(3) Existing law imposes certain licensing and registration requirements on out-of-state manufacturers and wholesalers doing business in this state, and on their principals.

This bill would delete these requirements. The bill *instead* would make a ~~wholesaler~~ *person* located outside the state that ships, mails, or delivers dangerous drugs or dangerous devices into this state a nonresident wholesaler. The bill would require a nonresident wholesaler to meet specified licensing and reporting requirements, to comply with ~~lawful~~ directions and requests for information, to maintain ~~a record~~ *records* in readily retrievable form of dangerous drugs or dangerous devices sold, traded, or transferred to persons in this state, and to designate an exemptee-in-charge to be responsible for compliance with laws governing wholesalers.

(4) Existing law requires any manufacturer who sells or transfers a dangerous drug or dangerous device into this state or who receives a dangerous drug or dangerous device from a person in this state to, upon request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer. Existing law makes a manufacturer who fails or refuses to comply with that request subject to a citation and a fine, an order of abatement, or both.

This bill ~~would~~ instead *would* apply these provisions to a wholesaler licensed by the board. The bill would delete the provision that makes the failure or refusal to comply with a request subject to a citation and a fine, an order of abatement, or both. *The bill would require a wholesaler to submit a surety bond of $100,000, or an equivalent means of security, for each site to be licensed.*

(5) The bill would prohibit a county or municipality from issuing a business license for an establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board.

The bill would prohibit a person or entity from purchasing, trading, selling, or transferring a dangerous drug or device under specified circumstances, including if he or she knew or reasonably should have

known the drug or device was adulterated or misbranded. The bill would make a violation of those provisions subject to a specified fine.

The bill would specify to whom a pharmacist may furnish dangerous drugs.

(6) Because a violation of the requirements and prohibitions created by this bill would be a crime, the bill would impose a state-mandated local program.

(7) 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 4021.5 is added to the Business and Professions Code, to read:*

4021.5. (a) "Closed pharmacy" means a pharmacy that purchases dangerous drugs for a limited patient population and that is not open for dispensing dangerous drugs to the general population.

(b) It is the intent of the Legislature to enact reasonable "due diligence" requirements for wholesalers supplying a closed pharmacy.

SEC. 2. Section 4034 is added to the Business and Professions Code, to read:

4034. (a) "Pedigree" means a record, in written or electronic form, containing information regarding each transaction involving a given dangerous drug, from sale by a manufacturer, through acquisition and sale by a wholesaler, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug.

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

(1) The source of the dangerous drug, including the name, state license number, including California license number if available, and principal address of the source.

(2) The quantity of the dangerous drug, its dosage form and strength, the date of the transaction, the sales invoice number, the container size, the number of containers, the expiration dates, and the lot numbers.

(3) The business name, address, and if appropriate, the state license number, including a California license number if available, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.

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

(c) This section shall become operative on January 1, 2007.

SEC. 3. Section 4043 of the Business and Professions Code is amended to read:

4043. ''Wholesaler'' means and includes ~~every~~ *a* person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent, *including a nonresident wholesaler,* who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or authorize the storage or warehousing of drugs with any person or at any location not licensed by the board.

SEC. 4. Section 4126.5 is added to the Business and Professions Code, to read:

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

(1) The wholesaler or manufacturer from whom the dangerous drug was purchased.

(2) A licensed reverse distributor.

(3) Another pharmacy or wholesaler to alleviate temporary shortages that could result in the denial of health care.

(4) A patient.

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

(b) Notwithstanding any other provision of law, a violation of this section by either a closed pharmacy or a person engaged in a prohibited transaction with a closed pharmacy may subject the persons who committed the violation to a fine not to exceed the

amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine 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.

SEC. 5. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) ~~No person shall~~ *A person may not* act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee. The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. ~~Each~~ *A* wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.

(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

(f) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships *dangerous* drugs of its own manufacture is exempt from this section.

~~SEC. 2.~~

SEC. 6. Section 4161 of the Business and Professions Code is repealed.

