



LEGISLATION AND REGULATION COMMITTEE

Legislation Report

FOR ACTION

Action Item #1 – Change the board’s position on Assembly Bill 1960 from oppose unless amended to no position.

Discussion: The bill was recently amended to remove its provisions from the pharmacy law as requested by the board in its previous position. Based on these amendments, staff recommends no position on the bill. An updated analysis of the bill is provided in Attachment 1.

Action Item #2 – Change the board’s position on Assembly Bill 746 from support to no position.

Discussion: The bill was recently amended to delete to prior version of the bill and add new items that do not directly impact the board. Based on these amendments, staff recommends no position on the bill. An updated analysis of the bill is provided in Attachment 2.

NO ACTION

Status Update for Bills with Board Position -

Assembly Bill 320 - Support
Location: Senate Appropriations Committee
Attachment 3

Assembly Bill 1826 - Support.
Location: Dead

Assembly Bill 1960 – Oppose Unless Amended
Location: Senate Floor

Assembly Bill 2184
Location: Senate Floor
Attachment 4

Assembly Bill 2660 – Support
Location: Senate Floor
Attachment 5

Assembly Bill 2682 - Support
Location: Senate Appropriations Committee

Attachment 6

Senate Bill 1159 – Support
Location: Assembly Floor
Attachment 7

Senate Bill 1427 - Support
Location: Dead

Senate Bill 1563 – Oppose Unless Amended
Location: Assembly Appropriations Committee
Attachment 8

Senate Bill 1735 - Support
Location: Senate Appropriations Committee Suspense File
Attachment 9

Status Update for Bills without Board Position

Assembly Bill 1957
Location: Senate Appropriations Committee
Attachment 10

Assembly Bill 2125
Location: Dead

Senate Bill 1149
Location: Assembly Appropriations Committee
Attachment 11

Senate Bill 1333
Location: Assembly Appropriations Committee
Attachment 12

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 bill is currently awaiting a hearing before the Assembly Appropriations Committee. Recent amendments have been made to address a range of issues raised by interested parties. Among the most notable are:

- Deleting provisions establishing a separate designation for “closed door pharmacies.”
- Permitting per occurrence fines for specified violations in pharmacies primarily serving long term care patients.
- Shifting provisions relating to non-resident wholesalers to Assembly Bill 2682 (Negrete McLeod).

Permitting the board to delay implementation of the electronic pedigree in pharmacies to January 1, 2009.

Clarifies provision requiring wholesalers to track furnishing to long term care pharmacies.

Modifying the bond requirement for wholesalers to accommodate small and start up wholesalers.

See Attachment 13 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 14 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 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 June 14, 2004

For your information the summary for the June 14, 2004 meeting of the Legislation and Regulation Committee meeting is attached to this report (Attachment 17).

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Attachment 1

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1960

VERSION: AS AMENDED JUNE 23, 2004

AUTHOR: PAVLEY

SPONSOR: CALIFORNIA LABOR FEDERATION

RECOMMENDED POSITION: NONE

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). (H&S 150000)
- 2) Defines "pharmacy benefits management" as the administration or management of prescription drug benefits including:
 - a. the procurement of prescription drugs at a negotiated rate for dispensing,
 - b. the processing of prescription drug claims,
 - c. the administration of payments related to prescription drug claims.
(H&S 150000)
- 3) Defines "pharmacy benefits manager" (PBM) as an entity that performs "pharmacy benefits management" as defined. (H&S 150000)
- 4) 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. (H&S 150000)
- 5) Requires PBMs to disclose to the purchaser the following:
 - a. The aggregate amount of all rebates that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.
 - b. The nature, type, and amount of all other revenue that the pharmacy benefits manager receives from pharmaceutical manufacturers in connection with prescription drug benefits related to the purchaser.
 - c. Any prescription drug utilization information related to the purchaser's enrollees or aggregate utilization data that is not specific to an individual consumer, prescriber, or purchaser.

- d. Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.
- e. The credentials of members of any pharmacy and therapeutic committee and any direct or indirect financial relationships between committee members and the pharmaceutical industry.
- f. Any arrangements with prescribers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(H&S 150001)

6) Requires PBMs to disclose to the prospective purchaser the following:

- a. The aggregate amount of all rebates that the pharmacy benefits manager estimates it will receive from pharmaceutical manufacturers in connection with prescription drug benefits related to the prospective purchaser.
- b. The nature, type, and amount of all other revenue that the pharmacy benefits manager estimates it will receive from pharmaceutical manufacturers in connection with prescription drug benefits related to the prospective purchaser.
- c. Any administrative or other fees charged by the pharmacy benefits manager to the prospective purchaser.
- d. The credentials of members of any pharmacy and therapeutic committee and any financial relationships between committee members and the pharmaceutical industry.
- e. Any arrangements with prescribing providers, medical groups, individual practice associations, or pharmacists that are associated with activities of the pharmacy benefits manager to encourage formulary compliance or otherwise manage prescription drug benefits.

(H&S 150002)

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

- a. The amount of the total revenues, rebates, and discounts identified in subdivisions (a) and (b) of Section 4131 and subdivisions (a) and (b) 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.
- c. Any administrative or other fees charged by the pharmacy benefits manager to the purchaser.
- d. Conditions under which an audit will be conducted of the contract for pharmacy benefits management services, who will conduct the audit, and who will pay for the audit.
- e. Any revenues, rebates, or discounts received by the pharmacy benefits manager directly or indirectly from entities other than manufacturers and labelers.
- f. The process for development of formularies and notification of changes to formularies, and approval of those changes by the purchaser, provided that the pharmacy benefits manager meets the requirements of Sections 4135 and 4136.

(H&S 150004)

8) Specifies the qualifications for members of a PBM pharmacy and therapeutics committee.

(H&S 150005)

9) Requires a PBM pharmacy and therapeutics committee to conduct a quarterly evaluation of the health effects of therapeutic substitution programs. (H&S 150006)

10) Prohibits a PBM from substituting a different drug than the drug prescribed unless the prescriber provides an express, verifiable authorization to substitute. (B&P 4137)

11) Requires a request from a PBM to a prescriber for a therapeutic substitution to contain the following information:

- a. The cost savings for the purchaser, if any, that are a result of the medication substitution.
- b. The difference, if any, in copayments or other out-of-pocket costs paid by the patient in order to obtain the medication.
- c. The existence of any additional payments received by the pharmacy benefits manager not reflected in the cost savings to the purchaser.
- d. The circumstances, if any, under which the currently prescribed medication will be covered.
- e. The circumstances and extent to which, if any, related health care costs arising from the change in medications will be compensated.
- f. Any known differences in potential effects on patient health and safety, including side-effects.
- g. The name and title of the individual authorizing the change if the authorization by the provider is given verbally. (H&S 150007)

12) Requires a PBM to provide a patient with the following information before a therapeutic substitution occurs:

- a. The proposed medication and the currently prescribed medication.
- b. The difference in copayments or other out-of-pocket costs paid by the patient, if any.
- c. Any known differences in potential effects on patient health and safety, including side-effects, if any.
- d. The circumstances, if any, under which the currently prescribed medication will be covered.
- e. The cost savings for the purchaser, taking into account all discounts, rebates, or other payments that lower the cost of the medication to the purchaser.
- f. The existence of any additional payments received by the pharmacy benefits manager not reflected in the cost savings to the purchaser.
- g. A toll-free telephone number to communicate with the pharmacy benefits manager.
- h. The circumstances and the extent to which, if any, related health care costs will be compensated. (H&S 150007)

13) Requires PBMs to comply with the privacy standards in HIPAA. (H&S 150008)

Comment:

1) Author's Intent. According to the author, this bill is needed to create consumer protection guidelines that PBMs must meet when doing business with California clients such as CalPERS, large employers, health plans, and union trust funds. The author notes that under this bill PBMs will have to provide the kind of information that health plans have been disclosing for years about such matters as formulary development and name brand and generic drug switching. The author believes that creating a more transparent market will shine a light on an industry that discloses an inadequate amount

of pricing and conflict of interest information and will enable clients to make informed decisions about the type of prescriptions and benefits they select on behalf of their enrollees. According to the author, this will allow clients to take full advantage of the free market by incentivizing PBMs to compete in a fair, transparent environment for California business.

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) Confused Roles. The bill confuses the roles of prescriber, pharmacist, pharmacy and PBM. The bill erroneously permits a PBM to substitute a drug after obtaining permission from the prescriber. A PBM does not have the legal authority to dispense a prescription drug much less substitute a different drug than the one prescribed. A pharmacist working in a pharmacy may substitute a different drug in the following circumstances:

- a. Substituting a generic equivalent to a brand name drug.
- b. Substituting a different dosage form of the prescribed drug.
- c. Substituting a different drug after obtaining authorization from the prescriber.

The PBM is responsible for administering a benefit and providing payment to the pharmacy, but it is not permitted to prescribe, dispense or substitute drugs.

Because of the inappropriate use of the term "pharmacy benefits manager," the intent of this section is unclear. The section could refer to: dispensing activity in a mail order pharmacy owned and operated by the PBM, dispensing activity in a pharmacy with which the PBM contracts with to dispense prescriptions, or so called therapeutic substitution programs operated by some PBMs that utilize health care practitioners to solicit prescription changes from prescribers. The intent of this section needs to be made clear and appropriate roles assigned to each party.

4) Prescribing Authority. The bill permits the patient to reverse a substitution after it has occurred. This provision gives patients the unprecedented authority to order a dangerous drug which previously has been reserved for appropriately licensed health care professionals. Providing such authority to the patient would effectively shift any prescription drug to over-the-counter status once it has been substituted for another prescribed drug. The selection of a prescription drug is the sole province of an appropriately licensed professional. Patients frequently request specific drugs from prescribers but the ultimate authority over the issuance of a prescription is held by the prescriber.

7) 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.

8) History.

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|---------|--|
| June 29 | Read second time. To third reading. |
| June 28 | Withdrawn from committee. Ordered placed on second reading file. |

June 23 Read second time, amended, and re-referred to Com. on RLS.
 June 22 From committee: Amend, do pass as amended, and re-refer to Com. On RLS. (Ayes 9. Noes 2.).
 June 9 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on H. & H.S.
 June 9 Referred to Coms. on H. & H.S. and RLS.
 May 27 In Senate. Read first time. To Com. on RLS. for assignment.
 May 26 Read third time, passed, and to Senate.
 May 24 Read second time. To third reading.
 May 20 From committee: Amend, and do pass as amended. (Ayes 16. Noes 0.)
 May 19 Read second time and amended. Ordered returned to second reading.
 May 5 In committee: Set, first hearing. Referred to APPR. suspense file.
 Apr. 26 Re-referred to Com. on APPR.
 Apr. 22 Read second time and amended.
 Apr. 21 From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 8. Noes 3.) (April 20).
 Apr. 16 Re-referred to Com. on B. & P.

 Apr. 15 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
 Apr. 14 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 13. Noes 5.) (April 13).
 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.

9) Support and Opposition

SUPPORT

California Labor Federation, AFL-CIO (co-source)
 California Alliance for Retired Americans (co-source)
 American Association of Retired Persons
 AIDS Healthcare Foundation
 American Federation of State, County and Municipal Employees
 Automotive and Allied Industries Employees of San Diego County, Teamsters Local No. 481
 California Conference Board of Amalgamated Transit Union
 California Conference of Machinists
 California Commission on Aging
 California Faculty Association
 California Health Advocates
 California Nurses Association
 California Pharmacists Association
 California Professional Firefighters
 California Public Interest Research Group
 California School Employees Association
 California Seniors Coalition
 California State Employees Association
 California Teamsters Public Affairs Council
 Communications Workers of America, Local 9423, District 1 & 2,
 Santa Clara, San Mateo, Santa Cruz, San Benito, Monterey, San Luis Obispo
 Communications Workers of America, Local 9575, Camarillo
 Communications Workers of America, Local 9586, Norwalk

Congress of California Seniors
Consumer Federation of California
Consumers Union
Engineers and Scientists of California, IFPTE Local 20
Foundation for Taxpayer and Consumer Rights
Graphic Communications Union Local No. 583, San Francisco
Gray Panthers California
Health Access California
Health Care for All - California
Hotel Employees and Restaurant Employees Local No. 49, Sacramento
International Association of Bridge, Structural, Ornamental and Reinforcing Iron Workers,
Local 155
International Brotherhood of Electrical Workers, Local 340
International Brotherhood of Electrical Workers, Local 551
Laborers' International Union of North America
Motion Picture Costumers, Local 705
Office and Professional Employees International Union, Local 29
Older Women's League of California
Plumbers and Steamfitters, Local 484
Professional & Technical Engineers, IFPTE Local 21
Riverside Sheriff's Association
Sacramento-Sierra Building and Construction Trades Council
San Mateo County Central Labor Council
Santa Clara and San Benito Counties Building and Construction Trades Council
Senior Action Network
Service Employees International Union
Service Employees International Union, Local 660
Southern California District Council of Laborers
Southern California Pipe Trades, District Council 16, Los Angeles
Sprinkler Fitters and Apprentices, Local 483
State Public Employees' Retirement System
Teamsters, Local 481
Teamsters, Local 853
Teamsters Warehouse Union, Local 853, San Francisco, San Mateo, Alameda, Marin, and
Contra Costa Counties
United Association of Plumbers, Pipe Fitters and Sprinkler
Fitters of the
U.S. Sprinkler Fitters and Apprentices Local 483, Hayward
United Food and Commercial Workers International Union, Butchers' Union Local 120,
Oakland
United Food and Commercial Workers International, Local 1179, Martinez
United Food and Commercial Workers Union, Local 839, Salinas
United Steelworkers of America, District 12, Covina
United Steelworkers of America, Local 7600, Fontana, Riverside
United Teachers of Los Angeles
Warehouse, Processing & Distribution Workers' Union, Local 26
Western Center on Law and Poverty

OPPOSITION

Academy of Managed Care Pharmacy
Aetna, Inc.
Blue Cross of California
California Association of Health Plans
Caremark Rx, Inc.
California Chamber of Commerce
PacifiCare

AMENDED IN SENATE JUNE 23, 2004

AMENDED IN SENATE JUNE 9, 2004

AMENDED IN ASSEMBLY MAY 20, 2004

AMENDED IN ASSEMBLY APRIL 22, 2004

AMENDED IN ASSEMBLY APRIL 15, 2004

AMENDED IN ASSEMBLY APRIL 12, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 1960

**Introduced by Assembly Members Pavley, Chu, Frommer, and
Ridley-Thomas
(Coauthors: Assembly Members Chan and Koretz)
(Coauthor: Senator Kuehl)**

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

LEGISLATIVE COUNSEL'S DIGEST

AB 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~~

~~Pharmacy Law is a crime provides for the regulation of health care benefits.~~

This bill would define the term “pharmacy benefits management” as the administration or management of prescription drug benefits. The bill would also define the term “pharmacy benefits manager” as an entity that performs pharmacy benefits management. The bill would require a pharmacy benefits manager to make specified disclosures to its purchasers and prospective purchasers, including specified information about the pharmacy benefit manager’s revenues and its drug formularies, and to make specified disclosures to the public upon request. The bill would also establish certain standards and requirements with regard to pharmacy benefits management contracts and the provision of certain drugs. The bill would impose certain requirements on the membership of a pharmacy and therapeutics committee for a pharmacy benefits manager. The bill would also require a pharmacy benefits manager to meet certain conditions before substituting a prescribed medication.

~~Because the bill would create additional requirements 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~~-no. State-mandated local program: ~~yes~~-no.

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

- 1 ~~SECTION 1.—Article 8 (commencing with Section 4130) is~~
- 2 ~~added to Chapter 9 of Division 2 of the Business and Professions~~
- 3 ~~SECTION 1. Division 113 (commencing with Section 150000)~~
- 4 ~~is added to the Health and Safety Code, to read:~~
- 5



1 ~~Article 8. Pharmacy Benefits Management~~

2
3 *DIVISION 113. PHARMACY BENEFITS MANAGEMENT*

4
5 ~~4130. For purposes of this article~~

6 *150000. For purposes of this division, the following*
7 *definitions shall apply:*

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

13 (b) “Pharmacy benefits management” is the administration or
14 management of prescription drug benefits. Pharmacy benefits
15 management includes the procurement of prescription drugs at a
16 negotiated rate for dispensation within this state, the processing of
17 prescription drug claims, and the administration of payments
18 related to prescription drug claims.

19 (c) “Pharmacy benefits manager” is any person who performs
20 pharmacy benefits management. The term does not include a
21 health care service plan or health insurer if the health care service
22 plan or health insurer offers or provides pharmacy benefits
23 management services and if those services are offered or provided
24 only to enrollees, subscribers, or insureds who are also covered by
25 health benefits offered or provided by that health care service plan
26 or health insurer, nor does the term include an affiliate, subsidiary,
27 or other related entity of the health care service plan or health
28 insurer that would otherwise qualify as a pharmacy benefits
29 manager, as long as the services offered or provided by the related
30 entity are offered or provided only to enrollees, subscribers, or
31 insureds who are also covered by the health benefits offered or
32 provided by that health care service plan or health insurer.

33 (d) “Prospective purchaser” is any person to whom a
34 pharmacy benefits manager offers to provide pharmacy benefit
35 management services.

36 (e) “Purchaser” is any person who enters into an agreement
37 with a pharmacy benefits manager for the provision of pharmacy
38 benefit management services.

39 ~~4131.~~



1 150001. A pharmacy benefits manager shall disclose to the
2 purchaser in writing all of the following:

3 (a) The aggregate amount of all rebates and other retrospective
4 utilization discounts that the pharmacy benefits manager receives,
5 directly or indirectly, from pharmaceutical manufacturers or
6 labelers in connection with prescription drug benefits specific to
7 the purchaser.

8 (b) For a specified list of therapeutic classes, the aggregate
9 amount for each therapeutic class of all rebates and other
10 retrospective utilization discounts that the pharmacy benefits
11 manager receives, directly or indirectly, from pharmaceutical
12 manufacturers or labelers in connection with prescription drug
13 benefits specific to the purchaser. A therapeutic class shall include
14 at least two drugs.

15 (c) The nature, type, and amount of all other revenue that the
16 pharmacy benefits manager receives, directly or indirectly, from
17 pharmaceutical manufacturers or labelers in connection with
18 prescription drug benefits related to the purchaser.

19 (d) Any prescription drug utilization information related to
20 utilization by the purchaser's enrollees or aggregate utilization
21 data that is not specific to an individual consumer, prescriber, or
22 purchaser.

23 (e) Any administrative or other fees charged by the pharmacy
24 benefits manager to the purchaser.

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

30 ~~4132.~~

31 150002. A pharmacy benefits manager shall disclose to a
32 prospective purchaser in writing all of the following:

33 (a) The aggregate amount of all rebates and other retrospective
34 utilization discounts that the pharmacy benefits manager estimates
35 it will receive, directly or indirectly, from pharmaceutical
36 manufacturers or labelers in connection with prescription drug
37 benefits related to the prospective purchaser.

38 (b) For a specified list of therapeutic classes, the aggregate
39 amount for each therapeutic class of all rebates and other
40 retrospective utilization discounts that the pharmacy benefits



1 manager estimates it will receive, directly or indirectly, from
2 pharmaceutical manufacturers or labelers in connection with
3 prescription drug benefits specific to the prospective purchaser. A
4 therapeutic class shall include at least two drugs.

5 (c) The nature, type, and amount of all other revenue that the
6 pharmacy benefits manager estimates it will receive, directly or
7 indirectly, from pharmaceutical manufacturers or labelers in
8 connection with prescription drug benefits related to the
9 prospective purchaser.

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

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

17 ~~4133.~~

18 *150003.* (a) A pharmacy benefits manager shall provide the
19 information described in Sections ~~4131 and 4132~~ *150001 and*
20 *150002* within 30 days of receipt of the request. If requested, the
21 information shall be provided no less than once each year.

22 (b) Except for utilization information, a pharmacy benefits
23 manager need not make the disclosures required in Sections ~~4131~~
24 ~~and 4132~~ *150001 and 150002* unless and until the purchaser or
25 prospective purchaser agrees in writing to maintain as confidential
26 any proprietary information. That agreement may provide for
27 equitable and legal remedies in the event of a violation of the
28 agreement. That agreement may also include persons or entities
29 with whom the purchaser or prospective purchaser contracts to
30 provide consultation regarding pharmacy services. Proprietary
31 information includes trade secrets, and information on pricing,
32 costs, revenues, taxes, market share, negotiating strategies,
33 customers and personnel held by a pharmacy benefits manager and
34 used for its business purposes.

35 ~~4134.~~

36 *150004.* A pharmacy benefits manager may not execute a
37 contract for the provision of pharmacy benefits management
38 services that fails to address the following items:

39 (a) The amount of the total revenues, rebates, and discounts
40 identified in subdivisions (a), (b), and (c) of Section ~~4131~~ *150001*



1 and subdivisions (a), (b), and (c) of Section ~~4132~~ 150002 that shall
2 be passed on to the purchaser.

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

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

8 (d) Conditions under which an audit will be conducted of the
9 contract for pharmacy benefits management services, who will
10 conduct the audit, and who will pay for the audit.

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

14 (f) The process for development of formularies and
15 notification of changes to formularies, and approval of those
16 changes by the purchaser, provided that the pharmacy benefits
17 manager meets the requirements of Sections ~~4135, 4136, and~~
18 ~~4137.~~

19 ~~4135, 150005, 150006, and 150007.~~

20 (g) *Whether there is a difference between the price paid to a*
21 *retail pharmacy and the amount that will be billed to the purchaser*
22 *for prescription drugs.*

23 150005. (a) All members of a pharmacy and therapeutics
24 committee for a pharmacy benefits manager shall be physicians,
25 pharmacists, or other health care professionals, and a majority of
26 committee members shall not be employed by the pharmacy
27 benefits manager.

28 (b) A pharmacy and therapeutics committee member shall not
29 be an officer, employee, director, or agent of, or any person who
30 has financial interest in, other than ownership of stock from open
31 market purchases of less than a nominal amount of the outstanding
32 stock of, pharmaceutical companies.

33 ~~4136.~~

34 150006. A pharmacy benefits manager shall report not less
35 than quarterly to the pharmacy and therapeutics committee which
36 shall monitor the health effects of medication substitutions on the
37 health of the patients, including identifying information from
38 patients and prescribers concerning the efficacy or health effects
39 of medication substitution.

40 ~~4137.~~



1 150007. (a) A pharmacy benefits manager shall not
2 substitute a medication for another currently prescribed
3 medication without first obtaining express verifiable authorization
4 from the prescriber of the currently prescribed drug except in the
5 following instances:

6 (1) As provided in Sections 4052.5 and 4073 *of the Business*
7 *and Professions Code*.

8 (2) If the medication substitution is initiated for patient safety
9 reasons.

10 (3) If the currently prescribed medication is no longer available
11 in the market.

12 (4) If initiated pursuant to a drug utilization review.

13 (5) If required for coverage reasons where the prescribed drug
14 is not covered by the individual's formulary or plan.

15 (b) The request for authorization to the prescriber shall include
16 all of the following:

17 (1) The cost savings for the purchaser, if any, that are a result
18 of the medication substitution.

19 (2) The difference, if any, in copayments or other out-of-pocket
20 costs paid by the patient in order to obtain the medication.

21 (3) The existence of any additional payments received by the
22 pharmacy benefits manager not reflected in the cost savings to the
23 purchaser.

24 (4) The circumstances, if any, under which the currently
25 prescribed medication will be covered.

26 (5) The circumstances and extent to which, if any, related
27 health care costs arising from the change in medications will be
28 compensated.

29 (6) Any known differences in potential effects on patient health
30 and safety, including side-effects.

31 (7) The name and title of the individual authorizing the change
32 if the authorization by the provider is given verbally.

33 (c) The pharmacy benefits manager shall not substitute a
34 medication for a currently prescribed medication unless the
35 pharmacy benefits manager communicates with the patient to
36 provide that patient or their representative the following
37 information:

38 (1) The proposed medication and the currently prescribed
39 medication.



1 (2) The difference in copayments or other out-of-pocket costs
2 paid by the patient, if any.

3 (3) Any known differences in potential effects on patient health
4 and safety, including side-effects, if any.

5 (4) The circumstances, if any, under which the currently
6 prescribed medication will be covered.

7 (5) The cost savings for the purchaser, taking into account all
8 discounts, rebates, or other payments that lower the cost of the
9 medication to the purchaser.

10 (6) The existence of any additional payments received by the
11 pharmacy benefits manager not reflected in the cost savings to the
12 purchaser.

13 (7) A toll-free telephone number to communicate with the
14 pharmacy benefits manager.

15 (8) The circumstances and the extent to which, if any, related
16 health care costs will be compensated

17 (d) Unless a prescribed drug is no longer on the purchaser's
18 formulary or the individual is unwilling to pay any higher
19 applicable copayment or other costs, the pharmacy benefits
20 manager shall cancel and reverse the medication substitution upon
21 written or verbal instructions from a prescriber or the individual.

22 (1) The pharmacy benefits manager shall maintain a toll-free
23 telephone number during normal business hours for a minimum of
24 eight hours per day Monday through Friday for prescribers and
25 patients.

26 (2) The pharmacy benefits manager shall not charge the
27 individual any additional copayments or fees related to the
28 replacement medication.

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



- 1 *150008. All disclosures made pursuant to this division shall*
- 2 *comply with the privacy standards of the federal Health Insurance*
- 3 *Portability and Accountability Act.*

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Attachment 2

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 746

VERSION: AS AMENDED JUNE 28, 2004

AUTHOR: MATTHEWS

SPONSOR: CA RETAILERS ASSOCIATION

RECOMMENDED POSITION: NONE

SUBJECT: DRUG MARKETING

Existing Law:

1) The Confidentiality of Medical Information Act (CMIA) generally prohibits the use of confidential medical information for marketing purposes. (Civil Code 56.10 (d))

2) The CMIA generally defines marketing as a communication about a product or service that encourages recipients of the communication to purchase or use the product or service. (Civil Code 56.05)

3) The CMIA exempts the following from the definition of marketing:

- a. Oral or written communication for which the communicator does not receive direct or indirect compensation from a third party.
- b. Communications made to enrollees of a health plan solely for the purpose of describing a provider's participation in that health plan.
- c. Communications made to enrollees of a health plan solely for the purpose of describing if, and the extent to which, a product or service is a covered benefit for the enrollee.
- d. Communications made to enrollees of a health plan describing the availability of more cost-effective pharmaceuticals.
- e. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, for a chronic and seriously debilitating or life-threatening condition.