~~SEC. 3.~~

SEC. 7. Section 4161 is added to the Business and Professions Code, to read:

4161. (a) ~~A wholesaler~~ *A person* located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler ~~for purposes of this chapter~~.

(b) A nonresident wholesaler shall be licensed by the board.

(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.

(d) ~~A nonresident wholesaler~~ *An applicant for a nonresident wholesaler license* shall disclose to the board the names, locations, and titles of each of the following:

(1) Its agent for service of process in this state.

(2) ~~Principal~~ *Its principal* corporate officers, as specified by the board*, if any.*

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

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

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

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

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

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

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

(i) The board ~~shall~~ *may* not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of the exemptee-in-charge.

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

(k) For purposes of this section, ''exemptee-in-charge'' means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.

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

~~SEC. 4.~~

SEC. 8. Section 4162 of the Business and Professions Code is repealed.

~~SEC. 5.~~

SEC. 9. Section 4162 is added to the Business and Professions Code, to read:

4162. (a) A wholesaler that applies to the board for a wholesaler license or the renewal of a wholesaler license shall submit a surety bond of one hundred thousand dollars ($100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

(b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine, or costs become final. The board may make a claim against the bond or security until one year after the license ceases to be valid, or until 60 days after the conclusion of any authorized administrative or legal proceeding, including an appeal, that involves the licensee, whichever occurs later.

SEC. 10. Section 4163 of the Business and Professions Code is amended to read:

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.

(c) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

~~SEC. 6.~~

SEC. 11. Section 4163 is added to the Business and Professions Code, to read:

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

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.

(c) A wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug or dangerous device without providing a pedigree.

(d) A wholesaler or pharmacy may not acquire a dangerous drug or dangerous device without providing a pedigree.

(e) This section shall become operative on January 1, 2007.

SEC. 12. Section 4163.5 is added to the Business and Professions Code, to read:

4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Section 4163 until January 1, 2008, if it determines that manufacturers, wholesalers, or pharmacies require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 13. Section 4164 of the Business and Professions Code is amended to read:

4164. ~~All wholesalers~~ *A wholesaler* licensed by the board that ~~distribute~~ *distributes* controlled substances, dangerous drugs, or

dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

~~SEC. 7.~~

SEC. 14. Section 4165 of the Business and Professions Code is amended to read:

4165. ~~Any~~ *A* wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.

~~SEC. 8.~~

SEC. 15. Section 4166 of the Business and Professions Code is amended to read:

4166. (a) Any wholesaler that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.

(b) Nothing in this section is intended to affect the liability of a wholesaler *or other distributor* for dangerous drugs or dangerous devices after their delivery to the transferee.

~~SEC. 9.~~

SEC. 16. Section 4168 is added to the Business and Professions Code, to read:

4168. A county or municipality may not issue a business license for any establishment that requires a wholesaler license unless the establishment possesses a current wholesaler license issued by the board. For purposes of this section, an "establishment" is the licensee's physical location in California.

SEC. 17. Section 4169 is added to the Business and Professions Code, to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy, in violation of Section 4163.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as set forth in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

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

(c) The Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax funds 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 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.

(d) This section shall remain in effect only until January 1, 2007, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2007, deletes or extends that date.

SEC. 18. Section 4169 is added to the Business and Professions Code, to read:

4169. (a) A person or entity may not do any of the following:

(1) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices at wholesale with a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as set forth in Article 3 (commencing with Section 111330) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

(4) Purchase, trade, sell, or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(5) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section or of subdivision (c) or (d) of Section 4163 may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence, pursuant to a citation issued by the board.

(c) The Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax funds 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 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.

(d) This section shall become operative on January 1, 2007.