4) Requires 14 point type be used in specified written patient communications. (Civil Code 56.10, 56.11, 56.21)

5) Defines "life-threatening" disease or condition as either or both:

- a. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.
- b. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival. (H&S 1367.21)

6) Defines "chronic and seriously debilitating" disease or condition to mean one that requires ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity. (H&S 1367.21)

This Bill:

- 1) Exempts from the definition of marketing in the Confidentiality of Medical Information Act any written communications to a patient provided to a pharmacy patient if the communication meets the following standards:
 - a. The communication is provided during a face to face interaction with the pharmacist.
 - b. The communication is made in conjunction with the dispensing of a drug to the patient.
 - c. The communication, in whole or in part, assists the pharmacy in meeting the goals of Section 601 of Public Law 104-180.
 - d. The majority of the communication describes the biochemical, pharmacological or other scientific or health related information related to a disease or health condition for which the dispensed drug is indicated, a treatment or therapy for that disease or health condition or the known sequelae of that disease or condition. (Civil Code 56.05)
- 2) Exempts from the definition of marketing in the CMLA communications that educate or advise individuals about treatment options for chronic, debilitating or life-threatening conditions and otherwise maintain the individual's adherence to prescribed therapy. (Civil Code 56.05)
- 3) Changes the specification of 14 point type for certain written notifications provided to patients to 12 point type. (Civil Code 56.10, 56.11, 56.21)
- 4) Declares that this is an urgency measure that would take effect immediately upon the Governor's signature.

Comment:

1) Author's Intent. Staff has not been able to contact the author prior to writing this analysis.

2) Public Law 104-180. According to the Food and Drug Administration (FDA), inadequate access to useful patient information is a major cause of inappropriate use of prescription medicines, leading to serious personal injury and costs to the health care system. In August 1995, the FDA published a proposed rule that aimed to increase the quality and quantity of written information about prescription medicines given to patients. The proposed rule encouraged the private sector to develop and distribute patient-oriented written information leaflets for all prescription drugs, and set targets for the distribution of these leaflets. In addition to setting target distribution goals by specific dates, the proposed rule set criteria by which written information would be judged to determine whether it was "useful" and should therefore count toward accomplishment of the target goals. The FDA's proposed goal for prescription drugs that did not require Medication Guides was that, by the year 2000, at least 75 percent of people receiving new prescriptions would receive useful written patient information, and that by 2006, 95 percent of people who receive new prescriptions would also receive useful written patient information.

However, in August 1996, the U.S. Congress passed Public Law 104-180 mandating that the private sector be given the opportunity to meet the distribution and quality goals proposed by the rulemaking on a voluntary basis. It also directed that the Secretary of Health and Human Services (the Secretary) facilitate the development of a long-range comprehensive action plan to meet these goals through private-sector efforts.

3) Written Drug Information. Historically, written patient information has either been required by regulation for particular prescription drug products or product classes, or has been distributed on a voluntary basis by the manufacturer. Since 1968, the FDA has occasionally required that prescription drug labeling written specifically for patients in non-technical language be distributed to patients whenever certain prescription drugs, or classes of prescription drugs, are dispensed. In the 1970s, the FDA began evaluating the usefulness of patient labeling for prescription drug products generally, and published a proposed rule to require written patient information for prescription drugs in 1979. In 1980, FDA published a final rule establishing requirements and procedures for the preparation and distribution of FDA-approved patient labeling for a large number of prescription drugs. FDA revoked those regulations in 1982 based, in part, on assurances by the private sector that the goals of the final rule would be met. A decision was made to allow voluntary private sector initiatives to proceed before a determination was made whether to impose a mandatory program.

4) Patient Compliance Programs. This bill exempts patient compliance programs operated by any organization (some pharmacy organizations operate patient compliance programs) from the marketing definition in the CMIA. Existing law only exempts disease management programs reference in the previous comment. Any entity with confidential patient information would be allowed to use that information to operate a patient compliance program for any individual with a chronic, debilitating or life-threatening condition. The bill would permit individuals to opt out of such programs and requires a written notice of that right.

5) History.

2004
 June 30 Re-referred to Com. on JUD.
 June 28 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on RLS.
 June 23 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on RLS.

2003
 Sept. 8 Read third time, amended, and re-referred to Com. on RLS.
 Aug. 20 Read second time. To third reading.
 Aug. 19 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
 Aug. 18 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on APPR.
 July 17 Read second time, amended, and re-referred to Com. on APPR.
 July 16 From committee: Amend, do pass as amended, and re-refer to Com. On APPR. (Ayes 5. Noes 0.).
 July 10 Joint Rule 61(a)(9) suspended. (Page 1731.)
 July 2 In committee: Hearing postponed by committee.
 June 5 Referred to Com. on B. & P.
 May 23 In Senate. Read first time. To Com. on RLS. for assignment.
 May 22 Read third time, passed, and to Senate. (Ayes 79. Noes 0. Page 1850.)
 May 21 Read second time. To third reading.
 May 20 Read second time and amended. Ordered returned to second reading.
 May 19 From committee: Amend, and do pass as amended. (Ayes 24. Noes 0.) (May 14).
 May 6 Re-referred to Com. on APPR.
 May 5 Read second time and amended.
 May 1 From committee: Amend, do pass as amended, and re-refer to Com. On APPR. (Ayes 10. Noes 0.) (April 29).
 Apr. 28 Re-referred to Com. on B. & P.
 Apr. 24 From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.

Apr. 8 In committee: Hearing postponed by committee.
Apr. 1 Re-referred to Com. on B. & P.
Mar. 28 From committee chair, with author's amendments: Amend, and re-refer to Com.
on B. & P. Read second time and amended.
Mar. 3 Referred to Com. on B. & P.
Feb. 20 From printer. May be heard in committee March 22.
Feb. 19 Read first time. To print.

AMENDED IN SENATE JUNE 28, 2004
AMENDED IN SENATE JUNE 23, 2004
AMENDED IN SENATE SEPTEMBER 8, 2003
AMENDED IN SENATE AUGUST 18, 2003
AMENDED IN SENATE JULY 17, 2003
AMENDED IN ASSEMBLY MAY 20, 2003
AMENDED IN ASSEMBLY MAY 5, 2003
AMENDED IN ASSEMBLY APRIL 24, 2003
AMENDED IN ASSEMBLY MARCH 28, 2003

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 746

Introduced by Assembly Member Matthews
(Principal coauthor: Assembly Member Chan)

February 19, 2003

An act to amend ~~Section 56.05~~ *Sections 56.05, 56.11, and 56.21* of the Civil Code, relating to medical information, *and declaring the urgency thereof, to take effect immediately.*

LEGISLATIVE COUNSEL'S DIGEST

AB 746, as amended, Matthews. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from

intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from the definition of marketing, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further exclude from that definition of marketing, a written communication that is provided by a pharmacy to a patient that meets specified conditions. *The bill would also make related changes.*

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

Vote: ~~majority~~ ^{2/3}. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

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

- 1 SECTION 1. Section 56.05 of the Civil Code is amended to
- 2 read:
- 3 56.05. For purposes of this part:
- 4 (a) “Authorization” means permission granted in accordance
- 5 with Section 56.11 or 56.21 for the disclosure of medical
- 6 information.
- 7 (b) “Authorized recipient” means any person who is
- 8 authorized to receive medical information pursuant to Section
- 9 56.10 or 56.20.
- 10 (c) “Contractor” means any person or entity that is a medical
- 11 group, independent practice association, pharmaceutical benefits
- 12 manager, or a medical service organization and is not a health care
- 13 service plan or provider of health care. “Contractor” does not
- 14 include insurance institutions as defined in subdivision (k) of
- 15 Section 791.02 of the Insurance Code or pharmaceutical benefits
- 16 managers licensed pursuant to the Knox-Keene Health Care



1 Service Plan Act of 1975 (Chapter 2.2 (commencing with Section
2 1340) of Division 2 of the Health and Safety Code).

3 (d) “Health care service plan” means any entity regulated
4 pursuant to the Knox-Keene Health Care Service Plan Act of 1975
5 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the
6 Health and Safety Code).

7 (e) “Licensed health care professional” means any person
8 licensed or certified pursuant to Division 2 (commencing with
9 Section 500) of the Business and Professions Code, the
10 Osteopathic Initiative Act or the Chiropractic Initiative Act, or
11 Division 2.5 (commencing with Section 1797) of the Health and
12 Safety Code.

13 (f) “Marketing” means to make a communication about a
14 product or service that encourages recipients of the
15 communication to purchase or use the product or service.

16 “Marketing” does not include any of the following:

17 (1) Communications made orally or in writing for which the
18 communicator does not receive direct or indirect remuneration,
19 including, but not limited to, gifts, fees, payments, subsidies, or
20 other economic benefits, from a third party for making the
21 communication.

22 (2) Communications made to current enrollees solely for the
23 purpose of describing a provider’s participation in an existing
24 health care provider network or health plan network of a
25 Knox-Keene licensed health plan to which the enrollees already
26 subscribe; communications made to current enrollees solely for
27 the purpose of describing if, and the extent to which, a product or
28 service, or payment for a product or service, is provided by a
29 provider, contractor, or plan or included in a plan of benefits of a
30 Knox-Keene licensed health plan to which the enrollees already
31 subscribe; or communications made to plan enrollees describing
32 the availability of more cost-effective pharmaceuticals.

33 (3) A written communication that is provided to a pharmacy
34 patient during a face-to-face interaction with a pharmacist or with
35 pharmacy personnel, in conjunction with the dispensing of a
36 prescription drug, if all of the following conditions are met:

37 (A) The communication, in whole or in part, assists the
38 pharmacy in meeting the goals of Section 601 of Public Law
39 104-180 with respect to the transmittal of useful information
40 regarding a prescription drug dispensed to the patient.



1 (B) The majority of the communication describes biochemical,
2 pharmacological, or other scientific or health information related
3 to a disease or health condition for which the dispensed drug is
4 indicated, a treatment or therapy for that disease or health
5 condition, or the known sequelae of that disease or condition.

6 (C) The pharmacist is available upon request to answer the
7 patient’s questions regarding the communication.

8 ~~(4) Communications that are tailored to the circumstances of a
9 particular individual to educate or advise the individual about
10 treatment options, and otherwise maintain the individual’s
11 adherence to a prescribed course of medical treatment, as provided
12 in Section 1399.901 of the Health and Safety Code, for a chronic~~

13 *(4) Communications that either (A) educate or advise the
14 individual about treatment options for a chronic and seriously
15 debilitating or life-threatening condition, as defined in
16 subdivisions (d) and (e) of Section 1367.21 of the Health and
17 Safety Code, ~~if~~ and otherwise maintain the individual’s adherence
18 to a prescribed course of medical treatment for the condition, or
19 (B) are part of a disease management program, as defined in
20 Section 1399.901 of the Health and Safety Code, if, under either
21 subparagraph (A) or (B), the health care provider, contractor, or
22 health plan receives direct or indirect remuneration, including, but
23 not limited to, gifts, fees, payments, subsidies, or other economic
24 benefits, from a third party for making the communication, ~~if~~ and
25 all of the following apply:*

26 ~~(A)–~~

27 *(i) The individual receiving the communication is notified in
28 the communication in typeface no smaller than ~~14-point~~ 12-point
29 type of the fact that the provider, contractor, or health plan has been
30 remunerated and the source of the remuneration.*

31 ~~(B)–~~

32 *(ii) The individual is provided the opportunity to opt out of
33 receiving future remunerated communications.*

34 ~~(C)–~~

35 *(iii) The communication contains instructions in typeface no
36 smaller than ~~14-point~~ 12-point type describing how the individual
37 can opt out of receiving further communications by calling a
38 toll-free number of the health care provider, contractor, or health
39 plan making the remunerated communications. No further
40 communication may be made to an individual who has opted out*



1 after 30 calendar days from the date the individual makes the opt
2 out request.

3 (g) “Medical information” means any individually
4 identifiable information, in electronic or physical form, in
5 possession of or derived from a provider of health care, health care
6 service plan, pharmaceutical company, or contractor regarding a
7 patient’s medical history, mental or physical condition, or
8 treatment. “Individually identifiable” means that the medical
9 information includes or contains any element of personal
10 identifying information sufficient to allow identification of the
11 individual, such as the patient’s name, address, electronic mail
12 address, telephone number, or social security number, or other
13 information that, alone or in combination with other publicly
14 available information, reveals the individual’s identity.

15 (h) “Patient” means any natural person, whether or not still
16 living, who received health care services from a provider of health
17 care and to whom medical information pertains.

18 (i) “Pharmaceutical company” means any company or
19 business, or an agent or representative thereof, that manufactures,
20 sells, or distributes pharmaceuticals, medications, or prescription
21 drugs. “Pharmaceutical company” does not include a
22 pharmaceutical benefits manager, as included in subdivision (c),
23 or a provider of health care.

24 (j) “Provider of health care” means any person licensed or
25 certified pursuant to Division 2 (commencing with Section 500)
26 of the Business and Professions Code; any person licensed
27 pursuant to the Osteopathic Initiative Act or the Chiropractic
28 Initiative Act; any person certified pursuant to Division 2.5
29 (commencing with Section 1797) of the Health and Safety Code;
30 any clinic, health dispensary, or health facility licensed pursuant
31 to Division 2 (commencing with Section 1200) of the Health and
32 Safety Code. “Provider of health care” does not include insurance
33 institutions as defined in subdivision (k) of Section 791.02 of the
34 Insurance Code.

35 *SEC. 2. Section 56.11 of the Civil Code is amended to read:*

36 56.11. Any person or entity that wishes to obtain medical
37 information pursuant to subdivision (a) of Section 56.10, other
38 than a person or entity authorized to receive medical information
39 pursuant to subdivision (b) or (c) of Section 56.10, shall obtain a
40 valid authorization for the release of this information.



1 An authorization for the release of medical information by a
2 provider of health care, health care service plan, pharmaceutical
3 company, or contractor shall be valid if it:

4 (a) Is handwritten by the person who signs it or is in a typeface
5 no smaller than ~~14-point~~ 12-point type.

6 (b) Is clearly separate from any other language present on the
7 same page and is executed by a signature which serves no other
8 purpose than to execute the authorization.

9 (c) Is signed and dated by one of the following:

10 (1) The patient. A patient who is a minor may only sign an
11 authorization for the release of medical information obtained by
12 a provider of health care, health care service plan, pharmaceutical
13 company, or contractor in the course of furnishing services to
14 which the minor could lawfully have consented under Part 1
15 (commencing with Section 25) or Part 2.7 (commencing with
16 Section 60).

17 (2) The legal representative of the patient, if the patient is a
18 minor or an incompetent. However, authorization may not be
19 given under this subdivision for the disclosure of medical
20 information obtained by the provider of health care, health care
21 service plan, pharmaceutical company, or contractor in the course
22 of furnishing services to which a minor patient could lawfully have
23 consented under Part 1 (commencing with Section 25) or Part 2.7
24 (commencing with Section 60).

25 (3) The spouse of the patient or the person financially
26 responsible for the patient, where the medical information is being
27 sought for the sole purpose of processing an application for health
28 insurance or for enrollment in a nonprofit hospital plan, a health
29 care service plan, or an employee benefit plan, and where the
30 patient is to be an enrolled spouse or dependent under the policy
31 or plan.

32 (4) The beneficiary or personal representative of a deceased
33 patient.

34 (d) States the specific uses and limitations on the types of
35 medical information to be disclosed.

36 (e) States the name or functions of the provider of health care,
37 health care service plan, pharmaceutical company, or contractor
38 that may disclose the medical information.

39 (f) States the name or functions of the persons or entities
40 authorized to receive the medical information.



1 (g) States the specific uses and limitations on the use of the
2 medical information by the persons or entities authorized to
3 receive the medical information.

4 (h) States a specific date after which the provider of health care,
5 health care service plan, pharmaceutical company, or contractor is
6 no longer authorized to disclose the medical information.

7 (i) Advises the person signing the authorization of the right to
8 receive a copy of the authorization.

9 *SEC. 3. Section 56.21 of the Civil Code is amended to read:*
10 56.21. An authorization for an employer to disclose medical
11 information shall be valid if it:

12 (a) Is handwritten by the person who signs it or is in typeface
13 no smaller than ~~14-point~~ 12-point type.

14 (b) Is clearly separate from any other language present on the
15 same page and is executed by a signature which serves no purpose
16 other than to execute the authorization.

17 (c) Is signed and dated by one of the following:

18 (1) The patient, except that a patient who is a minor may only
19 sign an authorization for the disclosure of medical information
20 obtained by a provider of health care in the course of furnishing
21 services to which the minor could lawfully have consented under
22 Part 1 (commencing with Section 25) or Part 2.7 (commencing
23 with Section 60) of Division 1.

24 (2) The legal representative of the patient, if the patient is a
25 minor or incompetent. However, authorization may not be given
26 under this subdivision for the disclosure of medical information
27 which pertains to a competent minor and which was created by a
28 provider of health care in the course of furnishing services to
29 which a minor patient could lawfully have consented under Part
30 1 (commencing with Section 25) or Part 2.7 (commencing with
31 Section 60) of Division 1.

32 (3) The beneficiary or personal representative of a deceased
33 patient.

34 (d) States the limitations, if any, on the types of medical
35 information to be disclosed.

36 (e) States the name or functions of the employer or person
37 authorized to disclose the medical information.

38 (f) States the names or functions of the persons or entities
39 authorized to receive the medical information.



1 (g) States the limitations, if any, on the use of the medical
2 information by the persons or entities authorized to receive the
3 medical information.

4 (h) States a specific date after which the employer is no longer
5 authorized to disclose the medical information.

6 (i) Advises the person who signed the authorization of the right
7 to receive a copy of the authorization.

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

12 *Because of the need to insure continued access to necessary*
13 *pharmacy services for California residents while maintaining*
14 *appropriate patient privacy standards, it is necessary for this act*
15 *to take effect immediately.*



Attachment 3

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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) History.

2004

June 23 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 5. Noes 2.).

June 15 In committee: Set first hearing. Failed passage. Reconsideration granted.

Apr. 13 From committee: Do pass, and re-refer to Com. on JUD. Re-referred. (Ayes 4. Noes 1.).

Mar. 22 In committee: Hearing postponed by committee.

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.

6) Support and Opposition

Support

State Attorney General's Office
 California Architects Board
 California Medical Board
 California Board of Accountancy
 California Board of Optometry
 California Board for Professional Engineers and Land Surveyors
 California State Board of Pharmacy
 Dental Board of California
 Board of Vocational Nursing and Psychiatric Technicians
 AARP California
 American Institute of Architects California Council
 Center for Public Interest Law, University of San Diego Law School
 California Public Interest Research Group (CalPIRG)
 Citizens Commission on Human Rights
 Congress of California Seniors
 Consumer Attorneys of California
 Consumers for Auto Reliability and Safety
 Consumer Federation of California
 Consumers Union
 The Fund for Animals

Opposition

Associated General Contractors of California (AGC)
 California Building Industry Association (CBIA)
 California Business Properties Association
 Consulting Engineers and Land Surveyors of California (CELSOC)
 Engineering Contractors' Association
 California Fence Contractors' Association
 Marin Builders' Exchange
 California Chapter of the American Fence Contractors' Association

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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 ~~is~~ defined in Section
20 23.7.



Attachment 4

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2184

VERSION: AS AMENDED MAY 27, 2004

AUTHOR: PLESCIA

SPONSOR: CARDINAL HEALTH

RECOMMENDED POSITION: SUPPORT

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)
- 3) Permits board inspectors to inspect licensees during normal business hours. (B&P 4008)

This Bill:

- 1) Permits board inspectors to enter a health facility in which an automated drug delivery system is located. (B&P 4008)
- 2) Permits a pharmacy to own and operate an automated drug delivery system (ADDS) in either a skilled nursing facility or an intermediate care facility. (B&P 4119.1)
- 3) 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)
- 4) Requires pharmacies operating an ADDS to segregate the records of acquisition and disposition for the ADDS. (B&P 4119.1)
- 5) Requires the operating pharmacy to provide training regarding the operation and use of the ADDS to pharmacy and facility personnel using the system. (B&P 4119.1)
- 6) Requires that the ADDS be operated in compliance with Section 1261.1 of the Health and Safety Code. (B&P 4119.1)
- 7) 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. According to the author, this bill would permit ADDS to be used in long-term care facilities for timely and accurate pharmaceutical care and treatment of patients. The author states that existing law prevents ADDS from being used for routine drug administration. Because of limitations in existing law, the author argues, two separate pharmacy systems are needed to serve long-term care facilities, which is not economically feasible, and therefore ADDS are not able to benefit providers and recipients of pharmacy services. The author asserts that the bill provides several new consumer protections to allow for greater oversight and utilization of ADDS in long-term care facilities.

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.

This bill would allow pharmacies operating an ADDS in these settings to provide full pharmacy services through the ADDS. The device would be under the control of a pharmacist who is responsible for evaluating orders and releasing drugs from the ADDS.

3) Recent Amendments. The bill was recently amended to address many concerns raised during the Legislation and Regulation Committee meeting. The committee recommended an oppose unless amended position at that time. The recent amendments require that the ADDS be owned and operated by a licensed pharmacy which eliminates many of the issues addressed by the committee. Staff is recommending a support position based on the new amendments.

4) 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.

5) History.

June 30	Read second time. To third reading. Ordered to Special Consent Calendar.
June 29	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
June 15	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 0.).
May 27	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.

May 20 Referred to Com. on B. & P.
 May 10 In Senate. Read first time. To Com. on RLS. for assignment.
 May 10 Read third time, passed, and to Senate. (Ayes 77. Noes 0. Page 5626.)
 May 3 Read second time. To Consent Calendar.
 Apr. 29 From committee: Do pass. To Consent Calendar. (April 28).
 Apr. 21 From committee: Do pass, and re-refer to Com. on APPR. With
 recommendation: To Consent Calendar. Re-referred. (Ayes 13. Noes 0.)
 (April 20).
 Apr. 19 Re-referred to Com. on B. & P.
 Apr. 16 From committee chair, with author's amendments: Amend, and re-refer to
 Com. on B. & P. Read second time and amended.
 Apr. 14 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred.
 (Ayes 16. Noes 0.) (April 13).
 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.

6) Support and Opposition

Support

Cardinal Health (sponsor)
 AmerisourceBergen (sponsor)
 California Healthcare Association
 California Medical Association
 California Association of Homes and Services for the Aging

Opposition

None

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AMENDED IN SENATE MAY 27, 2004

AMENDED IN ASSEMBLY APRIL 16, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 2184

Introduced by Assembly Member Plescia
(Coauthors: Assembly Members Shirley Horton and Wyland)

February 18, 2004

An act to amend Section 4008 of, and 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.

LEGISLATIVE COUNSEL'S DIGEST

AB 2184, as amended, 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. *When a pharmacist releases drugs for removal from the automated drug delivery system for administration to a patient, the bill would prohibit the automated drug delivery system from providing facility staff with access to drugs different from those released.* 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.

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: no. Fiscal committee: yes. State-mandated local program: yes.

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

- 1 SECTION 1. Section 4008 of the Business and Professions
- 2 Code is amended to read:
- 3 4008. (a) Except as provided by Section 159.5, the board
- 4 may employ inspectors of pharmacy. The inspectors, whether the
- 5 inspectors are employed by the board or the department’s Division
- 6 of Investigation, may inspect during business hours all
- 7 pharmacies, wholesalers, dispensaries, stores, or places where



1 drugs or devices are compounded, prepared, furnished, dispensed,
2 or stored.

3 (b) Notwithstanding subdivision (a), a pharmacy inspector
4 may inspect or examine a physician's office or clinic that does not
5 have a permit under Section 4180 or 4190 only to the extent
6 necessary to determine compliance with and to enforce either
7 Section 4080 or 4081.

8 (c) (1) (A) A pharmacy inspector employed by the board or in
9 the department's Division of Investigation shall have the authority,
10 as a public officer, to arrest, without warrant, any person whenever
11 the officer has reasonable cause to believe that the person to be
12 arrested has, in his or her presence, violated a provision of this
13 chapter or of Division 10 (commencing with Section 11000) of the
14 Health and Safety Code.

15 (B) If the violation is a felony, or if the arresting officer has
16 reasonable cause to believe that the person to be arrested has
17 violated any provision that is declared to be a felony, although no
18 felony has in fact been committed, he or she may make an arrest
19 although the violation or suspected violation did not occur in his
20 or her presence.

21 (2) In any case in which an arrest authorized by this subdivision
22 is made for an offense declared to be a misdemeanor, and the
23 person arrested does not demand to be taken before a magistrate,
24 the arresting inspector may, instead of taking the person before a
25 magistrate, follow the procedure prescribed by Chapter 5C
26 (commencing with Section 853.5) of Title 3 of Part 2 of the Penal
27 Code. That chapter shall thereafter apply with reference to any
28 proceeding based upon the issuance of a citation pursuant to this
29 authority.

30 (d) There shall be no civil liability on the part of, and no cause
31 of action shall arise against, a person, acting pursuant to
32 subdivision (a) within the scope of his or her authority, for false
33 arrest or false imprisonment arising out of an arrest that is lawful,
34 or that the arresting officer, at the time of the arrest, had reasonable
35 cause to believe was lawful. An inspector shall not be deemed an
36 aggressor or lose his or her right to self-defense by the use of
37 reasonable force to effect the arrest, to prevent escape, or to
38 overcome resistance.

39 (e) Any inspector may serve all processes and notices
40 throughout the state.



1 (f) A pharmacy inspector employed by the board may enter a
2 facility licensed pursuant to subdivision (c) or (d) of Section 1250
3 of the Health and Safety Code to inspect an automated drug
4 delivery system operated pursuant to Section 4119 or 4119.1.

5 SEC. 2. Section 4119.1 is added to the Business and
6 Professions Code, to read:

7 4119.1. (a) A pharmacy may provide pharmacy services to a
8 health facility licensed pursuant to subdivision (c), (d), or both, of
9 Section 1250 of the Health and Safety Code, through the use of an
10 automated drug delivery system that need not be located at the
11 same location as the pharmacy.

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

16 (c) (1) The pharmacy shall maintain records of the acquisition
17 and disposition of dangerous drugs and dangerous devices stored
18 in the automated drug delivery system separate from other
19 pharmacy records.

20 (2) The pharmacy shall own and operate the automated drug
21 delivery system.

22 (3) The pharmacy shall provide training regarding the
23 operation and use of the automated drug delivery system to both
24 pharmacy and health facility personnel using the system.

25 (4) The pharmacy shall operate the automated drug delivery
26 system in compliance with Section 1261.6 of the Health and Safety
27 Code.

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

33 (e) *Nothing in this section shall be construed to revise or limit*
34 *the use of automated drug delivery systems as permitted by the*
35 *board in any licensed health facility other than a facility defined*
36 *in subdivision (c) or (d), or both, of Section 1250 of the Health and*
37 *Safety Code.*

38 SEC. 3. Section 1261.5 of the Health and Safety Code is
39 amended to read:



1 1261.5. (a) The number of oral dosage form or suppository
2 form drugs provided by a pharmacy to a health facility licensed
3 pursuant to subdivision (c) or (d), or both (c) and (d), of Section
4 1250 for storage in a secured emergency supplies container,
5 pursuant to Section 4119 of the Business and Professions Code,
6 shall be limited to 24. The State Department of Health Services
7 may limit the number of doses of each drug available to not more
8 than four doses of any separate drug dosage form in each
9 emergency supply.

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

17 SEC. 4. Section 1261.6 of the Health and Safety Code is
18 amended to read:

19 1261.6. (a) (1) For purposes of this section and Section
20 1261.5, an “automated drug delivery system” means a mechanical
21 system that performs operations or activities, other than
22 compounding or administration, relative to the storage,
23 dispensing, or distribution of drugs. An automated drug delivery
24 system shall collect, control, and maintain all transaction
25 information to accurately track the movement of drugs into and out
26 of the system for security, accuracy, and accountability.

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

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

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

38 (d) (1) The facility and the pharmacy shall develop and
39 implement written policies and procedures to ensure safety,
40 accuracy, accountability, security, patient confidentiality, and



1 maintenance of the quality, potency, and purity of stored drugs.
2 Policies and procedures shall define access to the automated drug
3 delivery system and limits to access to equipment and drugs.

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

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

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

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

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

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

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

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

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



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

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

7 (6) *When a pharmacist releases drugs for removal from the*
8 *automated drug delivery system pursuant to paragraph (2), the*
9 *automated drug delivery system shall not provide facility staff with*
10 *access to drugs different from those released.*

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

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

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

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

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

35 (i) Drugs dispensed from an automated drug delivery system
36 that meets the requirements of this section shall not be subject to
37 the labeling requirements of Section 4076 of the Business and
38 Professions Code or Section 111480 of this code if the drugs to be
39 placed into the automated drug delivery system are in unit dose
40 packaging or unit of use and if the information required by Section



1 4076 of the Business and Professions Code and Section 111480 of
2 this code is readily available at the time of drug administration.
3 SEC. 5. No reimbursement is required by this act pursuant to
4 Section 6 of Article XIII B of the California Constitution because
5 the only costs that may be incurred by a local agency or school
6 district will be incurred because this act creates a new crime or
7 infraction, eliminates a crime or infraction, or changes the penalty
8 for a crime or infraction, within the meaning of Section 17556 of
9 the Government Code, or changes the definition of a crime within
10 the meaning of Section 6 of Article XIII B of the California
11 Constitution.

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Attachment 5

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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.

June 30	Read second time. To third reading. Ordered to Special Consent Calendar.
June 29	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
June 15	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 6. Noes 0.).
May 13	Referred to Com. on B. & P.
May 3	In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 29	Read third time, passed, and to Senate. (Ayes 72. Noes 0. Page 5433.)
Apr. 26	Read second time. To Consent Calendar.
Apr. 22	From committee: Do pass. To Consent Calendar. (April 21).
Apr. 14	From committee: Do pass, and re-refer to Com. on APPR. With recommendation: To Consent Calendar. Re-referred. (Ayes 13. Noes 0.) (April 13).
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.

6) Support and Opposition.

SUPPORT

Kaiser Permanente (source)
California Association of Nurse Practitioners (CANP)
California Association of Physician Groups (CAPG)
California Medical Association (CMA)
California Pharmacists Association (CPhA)
California Retailers Association (CRA)
California Society of Health-System Pharmacists (CSHP)
California State Board of Pharmacy

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:

1 SECTION 1. Section 4040 of the Business and Professions
2 Code is amended to read:
3 4040. (a) "Prescription" means an oral, written, or
4 electronic transmission order that is both of the following:
5 (1) Given individually for the person or persons for whom
6 ordered that includes all of the following:
7 (A) The name or names and address of the patient or patients.
8 (B) The name and quantity of the drug or device prescribed and
9 the directions for use.
10 (C) The date of issue.
11 (D) Either rubber stamped, typed, or printed by hand or typeset,
12 the name, address, and telephone number of the prescriber, his or
13 her license classification, and his or her federal registry number,
14 if a controlled substance is prescribed.
15 (E) A legible, clear notice of the condition for which the drug
16 is being prescribed, if requested by the patient or patients.
17 (F) If in writing, signed by the prescriber issuing the order, or
18 the certified nurse-midwife, nurse practitioner, or physician
19 assistant who issues a drug order pursuant to Section 2746.51,
20 2836.1, or 3502.1, respectively, or the pharmacist who issues a
21 drug order pursuant to either subparagraph (D) of paragraph (4) of,
22 or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision
23 (a) of Section 4052.



1 (2) Issued by a physician, dentist, optometrist, podiatrist, or
2 veterinarian or, if a drug order is issued pursuant to Section
3 2746.51, 2836.1, or 3502.1, by a certified nurse-midwife, nurse
4 practitioner, or physician assistant licensed in this state, or
5 pursuant to either subparagraph (D) of paragraph (4) of, or clause
6 (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of
7 Section 4052 by a pharmacist licensed in this state.

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

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

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

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

35 SEC. 2. Section 4052 of the Business and Professions Code
36 is amended to read:

37 4052. (a) Notwithstanding any other provision of law, a
38 pharmacist may:

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



- 1 (2) Transmit a valid prescription to another pharmacist.
- 2 (3) Administer, orally or topically, drugs and biologicals
- 3 pursuant to a prescriber's order.
- 4 (4) Perform the following procedures or functions in a licensed
- 5 health care facility in accordance with policies, procedures, or
- 6 protocols developed by health professionals, including physicians,
- 7 pharmacists, and registered nurses, with the concurrence of the
- 8 facility administrator:
 - 9 (A) Ordering or performing routine drug therapy-related
 - 10 patient assessment procedures including temperature, pulse, and
 - 11 respiration.
 - 12 (B) Ordering drug therapy-related laboratory tests.
 - 13 (C) Administering drugs and biologicals by injection pursuant
 - 14 to a prescriber's order (the administration of immunizations under
 - 15 the supervision of a prescriber may also be performed outside of
 - 16 a licensed health care facility).
 - 17 (D) Initiating or adjusting the drug regimen of a patient
 - 18 pursuant to an order or authorization made by the patient's
 - 19 prescriber and in accordance with the policies, procedures, or
 - 20 protocols of the licensed health care facility.
- 21 (5) (A) Perform the following procedures or functions as part
- 22 of the care provided by a health care facility, a licensed home
- 23 health agency, a licensed clinic in which there is a physician
- 24 oversight, a provider who contracts with a licensed health care
- 25 service plan with regard to the care or services provided to the
- 26 enrollees of that health care service plan, or a physician, in
- 27 accordance, as applicable, with policies, procedures, or protocols
- 28 of that facility, the home health agency, the licensed clinic, the
- 29 health care service plan, or that physician, in accordance with
- 30 subparagraph (C):
 - 31 (i) Ordering or performing routine drug therapy-related patient
 - 32 assessment procedures including temperature, pulse, and
 - 33 respiration.
 - 34 (ii) Ordering drug therapy-related laboratory tests.
 - 35 (iii) Administering drugs and biologicals by injection pursuant
 - 36 to a prescriber's order (the administration of immunizations under
 - 37 the supervision of a prescriber may also be performed outside of
 - 38 a licensed health care facility).
 - 39 (iv) Initiating or adjusting the drug regimen of a patient
 - 40 pursuant to a specific written order or authorization made by the



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

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

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

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

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

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

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

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



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

4 (8) (A) Furnish emergency contraception drug therapy in
5 accordance with either of the following:

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

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

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

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



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

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

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

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

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

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

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



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

3 SEC. 3. Section 4060 of the Business and Professions Code
4 is amended to read:

5 4060. No person shall possess any controlled substance,
6 except that furnished to a person upon the prescription of a
7 physician, dentist, podiatrist, optometrist, or veterinarian, or
8 furnished pursuant to a drug order issued by a certified
9 nurse-midwife pursuant to Section 2746.51, a nurse practitioner
10 pursuant to Section 2836.1, a physician assistant pursuant to
11 Section 3502.1, or a pharmacist pursuant to either subparagraph
12 (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of
13 paragraph (5) of, subdivision (a) of Section 4052. This section
14 shall not apply to the possession of any controlled substance by a
15 manufacturer, wholesaler, pharmacy, pharmacist, physician,
16 podiatrist, dentist, optometrist, veterinarian, certified
17 nurse-midwife, nurse practitioner, or physician assistant, when in
18 stock in containers correctly labeled with the name and address of
19 the supplier or producer.

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

23 SEC. 4. Section 4076 of the Business and Professions Code
24 is amended to read:

25 4076. (a) A pharmacist shall not dispense any prescription
26 except in a container that meets the requirements of state and
27 federal law and is correctly labeled with all of the following:

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



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

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

4 (3) The name of the patient or patients.

5 (4) The name of the prescriber or, if applicable, the name of the
6 certified nurse-midwife who functions pursuant to a standardized
7 procedure or protocol described in Section 2746.51, the nurse
8 practitioner who functions pursuant to a standardized procedure
9 described in Section 2836.1, or protocol, the physician assistant
10 who functions pursuant to Section 3502.1, or the pharmacist who
11 functions pursuant to a policy, procedure, or protocol pursuant to
12 either subparagraph (D) of paragraph (4) of, or clause (iv) of
13 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
14 4052.

15 (5) The date of issue.

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

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

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

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

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

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

29 (i) Prescriptions dispensed by a veterinarian.

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

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

36 (B) This paragraph applies to outpatient pharmacies only.

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



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

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

11 (c) If a pharmacist dispenses a dangerous drug or device in a
12 facility licensed pursuant to Section 1250 of the Health and Safety
13 Code, it is not necessary to include on individual unit dose
14 containers for a specific patient, the name of the certified
15 nurse-midwife who functions pursuant to a standardized
16 procedure or protocol described in Section 2746.51, the nurse
17 practitioner who functions pursuant to a standardized procedure
18 described in Section 2836.1, or protocol, the physician assistant
19 who functions pursuant to Section 3502.1, or the pharmacist who
20 functions pursuant to a policy, procedure, or protocol pursuant to
21 either subparagraph (D) of paragraph (4) of, or clause (iv) of
22 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
23 4052.

24 (d) If a pharmacist dispenses a prescription drug for use in a
25 facility licensed pursuant to Section 1250 of the Health and Safety
26 Code, it is not necessary to include the information required in
27 paragraph (11) of subdivision (a) when the prescription drug is
28 administered to a patient by a person licensed under the Medical
29 Practice Act (Chapter 5 (commencing with Section 2000)), the
30 Nursing Practice Act (Chapter 6 (commencing with Section
31 2700)), or the Vocational Nursing Practice Act (Chapter 6.5
32 (commencing with Section 2840)), who is acting within his or her
33 scope of practice.

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

36 4111. (a) Except as otherwise provided in subdivision (b),
37 (d), or (e), the board shall not issue or renew a license to conduct
38 a pharmacy to any of the following:



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

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

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

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

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

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

25 (e) Subdivision (a) shall not preclude the issuance of a new or
26 renewal license for a pharmacy to be owned or owned and operated
27 by a pharmacist authorized to issue a drug order pursuant to
28 subparagraph (D) of paragraph (4) of, or clause (iv) of
29 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
30 4052.

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

33 11150. No person other than a physician, dentist, podiatrist, or
34 veterinarian, or pharmacist acting within the scope of a project
35 authorized under Article 1 (commencing with Section 128125) of
36 Chapter 3 of Part 3 of Division 107 or within the scope of either
37 subparagraph (D) of paragraph (4) of, or clause (iv) of
38 subparagraph (A) of paragraph (5) of, subdivision (a) of Section
39 4052 of the Business and Professions Code, a registered nurse
40 acting within the scope of a project authorized under Article 1



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

13 SEC. 7. No reimbursement is required by this act pursuant to
14 Section 6 of Article XIII B of the California Constitution because
15 the only costs that may be incurred by a local agency or school
16 district will be incurred because this act creates a new crime or
17 infraction, eliminates a crime or infraction, or changes the penalty
18 for a crime or infraction, within the meaning of Section 17556 of
19 the Government Code, or changes the definition of a crime within
20 the meaning of Section 6 of Article XIII B of the California
21 Constitution.



Attachment 6

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 2682

VERSION: AS AMENDED JULY 6, 2004

AUTHOR: NEGRETE MCLEOD

SPONSOR: JAM PHARMACEUTICALS

RECOMMENDED POSITION: SUPPORT

SUBJECT: NON-RESIDENT 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 out-of-state distributors to meet the same requirements as resident wholesalers. (B&P 4161)
- 2) Renames "out-of-state distributors" as "non-resident wholesalers" effective January 1, 2006. (B&P 4161)
- 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)
- 4) Provides that the bill shall only become effective if Senate Bill 1307 (Figueroa) becomes effective.

Comment:

1) Author's Intent. According to the author, the bill is intended to tighten the stream of commerce in prescription drugs where fraud and counterfeit drugs exist, by requiring all out-of-state secondary drug wholesalers to obtain a California license from the board. Doing so also builds upon and is consistent with the provisions of the federal regulatory scheme for drug wholesalers.

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 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) Amendments. The bill was amended to incorporate the non-resident wholesaler provisions in Senate Bill 1307.

5) History.

July 6	Read second time, amended, and re-referred to Com. on APPR.
July 2	From committee: Amend, do pass as amended, and re-refer to Com. On APPR. (Ayes 8. Noes 3.).
June 23	Re-referred to Com. on H. & H.S.
June 22	From committee: Do pass, and re-refer to Com. on RLS. Re-referred. (Ayes 4. Noes 2.).
June 17	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.
June 3	Referred to Coms. on B. & P. and RLS.
May 18	In Senate. Read first time. To Com. on RLS. for assignment.
May 17	Read third time, passed, and to Senate. (Ayes 54. Noes 26. Page 5733.)
May 10	Read second time. To third reading.
May 6	From committee: Do pass. (Ayes 18. Noes 1.) (May 5).
Apr. 21	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 10. Noes 2.) (April 20).
Apr. 14	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 15. Noes 1.) (April 13).
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 SENATE JULY 6, 2004

AMENDED IN SENATE JUNE 17, 2004

CALIFORNIA LEGISLATURE—2003–04 REGULAR SESSION

ASSEMBLY BILL

No. 2682

Introduced by Assembly Member Negrete McLeod

February 20, 2004

An act to amend, repeal, and add Section 4043 of, to add and repeal Section 4162.5 of, and to repeal and add Section 4161 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

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

The Pharmacy Act provides for licensing and regulation of manufacturers and wholesalers of prescription drugs and devices by the California State Board of Pharmacy and makes a violation of its provisions a crime. Existing law requires out-of-state manufacturers and 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.

This bill would delete these requirements applicable to out-of-state manufacturers and wholesalers of prescription drugs and devices *on January 1, 2006*. The bill would instead, on and after January 1, 2006, require a nonresident wholesaler, as defined, that ships, mails, or delivers dangerous drugs or dangerous devices in this state to obtain a

nonresident wholesaler’s license from the board. The bill would, on and after January 1, 2006, require, until January 1, 2011, a nonresident wholesaler to submit a surety bond of \$100,000, or an equivalent means of security for each place of business owned or operated by the nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in California. Because this bill would require additional persons to pay 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.

This bill would become operative only if SB 1307 is also enacted and becomes effective on or before January 1, 2005.

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 4043 of the Business and Professions
 2 Code is amended to read:
 3 4043. (a) “Wholesaler” means and includes every person
 4 who acts as a wholesale merchant, broker, jobber, customs broker,
 5 reverse distributor, ~~or agent~~ *agent, or out-of-state distributor*, who
 6 sells for resale, or negotiates for distribution, or takes possession
 7 of, any drug or device included in Section 4022. Unless otherwise
 8 authorized by law, a wholesaler may not store, warehouse, or
 9 authorize the storage or warehousing of drugs with any person or
 10 at any location not licensed by the board.
 11 ~~(b) This section shall become inoperative and is repealed on~~
 12 ~~January 1, 2006.~~



1 (b) *This section shall remain in effect only until January 1,*
2 *2006, and as of that date is repealed, unless a later enacted statute,*
3 *that is enacted before January 1, 2006, deletes or extends that date.*

4 SEC. 2. Section 4043 is added to the Business and Professions
5 Code, to read:

6 4043. (a) “Wholesaler” means and includes a person who
7 acts as a wholesale merchant, broker, jobber, customs broker,
8 reverse distributor, ~~or agent, including agent,~~ or a nonresident
9 wholesaler, who sells for resale, or negotiates for distribution, or
10 takes possession of, any drug or device included in Section 4022.
11 Unless otherwise authorized by law, a wholesaler may not store,
12 warehouse, or authorize the storage or warehousing of drugs with
13 any person or at any location not licensed by the board.

14 (b) This section shall become operative January 1, 2006.

15 SEC. 3. Section 4161 of the Business and Professions Code
16 is repealed.

17 SEC. 4. *Section 4161 is added to the Business and Professions*
18 *Code, to read:*

19 4161. (a) *A person located outside this state that ships, mails,*
20 *or delivers dangerous drugs or dangerous devices into this state at*
21 *wholesale shall be considered an out-of-state distributor.*

22 (b) *An out-of-state distributor shall be licensed by the board*
23 *prior to shipping, mailing, or delivering dangerous drugs or*
24 *dangerous devices to a site located in this state.*

25 (c) *A separate license shall be required for each place of*
26 *business owned or operated by an out-of-state distributor from or*
27 *through which dangerous drugs or dangerous devices are shipped,*
28 *mailed, or delivered to a site located in this state. A license shall*
29 *be renewed annually and shall not be transferable.*

30 (d) *The following information shall be reported, in writing, to*
31 *the board at the time of initial application for licensure by a*
32 *nonresident wholesaler, on renewal of an out-of-state distributor*
33 *license, or within 30 days of a change in the following information:*

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

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

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

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



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

4 (f) An out-of-state distributor shall comply with all directions
5 and requests for information from the regulatory or licensing
6 agency of the state in which it is licensed, as well as with all
7 requests for information made by the board.

8 (g) An out-of-state distributor wholesaler shall maintain
9 records of dangerous drugs and dangerous devices sold, traded, or
10 transferred to persons in this state, so that the records are in a
11 readily retrievable form.

12 (h) An out-of-state distributor shall at all times maintain a
13 valid, unexpired license, permit, or registration to conduct the
14 business of the wholesaler in compliance with the laws of the state
15 in which it is a resident. An application for an out-of-state
16 distributor license in this state shall include a license verification
17 from the licensing authority in the applicant's state of residence.

18 (i) The board may not issue or renew an out-of-state distributor
19 license until the out-of-state distributor identifies an
20 exemptee-in-charge and notifies the board in writing of the identity
21 and license number of the exemptee-in-charge.

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

28 (k) The board may issue a temporary license, upon conditions
29 and for periods of time as the board determines to be in the public
30 interest. A temporary license fee shall be fixed by the board at an
31 amount not to exceed the annual fee for renewal of a license to
32 conduct business as an out-of-state distributor.

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

35 (m) A pharmacy that meets the requirements of Section 4001.2,
36 as added by Senate Bill 1149 of the 2003–04 Regular Session,
37 including any subsequent amendment thereto, shall not be
38 considered an out-of-state distributor for purposes of this section.

39 (n) This section shall remain in effect only until January 1,
40 2006, and as of that date is repealed, unless a later enacted statute,



1 *that is enacted before January 1, 2006, deletes or extends that date.*
2

3 SEC. 4.5. Section 4161 is added to the Business and
4 Professions Code, to read:

5 4161. (a) A person located outside this state that ships, mails,
6 or delivers dangerous drugs or dangerous devices into this state
7 shall be considered a nonresident wholesaler.

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

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

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

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

21 (2) Its principal corporate officers, as specified by the board, if
22 any.

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

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

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

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

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

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

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

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

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

15 (k) The board may issue a temporary license, upon conditions
16 and for periods of time as the board determines to be in the public
17 interest. A temporary license fee shall be fixed by the board at an
18 amount not to exceed the annual fee for renewal of a license to
19 conduct business as a nonresident wholesaler.

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

22 (m) *A pharmacy that meets the requirements of Section 4001.2,*
23 *as added by Senate Bill 1149 of the 2003–04 Regular Session,*
24 *including any subsequent amendment thereto, shall not be*
25 *considered a nonresident wholesaler for purposes of this section.*

26 (n) This section shall become operative January 1, 2006.

27 SEC. 5. Section 4162.5 is added to the Business and
28 Professions Code, to read:

29 4162.5. (a) (1) An applicant for the issuance or renewal of a
30 nonresident wholesaler license shall submit a surety bond of one
31 hundred thousand dollars (\$100,000) for each site to be licensed,
32 or other equivalent means of security acceptable to the board, such
33 as an irrevocable letter of credit, or a deposit in a trust account or
34 financial institution, payable to the Pharmacy Board Contingent
35 Fund. The purpose of the surety bond is to secure payment of any
36 administrative fine imposed by the board and any cost recovery
37 ordered pursuant to Section 125.3.

38 (2) For purpose of paragraph (1), the board may accept a surety
39 bond less than one hundred thousand dollars (\$100,000) if the
40 annual gross receipts of the previous tax year for the nonresident



1 wholesaler is ten million dollars (\$10,000,000) or less in which the
2 surety bond shall be twenty-five thousand dollars (\$25,000).

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

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

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

15 (d) This section shall become operative on January 1, 2006, and
16 shall become inoperative and is repealed on, January 1, 2011,
17 unless a later enacted statute, that is enacted before January 1,
18 2011, deletes or extends those dates.

19 SEC. 6. This act shall become operative only if Senate Bill
20 1307 is also enacted and becomes effective on or before January
21 1, 2005.

22 SEC. 7. No reimbursement is required by this act pursuant to
23 Section 6 of Article XIII B of the California Constitution because
24 the only costs that may be incurred by a local agency or school
25 district will be incurred because this act creates a new crime or
26 infraction, eliminates a crime or infraction, or changes the penalty
27 for a crime or infraction, within the meaning of Section 17556 of
28 the Government Code, or changes the definition of a crime within
29 the meaning of Section 6 of Article XIII B of the California
30 Constitution.



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Attachment 7

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 1159

VERSION: AS AMENDED JULY 2, 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. This authority is subject to a January 1, 2009 sunset provision. (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. This provision is subject to a January 1, 2009 sunset provision. (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. This provision is subject to a January 1, 2009 sunset provision. (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 State Department of Health Services.
 - b. provide patients with information on local drug treatment 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) Requires the Department of Health Services to evaluate the impact of this bill on report back to the Legislature on or before January 15, 2008. (H&S 121285)
- 8) Requires the Department of Health Services to convene an advisory panel including representation from the board. (H&S 121285)
- 9) Prohibits the disposal of a needle on a playground, beach, park, or school. (B&P 4147)
- 10) 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)
- 11) Requires the passage and signing of Senate Bill 1362 to become effective.

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:

- o Needle sharing among injection drug users has slightly declined since ESAP's inception.

- o More and more pharmacies and drug users are participating in the program, though greater awareness is needed.
- o Discarded needles or syringes have not been found in higher quantities on the street as a result of this program.
- o No increases in drug-related criminal arrests have occurred since this program began.
- o 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 on 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) SB 1362 (Figueroa). This bill authorizes the establishment of household hazardous waste disposal programs for sharps waste such as needles and syringes.

7) History

July 2	Read second time. Amended. To second reading.
July 1	From committee: Do pass as amended. (Ayes 15. Noes 4.)
June 23	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 13. Noes 4.) Re-referred to Com. on APPR.
June 21	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
June 15	Set, first hearing. Failed passage in committee. Reconsideration granted.
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.

8) Support and Opposition

Support

Drug Alliance Policy Network (co-sponsor)
 San Francisco AIDS Foundation (co-sponsor)
 AIDS Project Los Angeles
 AIDS Healthcare Foundation
 Alameda County Board of Supervisors
 American Civil Liberties Union
 American Liver Foundation
 Being Alive Los Angeles
 California Opioid Maintenance Providers
 California Medical Association
 California National Organization for Women
 California Nurses Association
 California Pharmacists Association
 California Primary Care Association
 California Public Defenders Association
 California Society of Addiction Medicine
 City and County of San Francisco
 County Alcohol and Drug Program Administrators Association of California
 Diabetes Coalition of California
 Equality California
 Gray Panthers
 Harm Reduction Coalition
 Health Officers Association of California
 Kaiser Permanente Medical Care Program
 Lambda Letters Project
 Marin Treatment Center
 Santa Clara County Board of Supervisors
 Sierra Club California
 Waste Management
 Several individuals

Opposition

California Narcotic Officers' Association
 California Peace Officers' Association
 Capitol Resource Institute
 County of San Diego
 Responsible Citizens, Inc.

AMENDED IN ASSEMBLY JULY 2, 2004
AMENDED IN ASSEMBLY JUNE 21, 2004
AMENDED IN SENATE MAY 11, 2004
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, *Koretz*, Laird, Levine, and Vargas)

February 2, 2004

An act to amend 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, 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 State Department of Health Services, thereby imposing a state-mandated local program~~ *a pharmacy that participates in the Disease and Demonstration Project to comply with specified requirements, including registering with the State Department of Health Services.* The bill would require 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. 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 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. 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) 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.~~

(4) 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.

(5) This bill would make the operation of its provisions contingent upon the enactment of SB 1362.

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

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

1 SECTION 1. Section 4145 of the Business and Professions
2 Code is amended to read:

3 4145. (a) Notwithstanding any other provision of law, a
4 pharmacist or physician may, without a prescription or a permit,
5 furnish hypodermic needles and syringes for human use, and a
6 person may, without a prescription or license, obtain hypodermic
7 needles and syringes from a pharmacist or physician for human
8 use, if one of the following requirements is met:

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

13 (2) For the period commencing January 1, 2005, and ending
14 December 31, 2008, a pharmacist may furnish or sell 10 or fewer
15 hypodermic needles or syringes at any one time to a person 18
16 years of age or older if the pharmacist works for a pharmacy that
17 is registered for the Disease Prevention Demonstration Project
18 pursuant to Chapter 13.5 (commencing with Section 121285) of
19 Part 4 of Division 105 of the Health and Safety Code and the
20 pharmacy complies with the provisions of that chapter.



1 (b) Notwithstanding any other provision of law, a pharmacist,
2 veterinarian, or person licensed pursuant to Section 4141 may,
3 without a prescription or license, furnish hypodermic needles and
4 syringes for use on animals, and a person may, without a
5 prescription or license, obtain hypodermic needles and syringes
6 from a pharmacist, veterinarian, or person licensed pursuant to
7 Section 4141 for use on animals, providing that no needle or
8 syringe shall be furnished to a person who is unknown to the
9 furnisher and unable to properly establish his or her identity.