SEC. 19. Section 4400 of the Business and Professions Code is amended to read:

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

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

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

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

(d) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If

an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

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

(f) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

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

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

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

(j) The fee for ~~an out-of-state drug distributor's~~ *a nonresident wholesaler's* license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

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

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

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

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

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

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

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

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

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

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

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

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

SEC. 20. 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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Attachment 15

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SENATE BILL No. 1913

Introduced by Committee on Business and Professions (Senators Figueroa (Chair), Brulte, Cedillo, Machado, Murray, and Vincent)

March 17, 2004

An act to amend Sections 28, 1274, 2041, 2462, 2470.14, 2902, 2915.7, 2936, 4005, 4030, 4059.5, 4076, 4081, 4101, 4114, 4200, 4409, 4980.395, 4990.4, 4995.26, 4996.18, and 4996.20 of, and to add Sections 4026.5, 4107, 4208, and 4209 to, the Business and Professions Code, and to amend Sections 11159.1, 11207, and 111625 of the Health and Safety Code, relating to professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 1913, as introduced, Committee on Business and Professions. Professions.

(1) Existing law provides for the licensing and regulation of psychologists, clinical social workers, and marriage and family therapists. Existing law requires a person applying for licensure as a psychologist, clinical social worker, or marriage and family therapist on and after January 1, 1987, to have completed specified coursework or training in child abuse assessment and reporting from certain types of institutions.

This bill would revise the types of educational institutions from which the training may be obtained.

(2) Existing law provides for the regulation of clinical laboratories. Existing law requires a clinical laboratory to send to persons submitting cytological samples for evaluation information letters on all cases of dysplasia, and requires that, when a clinical lab determines that an abnormality of dysplasia has been identified for a patient for whom the

www.psychboard.ca.gov, by calling ~~(insert appropriate regional number) or (insert appropriate telephone number)~~ *1-866-503-3221*, or by writing to the following address:

Board of Psychology
1422 Howe Avenue, ~~Ste.~~ *Suite* 22
Sacramento, California 95825-3236"

A licensee shall post the Notice to Consumers in English as well as in any other language(s) spoken by their patients during therapy.

SEC. 9. Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; ~~and~~ pertaining to the sale of drugs by or through any mechanical device *; and relating to pharmacy practice experience necessary for licensure as a pharmacist.*

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued

by the board shall be governed and controlled by the rules of professional conduct adopted by the board.

(d) The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 10. Section 4026.5 is added to the Business and Professions Code, to read:

4026.5. ''Good standing'' means a license issued by the board that is unrestricted by disciplinary action taken pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 11. Section 4030 of the Business and Professions Code is amended to read:

4030. ''Intern pharmacist'' means a person ~~registered with the board pursuant to Section 4200 who shall have completed the educational requirements as determined by the board~~ *issued a license pursuant to Section 4208*.

SEC. 12. Section 4059.5 of the Business and Professions Code is amended to read:

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

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

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

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

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

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

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

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

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

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

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

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

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

4076. (a) A pharmacist ~~shall~~ *may* 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~~ *or*, 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, *a pharmacist who functions under a protocol as described in Section 4052,* 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) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

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

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

(B) This paragraph applies to outpatient pharmacies only.

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

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

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

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, *a pharmacist who functions under a protocol as described in Section 4052*, or the physician assistant who functions pursuant to Section 3502.1.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in

paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 14. Section 4081 of the Business and Professions Code is amended to read:

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

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

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

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

SEC. 15. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) ~~Any~~ *A* pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.

(b) ~~Any exemptee who takes charge of, or acts as manager of,~~ *An exemptee-in-charge of* a wholesaler or veterinary ~~food-drug animal~~ *food drug-animal* retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.

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

SEC. 16. Section 4107 is added to the Business and Professions Code, to read:

4107. (a) The board may not issue or, effective July 1, 2005, renew a site license, including, but not limited to, a license to conduct a wholesaler, pharmacy, veterinary food-animal drug retailer, to a facility located in a personal residence.

(b) The board may not issue more than one site license to a single premises except to issue a veterinary food-animal drug retailer license to a wholesaler or to issue a license to compound sterile injectable drugs to a pharmacy. For the purposes of this subdivision, ''premises'' means a location with its own address and an independent means of ingress and egress.