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

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

14 4147. (a) For the purposes of this section, “playground”
15 means any park or outdoor recreational area specifically designed
16 to be used by children that has play equipment installed or any
17 similar facility located on public or private school grounds or
18 county parks.

19 (b) Any hypodermic needle or syringe that is to be disposed of,
20 shall be contained, treated, and disposed of, pursuant to Part 14
21 (commencing with Section 117600) of Division 104 of the Health
22 and Safety Code.

23 (c) It is unlawful to discard or dispose of a hypodermic needle
24 or syringe upon the grounds of a playground, beach, park, or any
25 public or private elementary, vocational, junior high, or high
26 school.

27 (d) A person who knowingly violates subdivision (c) is guilty
28 of a misdemeanor, and upon conviction shall be punished by a fine
29 of not less than two hundred dollars (\$200) and not more than two
30 thousand dollars (\$2,000), or by imprisonment in a county jail for
31 up to six months, or by both that fine and imprisonment.

32 (e) Subdivision (c) does not apply to the containment,
33 treatment, and disposal of medical sharps waste from medical care
34 or first aid services rendered on school grounds, nor to the
35 containment, treatment, and disposal of hypodermic needles or
36 syringes used for instructional or educational purposes on school
37 grounds.

38 SEC. 4. Section 11364 of the Health and Safety Code is
39 amended to read:



1 11364. (a) It is unlawful to possess an opium pipe or any
2 device, contrivance, instrument, or paraphernalia used for
3 unlawfully injecting or smoking (1) a controlled substance
4 specified in subdivision (b), (c), or (e), or paragraph (1) of
5 subdivision (f) of Section 11054, specified in paragraph (14), (15),
6 or (20) of subdivision (d) of Section 11054, specified in
7 subdivision (b) or (c) of Section 11055, or specified in paragraph
8 (2) of subdivision (d) of Section 11055, or (2) a controlled
9 substance which is a narcotic drug classified in Schedule III, IV,
10 or V.

11 (b) This section shall not apply to hypodermic needles or
12 syringes that have been containerized for safe disposal in a
13 container that meets state and federal standards for disposal of
14 sharps waste.

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

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

22

23 CHAPTER 13.5. DISEASE PREVENTION DEMONSTRATION PROJECT

24

25 121285. (a) The Disease Prevention Demonstration Project,
26 a collaboration between pharmacies and local and state health
27 officials, is hereby authorized for the purpose of evaluating the
28 long-term desirability of allowing licensed pharmacists to furnish
29 or sell nonprescription hypodermic needles or syringes to prevent
30 the spread of blood-borne pathogens, including HIV and hepatitis
31 C.

32 (b) The State Department of Health Services shall evaluate the
33 effects of allowing pharmacists to furnish or sell a limited number
34 of hypodermic needles or syringes without prescription, and
35 provide a report to the Governor and the Legislature on or before
36 January 15, 2008. The report shall include, but need not be limited
37 to, the effect of nonprescription hypodermic needle or syringe sale
38 on all of the following:

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



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

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

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

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

8 (6) Rates of injection of illegal drugs.

9 (c) The State Department of Health Services shall convene an
10 uncompensated evaluation advisory panel comprised of all of the
11 following: two or more specialists in the control of infectious
12 diseases; one or more representatives of the California State Board
13 of Pharmacy; one or more representatives of independent
14 pharmacies; one or more representatives of chain pharmacy
15 owners; one or more representatives of law enforcement
16 executives, such as police chiefs and sheriffs; one or more
17 representatives of rank and file law enforcement officers; a
18 specialist in hazardous waste management from the State
19 Department of Health Services; one or more representatives of the
20 waste management industry; and one or more representatives of
21 local health officers.

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

25 (1) Register with the ~~local health department~~ *State Department*
26 *of Health Services* by providing a contact name and related
27 information, and certify that it will provide, at the time of
28 furnishing or sale of hypodermic needles or syringes, written
29 information or verbal counseling on all of the following:

30 (A) ~~Local options for accessing~~ *How to access* drug treatment.

31 (B) ~~Local options for accessing~~ *How to access* testing and
32 treatment for HIV and hepatitis C.

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

38 (C) *How to safely dispose of sharps waste.*



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

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

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

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

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

16 ~~(e) Local health departments~~ *The State Department of Health*
17 *Services* shall be responsible for all of the following:

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

21 ~~(2) Providing pharmacies with written information that can be~~
22 ~~reproduced that is~~

23 (2) *Making available to pharmacies written information that*
24 *may be provided or reproduced* to be provided in writing or orally
25 by the pharmacy at the time of furnishing or the sale of
26 nonprescription hypodermic needles or syringes, including all of
27 the following:

28 (A) ~~Local options for accessing~~ *How to access* drug treatment.

29 (B) ~~Local options for accessing~~ *How to access* testing and
30 treatment for HIV and hepatitis C.

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

36 ~~(3) Cooperating with the State Department of Health Services~~
37 ~~in the collection and analysis of data relative to the evaluation of~~
38 ~~the Disease Prevention Demonstration Project, as needed.~~

39 (f) As used in this chapter, “sharps waste” means hypodermic
40 needles, syringes, and lancets.



1 ~~SEC. 6.—No reimbursement is required by this act pursuant to~~
 2 ~~Section 6 of Article XIII B of the California Constitution for~~
 3 ~~certain costs that may be incurred by a local agency or school~~
 4 ~~district because in that regard this act creates a new crime or~~
 5 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
 6 ~~for a crime or infraction, within the meaning of Section 17556 of~~
 7 ~~the Government Code, or changes the definition of a crime within~~
 8 ~~the meaning of Section 6 of Article XIII B of the California~~
 9 ~~Constitution.~~

10 ~~However, notwithstanding Section 17610 of the Government~~
 11 ~~Code, if the Commission on State Mandates determines that this~~
 12 ~~act contains other costs mandated by the state, reimbursement to~~
 13 ~~local agencies and school districts for those costs shall be made~~
 14 ~~pursuant to Part 7 (commencing with Section 17500) of Division~~
 15 ~~4 of Title 2 of the Government Code. If the statewide cost of the~~
 16 ~~claim for reimbursement does not exceed one million dollars~~
 17 ~~(\$1,000,000), reimbursement shall be made from the State~~
 18 ~~Mandates Claims Fund.~~

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

28 SEC. 7. This act shall become operative only if Senate Bill
 29 1362 of the 2003–04 Regular Session is enacted and becomes
 30 effective on or before January 1, 2005.



Attachment 8

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1563

VERSION: AS AMENDED JUNE 21, 2004

AUTHOR: ESCUTIA

**SPONSOR: CALIFORNIA PRIMARY CARE
ASSOCIATION**

BOARD POSITION: OPPOSE UNLESS AMENDED

SUBJECT: DRUG PRICING

Existing Law:

1) Requires the board to administer and enforce the provisions of the Pharmacy Law. (B&P 4011)

This Bill:

1) Requires manufacturers who distribute dangerous drugs in California to sell those drugs at no more than 105% of the 340B price to the following eligible entities:

- a. A licensed nonprofit community clinic or free clinic as defined in paragraphs (1) and (2) of subdivision (a) of Section 1204 of the Health and Safety Code.
- b. A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.
- c. A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.
- d. A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than 20 hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.
- e. A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code. (B&P 4168)

2) Specifies that a manufacturer does not have to comply with the bill if it only sells a drug for which there is no therapeutic alternative. (B&P 4168)

3) Prohibits the sale of drugs purchased under this authority to anyone but a patient of the entity purchasing the drugs. (B&P 4168)

4) Defines patient as an individual who receives health care services from the entity. (B&P 4168)

5) Requires wholesalers to disclose pricing information to eligible entities upon request. (B&P 4168)

Comment:

1) Author's Intent. According to the author, this bill makes pharmaceuticals available to qualifying primary care clinics at the same "best price" that manufacturers already freely negotiate with their largest commercial clients. Absent this bill, primary care clinics are often too small to negotiate for this preferential price. The author states that, even with recent federal legislation creating a prescription drug benefit for seniors, 52 million Americans lack access to prescription drugs that are necessary to ensure their health. For these uninsured populations, the lack of access to affordable prescription drugs continues to impact their health care outcomes. The author states that in, the backbone of our healthcare safety net is made up of the primary care clinics that have a statutory mandate to see all patients regardless of their ability to pay. Escalating prescription drug prices have squeezed clinic budgets as they struggle to continue serving their low income and uninsured patients. With rising drug prices comprising an increasing portion of primary care clinics' budgets, the author believes it is important that these "open door" providers have access to affordable prescription drugs.

2) 340 B Program. Federal law requires pharmaceutical manufacturers participating in the Medicaid program to participate in the 340B drug discount program. The 340B program requires the manufacturer to provide discounts on covered outpatient drugs purchased by specified government supported facilities, called "covered entities," that serve the nation's most vulnerable patient populations. These discounts are comparable to the best price discounts provided for Medicaid (Medi-Cal in California) drugs. Covered entities include:

- Federally-qualified health centers;
- Public Health Service grantees;
- Public housing primary care clinics;
- State-operated AIDS drug purchasing assistance programs;
- Black lung clinics;
- Comprehensive hemophilia diagnostic and treatment centers;
- Native Hawaiian Health Centers;
- Urban Indian organizations;
- Family planning and sexually transmitted disease clinics;
- Hemophilia treatment centers;
- Homeless clinics; and
- High-volume disproportionate share hospitals (DSHs)

3) Pharmacy Law. Section 4011 requires the board to enforce and administer the Pharmacy Law (B&P 4000 et seq.). Because this bill places the 340B pricing mandate in the Pharmacy Law, the board would assume the responsibility of enforcing this provision. Manufacturers who violate this new law would be subject to unspecified enforcement action by the board. The board does not currently license manufacturers and has few enforcement tools available to enforce such a law. This would constitute a new arena for board regulation of drug pricing agreements.

4) History.

- | | |
|---------|--|
| June 23 | From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 10. Noes 2.) Re-referred to Com. on APPR. |
| June 21 | From committee with author's amendments. Read second time. Amended. Re-referred to committee. |
| June 16 | From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 10. Noes 4.) Re-referred to Com. on B. & P. |
| June 3 | To Coms. on HEALTH and B. & P. |
| May 26 | In Assembly. Read first time. Held at Desk. |
| May 26 | Read third time. Passed. (Ayes 23. Noes 13. Page 3928.) To Assembly. |

May 25	Read third time. Amended. To third reading.
May 12	Read second time. To third reading.
May 11	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 29	Set for hearing May 10.
Apr. 28	Read second time. Amended. Re-referred to Com. on APPR.
Apr. 27	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 8. Noes 2. Page 3423.)
Apr. 14	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Apr. 13	Set for hearing April 21.
Apr. 1	Withdrawn from committee. Re-referred to Com. on H. & H.S.
Mar. 25	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 4	To Com. on RLS.
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.

5) Support and Opposition

Support

Alameda Health Consortium
 Alliance for Rural Community Health
 Altamed, Anderson Valley Health Center
 California Family Care Medical Group
 California National Organization for Women
 California Primary Care Association
 Coalition of Orange County Community Clinics
 Communicare Health Centers
 Comprehensive Health Center
 Council of Community Clinics
 El Dorado County Community Health Center
 Family Health Centers of San Diego
 Gray Panthers
 Health for All
 Indian Health Council
 Lamda Letters Project
 Latino Coalition for a Healthy California
 Lifelong Medical Care
 Livingston Medical Group
 Long Valley Health Center
 MCAH Action
 Mendocino Community Health Clinics
 National Health Services
 Northeastern Rural Health Clinics
 Planned Parenthood Affiliates of California
 Potter Valley Community Health Center
 Redwood Coast Medical Services
 Redwood Community Health Coalition
 Santa Barbara Neighborhood Clinics
 Shasta Community Health Center
 Tarzana Treatment Centers
 Valley Community Clinic
 Venice Family Clinic
 Westside Family Center

Opposition

AstraZeneca

California State Board of Pharmacy
L.P. Bristol-Myers Squibb Company
Novartis Pharmaceuticals Corp.
Pharmaceutical Research and Manufacturers of America (PhRMA)

AMENDED IN ASSEMBLY JUNE 21, 2004
AMENDED IN SENATE MAY 25, 2004
AMENDED IN SENATE APRIL 28, 2004
AMENDED IN SENATE APRIL 14, 2004
AMENDED IN SENATE MARCH 25, 2004

SENATE BILL

No. 1563

Introduced by Senator Escutia
(Coauthor: Assembly Member Koretz)

February 19, 2004

An act to add Section 4168 to the Business and Professions Code, relating to drug wholesalers and manufacturers.

LEGISLATIVE COUNSEL'S DIGEST

SB 1563, as amended, Escutia. Pharmacy manufacturers: price regulation.

Existing law, the Pharmacy Law, creates the California State Board of Pharmacy and makes a violation of that law a crime. Under existing law, the board is responsible for the licensure and regulation of a manufacturer and of a wholesaler of a dangerous drug or dangerous device and of other practices relating to the furnishing of dangerous drugs. Existing provisions of federal law require the United States Secretary of Health and Human Services to enter into an agreement with a drug manufacturer to provide specified drugs to designated entities at a discounted price.

This bill would ~~deem that~~ *require* a drug manufacturer ~~entering into a contract with state and local entities has agreed~~ to offer specified types

of clinics prices that do not exceed 105% of the discounted prices specified under federal law, with regard to certain *controlled substances, dangerous drugs, and dangerous devices, except if there is no suitable therapeutic alternative to the substance, drug, or device.* The bill would also require the manufacturer to disclose a list of prices to those clinics, upon request. The bill would prohibit ~~a clinic from reselling or transferring~~ *the resale or transfer of those drugs supplied to a clinic under these provisions* to a person who is not a patient of the clinic, as defined.

Because the bill would specify additional requirements and prohibitions 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:

1 SECTION 1. Section 4168 is added to the Business and
2 Professions Code, to read:
3 ~~4168. (a) Upon the enactment of this section, as a~~
4 ~~precondition to entering into a contract with this state or any state~~
5 ~~department, authority, bureau, commission, or officer, or with a~~
6 ~~local hospital district, city, county, or city and county, a~~
7 4168. (a) A manufacturer that directly, or indirectly through
8 a wholesaler or other distributor, sells or otherwise distributes
9 controlled substances, dangerous drugs, or dangerous devices
10 ~~shall be deemed to have agreed to within this state shall~~ offer prices
11 that do not exceed 105 percent of the best price defined by Section
12 1396r-8(c)(1)(C) of Title 42 of the United States Code with respect
13 to single source drugs or innovator multiple source drugs of the
14 manufacturer, ~~or the ceiling and the ceiling price~~ described in
15 Section 256b of Title 42 of the United States Code with respect to
16 any other drug offered by the manufacturer, to the following
17 *eligible* entities:



1 (1) A licensed nonprofit community clinic or free clinic as
2 defined in subparagraphs (A) and (B) of paragraph (1) of
3 subdivision (a) of Section 1204 of the Health and Safety Code.

4 (2) A primary care clinic owned or operated by a county as
5 described in subdivision (b) of Section 1206 of the Health and
6 Safety Code.

7 (3) A clinic operated by a federally recognized Indian tribe or
8 tribal organization as described in subdivision (c) of Section 1206
9 of the Health and Safety Code.

10 (4) A clinic operated by a primary care community, or free
11 clinic, that is operated on separate premises from a licensed clinic
12 and that is open no more than 20 hours per week, as described in
13 subdivision (h) of Section 1206 of the Health and Safety Code.

14 (5) A student health center clinic operated by a public
15 institution of higher education as described in subdivision (j) of
16 Section 1206 of the Health and Safety Code.

17 (b) The requirements of subdivision (a) shall not apply to a
18 “covered entity” as defined by Section 256b of Title 42 of the
19 United States Code.

20 (c) Notwithstanding subdivision (a), a ~~state and local entity~~
21 ~~may continue to contract for drugs for which they judge there are~~
22 ~~no suitable therapeutic alternatives if a manufacturer that is subject~~
23 ~~to subdivision (a) refuses to contract with that state or local entity.~~
24 *manufacturer shall not become subject to this section through the*
25 *sale or other distribution of controlled substances, dangerous*
26 *drugs, or dangerous devices within this state, if there is no suitable*
27 *therapeutic alternative as to each substance, drug, or device.*

28 (d) Drugs that are purchased at the ~~ceiling~~ prices set by this
29 section by; an entity described in paragraphs (1) to (5), inclusive,
30 of subdivision (a) may not ~~resell or otherwise transfer the drug be~~
31 *resold or otherwise transferred* to a person who is not a patient of
32 the entity.

33 (e) For purposes of this section, an individual is a “patient” of
34 an eligible entity if both of the following conditions apply:

35 (1) The entity has established a relationship with the individual
36 and the entity maintains records of that individual’s health care.

37 (2) The individual receives health care services from a health
38 care professional who is either employed by the entity or provides
39 health care under contractual or other arrangements, such as a



1 referral for consultation, and the responsibility for the care
2 provided remains with the entity.

3 (f) Nothing in this section prohibits a manufacturer or
4 distributor from charging a price for a drug that is lower than the
5 maximum price that may be charged under subdivision (a).

6 (g) Manufacturers that are subject to this section shall disclose
7 ~~the complete list of current, applicable prices described in~~
8 ~~subdivision (a) to any entity described in paragraphs (1) to (5),~~
9 ~~inclusive, of subdivision (a), upon request.~~ *the current, applicable*
10 *prices for all drugs sought to be purchased by an eligible entity as*
11 *described in subdivisions (a) and (b), upon request.*

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



Attachment 9

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 1735

VERSION: AS AMENDED APRIL 28, 2004

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) Restores positions lost by boards and bureaus within the Department of Consumer Affairs due to the six month rule or position reductions enacted in the 2003 Budget Act. (Government 12439.5)
- 2) Requires the Department of Consumer Affairs to provide the legislature with any staff or appointment vacancy information requested within 30 days. (Government 12439.5)
- 3) Exempts agencies within the Department of Consumer Affairs from the hiring freeze established by Executive Order D-70-03 and S-3-03. (Government 12439.5)
- 4) Prohibits special fund agencies from making loans to the General Fund. (Government 16321)

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.

June 30	Placed on APPR. suspense file.
June 23	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 11. Noes 0.) Re-referred to Com. on APPR.
June 10	To Com. on B. & P.
May 26	In Assembly. Read first time. Held at Desk.
May 26	Read third time. Passed. (Ayes 23. Noes 12. Page 3921.) To Assembly.
May 20	From committee: Do pass. (Ayes 9. Noes 1. Page 3855.) Read second time. To third reading.
May 17	Set for hearing May 20.
May 10	Placed on APPR. suspense file.
Apr. 29	Set for hearing May 10.
Apr. 28	Read second time. Amended. Re-referred to Com. on APPR.
Apr. 27	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 4. Noes 0. Page 3353.)
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.

5) Support and Opposition.

Support

Air Conditioning Sheet Metal Association
Air-conditioning and Refrigeration Contractors Association
American Federation of State, County, and Municipal Employees, AFL-CIO
American Nurses Association of California
Associated General Contractors and Associated General Contractors-San Diego Chapter
California Board of Accountancy
California Board of Cosmetology

California Chapter of the American Fence Contractors' Association
California Chapters of the National Electrical Contractors Association
California Fence Contractor's Association
California Landscape Contractors Association
California Legislative Conference of the Plumbing, Heating and Piping Industry
California Veterinary Medical Association
Construction Industry Legislative Council
Engineering Contractors' Association
Flasher/Barricade Association
Marin Builders' Exchange
Medical Board of California
Professional Investigators of California
Veterinary Medical Board
Western Wall and Ceiling Contractors Association

Opposition

None

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AMENDED IN SENATE APRIL 28, 2004

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 amended, 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.

The Budget Act of 2003 provides for the abolishment of a specified number of permanent positions from departments including all boards and commissions of the state, as determined by the Director of Finance, which may include vacant positions abolished by the Controller as described above. The act authorizes the Department of Finance to reestablish any position eliminated as a result of these provisions, or reduce the total number of positions to be abolished, under specified circumstances.

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 abolished under these provisions, 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:

1 SECTION 1. Section 12439.5 is added to the Government
2 Code, to read:

3 ~~12439.5. (a) Section 12439 shall not apply to any position on~~
4 ~~any board under the jurisdiction of the Department of Consumer~~
5 ~~Affairs that is funded solely from non-General Fund sources, or to~~
6 ~~the Division of Investigation within the department.~~

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

9 *12439.5. (a) (1) Any position on a board, that was abolished*
10 *pursuant to Section 4.10 of the Budget Act of 2003 or pursuant to*
11 *Section 12439 prior to January 1, 2004, shall be reestablished to*
12 *the extent that non-General Fund moneys are available for that*
13 *purpose.*

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

21 ~~(e)~~
22 (b) The Director of Consumer Affairs shall provide to the
23 Legislature information on all staff and appointment vacancies for
24 ~~boards, and the division, described in subdivision (a), within 30~~
25 *boards within 30 days of receiving the Legislature’s request for*
26 *that information.*

27 ~~(d)~~
28 (c) The provisions of Executive Order D-70-03 ~~and~~, Executive
29 Order D-71-03, *and Executive Order S-3-03* shall not apply to any
30 board under the jurisdiction of the Department of Consumer
31 Affairs, nor to the Division of Investigation within the department.

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

34 16321. (a) Notwithstanding any other provision of law, no
35 non-General Fund moneys deposited in any fund or account
36 supporting a board under the jurisdiction of the Department of
37 Consumer Affairs may be loaned to, or used to secure a loan to, the
38 General Fund.



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

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Attachment 10

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 1957

VERSION: AS AMENDED JUNE 24, 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 provide consumers with information how to purchase prescription drugs more affordably. The website shall include at least the following information:
 - a. The availability of a prescription drug benefit through Medicare.
 - b. Discount drug programs available through the state.
 - c. Discount drug programs operated by drug manufacturers.
 - d. Canadian pharmacies that are approved by the department.
 - e. Links to any other websites deemed appropriate by the department. (H&S 110242)
- 2) Requires this Web site to include price comparisons between typical pharmacy prices and Canadian pharmacy prices for the 50 most commonly prescribed drugs. (H&S 110242)
- 3) 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. This determination will be made in consultation with the board.
 - c. 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.
 - i. Prohibits the pharmacy from furnishing the following drugs:
 - i. Controlled substances.
 - ii. Biologics.

- iii. Infused drugs.
- iv. Intravenous drugs.
- v. Drugs inhaled during surgery.
- vi. Drugs requiring refrigeration or that are otherwise inappropriate for mail delivery.
- j. Sale of only drugs approved by Health Canada.
- k. Comply with California law relating to drug pedigree.
- l. Prohibits requiring patients to sign a waiver of liability.
- m. Requires the pharmacy to maintain a customer service department.
- n. Requires the pharmacy to employ professionals that are licensed in good standing.
- o. Requires the pharmacy to comply with California privacy laws.
- p. Prohibits filling a prescription if the patient hasn't taken the drug previously.
- q. Prohibits furnishing drugs that have no equivalent approved by the FDA.
(H&S 110242)

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

5) Permits the department to assess a fee on Canadian pharmacies to fund this act. (H&S 110242)

6) Sunsets the bill on January 1, 2008.

7) 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)

8) 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.

June 24	Read second time, amended, and re-referred to Com. on APPR.
June 23	From committee: Amend, do pass as amended, and re-refer to Com. On APPR. (Ayes 8. Noes 2.).
June 9	Referred to Com. on H. & H.S. From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on H. & H.S.
May 27	In Senate. Read first time. To Com. on RLS. for assignment.
May 26	Read third time, passed, and to Senate. (Ayes 51. Noes 23. Page 6054.)
May 24	Read third time, amended, and returned to third reading. (Ayes 45. Noes 18. Page 2940.)
May 20	From committee: Do pass. (Ayes 15. Noes 5.) (May 19). Read second time. To third reading.
May 5	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 21	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 10. Noes 2.) (April 20).
Apr. 16	Re-referred to Com. on B. & P.
Apr. 15	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.

Apr. 14 From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 13. Noes 4.) (April 13).
 Apr. 12 Re-referred to Com. on HEALTH.
 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.

7) Support and Opposition.

Support: AARP California
 AIDS Healthcare Foundation
 AIDS Project Los Angeles
 Alzheimer's Association California Council
 American Federation of State, County and Municipal Employees
 Area Agency on Aging Advisory Council for San Luis Obispo and Santa Barbara Counties
 Being Alive Los Angeles, Inc.
 California Alliance for Retired Americans
 California Commission On Aging
 California Faculty Association
 California Federation of Teachers
 California Independent Public Employees Legislative Council
 California Labor Federation
 California Medical Association
 California Nurses Association
 California Public Interest Research Group
 California School Employees Association
 California Seniors Coalition
 California Small Business Association
 California State Employees Association
 California Teachers Association
 Congress of California Seniors
 Consumer Federation of California
 Consumers Union
 Gray Panthers
 Health Access California
 Lieutenant Governor, Cruz Bustamante
 National Association of Social Workers, California Chapter
 Northern Sierra Rural Health Network
 Office of the Attorney General
 Older Women's League of California
 Peace Officers Research Association of California
 Santa Clara County Board of Supervisors
 Service Employees International Union
 The Foundation for Taxpayer and Consumer Rights
 United Nurses Association of California/Union of Health Care Professionals
 Western Center on Law and Poverty

Oppose: Abbott Laboratories
 Amyotrophic Lateral Sclerosis
 Aventis Pharmaceuticals, Inc.
 Bristol-Myers Squibb Company
 California Chamber of Commerce
 California Healthcare Institute
 National Association of Cancer Patients, California Chapter

Novartis Pharmaceuticals Corporation
Pharmaceutical Research and Manufacturers of America
San Joaquin County Commission on Aging
Pfizer Inc.
Seniors Coalition
Silicon Valley Manufacturing Group
One individual

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AMENDED IN SENATE JUNE 24, 2004

AMENDED IN SENATE JUNE 9, 2004

AMENDED IN ASSEMBLY MAY 24, 2004

AMENDED IN ASSEMBLY APRIL 15, 2004

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
(Principal coauthor: Assembly Member Koretz)**

February 12, 2004

An act to add *and repeal* Sections 14982 and 14983 to the Government Code, and to add *and repeal* Article 5 (commencing with Section 110242) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 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 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 department to establish the California Rx Prescription Drug Web site on or before July 1, 2005, to provide information to California residents about options for obtaining prescription drugs at affordable prices. It would require that the Web site, at a minimum, provide information about, and establish electronic links to, specified programs, pharmacies that are located in Canada and that meet specified requirements, and other Web sites. *The bill would authorize the department to assess a fee from Canadian pharmacies that the department reviews for possible inclusion on the Web site to offset the cost of reviewing them.* 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 and whose Web sites are linked to the department's. *The bill would also require the department to ensure that the Web site is coordinated with and does not duplicate other Web sites that provide information about prescription drug options and costs.*

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 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 sources other than those from which the state now purchases,



including Canadian sources that meet the requirements to be listed on the Web site and established by the bill. The bill would require the department to report to the Legislature and recommend options to facilitate more cost-effective acquisition of prescription drugs. 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.