SEC. 17. Section 4114 of the Business and Professions Code is amended to read:

4114. *(a)* An intern pharmacist may perform ~~any activities pertaining to the practice of pharmacy as the board may determine by regulation. Whenever in this chapter the performance of an act is restricted to a pharmacist, the act may be performed by an intern pharmacist under the supervision of a pharmacist. The pharmacist shall not supervise more than one intern pharmacist~~ *all functions of a pharmacist at the discretion of and under the supervision of a pharmacist whose license is in good standing with the board.*

(b) A pharmacist may not supervise more than two intern pharmacists at any one time.

SEC. 18. Section 4200 of the Business and Professions Code is amended to read:

4200. (a) The board ~~shall~~ *may* license as a pharmacist~~, and issue a certificate to,~~ any applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the *foreign-educated* applicant has ~~received a grade satisfactory to the board on an examination designed to measure the equivalency of foreign pharmacy education with that required of domestic graduates~~ *been certified by the Foreign Pharmacy Graduate Examination Committee*.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has ~~had~~ *carried* 1,500 hours of ~~pharmaceutical~~ *pharmacy practice* experience *or the equivalent* in accordance with ~~regulations adopted by the board~~ *Section 4209*.

~~(A) "Pharmaceutical experience," constitutes service and experience in a pharmacy under the personal supervision of a pharmacist, and consists of service and experience predominantly related to the selling of drugs, compounding physician's prescriptions, preparing pharmaceutical preparations, and keeping records and making reports required under state and federal statutes.~~

~~(B) To be credited to the total number of hours required by this subdivision, this experience shall have been obtained in pharmacies and under conditions set forth by rule or regulation of the board.~~

(6) Has passed a written and practical examination given by the board prior to December 31, 2003, or has passed the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California on or after January 1, 2004.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist, shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board, the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

SEC. 19. Section 4208 is added to the Business and Professions Code, to read:

4208. (a) At the discretion of the board, an intern pharmacist license may be issued for a period of:

(1) One to six years to a person who is currently enrolled in a school of pharmacy recognized by the board.

(2) Two years to a person who is a graduate of a school of pharmacy recognized by the board and who has applied to become licensed as a pharmacist in California.

(3) Two years to a foreign graduate who has met educational requirements described in paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

(4) One year to a person who has failed the pharmacist licensure examination four times and has reenrolled in a school of pharmacy to satisfy the requirements of Section 4200.1.

(b) The board may issue an intern pharmacist license to an individual for the period of time specified in a decision of reinstatement adopted by the board.

(c) An intern pharmacist shall notify the board within 30 days of any change of address.

(d) An intern pharmacist whose license has been issued pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall return his or her license, by registered mail, within 30 days of no longer being enrolled in a school of pharmacy. The intern pharmacist license will be cancelled by the board. Notwithstanding subdivision (c), an intern pharmacist license may be reinstated if the student re-enrolls in a school of pharmacy recognized by the board to fulfill the education requirements of paragraphs (1) to (4), inclusive, of subdivision (a) of Section 4200.

SEC. 20. Section 4209 is added to the Business and Professions Code, to read:

4209. (a) An intern pharmacist shall complete 1,500 hours of pharmaceutical experience before applying for the pharmacist licensure examination.

(1) This pharmaceutical experience shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, which shall be certified under penalty of perjury by a pharmacist under whose supervision

such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (a). Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

SEC. 21. Section 4409 of the Business and Professions Code is amended to read:

4409. At the time a pharmacy license is renewed pursuant to subdivision (a) of Section 4110 or a pharmacist license is renewed pursuant to Section 4401, the pharmacy or pharmacist may make a ~~twenty-five dollar ($25)~~ contribution *of at least twenty-five dollars ($25)*, to be submitted to the board, for the sole purpose of funding the California Pharmacist Scholarship and Loan Repayment Program established pursuant to Article 2 (commencing with Section 129198) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code. The contribution submitted pursuant to this section shall be paid into the State Treasury and credited to the California Pharmacist Scholarship and Loan Repayment Program Fund established pursuant to Section ~~129198.5~~ *128198.5* of the Health and Safety Code.