This bill would repeal all the above 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:

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

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

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

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

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

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

23 (f) The rising cost of prescription drugs also places a significant
24 burden on state government, with the cost of providing
25 prescription drugs to Medi-Cal beneficiaries, to inmates of the
26 California Department of Corrections, and to other participants in



1 state programs growing in some cases at over 20 percent annually
2 in recent years.

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

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

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

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

22 SEC. 2. Section 14982 is added to the Government Code, to
23 read:

24 14982. (a) The department shall coordinate a review of state
25 departments and agencies that purchase prescription drugs to
26 determine which state programs may save significant state funds
27 by purchasing from sources other than those from which the state
28 now purchases, including Canadian sources that meet the
29 requirements of Section 110242 of the Health and Safety Code.
30 State departments to be reviewed shall include, but not be limited
31 to, all of the following:

- 32 (1) The State Department of Health Services.
- 33 (2) The Managed Risk Medical Insurance Board.
- 34 (3) The Department of General Services.
- 35 (4) The California Public Employees' Retirement System
36 (CalPERS).

37 (b) The department shall report its findings based on the review
38 required under subdivision (a) to the Legislature and shall
39 recommend options to the Legislature, including conducting pilot
40 programs, to facilitate more cost-effective acquisition of



1 prescription drugs. The recommendations shall include a
2 determination of the need to seek any federal approvals or waivers.

3 SEC. 3. Section 14983 is added to the Government Code, to
4 read:

5 14983. (a) The department may establish pilot programs
6 under which purchases of prescription drugs from Canada are
7 made at reduced prices for purposes of state departments and
8 agencies.

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

13 SEC. 4. Article 5 (commencing with Section 110242) is
14 added to Chapter 2 of Part 5 of Division 104 of the Health and
15 Safety Code, to read:

16

17 Article 5. California Rx Prescription Drug Web Site

18

19 110242. (a) The department shall establish the California Rx
20 program to provide information to consumers and health care
21 providers about options for obtaining prescription drugs at
22 affordable prices.

23 (b) The department shall establish a Web site on or before July
24 1, 2005, to provide information to California residents about
25 options for obtaining prescription drugs at affordable prices. The
26 Web site shall, at a minimum, provide information about, and
27 electronic links to, all of the following:

28 (1) Prescription drug benefits available to Medicare
29 beneficiaries, including the Voluntary Prescription Drug Benefit
30 Program and the Medicare Prescription Drug Discount and
31 Transitional Assistance Program.

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

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

37 (4) Canadian pharmacies that provide mail order service to the
38 United States and who meet the requirements of paragraph (2) of
39 subdivision (c).



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

5 (c) (1) The Web site shall include price comparisons of at least
6 50 commonly prescribed brand name prescription drugs,
7 including typical prices charged by licensed pharmacies in the
8 state and by Canadian pharmacies that provide mail order service
9 to the United States and whose Web sites are linked to the
10 department's Web site pursuant to paragraph (2).

11 (2) The Web site shall establish electronic links to pharmacies
12 that are located in Canada that provide mail order services to the
13 United States and that meet the following requirements:

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

15 (B) Comply with the requirements of a nonresident pharmacy
16 as specified in Section 4112 of the Business and Professions Code,
17 except that for purposes of this section all references to "state" in
18 subdivision (d) of Section 4112 of the Business and Professions
19 Code shall be deemed to refer to "province in which it is located."
20 *Compliance with this subparagraph shall be determined by the*
21 *department in consultation with the California State Board of*
22 *Pharmacy.*

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

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

27 (E) Require a signed patient agreement.

28 (F) Ship prescription drugs in tamper proof original
29 manufacturer containers to individuals in the United States, unless
30 the consumer requests to receive the drug in a childproof container.

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

33 (H) Do not furnish any of the following:

34 (i) A controlled substance.

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

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

38 (iv) An intravenously injected drug.

39 (v) A drug that is inhaled during surgery.



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

3 (I) Sell only prescription drugs that have been approved for sale
4 in Canada by the Therapeutic Products Directorate of Health
5 Canada and for which no exemption is claimed under Section 37
6 of the Canadian Food and Drugs Act or any other similar provision
7 of Canadian law.

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

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

12 (L) *Maintain a service department to respond to consumer*
13 *inquiries and provide information to consumers about how they*
14 *may file complaints with the provincial licensing authority.*

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

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

20 (O) *Not provide more than the prescribed amount or a*
21 *three-month supply of any drug.*

22 (P) *Not furnish a drug if the consumer indicates that he or she*
23 *has not previously taken the drug.*

24 (Q) *Not furnish drugs for which there is no equivalent drug*
25 *approved for sale in the United States by the federal Food and*
26 *Drug Administration.*

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

30 (3) Any electronic link to the department's Web site pursuant
31 to paragraph (2) shall be deleted if the department determines that
32 the requirements of paragraph (2) are no longer met.

33 (4) *The department may assess a fee from Canadian*
34 *pharmacies that the department reviews pursuant to paragraph (2)*
35 *to offset the cost of reviewing them.*

36 (d) *The department shall ensure that the Web site it is required*
37 *to establish pursuant to this section is coordinated with and does*
38 *not duplicate other Web sites that provide information about*
39 *prescription drug options and costs.*



1 *SEC. 5. Sections 1 to 4, inclusive, of this act shall remain in*
2 *effect only until January 1, 2008, and as of that date are repealed*
3 *unless a later enacted statute, that is enacted before January 1,*
4 *2008, deletes or extends that date.*

O



Attachment 11

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 1149

VERSION: AS AMENDED JUNE 21, 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) Requires the Board to develop and disseminate information, through an interactive website, that identifies Canadian pharmacies that meet recognized standards for the safe acquisition, shipment, handling, and dispensing of prescription drugs to persons in California. (B&P 4001.2)
- 2) 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 in good standing by the province in which it is located.
 - b. Notifies the board of any change in its licensure status and any pending disciplinary action within three business days.
 - c. 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.
 - d. Meets the requirements for licensure as a California pharmacy.
 - e. Does not require its customers to sign a waiver of liability.
 - f. Requires patients to provide a valid prescription from a U.S. physician;
 - g. Maintains a service department to respond to all consumer inquiries.
 - h. Discloses on its Website and in any packaging that the consumer may file a complaint with the relevant Canadian provincial licensing authority.
 - i. Discloses the contact information for the relevant provincial regulatory agency on its Website and in its packaging.
 - j. Does not furnish any of the following categories of drugs:
 1. Controlled substances.
 2. Drugs for which there is no equivalent drug approved by the FDA.
 3. Drugs not approved for sale in Canada.
 4. Drugs that require refrigeration or are otherwise unable to be mailed safely.
 5. Biologicals.
 6. Intravenous drugs.

7. Infused drugs.
 8. Drugs inhaled during surgery.
 - k. Employs only individuals who are appropriately licensed in good standing to practice in Canada.
 - l. Complies with personal health and medical privacy laws in California.
 - m. Does not furnish a quantity in excess of that prescribed or an amount in excess of a three month supply.
 - n. Complies with all Canadian laws relating to the furnishing of drugs.
 - o. Does not furnish a drug the patient has not received before.
 - p. Does not repackage drugs from original manufacturers packaging unless necessary.
 - q. Complies with subdivisions (c), (e), and (f) of Section 4112.
(B&P 4001.2)
- 5) Requires the board to remove pharmacies from the website if they fail to comply with the requirements enumerated above. (B&P 4001.2)
- 6) Requires Canadian pharmacies seeking inclusion on the website to pay an annual \$1500 fee. (B&P 4001.2)
- 7) Permits the board to include other information on the website regarding programs and methods for obtaining affordable prescription drugs. (B&P 4001.2)
- 8) Repeals these provisions effective January 1, 2008. (B&P 4001.2)
- 9) 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)
- 10) 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)
- 11) Repeals these provisions on January 1, 2008. (B&P 4001.3)
- 12) Requires the board to annually study the workload and resource requirements needed to implement this bill through a request for proposal process. (B&P 4001.4)
- 13) Permits the board to receive voluntary contributions to a fund dedicated to implementing this bill. (B&P 4001.4)
- 14) Appropriates an unspecified sum to fund the implementation of this bill in the 2004-2005 fiscal year. (B&P 4001.4)
- 15) Permits the board to contract for any resources required to implement this bill. (B&P 4001.4)
- 16) Specifies that the bill will only be implemented to the extent monies are available in the new fund created for this activity. (B&P 4001.4)

Comment:

1) Author's Intent. According to the author, rising prescription drug costs are impacting more and more Californians. The author notes that while Congress has enacted a Medicare prescription drug benefit that will take effect in 2006, beneficiaries will still be facing large and growing out-of-pocket costs for their once that coverage

takes effect. The author reports that the prices of the 50 prescriptions used most by the elderly rose over three times the rate of inflation in 2002 and that over 1 million Americans, many of them seniors, currently import drugs. Despite the fact that the federal Food and Drug Administration (FDA) is aware of such importation, neither the FDA nor any other entity is providing any guidance to consumers to steer them to safe and reliable pharmacies. The author believes the information made available by this will fill this gap and provide a vital public health and safety function.

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. **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 limited ability to take enforcement action against the "certification" should a "certified" pharmacy fall out of compliance with the certification standards or violate California law. The board's enforcement actions would be limited to removing references to the offending pharmacy from the website.

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. The bill does provide for some additional revenue from fees for Canadian pharmacies and it does provide for an unspecified appropriation to the board for the 2004-05 fiscal year.

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.

9) Support and Opposition.

Support

- AARP California (sponsor)
- Attorney General of California
- AIDS Healthcare Foundation
- California Alliance for Retired Americans
- California Commission on Aging
- California Federation of Teachers
- California Independent Public Employees Legislative Council
- California Labor Federation
- California Latino Medical Association
- California Medical Association
- California Nurses Association
- California Public Interest Research Group
- California Retired Teachers Association
- California School Employees Association
- California Teachers Association
- Congress of California Seniors
- Consumer Federation of California

Consumers Union
 Foundation for Taxpayer and Consumer Rights
 Gray Panthers
 Greenlining Institute
 Health Access California
 Lambda Letters Project
 Latino Coalition for a Health California
 National Patient Advocate Foundation
 Older Women's League of California
 Retired Public Employees Association
 Santa Clara County Board of Supervisors
 Senior Action Network
 Service Employees International Union
 United Nurses Association of California/Union of Health Care Professionals
 Western Center on Law and Poverty

Opposition

Abbott Laboratories
 BIOCOM
 Boehringer Ingelheim Pharmaceuticals, Inc.
 Bristol-Myers Squibb Company
 California Chamber of Commerce
 California Healthcare Institute
 Citizens Against Law Suit Abuse, San Joaquin County Chapter
 Eli Lilly and Company
 Hepatitis C Global Foundation
 Latino Behavioral Health Institute
 Novartis Pharmaceuticals Corporation
 Pfizer Inc.
 Pharmaceutical Research and Manufacturers of America (PhRMA)
 Seniors Coalition
 Silicon Valley Manufacturing Group
 TMJ Society of California
 Wyeth Pharmaceuticals
 60 Plus Association

10) History.

June 23 From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 8. Noes 4.) Re-referred to Com. on APPR.
 June 21 From committee with author's amendments. Read second time. Amended. Re-referred to committee.
 June 16 From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 11. Noes 5.) Re-referred to Com. on B. & P.
 June 8 From committee with author's amendments. Read second time. Amended. Re-referred to committee.
 June 3 To Coms. on HEALTH and B. & P.
 May 25 In Assembly. Read first time. Held at Desk.
 May 25 Read third time. Passed. (Ayes 24. Noes 13. Page 3887.) To Assembly.
 May 24 From committee: Do pass as amended. (Ayes 8. Noes 5. Page 3844.) Read second time. Amended. To third reading.
 May 17 Set for hearing May 20.
 May 3 Placed on APPR. suspense file.
 Apr. 22 Set for hearing May 3.
 Apr. 19 Read second time. Amended. Re-referred to Com. on APPR.
 Apr. 16 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 4. Noes 1. Page 3262.)

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 ASSEMBLY JUNE 21, 2004
AMENDED IN ASSEMBLY JUNE 8, 2004
AMENDED IN SENATE MAY 24, 2004
AMENDED IN SENATE APRIL 19, 2004
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
(Coauthor: Senator Murray)**

January 26, 2004

An act to add Section 4001.4 to, and to add and repeal Sections 4001.2 and 4001.3 of, the Business and Professions Code, relating to pharmacy, and making an appropriation therefor.

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 require each pharmacy located in Canada that seeks to be identified for these purposes to pay the board an annual fee of \$1,500. 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 also authorize the board to provide Internet Web site links to other sources of information about obtaining affordable prescription medications and cost comparisons for those medications.* The bill would repeal these provisions on January 1, 2008.

The bill would require the board to determine the workload and resource requirements to implement these provisions. The bill would create the Access to Affordable Prescription Drugs Fund where fees and voluntary contributions to support those activities would be deposited. The bill would make implementation of its provisions subject to sufficient moneys in the fund for those purposes. The bill would appropriate an unspecified sum to the board from the fund for the 2004–05 fiscal year and would make additional moneys available in subsequent fiscal years subject to appropriation in the annual Budget Act.

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

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

- 1 SECTION 1. The Legislature finds all of the following:
- 2 (a) Prescription medications are an essential part of health care
- 3 delivery and have contributed to increasing the life expectancy of
- 4 patients and treating their diseases and conditions.
- 5 (b) Despite this, due to the high cost of prescription
- 6 medications, many Californians, especially elderly, disabled, and
- 7 low-income persons, face difficulty accessing the medications
- 8 they need to maintain their health.
- 9 (c) As one means of accessing affordable prescription
- 10 medications, increasing numbers of Californians are purchasing
- 11 prescription medications from foreign countries, in many cases
- 12 through an Internet Web site.
- 13 (d) California consumers currently have few ways of
- 14 determining which outlets and suppliers of prescription



1 medications in foreign countries are safe and reliable, particularly
2 those offering their products through an Internet Web site.

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

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

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

16 4001.2. (a) The board shall develop and disseminate
17 information identifying Canadian pharmacies that have
18 established that they meet recognized standards for the safe
19 acquisition, shipment, handling, and dispensing of dangerous
20 drugs to persons in California. As part of this requirement, the
21 board shall establish an interactive Internet Web site that links
22 consumers to, or provides information about, Canadian
23 pharmacies that the board has determined meet recognized
24 standards for the safe acquisition, shipment, handling, and
25 dispensing of dangerous drugs to persons in California.

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

31 (1) Is licensed as a pharmacy by the province in which it is
32 located and its license is not revoked, suspended, or subject to
33 other disciplinary action.

34 (2) Notifies the board within three business days of any change
35 in its licensure status and any pending disciplinary action against
36 it.

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



- 1 (4) Meets the requirements for licensure by the board as a
2 pharmacy.
- 3 (5) Does not require a consumer to sign a waiver of liability or
4 a release of liability for a negligent act by the pharmacy.
- 5 (6) Requires a valid prescription from a physician and surgeon
6 licensed to practice in the United States before selling the
7 prescribed drug.
- 8 (7) Maintains a service department to respond to all consumer
9 inquiries.
- 10 (8) Discloses, on its Internet Web site and in packaging
11 accompanying any shipped drugs, that the consumer may file a
12 complaint regarding the pharmacy with the relevant Canadian
13 provincial licensing authority and with the pharmacy, and
14 provides the contact information for filing the complaint.
- 15 (9) Does not furnish any of the following types of drugs:
- 16 (A) Narcotics and other controlled substances.
- 17 (B) Drugs for which there is no equivalent drug approved for
18 sale in the United States by the federal Food and Drug
19 Administration.
- 20 (C) Drugs that are not approved by the Canadian Therapeutic
21 Products Directorate for sale in Canada.
- 22 (D) Drugs that require refrigeration or that cannot be safely
23 shipped by mail.
- 24 (E) *A biological product, as defined in Section 351 of the*
25 *Public Health Service Act (42 U.S.C. Sec. 262).*
- 26 (F) *An intravenously injected drug.*
- 27 (G) *An infused drug, including a peritoneal dialysis solution.*
- 28 (H) *A drug that is inhaled during surgery.*
- 29 (10) Ensures that all physicians and surgeons, pharmacists, and
30 technicians in its employ are properly licensed according to
31 Canadian laws and their licenses are not revoked, suspended, or
32 subject to other disciplinary action.
- 33 (11) Complies with all personal health and medical
34 information privacy laws applicable to a pharmacy located in
35 California.
- 36 (12) Does not exceed the prescribed amount and does not
37 exceed a three-month supply of the prescribed drug.
- 38 (13) Complies with all Canadian laws applicable to furnishing
39 drugs.



1 (14) Does not furnish a drug if the consumer indicates he or she
2 has not previously taken that drug.

3 (15) Does not repackage the drug from the original packaging
4 by the drug manufacturer unless required to dispense the
5 prescription or to package the drug at the consumer's request in a
6 childproof container.

7 *(16) Complies with the requirements of subdivisions (c), (e),
8 and (f) of Section 4112.*

9 (c) The board shall discontinue providing information to
10 consumers and providing Internet Web site links to a pharmacy
11 that the board determines does not meet the requirements of this
12 section.

13 (d) Each pharmacy located in Canada that seeks to be identified
14 by the board pursuant to this section shall pay the board an annual
15 fee of one thousand five hundred dollars (\$1,500). The fees shall
16 be deposited into the Access to Affordable Prescription Drugs
17 Fund created by Section 4001.4.

18 *(e) The board may provide Internet Web site links to other
19 sources of information about obtaining affordable prescription
20 medications, including discount programs offered by public
21 entities or pharmaceutical companies, and cost comparisons of
22 prescription medications.*

23 *(f) This section shall remain in effect only until January 1,
24 2008, and as of that date is repealed, unless a later enacted statute,
25 that is enacted before January 1, 2008, deletes or extends that date.*

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

28 4001.3. (a) The board shall collect, publish, and post on an
29 Internet Web site created pursuant to Section 4001.2, information
30 concerning suppliers of dangerous drugs that are located and
31 operating outside of the United States that have been found to have
32 violated recognized standards for the safe shipment, handling, and
33 processing of dangerous drugs.

34 (b) In carrying out this section, the board may rely on
35 information made available by regulatory and law enforcement
36 bodies, including, but not limited to, the federal Food and Drug
37 Administration, the United States Customs Service, prescription
38 drug regulatory bodies of foreign countries, the Attorney General,
39 the United States Department of Justice, the boards of pharmacy



1 of other states, and the National Association of Boards of
2 Pharmacy.

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

7 (d) This section shall remain in effect only until January 1,
8 2008, and as of that date is repealed, unless a later enacted statute,
9 that is enacted before January 1, 2008, deletes or extends that date.

10 SEC. 4. Section 4001.4 is added to the Business and
11 Professions Code, to read:

12 4001.4. (a) The board shall determine its annual workload
13 and resource requirements to implement Sections 4001.2 and
14 4001.3, including through a request for proposal process to
15 determine the number of pharmacies that are interested in being
16 identified and having their information provided to California
17 consumers.

18 (b) The board may receive voluntary contributions to support
19 its activities pursuant to Sections 4001.2 and 4001.3. The
20 contributions shall be deposited into the Access to Affordable
21 Prescription Drugs Fund which is hereby created in the State
22 Treasury. The revenue in the fund shall be made available to the
23 board for expenditure solely for the purpose of supporting the
24 board’s activities pursuant to Sections 4001.2 and 4001.3. The sum
25 of ____ dollars (\$____) is hereby appropriated to the board from
26 the fund for the 2004–05 fiscal year to implement Sections 4001.2
27 and 4001.3. In subsequent fiscal years, additional moneys shall be
28 made available upon appropriation by the Legislature in the annual
29 Budget Act.

30 (c) The board may contract for any resources needed to
31 implement this section and Sections 4001.2 and 4001.3.

32 (d) Sections 4001.2 and 4001.3 shall be implemented only to
33 the extent that sufficient moneys are available in the Access to
34 Affordable Prescription Drugs Fund for those purposes.

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Attachment 12

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: SB 1333

VERSION: AS AMENDED JUNE 22, 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. (H&S Code 120596, W&I Code 14105.75)
- 2) Provides that the reimbursement rate paid to a pharmacy for a Canadian drug dispensed to a beneficiary shall be up to, but not exceed, 10% less than 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. (H&S Code 120596, W&I Code 14105.75)
- 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. (H&S Code 120596, W&I Code 14105.75)
- 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. (H&S Code 120596, W&I Code 14105.75)
- 5) Requires Canadian pharmacies providing drugs for these programs to pay the annual licensing fee required of pharmacies licensed by the board. (H&S Code 120596, W&I Code 14105.75)
- 6) 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. (H&S Code 120596, W&I Code 14105.75)

7) Provides that this bill will only become operative if federal financial participation is available. (H&S Code 120596, W&I Code 14105.75)

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 if 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)
- AIDS Services Foundation, Orange County
- California Alliance for Retired Americans
- California Commission on Aging
- California Federation of Teachers
- California Labor Federation
- California Nurses Association
- California Public Interest Research Group
- California School Employees Association
- California Seniors Coalition
- Caring for Children and Families with AIDS
- City of West Hollywood
- Consumer Federation of California
- Consumers Union
- Gray Panthers
- Greenlining Institute
- Health Access California
- Latino Coalition for a Healthy California
- National Patient Advocate Foundation
- Older Women's League of California
- Santa Clara County of Board of Supervisors
- United Nurses Association/Union of Health Care Professionals
- Western Center on Law and Poverty

Opposition

- Biotechnology Industry Organization
- Bristol-Myers Squibb Company
- California Chamber of Commerce
- California Healthcare Institute
- Hepatitis C Global Foundation
- Novartis Pharmaceuticals
- Pfizer, Inc.
- Pharmaceutical Research and Manufacturers of America
- Silicon Valley Manufacturing Group

8) History.

- June 22 Read second time. Amended. Re-referred to Com. on APPR.
- June 21 From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 10. Noes 5.)
- June 1 To Com. on HEALTH.
- May 25 In Assembly. Read first time. Held at Desk.
- May 25 Read third time. Passed. (Ayes 24. Noes 9. Page 3866.) To Assembly.
- May 20 From committee: Do pass. (Ayes 7. Noes 4. Page 3847.) Read second time. To third reading.
- May 17 Set for hearing May 20.
- May 13 From committee with author's amendments. Read second time. Amended. Re-referred to committee.

Apr. 19 Placed on APPR. suspense file.
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.

AMENDED IN ASSEMBLY JUNE 22, 2004

AMENDED IN SENATE MAY 13, 2004

AMENDED IN SENATE MARCH 16, 2004

SENATE BILL

No. 1333

Introduced by Senator Perata

(Principal coauthor: Assembly Member Koretz)

(Coauthor: Senator Romero)

*(Coauthor: Assembly Member ~~Lieber~~ Members Hancock and
Lieber)*

February 18, 2004

An act to add Section 120956 to the Health and Safety Code, 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. Prescription drug reimbursement: pharmacy purchases from Canadian sources: Medi-Cal: AIDS Drug Assistance program.

(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.

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, including the payment of a registration fee, 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. The bill would require the Canadian pharmacy to be licensed by the board as a pharmacy and pay a registration fee. 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)~~ (1) above, a pharmacy that has provided to a person eligible for benefits under ADAP a prescription drug that was purchased from a Canadian pharmacy.

This bill would provide that it shall be implemented only if, and to the extent that, the department determines that federal financial participation is available.

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 120956 is added to the Health and
2 Safety Code, to read:
3 120956. (a) Notwithstanding any other provision of law, the
4 department may reimburse a pharmacy that provides to a person
5 eligible for benefits under this chapter a prescription drug that was
6 purchased from a Canadian pharmacy, and shall reimburse that
7 pharmacy for those prescription drugs pursuant to this section.
8 (b) The reimbursement rate for a prescription drug described in
9 subdivision (a) may be up to, but not exceeding, 10 percent less
10 than the most recent allowable drug product price, but in no case
11 shall this reduced reimbursement rate be more than 50 percent of
12 the difference between the purchase price from the Canadian
13 pharmacy and the purchase price the pharmacy would have paid
14 to a pharmaceutical wholesaler.
15 (c) Notwithstanding any other provision, a drug shall not be
16 eligible for reimbursement under this section if the department
17 finds that the drug price, after rebates from the drug's
18 manufacturer, is the same as or lower than the lowest available
19 Canadian price for the same drug.
20 (d) In order for a pharmacy to be reimbursed pursuant to this
21 section, the Canadian pharmacy from which it purchases a
22 prescription drug shall meet the requirements for licensure by the
23 California State Board of Pharmacy as a pharmacy and comply
24 with all lawful directions and licensing and registration
25 requirements of the applicable Canadian regulatory and licensing



1 agency or agencies. A fee *to be paid by the Canadian pharmacy*
2 shall be assessed biennially and shall be the fee specified in
3 subdivision (a) of Section 4400 of the Business and Professions
4 Code.

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

8 (f) *Notwithstanding any other provision of law, this section*
9 *shall be implemented only if, and to the extent that, the department*
10 *determines that federal financial participation is available.*

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

13 14105.75. (a) Notwithstanding any other provision of law,
14 the department may reimburse a pharmacy that provides a
15 prescription drug that was purchased from a Canadian pharmacy
16 to a Medi-Cal beneficiary, and shall reimburse that pharmacy for
17 those prescription drugs pursuant to this section.

18 (b) The reimbursement rate for a prescription drug described in
19 subdivision (a) may be up to, but not exceeding, 10 percent less
20 than the most recent allowable drug product price, but in no case
21 shall this reduced reimbursement rate be more than 50 percent of
22 the difference between the purchase price from the Canadian
23 pharmacy and the purchase price the pharmacy would have paid
24 to a pharmaceutical wholesaler.

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

30 (d) In order for a pharmacy to be reimbursed pursuant to this
31 section, the Canadian pharmacy from which it purchases a
32 prescription drug shall meet the requirements for licensure by the
33 California State Board of Pharmacy as a pharmacy and comply
34 with all lawful directions and licensing and registration
35 requirements of the applicable Canadian regulatory and licensing
36 agency or agencies. A fee *to be paid by the Canadian pharmacy*
37 shall be assessed biennially and shall be the fee specified in
38 subdivision (a) of Section 4400 of the Business and Professions
39 Code.