SEC. 22. Section 4980.395 of the Business and Professions Code is amended to read:

4980.395. (a) ~~Effective January 1, 2005, as a condition of the first renewal of a person's license pursuant to this chapter, any person~~ *A licensee* who began graduate study prior to January 1, 2004, shall complete a three-hour continuing education course in aging and long-term care *during his or her first renewal period after the operative date of this section* and shall submit to the board evidence, acceptable to the board, of the person's satisfactory completion of the course.

(b) The course ~~could~~ *shall* include, but is not limited to, the biological, social, and psychological aspects of aging.

(c) ~~Any~~ *A* person seeking ~~the first renewal of his or her license pursuant to this chapter~~ *to meet the requirements of subdivision (a) of this section* may submit to the board a certificate evidencing completion of equivalent courses in aging and long-term care taken prior to the operative date of this section, or proof of

SEC. 26. Section 4996.26 of the Business and Professions Code is amended to read:

4996.26. (a) ~~Effective January 1, 2005, as a condition of the first renewal of a person's license pursuant to this chapter, any person~~ *A licensee* who began graduate study prior to January 1, 2004, shall complete a three-hour continuing education course in aging and long-term care *during his or her first renewal period after the operative date of this section,* and shall submit to the board evidence acceptable to the board of the person's satisfactory completion of the course.

(b) The course ~~could~~ *shall* include, but is not limited to, the biological, social, and psychological aspects of aging.

(c) Any person seeking ~~the first renewal of his or her license pursuant to this chapter~~ *to meet the requirements of subdivision (a) of this section* may submit to the board a certificate evidencing completion of equivalent courses in aging and long-term care taken prior to the operative date of this section, or proof of equivalent teaching or practice experience. The board, in its discretion, may accept that certification as meeting the requirements of this section.

(d) The board ~~shall~~ *may* not renew an applicant's license ~~upon the applicant's application for the first renewal of his or her license~~ until the applicant has met the requirements of this section.

(e) Continuing education courses taken pursuant to this section shall be applied to the 36 hours of approved continuing education required in Section 4996.22.

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

SEC. 27. Section 11159.1 of the Health and Safety Code is amended to read:

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article ~~3.5~~ *13* (commencing with Section ~~4063)~~ *4180)* of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article ~~but~~ *and* shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under

the provisions of Article ~~3.5~~ *13* (commencing with Section ~~4063)~~ *4180)* of Chapter 9 of Division 2 of the Business and Professions Code.

Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

SEC. 28. Section 11207 of the Health and Safety Code is amended to read:

11207. *(a)* No person other than a ~~registered~~ pharmacist ~~under the laws of this state~~ *as defined in Section 4036 of the Business and Professions Code* or an intern pharmacist, as defined in Section ~~4038.1~~ *4030* of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.

(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

SEC. 29. Section 111625 of the Health and Safety Code is amended to read:

111625. *(a)* A license application shall be completed annually and accompanied by an application fee as prescribed in Section 111630. This fee is not refundable if the license is refused.

(b) A manufacturer licensed pursuant to this article may not operate without employing sufficient, qualified supervision to adequately safeguard and protect the public health. Either a pharmacist licensed pursuant to Section 4200 of the Business and Professions Code or an individual issued a certificate of exemption pursuant to Section 4053 of the Business and Professions Code shall be deemed qualified to provide sufficient, qualified supervision, as required by this subdivision.

SEC. 30. 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

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Legislation and Regulation Committee
Strategic Plan Update for April 2004

Goal 3:	**Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.**
Outcome:	**Improve the health and safety of Californians.**

Objective 3.1:	**Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.**
Measure:	**100 percent successful enactment of promoted legislative changes**
Tasks:	1. Secure extension of board's sunset date. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 3. Sponsor legislation to add enforcement options for non-compliance issues. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. **Advocacy: AB 1196, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774** **Technical Assistance: AB 262, AB 746, AB 1196, AB 1957, AB 2125, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907, SB 1149** 6. Sponsor clean-up language to B & P Code section 4312. **Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361)** 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. **Public meetings held on March 27, 2003 and September 11, 2003.** **Public meeting scheduled for March 30, 2004.** 8. Sponsor legislation to strengthen consumer protections in wholesale transactions. **January 2004 - Board approved draft legislation.** **February 2004 – SB 1307 introduced.** 9. Sponsor legislation to address licensing issues related to the UC Davis Veterinary Medical Teaching Hospital.