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

4 (f) *Notwithstanding any other provision of law, this section*
5 *shall be implemented only if, and to the extent that, the department*
6 *determines that federal financial participation is available.*

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Attachment 13

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AMENDED IN ASSEMBLY JULY 8, 2004
AMENDED IN ASSEMBLY JUNE 14, 2004
AMENDED IN ASSEMBLY MAY 28, 2004
AMENDED IN SENATE APRIL 14, 2004
AMENDED IN SENATE APRIL 1, 2004

SENATE BILL

No. 1307

Introduced by Senator Figueroa

February 17, 2004

An act to amend Sections 4054, 4165, and 4166 of, to amend, repeal, and add Sections ~~4043~~, 4053, 4059.5, 4081, 4100, 4105, ~~4110~~, 4160, 4163, ~~4163.6~~, 4164, 4196, 4301, 4305.5, 4331, and 4400 of, to add Sections ~~4021.5~~, 4022.5, 4034, 4084, 4085, 4086, 4126.5, 4163.5, and 4168 to, to add and repeal Sections 4053.1, 4162, and 4169 of, and to repeal and add ~~Sections 4161 and~~ *Section* 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 pharmacists and wholesalers of dangerous drugs or dangerous devices by the Pharmacy Board. Existing law requires that dangerous drugs or dangerous devices be dispensed only by licensed pharmacists and only to certain persons or entities. Existing law provides certain exemptions from this requirement for manufacturers, veterinary food-animal drug retailers, and wholesalers, including those



that employ sufficient qualified supervision by a person who possesses a certificate of exemption. Existing law also requires the board to take action against a licensee who is guilty of unprofessional conduct, as defined. Existing law makes a violation of the Pharmacy Law a crime.

This bill would revise the list of persons to whom a pharmacy may furnish dangerous drugs. The bill would also revise the exemption provisions related to manufacturers, veterinary food-animal drug retailers, and wholesalers, and would change the certificate of exemption requirement to a requirement of licensure as a designated representative, as defined. The bill would require a wholesaler to keep track of ~~and report to the board~~ excessive purchases of dangerous drugs by a ~~contracting~~ pharmacy, ~~as defined that primarily or solely dispenses those drugs to patients of long-term care facilities,~~ and would make the clearly excessive furnishing of dangerous drugs to a ~~contracting~~ pharmacy by a wholesaler unprofessional conduct. The bill would make other related changes.

This bill would, 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 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 without a pedigree, and would prohibit a wholesaler or pharmacy from acquiring a dangerous drug 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 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 *and agents*.

This bill would delete these requirements. ~~The bill instead would make a 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~~



~~directions and requests for information, to maintain 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 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~~ *all sites* 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) The bill would make its provisions operative on January 1, 2006, except as specified.

(7) 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.

(8) 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.



(9) This bill would become operative only if AB 2682 is also enacted and becomes effective on or before January 1, 2005.

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

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

1 SECTION 1. ~~Section 4021.5 is added to the Business and~~
2 ~~Professions Code, to read:~~

3 ~~4021.5. (a) “Contracting pharmacy” means a pharmacy that~~
4 ~~purchases dangerous drugs or dangerous devices at preferential or~~
5 ~~contract prices, as defined in subdivision (e) of Section 4164, from~~
6 ~~a manufacturer or wholesaler for dispensing to patients in licensed~~
7 ~~health facilities or community care facilities.~~

8 ~~(b) A contract pharmacy shall be separately designated on the~~
9 ~~pharmacy license issued by the board.~~

10 ~~(c) A pharmacy operated by a health care service plan or~~
11 ~~hospital primarily to serve its own members or patients shall not~~
12 ~~be considered a contract pharmacy.~~

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

14 SEC. 2. Section 4022.5 is added to the Business and
15 Professions Code, to read:

16 4022.5. (a) “Designated representative” means an
17 individual to whom a license has been granted pursuant to Section
18 4053.

19 (b) “Designated representative-in-charge” means a designated
20 representative or a pharmacist who is the supervisor or manager of
21 a wholesaler or veterinary food-animal drug retailer.

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

23 SEC. 3. Section 4034 is added to the Business and Professions
24 Code, to read:

25 4034. (a) “Pedigree” means a record, in electronic form,
26 containing information regarding each transaction resulting in a
27 change of ownership of a given dangerous drug, from sale by a
28 manufacturer, through acquisition and sale by a wholesaler, until
29 final sale to a pharmacy or other person furnishing, administering,
30 or dispensing the dangerous drug.

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



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

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

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

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

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

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

22 ~~SEC. 4. Section 4043 of the Business and Professions Code~~
23 ~~is amended to read:~~

24 ~~4043. (a) "Wholesaler" means and includes a person who~~
25 ~~acts as a wholesale merchant, broker, jobber, customs broker,~~
26 ~~reverse distributor, or agent, including a out-of-state distributor,~~
27 ~~who sells for resale, or negotiates for distribution, or takes~~
28 ~~possession of, any drug or device included in Section 4022. Unless~~
29 ~~otherwise authorized by law, a wholesaler may not store,~~
30 ~~warehouse, or authorize the storage or warehousing of drugs with~~
31 ~~any person or at any location not licensed by the board.~~

32 ~~(b) This section shall become inoperative and is repealed on~~
33 ~~January 1, 2006, unless a later enacted statute, that becomes~~
34 ~~operative before January 1, 2006, amends or repeals that date.~~

35 ~~SEC. 5. Section 4043 is added to the Business and Professions~~
36 ~~Code, to read:~~

37 ~~4043. (a) "Wholesaler" means and includes a person who~~
38 ~~acts as a wholesale merchant, broker, jobber, customs broker,~~
39 ~~reverse distributor, or agent, including a nonresident wholesaler,~~
40 ~~who sells for resale, or negotiates for distribution, or takes~~



1 possession of, any drug or device included in Section 4022. Unless
2 otherwise authorized by law, a wholesaler may not store,
3 warehouse, or authorize the storage or warehousing of drugs with
4 any person or at any location not licensed by the board.

5 ~~(b) This section shall become operative on January 1, 2006.~~

6 SEC. 6. Section 4053 of the Business and Professions Code
7 is amended to read:

8 4053. (a) Subdivision (a) of Section 4051 shall not apply to
9 a veterinary food-animal drug retailer or wholesaler if the board
10 shall find that sufficient, qualified supervision is employed by the
11 veterinary food-animal drug retailer or wholesaler to adequately
12 safeguard and protect the public health, nor shall Section 4051
13 apply to any laboratory licensed under Section 351 of Title III of
14 the Public Health Service Act (Public Law 78-410).

15 (b) An individual employed by a veterinary food-animal drug
16 retailer or wholesaler may apply for an exemption from Section
17 4051. In order to obtain and maintain that exemption, the
18 individual shall meet the following requirements:

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

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

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

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

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

33 (C) Knowledge and understanding of quality control systems.

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

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

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



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

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

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

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

12 (e) This section shall become inoperative and is repealed on
13 January 1, 2006, unless a later enacted statute, that becomes
14 operative before January 1, 2006, amends or repeals that date.

15 SEC. 7. Section 4053 is added to the Business and Professions
16 Code, to read:

17 4053. (a) Subdivision (a) of Section 4051 shall not apply to
18 a veterinary food-animal drug retailer or wholesaler that employs
19 a designated representative to adequately safeguard and protect the
20 public health, nor shall Section 4051 apply to any laboratory
21 licensed under Section 351 of Title III of the Public Health Service
22 Act (Public Law 78-410).

23 (b) An individual may apply for a designated representative
24 license. In order to obtain and maintain that license, the individual
25 shall meet all of the following requirements:

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

28 (2) He or she shall have a minimum of one year of paid work
29 experience, in the past three years, related to the distribution or
30 dispensing of dangerous drugs or dangerous devices or meet all of
31 the prerequisites to take the examination required for licensure as
32 a pharmacist by the board.

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

35 (A) Knowledge and understanding of California law and
36 federal law relating to the distribution of dangerous drugs and
37 dangerous devices.

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

40 (C) Knowledge and understanding of quality control systems.



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

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

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

8 (5) The board may not issue a license as a designated
9 representative until the applicant provides proof of completion of
10 the required training to the board.

11 (c) The veterinary food-animal drug retailer or wholesaler shall
12 not operate without a pharmacist or a designated representative on
13 its premises.

14 (d) Only a pharmacist or a designated representative shall
15 prepare and affix the label to veterinary food-animal drugs.

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

17 SEC. 8. Section 4053.1 is added to the Business and
18 Professions Code, to read:

19 4053.1. (a) Certificates of exemption issued or renewed
20 pursuant to Section 4053 prior to January 1, 2005, shall remain
21 valid until their expiration date or until January 1, 2007, whichever
22 date is earlier.

23 (b) Individuals in possession of a current and valid certificate
24 of exemption shall be issued a license as a designated
25 representative if the individual satisfies the requirements of
26 Section 4053 and pays the fee required by subdivision (i) of
27 Section 4400.

28 (c) This section shall become inoperative and be repealed on
29 January 1, 2007, unless a later enacted statute, that becomes
30 operative on or before December 31, 2006, amends or repeals that
31 date.

32 SEC. 9. Section 4054 of the Business and Professions Code
33 is amended to read:

34 4054. Section 4051 shall not apply to a manufacturer or
35 wholesaler that provides dialysis drugs and devices directly to
36 patients.

37 SEC. 10. Section 4059.5 of the Business and Professions
38 Code is amended to read:

39 4059.5. (a) Except as otherwise provided in this chapter,
40 dangerous drugs or dangerous devices may only be ordered by an



1 entity licensed by the board and must be delivered to the licensed
2 premises and signed for and received by the pharmacist-in-charge
3 or, in his or her absence, another pharmacist designated by the
4 pharmacist-in-charge. Where a licensee is permitted to operate
5 through an exemptee, the exemptee may sign for and receive the
6 delivery.

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

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

18 (d) Notwithstanding any other provision of law, a dangerous
19 drug or dangerous device may be ordered by and provided to a
20 manufacturer, physician, dentist, podiatrist, optometrist,
21 veterinarian, or laboratory, or a physical therapist acting within the
22 scope of his or her license. Any person or entity receiving delivery
23 of any dangerous drugs or dangerous devices, or a duly authorized
24 representative of the person or entity, shall sign for the receipt of
25 the dangerous drugs or dangerous devices.

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

38 (f) This section shall become inoperative and is repealed on
39 January 1, 2006, unless a later enacted statute, that becomes



1 operative on or before December 31, 2005, amends or repeals that
2 date.

3 SEC. 11. Section 4059.5 is added to the Business and
4 Professions Code, to read:

5 4059.5. (a) Except as otherwise provided in this chapter,
6 dangerous drugs or dangerous devices may only be ordered by an
7 entity licensed by the board and shall be delivered to the licensed
8 premises and signed for and received by the pharmacist-in-charge
9 or, in his or her absence, another pharmacist designated by the
10 pharmacist-in-charge. Where a licensee is permitted to operate
11 through a designated representative, the designated representative
12 may sign for and receive the delivery.

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

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

24 (d) Notwithstanding any other provision of law, a dangerous
25 drug or dangerous device may be ordered by and provided to a
26 manufacturer, physician, dentist, podiatrist, optometrist,
27 veterinarian, or laboratory, or physical therapist acting within the
28 scope of his or her license. A person or entity receiving delivery
29 of any dangerous drugs or dangerous devices, or a duly authorized
30 representative of the person or entity, shall sign for the receipt of
31 the dangerous drugs or dangerous devices.

32 (e) A dangerous drug or dangerous device shall not be
33 transferred, sold, or delivered to any person outside this state,
34 whether foreign or domestic, unless the transferor, seller, or
35 deliverer does so in compliance with the laws of this state and of
36 the United States and of the state or country to which the dangerous
37 drugs or dangerous devices are to be transferred, sold, or delivered.
38 Compliance with the laws of this state and the United States and
39 of the state or country to which the dangerous drugs or dangerous
40 devices are to be delivered shall include, but not be limited to,



1 determining that the recipient of the dangerous drugs or dangerous
2 devices is authorized by law to receive the dangerous drugs or
3 dangerous devices.

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

5 SEC. 12. Section 4081 of the Business and Professions Code
6 is amended to read:

7 4081. (a) All records of manufacture and of sale, acquisition,
8 or disposition of dangerous drugs or dangerous devices shall be at
9 all times during business hours open to inspection by authorized
10 officers of the law, and shall be preserved for at least three years
11 from the date of making. A current inventory shall be kept by every
12 manufacturer, wholesaler, pharmacy, veterinary food-animal drug
13 retailer, physician, dentist, podiatrist, veterinarian, laboratory,
14 clinic, hospital, institution, or establishment holding a currently
15 valid and unrevoked certificate, license, permit, registration, or
16 exemption under Division 2 (commencing with Section 1200) of
17 the Health and Safety Code or under Part 4 (commencing with
18 Section 16000) of Division 9 of the Welfare and Institutions Code
19 who maintains a stock of dangerous drugs or dangerous devices.

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

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

29 (d) This section shall become inoperative and is repealed on
30 January 1, 2006, unless a later enacted statute, that becomes
31 operative on or before January 1, 2006, amends or repeals that
32 date.

33 SEC. 13. Section 4081 is added to the Business and
34 Professions Code, to read:

35 4081. (a) All records of manufacture and of sale, acquisition,
36 or disposition of dangerous drugs or dangerous devices shall be at
37 all times during business hours open to inspection by authorized
38 officers of the law, and shall be preserved for at least three years
39 from the date of making. A current inventory shall be kept by every
40 manufacturer, wholesaler, pharmacy, veterinary food-animal drug



1 retailer, physician, dentist, podiatrist, veterinarian, laboratory,
2 clinic, hospital, institution, or establishment holding a currently
3 valid and unrevoked certificate, license, permit, registration, or
4 exemption under Division 2 (commencing with Section 1200) of
5 the Health and Safety Code or under Part 4 (commencing with
6 Section 16000) of Division 9 of the Welfare and Institutions Code
7 who maintains a stock of dangerous drugs or dangerous devices.

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

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

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

20 SEC. 14. Section 4084 is added to the Business and
21 Professions Code, to read:

22 4084. (a) When a board inspector finds, or has probable
23 cause to believe, that any dangerous drug or dangerous device is
24 adulterated or counterfeit, the board inspector shall affix a tag or
25 other marking to that dangerous drug or dangerous device. The
26 board inspector shall give notice to the person that the dangerous
27 drug or dangerous device bearing the tag or marking has been
28 embargoed.

29 (b) When a board inspector has found that an embargoed
30 dangerous drug or dangerous device is not adulterated or
31 counterfeit, a board inspector shall remove the tag or other
32 marking.

33 (c) A board inspector may secure a sample or specimen of a
34 dangerous drug or dangerous device. If the board inspector obtains
35 a sample prior to leaving the premises, the board inspector shall
36 leave a receipt describing the sample.

37 (d) For the purposes of this article “counterfeit” shall have the
38 meaning defined in Section 109905 of the Health and Safety Code.

39 (e) For the purposes of this article “adulterated” shall have the
40 meaning defined in Article 2 (commencing with Section 111250)



1 of Chapter 6 of Part 5 of Division 104 of the Health and Safety
2 Code.

3 SEC. 15. Section 4085 is added to the Business and
4 Professions Code, to read:

5 4085. (a) It is unlawful for any person to remove, sell, or
6 dispose of an embargoed dangerous drug or dangerous device
7 without permission of the board.

8 (b) When a board inspector has reasonable cause to believe,
9 that the embargo will be violated, a board inspector may remove
10 the embargoed dangerous drug or dangerous device from the
11 premises.

12 SEC. 16. Section 4086 is added to the Business and
13 Professions Code, to read:

14 4086. (a) If a dangerous drug or dangerous device is alleged
15 to be adulterated or counterfeit, the board shall commence
16 proceedings in the superior court in whose jurisdiction the
17 dangerous drug or dangerous device is located, for condemnation
18 of the dangerous drug or dangerous device.

19 (b) If the court finds that an embargoed dangerous drug or
20 dangerous device is adulterated or counterfeit, the dangerous drug
21 or dangerous device shall, after entry of the judgment, be
22 destroyed at the expense of the claimant or owner, under the
23 supervision of the board. All court costs and fees and all reasonable
24 costs incurred by the board in investigating and prosecuting the
25 action, including, but not limited to, the costs of storage and
26 testing, shall be paid by the claimant or owner of the dangerous
27 drug or dangerous device.

28 (c) A superior court of this state may condemn any dangerous
29 drug or dangerous device pursuant to this article. In the absence of
30 an order, the dangerous drug or dangerous device may be
31 destroyed under the supervision of the board who has the written
32 consent of the owner, his or her attorney, or authorized
33 representative. If the board cannot ascertain ownership of the
34 dangerous drug or dangerous device within 30 days of establishing
35 an embargo, the board may destroy the dangerous drug or
36 dangerous device.

37 SEC. 17. Section 4100 of the Business and Professions Code
38 is amended to read:

39 4100. (a) Within 30 days after changing his or her address of
40 record with the board or after changing his or her name according



1 to law, every pharmacist, intern pharmacist, technician, or
2 exemptee shall notify the executive officer of the board of the
3 change of address or change of name.

4 (b) This section shall become inoperative and is repealed on
5 January 1, 2006, unless a later enacted statute, that becomes
6 operative on or before January 1, 2006, amends or repeals that
7 date.

8 SEC. 18. Section 4100 is added to the Business and
9 Professions Code, to read:

10 4100. (a) Within 30 days after changing his or her address of
11 record with the board or after changing his or her name according
12 to law, a pharmacist, intern pharmacist, technician, or designated
13 representative shall notify the executive officer of the board of the
14 change of address or change of name.

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

16 SEC. 19. Section 4105 of the Business and Professions Code
17 is amended to read:

18 4105. (a) All records or other documentation of the
19 acquisition and disposition of dangerous drugs and dangerous
20 devices by any entity licensed by the board shall be retained on the
21 licensed premises in a readily retrievable form.

22 (b) The licensee may remove the original records or
23 documentation from the licensed premises on a temporary basis
24 for license-related purposes. However, a duplicate set of those
25 records or other documentation shall be retained on the licensed
26 premises.

27 (c) The records required by this section shall be retained on the
28 licensed premises for a period of three years from the date of
29 making.

30 (d) Any records that are maintained electronically shall be
31 maintained so that the pharmacist-in-charge, the pharmacist on
32 duty if the pharmacist-in-charge is not on duty, or, in the case of
33 a veterinary food-animal drug retailer or wholesaler, the
34 exemptee, shall, at all times during which the licensed premises are
35 open for business, be able to produce a hard copy and electronic
36 copy of all records of acquisition or disposition or other drug or
37 dispensing-related records maintained electronically.

38 (e) (1) Notwithstanding subdivisions (a), (b), and (c), the
39 board, may upon written request, grant to a licensee a waiver of the



1 requirements that the records described in subdivisions (a), (b),
2 and (c) be kept on the licensed premises.

3 (2) A waiver granted pursuant to this subdivision shall not
4 affect the board's authority under this section or any other
5 provision of this chapter.

6 (f) This section shall become inoperative and is repealed on
7 January 1, 2006, unless a later enacted statute, that becomes
8 operative on or before January 1, 2006, amends or repeals that
9 date.

10 SEC. 20. Section 4105 is added to the Business and
11 Professions Code, to read:

12 4105. (a) All records or other documentation of the
13 acquisition and disposition of dangerous drugs and dangerous
14 devices by any entity licensed by the board shall be retained on the
15 licensed premises in a readily retrievable form.

16 (b) The licensee may remove the original records or
17 documentation from the licensed premises on a temporary basis
18 for license-related purposes. However, a duplicate set of those
19 records or other documentation shall be retained on the licensed
20 premises.

21 (c) The records required by this section shall be retained on the
22 licensed premises for a period of three years from the date of
23 making.

24 (d) Any records that are maintained electronically shall be
25 maintained so that the pharmacist-in-charge, the pharmacist on
26 duty if the pharmacist-in-charge is not on duty, or, in the case of
27 a veterinary food-animal drug retailer or wholesaler, the
28 designated representative on duty, shall, at all times during which
29 the licensed premises are open for business, be able to produce a
30 hard copy and electronic copy of all records of acquisition or
31 disposition or other drug or dispensing-related records maintained
32 electronically.

33 (e) (1) Notwithstanding subdivisions (a), (b), and (c), the
34 board, may upon written request, grant to a licensee a waiver of the
35 requirements that the records described in subdivisions (a), (b),
36 and (c) be kept on the licensed premises.

37 (2) A waiver granted pursuant to this subdivision shall not
38 affect the board's authority under this section or any other
39 provision of this chapter.

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



1 ~~SEC. 21.—Section 4110 of the Business and Professions Code~~
2 ~~is amended to read:~~

3 ~~4110.—(a) No person shall conduct a pharmacy in the State of~~
4 ~~California unless he or she has obtained a license from the board.~~
5 ~~A license shall be required for each pharmacy owned or operated~~
6 ~~by a specific person. A separate license shall be required for each~~
7 ~~of the premises of any person operating a pharmacy in more than~~
8 ~~one location. The license shall be renewed annually. The board~~
9 ~~may, by regulation, determine the circumstances under which a~~
10 ~~license may be transferred.~~

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

30 ~~(c) This section shall become inoperative and is repealed on~~
31 ~~January 1, 2006, unless a later enacted statute, that becomes~~
32 ~~operative on or before January 1, 2006, amends or repeals that~~
33 ~~date.~~

34 ~~SEC. 22.—Section 4110 is added to the Business and~~
35 ~~Professions Code, to read:~~

36 ~~4110.—(a) No person shall conduct a pharmacy in the State of~~
37 ~~California unless he or she has obtained a license from the board.~~
38 ~~A license shall be required for each pharmacy owned or operated~~
39 ~~by a specific person. A separate license shall be required for each~~
40 ~~of the premises of any person operating a pharmacy in more than~~



1 ~~one location. The license shall be renewed annually. The board~~
2 ~~may, by regulation, determine the circumstances under which a~~
3 ~~license may be transferred.~~

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

23 (c) ~~An applicant for either the issuance or renewal of a~~
24 ~~pharmacy license that meets the definition of a contracting~~
25 ~~pharmacy in Section 4021.5 shall notify the board on a form~~
26 ~~approved by the board.~~

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

28 SEC. 23. Section 4126.5 is added to the Business and
29 Professions Code, to read:

30 4126.5. (a) A pharmacy may furnish dangerous drugs only to
31 the following:

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

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

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

37 (4) Another pharmacy or wholesaler to alleviate a temporary
38 shortage of a dangerous drug that could result in the denial of
39 health care. A pharmacy furnishing dangerous drugs pursuant to



1 this paragraph may only furnish a quantity sufficient to alleviate
2 the temporary shortage.

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

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

7 (7) To another pharmacy under common control.

8 (b) Notwithstanding any other provision of law, a violation of
9 ~~this section by either a closed pharmacy or a person engaged in a~~
10 ~~prohibited transaction with a closed pharmacy may subject the~~
11 ~~persons who committed the violation to a fine not to exceed the~~
12 ~~amount specified in Section 125.9 for each occurrence pursuant to~~
13 ~~a citation issued by the board.~~

14 ~~(c) For notifications made on and after January 1, 2005, the~~
15 ~~Franchise Tax Board, upon notification by the board of a final~~
16 ~~judgment in an action brought under this section, shall subtract the~~
17 ~~amount of the fine from any tax refunds or lottery winnings due~~
18 ~~to the person who is a defendant in the action using the offset~~
19 ~~authority under Section 12419.5 of the Government Code, as~~
20 ~~delegated by the Controller, and the processes as established by the~~
21 ~~Franchise Tax Board for this purpose. That amount shall be~~
22 ~~forwarded to the board for deposit in the Pharmacy Board~~
23 ~~Contingent Fund. this section by either a pharmacy whose primary~~
24 ~~or sole business is filling prescriptions for patients of long-term~~
25 ~~care facilities or a person engaged in a prohibited transaction with~~
26 ~~a pharmacy whose primary or sole business is filling prescriptions~~
27 ~~for patients of long-term care facilities may subject the persons~~
28 ~~who committed the violation to a fine not to exceed the amount~~
29 ~~specified in Section 125.9 for each occurrence pursuant to a~~
30 ~~citation issued by the board.~~

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

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



1 (e) For purposes of subdivision (b) of this section and
2 subdivision (s) of Section 4301, “long-term care facility” shall
3 have the same meaning given the term in Section 1418 of the
4 Health and Safety Code.

5 SEC. 24. Section 4160 of the Business and Professions Code
6 is amended to read:

7 4160. (a) A person may not act as a wholesaler of any
8 dangerous drug or dangerous device unless he or she has obtained
9 a license from the board.

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

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

15 (d) The board shall not issue or renew a wholesaler license until
16 the wholesaler designates an exemptee-in-charge and notifies the
17 board in writing of the identity and license number of that
18 exemptee-in-charge. The exemptee-in-charge shall be responsible
19 for the wholesaler’s compliance with state and federal laws
20 governing wholesalers. A wholesaler shall designate, and notify
21 the board of, a new exemptee-in-charge within 30 days of the date
22 that the prior exemptee-in-charge ceases to be the
23 exemptee-in-charge. A pharmacist may be designated as the
24 exemptee-in-charge.

25 (e) For purposes of this section, “exemptee-in-charge” means
26 a person granted a certificate of exemption pursuant to Section
27 4053, or a registered pharmacist, who is the supervisor or manager
28 of the facility.

29 (f) A drug manufacturer licensed by the Food and Drug
30 Administration or pursuant to Section 111615 of the Health and
31 Safety Code that only ships dangerous drugs or dangerous devices
32 of its own manufacture is exempt from this section.

33 (g) This section shall become inoperative and is repealed on
34 January 1, 2006, unless a later enacted statute, that becomes
35 operative on or before January 1, 2006, amends or repeals that
36 date.

37 SEC. 25. Section 4160 is added to the Business and
38 Professions Code, to read:



1 4160. (a) A person may not act as a wholesaler of any
2 dangerous drug or dangerous device unless he or she has obtained
3 a license from the board.

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

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

9 (d) The board shall not issue or renew a wholesaler license until
10 the wholesaler identifies a designated representative-in-charge
11 and notifies the board in writing of the identity and license number
12 of that designated representative. The designated
13 representative-in-charge shall be responsible for the wholesaler's
14 compliance with state and federal laws governing wholesalers. A
15 wholesaler shall identify and notify the board of a new designated
16 representative-in-charge within 30 days of the date that the prior
17 designated representative-in-charge ceases to be the designated
18 representative-in-charge. A pharmacist may be identified as the
19 designated representative-in-charge.

20 (e) A drug manufacturer licensed by the Food and Drug
21 Administration or licensed pursuant to Section 111615 of the
22 Health and Safety Code that only distributes dangerous drugs and
23 dangerous devices of its own manufacture is exempt from this
24 section and Section 4161.

25 (f) The board may issue a temporary license, upon conditions
26 and for periods of time as the board determines to be in the public
27 interest. A temporary license fee shall be fixed by the board at an
28 amount not to exceed the annual fee for renewal of a license to
29 conduct business as a wholesaler.

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

31 ~~SEC. 26. Section 4161 of the Business and Professions Code~~
32 ~~is repealed.~~

33 ~~SEC. 27. Section 4161 is added to the Business and~~
34 ~~Professions Code, to read:~~

35 ~~4161. (a) A person located outside this state that ships, mails,~~
36 ~~or delivers dangerous drugs or dangerous devices into this state at~~
37 ~~wholesale shall be considered an out-of-state distributor.~~

38 ~~(b) An out-of-state distributor shall be licensed by the board~~
39 ~~prior to shipping, mailing, or delivering dangerous drugs or~~
40 ~~dangerous devices to a site located in this state.~~



1 ~~(c) A separate license shall be required for each place of~~
2 ~~business owned or operated by an out-of-state distributor from or~~
3 ~~through which dangerous drugs or dangerous devices are shipped,~~
4 ~~mailed, or delivered to a site located in this state. A license shall~~
5 ~~be renewed annually and shall not be transferable.~~

6 ~~(d) The following information shall be reported, in writing, to~~
7 ~~the board at the time of initial application for licensure by a~~
8 ~~nonresident wholesaler, on renewal of an out-of-state distributor~~
9 ~~license, or within 30 days of a change in the following information:~~

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

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

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

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

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

19 ~~(f) An out-of-state distributor shall comply with all directions~~
20 ~~and requests for information from the regulatory or licensing~~
21 ~~agency of the state in which it is licensed, as well as with all~~
22 ~~requests for information made by the board.~~

23 ~~(g) An out-of-state distributor wholesaler shall maintain~~
24 ~~records of dangerous drugs and dangerous devices sold, traded, or~~
25 ~~transferred to persons in this state, so that the records are in a~~
26 ~~readily retrievable form.~~

27 ~~(h) An out-of-state distributor shall at all times maintain a~~
28 ~~valid, unexpired license, permit, or registration to conduct the~~
29 ~~business of the wholesaler in compliance with the laws of the state~~
30 ~~in which it is a resident. An application for an out-of-state~~
31 ~~distributor license in this state shall include a license verification~~
32 ~~from the licensing authority in the applicant's state of residence.~~

33 ~~(i) The board may not issue or renew an out-of-state distributor~~
34 ~~license until the out-of-state distributor identifies an~~
35 ~~exemptee in charge and notifies the board in writing of the~~
36 ~~identity and license number of the exemptee in charge.~~

37 ~~(j) The exemptee in charge shall be responsible for the~~
38 ~~nonresident wholesaler's compliance with state and federal laws~~
39 ~~governing wholesalers. A nonresident wholesaler shall identify~~
40 ~~and notify the board of a new exemptee in charge within 30 days~~



1 of the date that the prior exemptee in charge ceases to be the
2 exemptee in charge.

3 (k) The board may issue a temporary license, upon conditions
4 and for periods of time as the board determines to be in the public
5 interest. A temporary license fee shall be fixed by the board at an
6 amount not to exceed the annual fee for renewal of a license to
7 conduct business as an out-of-state distributor.

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

10 (m) This section shall become inoperative and be repealed on
11 January 1, 2006, unless a later enacted statute, that becomes
12 operative on or before December 31, 2006, amends or repeals that
13 date.

14 SEC. 28. Section 4161 is added to the Business and
15 Professions Code, to read:

16 4161. (a) A person located outside this state that ships, mails,
17 or delivers dangerous drugs or dangerous devices into this state at
18 wholesale shall be considered a nonresident wholesaler.

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

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

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

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

32 (2) Its principal corporate officers, as specified by the board, if
33 any.

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

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

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



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

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

9 ~~(h) A nonresident wholesaler shall at all times maintain a valid,~~
10 ~~unexpired license, permit, or registration to conduct the business~~
11 ~~of the wholesaler in compliance with the laws of the state in which~~
12 ~~it is a resident. An application for a nonresident wholesaler license~~
13 ~~in this state shall include a license verification from the licensing~~
14 ~~authority in the applicant's state of residence.~~

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

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

27 ~~(k) The board may issue a temporary license, upon conditions~~
28 ~~and for periods of time as the board determines to be in the public~~
29 ~~interest. A temporary license fee shall be fixed by the board at an~~
30 ~~amount not to exceed the annual fee for renewal of a license to~~
31 ~~conduct business as a nonresident wholesaler.~~

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

34 ~~(m) This section shall become operative on January 1, 2006.~~
35 SEC. 29. Section 4162 of the Business and Professions Code
36 is repealed.

37 SEC. 30. Section 4162 is added to the Business and
38 Professions Code, to read:

39 4162. (a) (1) An applicant for the issuance or renewal of a
40 wholesaler license shall submit a surety bond of one hundred



1 thousand dollars (\$100,000) or other equivalent means of security
2 acceptable to the board payable to the Pharmacy Board Contingent
3 Fund. The purpose of the surety bond is to secure payment of any
4 administrative fine imposed by the board and any cost recovery
5 ordered pursuant to Section 125.3.

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

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

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

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

23 (d) This section shall become operative on January 1, 2006, and
24 shall remain in effect only until January 1, 2011, and as of that date
25 is repealed, unless a later enacted statute, that is enacted before
26 January 1, 2011, deletes or extends those dates.

27 SEC. 31. Section 4163 of the Business and Professions Code
28 is amended to read:

29 4163. (a) No manufacturer or wholesaler shall furnish any
30 dangerous drugs or dangerous devices to any unauthorized
31 persons.

32 (b) No person shall acquire dangerous drugs or dangerous
33 devices from a person not authorized by law to possess or furnish
34 those dangerous drugs or dangerous devices.

35 (c) This section shall remain in effect only until January 1,
36 2007, and as of that date is repealed, unless a later enacted statute,
37 that is enacted before January 1, 2007, deletes or extends that date.

38 SEC. 32. Section 4163 is added to the Business and
39 Professions Code, to read:



1 4163. (a) A manufacturer or wholesaler may not furnish a
2 dangerous drug or dangerous device to an unauthorized person.

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

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

8 (d) A wholesaler or pharmacy may not acquire a dangerous
9 drug without receiving a pedigree.

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

11 SEC. 33. Section 4163.5 is added to the Business and
12 Professions Code, to read:

13 4163.5. The board may extend the date for compliance with
14 the requirement for a pedigree set forth in Section 4163 until
15 January 1, 2008, if it determines that manufacturers, ~~wholesalers,~~
16 ~~or pharmacies~~ *or wholesalers* require additional time to
17 implement electronic technologies to track the distribution of
18 dangerous drugs within the state. A determination by the board to
19 extend the deadline for providing pedigrees shall not be subject to
20 the requirements of Chapter 3.5 (commencing with Section
21 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

22 *SEC. 33.1. Section 4163.6 is added to the Business and*
23 *Professions Code, to read:*

24 *4163.6. If the board determines that it is not yet economically*
25 *and technically feasible for pharmacies to implement electronic*
26 *technologies to track the distribution of drugs within the state, the*
27 *board may extend the date for compliance with the requirement for*
28 *a pedigree for pharmacies set forth in Section 4163 until January*
29 *1, 2009. A determination by the board to extend the deadline for*
30 *providing pedigrees shall not be subject to the requirements of*
31 *Chapter 3.5 (commencing with Section 11340) of Part 1 of*
32 *Division 3 of Title 2 of the Government Code.*

33 SEC. 34. Section 4164 of the Business and Professions Code
34 is amended to read:

35 4164. (a) All wholesalers licensed by the board and all
36 manufacturers who distribute controlled substances, dangerous
37 drugs, or dangerous devices within or into this state shall report to
38 the board all sales of dangerous drugs and controlled substances
39 that are subject to abuse, as determined by the board.



1 (b) This section shall become inoperative and is repealed on
 2 January 1, 2006, unless a later enacted statute, that becomes
 3 operative on or before January 1, 2006, amends or repeals that
 4 date.

5 SEC. 35. Section 4164 is added to the Business and
 6 Professions Code, to read:

7 4164. (a) A wholesaler licensed by the board that distributes
 8 controlled substances, dangerous drugs, or dangerous devices
 9 within or into this state shall report to the board all sales of
 10 dangerous drugs and controlled substances that are subject to
 11 abuse, as determined by the board.

12 ~~(b) Each wholesaler shall report excessive purchases of~~
 13 ~~dangerous drugs at preferential or contract prices by contracting~~
 14 ~~pharmacies to the board, as designated by the board pursuant to~~
 15 ~~Section 4021.5.~~

16 ~~(c)~~

17 (b) Each wholesaler shall develop and maintain a system for
 18 tracking individual sales of dangerous drugs at preferential or
 19 contract prices to ~~contracting pharmacies~~ *pharmacies that*
 20 *primarily or solely dispense prescription drugs to patients of*
 21 *long-term care facilities.* The system shall be capable of
 22 identifying purchases ~~by an established customer which~~ *of any*
 23 *dangerous drug at preferential or contract prices by customers that*
 24 *vary significantly from prior ordering patterns for the same*
 25 *customer, including by identifying purchases in the preceding 12*
 26 *calendar months by that customer or similar customers and*
 27 *identifying current purchases that exceed prior purchases by either*
 28 *that customer or similar customers by a factor of 20 percent. Each*
 29 *wholesaler shall have the tracking system required by this*
 30 *subdivision in place no later than January 1, 2006.*

31 ~~(d)~~

32 (c) Upon written, oral, or electronic request by the board, a
 33 wholesaler shall furnish ~~that data, or any specific portion thereof,~~
 34 *data tracked pursuant to subdivision (b) to the board in written,*
 35 *hardcopy, or electronic form. The board shall specify the*
 36 *dangerous drugs, the customers, or both the dangerous drugs and*
 37 *customers for which data are to be furnished, and the wholesaler*
 38 *shall have 30 calendar days to comply with the request.*

39 ~~(e)~~



1 (d) As used in this section, “preferential or contract prices”
2 means and refers to purchases by contract of dangerous drugs at
3 prices below the market wholesale price for those drugs.

4 ~~(f)~~

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

6 SEC. 36. Section 4165 of the Business and Professions Code
7 is amended to read:

8 4165. A wholesaler licensed by the board who sells or
9 transfers any dangerous drug or dangerous device into this state or
10 who receives, by sale or otherwise, any dangerous drug or
11 dangerous device from any person in this state shall, on request,
12 furnish an authorized officer of the law with all records or other
13 documentation of that sale or transfer.

14 SEC. 37. Section 4166 of the Business and Professions Code
15 is amended to read:

16 4166. (a) Any wholesaler that uses the services of any carrier,
17 including, but not limited to, the United States Postal Service or
18 any common carrier, shall be liable for the security and integrity
19 of any dangerous drugs or dangerous devices through that carrier
20 until the drugs or devices are delivered to the transferee at its
21 board-licensed premises.

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

25 SEC. 38. Section 4168 is added to the Business and
26 Professions Code, to read:

27 4168. A county or municipality may not issue a business
28 license for any establishment that requires a wholesaler license
29 unless the establishment possesses a current wholesaler license
30 issued by the board. For purposes of this section, an
31 “establishment” is the licensee’s physical location in California.

32 SEC. 39. Section 4169 is added to the Business and
33 Professions Code, to read:

34 4169. (a) A person or entity may not do any of the following:

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

39 (2) Purchase, trade, sell, or transfer dangerous drugs that the
40 person knew or reasonably should have known were adulterated,



1 as set forth in Article 2 (commencing with Section 111250) of
2 Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

3 (3) Purchase, trade, sell, or transfer dangerous drugs that the
4 person knew or reasonably should have known were misbranded,
5 as defined in Section 111335 of the Health and Safety Code.

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

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

10 (b) Notwithstanding any other provision of law, a violation of
11 this section may subject the person or entity that has committed the
12 violation to a fine not to exceed the amount specified in Section
13 125.9 for each occurrence, pursuant to a citation issued by the
14 board.

15 ~~(e) The Franchise Tax Board, upon notification by the board of~~
16 ~~a final judgment in an action brought under this section, shall~~
17 ~~subtract the amount of the fine from any tax funds or lottery~~
18 ~~winnings due to the person who is a defendant in the action using~~
19 ~~the offset authority under Section 12419.5 of the Government~~
20 ~~Code, as delegated by the Controller, and the processes established~~
21 ~~by the Franchise Tax Board for this purpose. That amount shall be~~
22 ~~forwarded to the board for deposit in the Pharmacy Board~~
23 ~~Contingent Fund.~~

24 *(c) Amounts due from any person under this section shall be*
25 *offset as provided under Section 12419.5 of the Government Code.*
26 *Amounts received by the board under this section shall be*
27 *deposited into the Pharmacy Board Contingent Fund.*

28 (d) This section shall not apply to a pharmaceutical
29 manufacturer licensed by the Food and Drug Administration or by
30 the State Department of Health Services.

31 (e) This section shall remain in effect only until January 1,
32 2007, and as of that date is repealed, unless a later enacted statute,
33 that is enacted before January 1, 2007, deletes or extends that date.

34 SEC. 40. Section 4169 is added to the Business and
35 Professions Code, to read:

36 4169. (a) A person or entity may not do any of the following:

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



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

5 (3) Purchase, trade, sell, or transfer dangerous drugs that the
6 person knew or reasonably should have known were misbranded,
7 as defined in Section 111335 of the Health and Safety Code.

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

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

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

17 ~~(e) The Franchise Tax Board, upon notification by the board of
18 a final judgment in an action brought under this section, shall
19 subtract the amount of the fine from any tax funds or lottery
20 winnings due to the person who is a defendant in the action using
21 the offset authority under Section 12419.5 of the Government
22 Code, as delegated by the Controller, and the processes established
23 by the Franchise Tax Board for this purpose. That amount shall be
24 forwarded to the board for deposit in the Pharmacy Board
25 Contingent Fund.~~

26 *(c) Amounts due from any person under this section shall be*
27 *offset as provided under Section 12419.5 of the Government Code.*
28 *Amounts received by the board under this section shall be*
29 *deposited into the Pharmacy Board Contingent Fund.*

30 (d) This section shall not apply to a pharmaceutical
31 manufacturer licensed by the Food and Drug Administration or by
32 the State Department of Health Services.

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

34 SEC. 41. Section 4196 of the Business and Professions Code
35 is amended to read:

36 4196. (a) No person shall conduct a veterinary food-animal
37 drug retailer in the State of California unless he or she has obtained
38 a license from the board. A license shall be required for each
39 veterinary food-animal drug retailer owned or operated by a
40 specific person. A separate license shall be required for each of the



1 premises of any person operating a veterinary food-animal drug
2 retailer in more than one location. The license shall be renewed
3 annually and shall not be transferable.

4 (b) The board may issue a temporary license, upon conditions
5 and for periods of time as the board determines to be in the public
6 interest. A temporary license fee shall be fixed by the board at an
7 amount not to exceed the annual fee for renewal of a license to
8 conduct a veterinary food-animal drug retailer.

9 (c) No person other than a pharmacist, an intern pharmacist, an
10 exempt person, an authorized officer of the law, or a person
11 authorized to prescribe, shall be permitted in that area, place, or
12 premises described in the permit issued by the board pursuant to
13 Section 4041, wherein veterinary food-animal drugs are stored,
14 possessed, or repacked. A pharmacist or exemptee shall be
15 responsible for any individual who enters the veterinary
16 food-animal drug retailer for the purpose of performing clerical,
17 inventory control, housekeeping, delivery, maintenance, or
18 similar functions relating to the veterinary food-animal drug
19 retailer.

20 (d) The board shall not issue or renew a veterinary food-animal
21 retailer license until the veterinary food-animal drug retailer
22 designates an exemptee-in-charge and notifies the board in writing
23 of the identity and license number of that exemptee. The
24 exemptee-in-charge shall be responsible for the veterinary
25 food-animal drug retailer's compliance with state and federal laws
26 governing veterinary food-animal drug retailers. Each veterinary
27 food-animal drug retailer shall designate, and notify the board of,
28 a new exemptee-in-charge within 30 days of the date that the prior
29 exemptee-in-charge ceases to be the exemptee-in-charge. A
30 pharmacist may be designated as the exemptee-in-charge.

31 (e) For purposes of this section, "exemptee-in-charge" means
32 a person granted a certificate of exemption pursuant to Section
33 4053, or a registered pharmacist, who is the supervisor or manager
34 of the facility.

35 (f) This section shall become inoperative and is repealed on
36 January 1, 2006, unless a later enacted statute, that becomes
37 operative on or before January 1, 2006, amends or repeals that
38 date.

39 SEC. 42. Section 4196 is added to the Business and
40 Professions Code, to read:



1 4196. (a) No person shall conduct a veterinary food-animal
2 drug retailer in the State of California unless he or she has obtained
3 a license from the board. A license shall be required for each
4 veterinary food-animal drug retailer owned or operated by a
5 specific person. A separate license shall be required for each of the
6 premises of any person operating a veterinary food-animal drug
7 retailer in more than one location. The license shall be renewed
8 annually and shall not be transferable.

9 (b) The board may issue a temporary license, upon conditions
10 and for periods of time as the board determines to be in the public
11 interest. A temporary license fee shall be fixed by the board at an
12 amount not to exceed the annual fee for renewal of a license to
13 conduct a veterinary food-animal drug retailer.

14 (c) No person other than a pharmacist, an intern pharmacist, a
15 designated representative, an authorized officer of the law, or a
16 person authorized to prescribe, shall be permitted in that area,
17 place, or premises described in the permit issued by the board
18 pursuant to Section 4041, wherein veterinary food-animal drugs
19 are stored, possessed, or repacked. A pharmacist or designated
20 representative shall be responsible for any individual who enters
21 the veterinary food-animal drug retailer for the purpose of
22 performing clerical, inventory control, housekeeping, delivery,
23 maintenance, or similar functions relating to the veterinary
24 food-animal drug retailer.

25 (d) The board shall not issue or renew a veterinary food-animal
26 retailer license until the veterinary food-animal drug retailer
27 identifies a designated representative-in-charge and notifies the
28 board in writing of the identity and license number of that
29 designated representative. The designated
30 representative-in-charge shall be responsible for the veterinary
31 food-animal drug retailer's compliance with state and federal laws
32 governing veterinary food-animal drug retailers. Each veterinary
33 food-animal drug retailer shall identify, and notify the board of, a
34 new designated representative-in-charge within 30 days of the date
35 that the prior designated representative-in-charge ceases to be the
36 designated representative-in-charge. A pharmacist may be
37 identified as the designated representative-in-charge.

38 (e) For purposes of this section, designated
39 representative-in-charge means a person granted a designated



1 representative license pursuant to Section 4053, or a registered
2 pharmacist, who is the supervisor or manager of the facility.

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

4 SEC. 43. Section 4301 of the Business and Professions Code
5 is amended to read:

6 4301. The board shall take action against any holder of a
7 license who is guilty of unprofessional conduct or whose license
8 has been procured by fraud or misrepresentation or issued by
9 mistake. Unprofessional conduct shall include, but is not limited
10 to, any of the following:

11 (a) Gross immorality.

12 (b) Incompetence.

13 (c) Gross negligence.

14 (d) The clearly excessive furnishing of controlled substances in
15 violation of subdivision (a) of Section 11153 of the Health and
16 Safety Code.

17 (e) The clearly excessive furnishing of controlled substances in
18 violation of subdivision (a) of Section 11153.5 of the Health and
19 Safety Code. Factors to be considered in determining whether the
20 furnishing of controlled substances is clearly excessive shall
21 include, but not be limited to, the amount of controlled substances
22 furnished, the previous ordering pattern of the customer (including
23 size and frequency of orders), the type and size of the customer,
24 and where and to whom the customer distributes its product.

25 (f) The commission of any act involving moral turpitude,
26 dishonesty, fraud, deceit, or corruption, whether the act is
27 committed in the course of relations as a licensee or otherwise, and
28 whether the act is a felony or misdemeanor or not.

29 (g) Knowingly making or signing any certificate or other
30 document that falsely represents the existence or nonexistence of
31 a state of facts.

32 (h) The administering to oneself, of any controlled substance,
33 or the use of any dangerous drug or of alcoholic beverages to the
34 extent or in a manner as to be dangerous or injurious to oneself, to
35 a person holding a license under this chapter, or to any other person
36 or to the public, or to the extent that the use impairs the ability of
37 the person to conduct with safety to the public the practice
38 authorized by the license.

39 (i) Except as otherwise authorized by law, knowingly selling,
40 furnishing, giving away, or administering or offering to sell,



1 furnish, give away, or administer any controlled substance to an
2 addict.

3 (j) The violation of any of the statutes of this state or of the
4 United States regulating controlled substances and dangerous
5 drugs.

6 (k) The conviction of more than one misdemeanor or any
7 felony involving the use, consumption, or self-administration of
8 any dangerous drug or alcoholic beverage, or any combination of
9 those substances.

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

34 (m) The cash compromise of a charge of violation of Chapter
35 13 (commencing with Section 801) of Title 21 of the United States
36 Code regulating controlled substances or of Chapter 7
37 (commencing with Section 14000) of Part 3 of Division 9 of the
38 Welfare and Institutions Code relating to the Medi-Cal program.
39 The record of the compromise is conclusive evidence of
40 unprofessional conduct.



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

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

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

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

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

19 (s) This section shall become inoperative and is repealed on
20 January 1, 2006, unless a later enacted statute, that becomes
21 operative on or before January 1, 2006, amends or repeals that
22 date.

23 SEC. 44. Section 4301 is added to the Business and
24 Professions Code, to read:

25 4301. The board shall take action against any holder of a
26 license who is guilty of unprofessional conduct or whose license
27 has been procured by fraud or misrepresentation or issued by
28 mistake. Unprofessional conduct shall include, but is not limited
29 to, any of the following:

30 (a) Gross immorality.

31 (b) Incompetence.

32 (c) Gross negligence.

33 (d) The clearly excessive furnishing of controlled substances in
34 violation of subdivision (a) of Section 11153 of the Health and
35 Safety Code.

36 (e) The clearly excessive furnishing of controlled substances in
37 violation of subdivision (a) of Section 11153.5 of the Health and
38 Safety Code. Factors to be considered in determining whether the
39 furnishing of controlled substances is clearly excessive shall
40 include, but not be limited to, the amount of controlled substances



1 furnished, the previous ordering pattern of the customer (including
2 size and frequency of orders), the type and size of the customer,
3 and where and to whom the customer distributes its product.

4 (f) The commission of any act involving moral turpitude,
5 dishonesty, fraud, deceit, or corruption, whether the act is
6 committed in the course of relations as a licensee or otherwise, and
7 whether the act is a felony or misdemeanor or not.

8 (g) Knowingly making or signing any certificate or other
9 document that falsely represents the existence or nonexistence of
10 a state of facts.

11 (h) The administering to oneself, of any controlled substance,
12 or the use of any dangerous drug or of alcoholic beverages to the
13 extent or in a manner as to be dangerous or injurious to oneself, to
14 a person holding a license under this chapter, or to any other person
15 or to the public, or to the extent that the use impairs the ability of
16 the person to conduct with safety to the public the practice
17 authorized by the license.

18 (i) Except as otherwise authorized by law, knowingly selling,
19 furnishing, giving away, or administering or offering to sell,
20 furnish, give away, or administer any controlled substance to an
21 addict.

22 (j) The violation of any of the statutes of this state or of the
23 United States regulating controlled substances and dangerous
24 drugs.

25 (k) The conviction of more than one misdemeanor or any
26 felony involving the use, consumption, or self-administration of
27 any dangerous drug or alcoholic beverage, or any combination of
28 those substances.

29 (l) The conviction of a crime substantially related to the
30 qualifications, functions, and duties of a licensee under this
31 chapter. The record of conviction of a violation of Chapter 13
32 (commencing with Section 801) of Title 21 of the United States
33 Code regulating controlled substances or of a violation of the
34 statutes of this state regulating controlled substances or dangerous
35 drugs shall be conclusive evidence of unprofessional conduct. In
36 all other cases, the record of conviction shall be conclusive
37 evidence only of the fact that the conviction occurred. The board
38 may inquire into the circumstances surrounding the commission
39 of the crime, in order to fix the degree of discipline or, in the case
40 of a conviction not involving controlled substances or dangerous



1 drugs, to determine if the conviction is of an offense substantially
2 related to the qualifications, functions, and duties of a licensee
3 under this chapter. A plea or verdict of guilty or a conviction
4 following a plea of nolo contendere is deemed to be a conviction
5 within the meaning of this provision. The board may take action
6 when the time for appeal has elapsed, or the judgment of
7 conviction has been affirmed on appeal or when an order granting
8 probation is made suspending the imposition of sentence,
9 irrespective of a subsequent order under Section 1203.4 of the
10 Penal Code allowing the person to withdraw his or her plea of
11 guilty and to enter a plea of not guilty, or setting aside the verdict
12 of guilty, or dismissing the accusation, information, or indictment.

13 (m) The cash compromise of a charge of violation of Chapter
14 13 (commencing with Section 801) of Title 21 of the United States
15 Code regulating controlled substances or of Chapter 7
16 (commencing with Section 14000) of Part 3 of Division 9 of the
17 Welfare and Institutions Code relating to the Medi-Cal program.
18 The record of the compromise is conclusive evidence of
19 unprofessional conduct.

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

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

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

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

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

38 ~~(s) The clearly excessive furnishing of dangerous drugs to a~~
39 ~~contracting pharmacy by a wholesaler. Factors to be~~



1 (s) *The clearly excessive furnishing of dangerous drugs by a*
2 *wholesaler to a pharmacy that primarily or solely dispenses*
3 *prescription drugs to patients of long-term care facilities. Factors*
4 *to be considered in determining whether the furnishing of*
5 *dangerous drugs is clearly excessive shall include, but shall not be*
6 *limited to, the amount of dangerous drugs furnished to a ~~closed~~*
7 *~~door-pharmacy~~ pharmacy that primarily or solely dispenses*
8 *prescription drugs to patients of long-term care facilities, the*
9 *previous ordering pattern of the ~~closed-door~~ pharmacy, and the*
10 *general patient population to whom the ~~closed-door~~ pharmacy*
11 *distributes the dangerous drugs. That a wholesaler has*
12 *established, and employs, a tracking system that complies with the*
13 *requirements of subdivision (b) of Section 4164 shall be considered*
14 *in determining whether there has been a violation of this*
15 *subdivision. This provision shall not be interpreted to require a*
16 *wholesaler to obtain personal medical information or be*
17 *authorized to permit a wholesaler to have access to personal*
18 *medical information except as otherwise authorized by Section 56*
19 *and following of the Civil Code.*

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

21 SEC. 45. Section 4305.5 of the Business and Professions
22 Code is amended to read:

23 4305.5. (a) Any person who has obtained a license to conduct
24 a wholesaler or veterinary food-animal drug retailer, shall notify
25 the board within 30 days of the termination of employment of any
26 pharmacist or exemptee who takes charge of, or acts as manager
27 of the licensee. Failure to notify the board within the 30-day period
28 shall constitute grounds for disciplinary action.