	July 2003 – Board approves draft language.

Objective 3.2:	**Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.**
Measure:	**Percentage successful enactment of promoted regulatory changes**
Tasks:	1. Strengthen standards for compounding sterile injectable drug products. **In process. Rulemaking approved by board in October 2003.** **February 2004 – Rulemaking Submitted to OAL** 2. Authorize the executive officer the authority to issue citations and fines. **Completed. Regulation effective October 11, 2003.** 3. Eliminate the clerk typist ratio. **September 2003 - Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. **September 2003 - Informational hearing held.** **February 2004 - Rulemaking Notice Published.** 5. Update pharmacy self-assessment form. 6. Allow central filling by hospital pharmacies. **September 2003 - Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. **September 2003 - Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 8. Modify patient notification provision of the quality assurance regulation to require notification only if the error results in the medication being administerd to the patient or a clinically significant delay in therapy. **July 2003 – Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 9. Require pharmacies using a common electronic file to adopt policies to ensure confidentiality of patient information. **September 2003 – Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 10. Update pharmacy technician regulations to conform to SB 361. **September 2003 – Informational hearing held.** **February 2004 – Rulemaking Notice Published.** 11. Update pharmacist licensure regulations to conform to SB 361.

	September 2003 – Informational hearing held. **February 2004 – Rulemaking Notice Published.** 12. Complete a Section 100 filing to clean up regulations in conformity with recent legislation.

Objective 3.3: **Measure:**	**Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.** **Number of areas of pharmacy law reviewed**
Tasks:	1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. **Completed – Chapter 250, Statutes of 2003 (SB 175)** 3. Evaluate group dispensing by prescribers. **August 2003 - Draft legislation developed in concert with the Medical Board. Awaiting board action.** 4. Evaluate pharmacist intern statutes and regulations. **December 2003 – Draft legislation and regulations prepared and presented to the Licensing Committee.** **January 2004 – Draft legislation and regulations approved by the board.** **February 2004 – Rulemaking noticed on approved regulations.** **March 2004 – Statutory provisions introduced in SB 1913.**

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MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: MARCH 30, 2004
LOCATION: TELECONFERENCE

BOARD MEMBERS PRESENT:

ANDREA ZINDER, CHAIR
DAVE FONG

BOARD STAFF PRESENT:

PATRICIA HARRIS
VIRGINIA HEROLD
PAUL RICHES

The meeting was convened at 10:35 a.m.

Legislation

The committee was provided with an update regarding Senate Bill 1307 (Figueroa) which is a board sponsored bill relating to wholesalers. The committee was informed that the bill would be amended to reflect the board approved policy on this issue. A draft of the amendments was included in the meeting materials for the committee's reference.

It was observed that the bill has broad implications in for both wholesalers and pharmacies and that many in the pharmacy community have not formulated a position on the proposal at this time. Staff indicated its continuing willingness to work on issues identified by any interested party as the bill moves through the legislative process.

The committee was also provided with an update regarding Senate Bill 1913 (Business and Professions Committee) which contains numerous technical or non-controversial changes to the pharmacy law. The text of the relevant provisions was provided in the meeting materials for the committee's reference.

The Legislation and Regulation Committee (committee) recommended that the board support Assembly Bill 320.

Discussion: The committee inquired as to how the enforcement cases involving civil complaints were handled currently. Staff informed the committee that existing law requires the board to be notified by the court of civil settlements exceeding $5,000 and that the board does received such notifications. This bill would be consistent with preserving the board's role of public protection by ensuring that consumers would be free to report potential violations at any time.

The committee recommended that the board support Assembly Bill 1826.

Discussion: The committee inquired about the potential fiscal impact of this bill. Staff indicated that the criminal charges allowed by this bill would have to be filed by a prosecutor and would have no additional fiscal impact for the board.

The committee recommended that the board consider Assembly Bill 1957 without a recommendation from the Committee.

Discussion: The bill discussed the tension between affordability and the present law relating to the importation of prescription drugs and the potential conflicts that the bill would present to the board. In light of the fluid nature of bill relating to importation, the committee chose to forward the bills relating to importation to the full board without recommendation. These bills are likely to be subject to significant amendments during the legislative hearing process in the coming weeks.

The committee recommended that the board support Assembly Bill 1960 if it is amended.

Discussion: The committee discussed the findings of the board's 2003 task force regarding pharmacy benefits managers. The task force found that there was not sufficient demonstrated consumer harm to justify licensing pharmacy benefits managers at this time. The task force did identify numerous concerns between pharmacy benefit managers, their clients and pharmacies that would be best resolved by collaboration among those entities. Staff indicated that the bill would require the board to administer and enforce its provisions despite the findings of the task force. The committee recommended that the bill be amended to ensure that the board would not be responsible for enforcing its provisions.

The committee recommended that the board consider Assembly Bill 2125 without a recommendation from the Committee.

Discussion: The committee discussed the balance between the potential benefit to older patients and caregivers of having an indication or diagnosis on the prescription and the prescription label. The committee expressed concern about adopting this change absent hard evidence to indicate that this would increase patient compliance with prescribed therapy. In light of the potentially competing concerns presented the committee forwarded this bill for consideration without a recommendation.

The committee recommends that the board oppose Assembly Bill 2184 unless it is amended.

Discussion: The committee discussed the implications of expanding the use of automated dispensing devices and the bill's requirement to license these devices individually. The committee also discussed the need for a license category for these devices and the need for such new license categories to be subject to a sunrise review. The committee directed staff to continue working with the sponsor to find an acceptable resolution to this bill.

The committee recommends that the board support Assembly Bill 2660.

Discussion: The committee discussed recent amendments to the bill that resolved concerns articulated by staff in the analysis provided and recommended a support position

The committee recommended that the board support Assembly Bill 2682 if it is amended.

Discussion: The committee discussed the overlap and inconsistencies with the board sponsored bill on wholesaling (SB 1307). The committee indicated support for the concept of improving the safety of the wholesale distribution system but requested amendments to the bill ensuring consistency with SB 1307.

The committee recommended that the board consider Senate Bill 1149 without a recommendation from the Committee.

Discussion: The bill discussed the tension between affordability and the present law relating to the importation of prescription drugs and the potential conflicts that the bill would present to the board. In light of the fluid nature of bill relating to importation, the committee chose to forward the bills relating to importation to the full board without recommendation. These bills are likely to be subject to significant amendments during the legislative hearing process in the coming weeks.

The committee recommended that the board support Senate Bill 1159.

Discussion: The committee indicated continued support for eliminating the prescription requirement for needles and syringes. The discussion included consideration of the needle disposal options provided in the bill.

The committee recommended that the board consider Senate Bill 1333 without a recommendation from the Committee.

Discussion: The bill discussed the tension between affordability and the present law relating to the importation of prescription drugs and the potential conflicts that the bill would present to the board. In light of the fluid nature of bill relating to importation, the committee chose to forward the bills relating to importation to the full board without recommendation. These bills are likely to be subject to significant amendments during the legislative hearing process in the coming weeks.

The committee recommended that the board support Senate Bill 1427.

Discussion: The committee indicated its support for increased penalties for drug counterfeiting.

The committee recommended that the board oppose Senate Bill 1728 unless it is amended.

Discussion: The committee discussed the challenges that this bill would present for pharmacy inspections and requested amendments excluding the board from its provisions.

The committee recommended that the board support Senate Bill 1735.

Discussion: The committee discussed the impact of lost resources (both personnel and financial) that have resulted from the hiring freeze and other budget reductions. The committee indicated its support for the bill as it would result in better service to the public without harming the state's general fund budget deficit.

Regulations Update

The committee was provided with a status update on pending regulations and notified that the board would have two regulation hearings followed by votes and one regulation vote without a hearing at the April 2004 board meeting.

The committee was further informed that the pending regulations cleared the board's regulation backlog with the exception of updating the pharmacy self-assessment form which would be done later this year.

Adjournment

The committee adjourned at 12:30 p.m.