29 (b) Any person who has obtained a license to conduct a
30 wholesaler or veterinary food-animal drug retailer, who willfully
31 fails to notify the board of the termination of employment of any
32 pharmacist or exemptee who takes charge of, or acts as manager
33 of the licensee, and who continues to operate the licensee in the
34 absence of a pharmacist or an exemptee approved for that location,
35 shall be subject to summary suspension or revocation of his or her
36 license to conduct a wholesaler or veterinary food-animal drug
37 retailer.

38 (c) Any pharmacist or exemptee who takes charge of, or acts as
39 manager of a wholesaler or veterinary food-animal drug retailer,
40 who terminates his or her employment at the licensee, shall notify



1 the board within 30 days of the termination of employment.
2 Failure to notify the board within the 30-day period shall constitute
3 grounds for disciplinary action.

4 (d) This section shall become inoperative and is repealed on
5 January 1, 2006, unless a later enacted statute, that becomes
6 operative on or before January 1, 2006, amends or repeals that
7 date.

8 SEC. 46. Section 4305.5 is added to the Business and
9 Professions Code, to read:

10 4305.5. (a) A person who has obtained a license to conduct
11 a wholesaler or veterinary food-animal drug retailer, shall notify
12 the board within 30 days of the termination of employment of the
13 designated representative-in-charge. Failure to notify the board
14 within the 30-day period shall constitute grounds for disciplinary
15 action.

16 (b) A person who has obtained a license to conduct a wholesaler
17 or veterinary food-animal drug retailer, who willfully fails to
18 notify the board of the termination of employment of the
19 designated representative-in-charge, and who continues to operate
20 the licensee in the absence of the designated
21 representative-in-charge for that location, shall be subject to
22 summary suspension or revocation of his or her license to conduct
23 a wholesaler or veterinary food-animal drug retailer.

24 (c) A designated representative-in-charge of a wholesaler or
25 veterinary food-animal drug retailer, who terminates his or her
26 employment at the licensee, shall notify the board within 30 days
27 of the termination of employment. Failure to notify the board
28 within the 30-day period shall constitute grounds for disciplinary
29 action.

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

31 SEC. 47. Section 4331 of the Business and Professions Code
32 is amended to read:

33 4331. (a) Any person who is neither a pharmacist nor an
34 exemptee and who takes charge of a wholesaler or veterinary
35 food-animal drug retailer or who dispenses a prescription or
36 furnishes dangerous devices except as otherwise provided in this
37 chapter is guilty of a misdemeanor.

38 (b) Any person who has obtained a license to conduct a
39 veterinary food-animal drug retailer and who fails to place in
40 charge of that veterinary food-animal drug retailer a pharmacist or



1 exemptee, or any person who, by himself or herself, or by any
2 other person, permits the dispensing of prescriptions, except by a
3 pharmacist or exemptee, or as otherwise provided in this chapter,
4 is guilty of a misdemeanor.

5 (c) Any person who has obtained a license to conduct a
6 wholesaler and who fails to place in charge of that wholesaler a
7 pharmacist or exemptee, or any person who, by himself or herself,
8 or by any other person, permits the furnishing of dangerous drugs
9 or dangerous devices, except by a pharmacist or exemptee, or as
10 otherwise provided in this chapter, is guilty of a misdemeanor.

11 (d) This section shall become inoperative and is repealed on
12 January 1, 2006, unless a later enacted statute, that becomes
13 operative on or before January 1, 2006, amends or repeals that
14 date.

15 SEC. 48. Section 4331 is added to the Business and
16 Professions Code, to read:

17 4331. (a) A person who is neither a pharmacist nor a
18 designated representative and who takes charge of a wholesaler or
19 veterinary food-animal drug retailer or who dispenses a
20 prescription or furnishes dangerous devices except as otherwise
21 provided in this chapter is guilty of a misdemeanor.

22 (b) A person who has obtained a license to conduct a veterinary
23 food-animal drug retailer and who fails to place in charge of that
24 veterinary food-animal drug retailer a pharmacist or designated
25 representative, or any person who, by himself or herself, or by any
26 other person, permits the dispensing of prescriptions, except by a
27 pharmacist or designated representative, or as otherwise provided
28 in this chapter, is guilty of a misdemeanor.

29 (c) A person who has obtained a license to conduct a wholesaler
30 and who fails to place in charge of that wholesaler a pharmacist or
31 designated representative, or any person who, by himself or
32 herself, or by any other person, permits the furnishing of
33 dangerous drugs or dangerous devices, except by a pharmacist or
34 designated representative, or as otherwise provided in this chapter,
35 is guilty of a misdemeanor.

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

37 SEC. 49. Section 4400 of the Business and Professions Code
38 is amended to read:



1 4400. The amount of fees and penalties prescribed by this
2 chapter, except as otherwise provided, is that fixed by the board
3 according to the following schedule:

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

7 (b) The fee for a nongovernmental pharmacy or medical device
8 retailer annual renewal shall be one hundred seventy-five dollars
9 (\$175) and may be increased to two hundred fifty dollars (\$250).

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

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

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

20 (f) The fee for a wholesaler license and annual renewal shall be
21 five hundred fifty dollars (\$550) and may be increased to six
22 hundred dollars (\$600).

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

26 (h) The fee for application and investigation for an exemptee
27 license under Section 4053 shall be seventy-five dollars (\$75) and
28 may be increased to one hundred dollars (\$100), except for a
29 veterinary food-animal drug retailer exemptee, for whom the fee
30 shall be one hundred dollars (\$100).

31 (i) The fee for an exemptee license and annual renewal under
32 Section 4053 shall be one hundred ten dollars (\$110) and may be
33 increased to one hundred fifty dollars (\$150), except that the fee
34 for the issuance of a veterinary food-animal drug retailer exemptee
35 license shall be one hundred fifty dollars (\$150), for renewal one
36 hundred ten dollars (\$110), which may be increased to one
37 hundred fifty dollars (\$150), and for filing a late renewal fifty-five
38 dollars (\$55).

39 (j) The fee for an out-of-state drug distributor's license and
40 annual renewal issued pursuant to Section 4120 shall be five



1 hundred fifty dollars (\$550) and may be increased to six hundred
2 dollars (\$600).

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

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

9 (m) The fee for evaluation of applications submitted by
10 graduates of foreign colleges of pharmacy or colleges of pharmacy
11 not recognized by the board shall be one hundred sixty-five dollars
12 (\$165) and may be increased to one hundred seventy-five dollars
13 (\$175).

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

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

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

26 (q) The fee for the reissuance of any license, or renewal thereof,
27 that must be reissued because of a change in the information, is
28 sixty dollars (\$60) and may be increased to one hundred dollars
29 (\$100).

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

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

39 (t) The board shall charge a fee for the processing and issuance
40 of a registration to a pharmacy technician and a separate fee for the



1 biennial renewal of the registration. The registration fee shall be
2 twenty-five dollars (\$25) and may be increased to fifty dollars
3 (\$50). The biennial renewal fee shall be twenty-five dollars (\$25)
4 and may be increased to fifty dollars (\$50).

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

9 (v) The fee for issuance of a retired license pursuant to Section
10 4200.5 shall be thirty dollars (\$30).

11 (w) This section shall become inoperative and is repealed on
12 January 1, 2006, unless a later enacted statute, that becomes
13 operative on or before January 1, 2006, amends or repeals that
14 date.

15 SEC. 50. Section 4400 is added to the Business and
16 Professions Code, to read:

17 4400. The amount of fees and penalties prescribed by this
18 chapter, except as otherwise provided is that fixed by the board
19 according to the following schedule:

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

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

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

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

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

36 (f) The fee for a wholesaler license and annual renewal shall be
37 five hundred fifty dollars (\$550) and may be increased to six
38 hundred dollars (\$600).



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

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

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

18 (j) The fee for a nonresident wholesaler's license and annual
19 renewal issued pursuant to Section 4120 shall be five hundred fifty
20 dollars (\$550) and may be increased to six hundred dollars (\$600).

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

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

27 (m) The fee for evaluation of applications submitted by
28 graduates of foreign colleges of pharmacy or colleges of pharmacy
29 not recognized by the board shall be one hundred sixty-five dollars
30 (\$165) and may be increased to one hundred seventy-five dollars
31 (\$175).

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

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



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

4 (q) The fee for the reissuance of any license, or renewal thereof,
5 that must be reissued because of a change in the information, is
6 sixty dollars (\$60) and may be increased to one hundred dollars
7 (\$100).

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

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

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

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

27 (v) The fee for issuance of a retired license pursuant to Section
28 4200.5 shall be thirty dollars (\$30).

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

30 SEC. 51. *This act shall become operative only if Assembly Bill*
31 *2682 is also enacted and becomes effective on or before January*
32 *1, 2005.*

33 SEC. 52. No reimbursement is required by this act pursuant
34 to Section 6 of Article XIII B of the California Constitution
35 because the only costs that may be incurred by a local agency or
36 school district will be incurred because this act creates a new crime
37 or infraction, eliminates a crime or infraction, or changes the
38 penalty for a crime or infraction, within the meaning of Section
39 17556 of the Government Code, or changes the definition of a



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

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Attachment 14

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AMENDED IN ASSEMBLY JULY 2, 2004
AMENDED IN ASSEMBLY JUNE 16, 2004
AMENDED IN ASSEMBLY JUNE 7, 2004
AMENDED IN SENATE APRIL 21, 2004

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, 1054, 1274, 2041, 2082, 2087, 2107, 2274, 2317, 2420, 2423, 2462, 2532.6, 2570.14, 2902, 2915.7, 2936, 3750.5, 4005, 4030, 4059.5, 4076, 4081, 4101, 4114, *4115*, 4200, 4207, 4409, 4980.395, 4990.4, 4996.18, 4996.20, and 4996.26 of, to amend and repeal Section 5810 of, to add Sections 1005, *2475.1*, 2514, 2571, ~~3702.5~~, 3702.7, 3719.5, 3769.3, 4026.5, 4068, 4107, 4127.7, 4170.5, 4208, and 4209 to, and to repeal Section 2265 of, the Business and Professions Code, to amend Section 13401 of the Corporations Code, and to amend Sections 11159.1, ~~11207~~, and ~~111625~~ *and 11207* of the Health and Safety Code, relating to professions.

LEGISLATIVE COUNSEL'S DIGEST

SB 1913, as amended, 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

1 reprimand, after it has conducted an investigation, in lieu of filing
2 or prosecuting a formal accusation.

3 (b) The stipulation shall contain the authority, grounds, and
4 causes and circumstances for taking such action and by way of
5 waiving the affected licensee's rights, inform the licensee of his or
6 her rights to have a formal accusation filed and stipulate to a
7 settlement thereafter or have the matter in the statement of issues
8 heard before an administrative law judge in accordance with the
9 Administrative Procedures Act.

10 (c) The stipulation shall be public information and shall be used
11 as evidence in any future disciplinary or penalty action taken by
12 the board.

13 ~~SEC. 27.~~

14 *SEC. 26.* Section 4005 of the Business and Professions Code
15 is amended to read:

16 4005. (a) The board may adopt rules and regulations, not
17 inconsistent with the laws of this state, as may be necessary for the
18 protection of the public. Included therein shall be the right to adopt
19 rules and regulations as follows: for the proper and more effective
20 enforcement and administration of this chapter; pertaining to the
21 practice of pharmacy; relating to the sanitation of persons and
22 establishments licensed under this chapter; pertaining to
23 establishments wherein any drug or device is compounded,
24 prepared, furnished, or dispensed; providing for standards of
25 minimum equipment for establishments licensed under this
26 chapter; pertaining to the sale of drugs by or through any
27 mechanical device; and relating to pharmacy practice experience
28 necessary for licensure as a pharmacist.

29 (b) Notwithstanding any provision of this chapter to the
30 contrary, the board may adopt regulations permitting the
31 dispensing of drugs or devices in emergency situations, and
32 permitting dispensing of drugs or devices pursuant to a
33 prescription of a person licensed to prescribe in a state other than
34 California where the person, if licensed in California in the same
35 licensure classification would, under California law, be permitted
36 to prescribe drugs or devices and where the pharmacist has first
37 interviewed the patient to determine the authenticity of the
38 prescription.

39 (c) The board may, by rule or regulation, adopt, amend, or
40 repeal rules of professional conduct appropriate to the



1 establishment and maintenance of a high standard of integrity and
2 dignity in the profession. Every person who holds a license issued
3 by the board shall be governed and controlled by the rules of
4 professional conduct adopted by the board.

5 (d) The adoption, amendment, or repeal by the board of these
6 or any other board rules or regulations shall be in accordance with
7 Chapter 3.5 (commencing with Section 11340) of Part 1 of
8 Division 3 of Title 2 of the Government Code.

9 ~~SEC. 28.~~

10 *SEC. 27.* Section 4026.5 is added to the Business and
11 Professions Code, to read:

12 4026.5. “Good standing” means a license issued by the board
13 that is unrestricted by disciplinary action taken pursuant to Chapter
14 5 (commencing with Section 11500) of Part 1 of Division 3 of Title
15 2 of the Government Code.

16 ~~SEC. 29.~~

17 *SEC. 28.* Section 4030 of the Business and Professions Code
18 is amended to read:

19 4030. “Intern pharmacist” means a person issued a license
20 pursuant to Section 4208.

21 ~~SEC. 30.~~

22 *SEC. 29.* Section 4059.5 of the Business and Professions
23 Code is amended to read:

24 4059.5. (a) Except as otherwise provided in this chapter,
25 dangerous drugs or dangerous devices may only be ordered by an
26 entity licensed by the board and shall be delivered to the licensed
27 premises and signed for and received by a pharmacist. Where a
28 licensee is permitted to operate through an exemptee, the
29 exemptee may sign for and receive the delivery.

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

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



1 (d) Notwithstanding any other provision of law, a dangerous
2 drug or dangerous device may be ordered by and provided to a
3 manufacturer, physician, dentist, podiatrist, optometrist,
4 veterinarian, or laboratory, or a physical therapist, *certified*
5 *nurse-midwife, nurse practitioner, or physician assistant* acting
6 within the scope of his or her license. A person or entity receiving
7 delivery of a dangerous drug or device, or a duly authorized
8 representative of the person or entity, shall sign for the receipt of
9 the dangerous drug or dangerous device.

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

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

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

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

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

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

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



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

6 ~~SEC. 31.~~

7 *SEC. 30.* Section 4068 is added to the Business and
8 Professions Code, to read:

9 4068. (a) Notwithstanding any provision of this chapter, a
10 prescriber may dispense a dangerous drug, including a controlled
11 substance, to an emergency room patient if all of the following
12 apply:

13 (1) The hospital pharmacy is closed and there is no pharmacist
14 available in the hospital.

15 (2) The dangerous drug is acquired by the hospital pharmacy.

16 (3) The dispensing information is recorded and provided to the
17 pharmacy when the pharmacy reopens.

18 (4) The hospital pharmacy retains the dispensing information
19 and, if the drug is a schedule II or schedule III controlled
20 substance, reports the dispensing information to the Department
21 of Justice pursuant to Section 11165 of the Health and Safety Code.

22 (5) The prescriber determines that it is in the best interest of the
23 patient that a particular drug regimen be immediately commenced
24 or continued, and the prescriber reasonably believes that a
25 pharmacy located outside the hospital is not available and
26 accessible at the time of dispensing to the patient.

27 (6) The quantity of drugs dispensed to any patient pursuant to
28 this section are limited to that amount necessary to maintain
29 uninterrupted therapy during the period when pharmacy services
30 outside the hospital are not readily available or accessible, but shall
31 not exceed a 72-hour supply.

32 (7) The ~~physician~~ *prescriber* shall ensure that the label on the
33 drug contains all the information required by Section 4076.

34 (b) The prescriber shall be responsible for any error or
35 omission related to the drugs dispensed.

36 ~~SEC. 32.~~

37 *SEC. 31.* Section 4076 of the Business and Professions Code
38 is amended to read:



1 4076. (a) A pharmacist may not dispense any prescription
2 except in a container that meets the requirements of state and
3 federal law and is correctly labeled with all of the following:

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

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

16 (3) The name of the patient or patients.

17 (4) The name of the prescriber or, if applicable, the certified
18 nurse-midwife who functions pursuant to a standardized
19 procedure or protocol described in Section 2746.51, the nurse
20 practitioner who functions pursuant to a standardized procedure
21 described in Section 2836.1, or protocol, a pharmacist who
22 functions under a protocol as described in Section 4052, or the
23 physician assistant who functions pursuant to Section 3502.1.

24 (5) The date of issue.

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

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

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

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

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

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

38 (i) Prescriptions dispensed by a veterinarian.

39 (ii) An exemption from the requirements of this paragraph
40 shall be granted to a new drug for the first 120 days that the drug



1 is on the market and for the 90 days during which the national
2 reference file has no description on file.

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

5 (B) This paragraph applies to outpatient pharmacies only.

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

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

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

18 (c) If a pharmacist dispenses a dangerous drug or device in a
19 facility licensed pursuant to Section 1250 of the Health and Safety
20 Code, it is not necessary to include on individual unit dose
21 containers for a specific patient, the name of the certified
22 nurse-midwife who functions pursuant to a standardized
23 procedure or protocol described in Section 2746.51, the nurse
24 practitioner who functions pursuant to a standardized procedure
25 described in Section 2836.1, or protocol, a pharmacist who
26 functions under a protocol as described in Section 4052, or the
27 physician assistant who functions pursuant to Section 3502.1.

28 (d) If a pharmacist dispenses a prescription drug for use in a
29 facility licensed pursuant to Section 1250 of the Health and Safety
30 Code, it is not necessary to include the information required in
31 paragraph (11) of subdivision (a) when the prescription drug is
32 administered to a patient by a person licensed under the Medical
33 Practice Act (Chapter 5 (commencing with Section 2000)), the
34 Nursing Practice Act (Chapter 6 (commencing with Section
35 2700)), or the Vocational Nursing Practice Act (Chapter 6.5
36 (commencing with Section 2840)), who is acting within his or her
37 scope of practice.

38 ~~SEC. 33.~~

39 *SEC. 32.* Section 4081 of the Business and Professions Code
40 is amended to read:



1 4081. (a) All records of manufacture and of sale, acquisition,
2 or disposition of dangerous drugs or dangerous devices shall be at
3 all times during business hours open to inspection by authorized
4 officers of the law, and shall be preserved for at least three years
5 from the date of making. A current inventory shall be kept by every
6 manufacturer, wholesaler, pharmacy, veterinary food-animal drug
7 retailer, physician, dentist, podiatrist, veterinarian, laboratory,
8 clinic, hospital, institution, or establishment holding a currently
9 valid and unrevoked certificate, license, permit, registration, or
10 exemption under Division 2 (commencing with Section 1200) of
11 the Health and Safety Code or under Part 4 (commencing with
12 Section 16000) of Division 9 of the Welfare and Institutions Code
13 who maintains a stock of dangerous drugs or dangerous devices.

14 (b) The owner, officer, and partner of any pharmacy,
15 wholesaler, or veterinary food-animal drug retailer shall be jointly
16 responsible, with the pharmacist-in-charge or
17 exemptee-in-charge, for maintaining the records and inventory
18 described in this section.

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

24 ~~SEC. 34.~~

25 *SEC. 33.* Section 4101 of the Business and Professions Code
26 is amended to read:

27 4101. (a) A pharmacist who takes charge of, or acts as
28 pharmacist-in-charge of a pharmacy or other entity licensed by the
29 board, who terminates his or her employment at the pharmacy or
30 other entity, shall notify the board within 30 days of the
31 termination of employment.

32 (b) An exemptee-in-charge of a wholesaler or veterinary food
33 drug-animal retailer, who terminates his or her employment at that
34 entity shall notify the board within 30 days of the termination of
35 employment.

36 ~~SEC. 35.~~

37 *SEC. 34.* Section 4107 is added to the Business and
38 Professions Code, to read:

39 4107. The board may not issue more than one site license to
40 a single premises except to issue a veterinary food-animal drug



1 retailer license to a wholesaler or to issue a license to compound
2 sterile injectable drugs to a pharmacy. For the purposes of this
3 subdivision, “premises” means a location with its own address
4 and an independent means of ingress and egress.

5 ~~SEC. 36.~~

6 *SEC. 35.* Section 4114 of the Business and Professions Code
7 is amended to read:

8 4114. (a) An intern pharmacist may perform all functions of
9 a pharmacist at the discretion of and under the supervision of a
10 pharmacist whose license is in good standing with the board.

11 (b) A pharmacist may not supervise more than two intern
12 pharmacists at any one time.

13 *SEC. 36.* *Section 4115 of the Business and Professions Code*
14 *is amended to read:*

15 4115. (a) Notwithstanding any other provision of law, a
16 pharmacy technician may perform packaging, manipulative,
17 repetitive, or other nondiscretionary tasks, only while assisting,
18 and while under the direct supervision and control of, a
19 pharmacist.

20 (b) This section does not authorize the performance of any
21 tasks specified in subdivision (a) by a pharmacy technician
22 without a pharmacist on duty, nor does this section authorize the
23 use of a pharmacy technician to perform tasks specified in
24 subdivision (a) except under the direct supervision and control of
25 a pharmacist.

26 (c) This section does not authorize a pharmacy technician to
27 perform any act requiring the exercise of professional judgment by
28 a pharmacist.

29 (d) The board shall adopt regulations to specify tasks pursuant
30 to subdivision (a) that a pharmacy technician may perform under
31 the direct supervision and control of a pharmacist. Any pharmacy
32 that employs a pharmacy technician to perform tasks specified in
33 subdivision (a) shall do so in conformity with the regulations
34 adopted by the board pursuant to this subdivision.

35 (e) (1) No person shall act as a pharmacy technician without
36 first being registered with the board as a pharmacy technician as
37 set forth in Section 4202.

38 (2) The registration requirements in paragraph (1) and Section
39 4202 shall not apply during the first year of employment for a
40 person employed or utilized as a pharmacy technician to assist in



1 the filling of prescriptions for an inmate of a correctional facility
2 of the Department of the Youth Authority or the Department of
3 Corrections, or for a person receiving treatment in a facility
4 operated by the State Department of Mental Health, the State
5 Department of Developmental Services, or the Department of
6 Veterans Affairs.

7 (f) (1) The performance of duties by a pharmacy technician
8 shall be under the direct supervision and control of a pharmacist.
9 The pharmacist on duty shall be directly responsible for the
10 conduct of a pharmacy technician. A pharmacy technician may
11 perform the duties, as specified in subdivision (a), only under the
12 immediate, personal supervision and control of a pharmacist. Any
13 pharmacist responsible for a pharmacy technician shall be on the
14 premises at all times, and the pharmacy technician shall be within
15 the pharmacist's view. A pharmacist shall indicate verification of
16 the prescription by initialing the prescription label before the
17 medication is provided to the patient, *or by engaging in other*
18 *verification procedures that are specifically approved by board*
19 *regulations.*

20 (2) This subdivision shall not apply to a person employed or
21 utilized as a pharmacy technician to assist in the filling of
22 prescriptions for an inpatient of a hospital or for an inmate of a
23 correctional facility. Notwithstanding the exemption in this
24 subdivision, the requirements of subdivisions (a) and (b) shall
25 apply to a person employed or utilized as a pharmacy technician
26 to assist in the filling of prescriptions for an inpatient of a hospital
27 or for an inmate of a correctional facility.

28 (g) (1) A pharmacy with only one pharmacist shall have no
29 more than one pharmacy technician performing the tasks specified
30 in subdivision (a). The ratio of pharmacy technicians performing
31 the tasks specified in subdivision (a) to any additional pharmacist
32 shall not exceed 2:1, except that this ratio shall not apply to
33 personnel performing clerical functions pursuant to Section 4116
34 or 4117. This ratio is applicable to all practice settings, except for
35 an inpatient of a licensed health facility, a patient of a licensed
36 home health agency, as specified in paragraph (2), an inmate of a
37 correctional facility of the Department of the Youth Authority or
38 the Department of Corrections, and for a person receiving
39 treatment in a facility operated by the State Department of Mental



1 Health, the State Department of Developmental Services, or the
2 Department of Veterans Affairs.

3 (2) The board may adopt regulations establishing the ratio of
4 pharmacy technicians performing the tasks specified in
5 subdivision (a) to pharmacists applicable to the filling of
6 prescriptions of an inpatient of a licensed health facility and for a
7 patient of a licensed home health agency. Any ratio established by
8 the board pursuant to this subdivision shall allow, at a minimum,
9 at least one pharmacy technician for a single pharmacist in a
10 pharmacy and two pharmacy technicians for each additional
11 pharmacist, except that this ratio shall not apply to personnel
12 performing clerical functions pursuant to Section 4116 or 4117.

13 (3) A pharmacist scheduled to supervise a second pharmacy
14 technician may refuse to supervise a second pharmacy technician
15 if the pharmacist determines, in the exercise of his or her
16 professional judgment, that permitting the second pharmacy
17 technician to be on duty would interfere with the effective
18 performance of the pharmacist's responsibilities under this
19 chapter. A pharmacist assigned to supervise a second pharmacy
20 technician shall notify the pharmacist in charge in writing of his
21 or her determination, specifying the circumstances of concern
22 with respect to the pharmacy or the pharmacy technician that have
23 led to the determination, within a reasonable period, but not to
24 exceed 24 hours, after the posting of the relevant schedule. No
25 entity employing a pharmacist may discharge, discipline, or
26 otherwise discriminate against any pharmacist in the terms and
27 conditions of employment for exercising or attempting to exercise
28 in good faith the right established pursuant to this paragraph.

29 (h) Notwithstanding subdivisions (b) and (f), the board shall by
30 regulation establish conditions to permit the temporary absence of
31 a pharmacist for breaks and lunch periods pursuant to Section 512
32 of the Labor Code and the orders of the Industrial Welfare
33 Commission without closing the pharmacy. During these
34 temporary absences, a pharmacy technician may, at the discretion
35 of the pharmacist, remain in the pharmacy but may only perform
36 nondiscretionary tasks. The pharmacist shall be responsible for a
37 pharmacy technician and shall review any task performed by a
38 pharmacy technician during the pharmacist's temporary absence.
39 Nothing in this subdivision shall be construed to authorize a



1 pharmacist to supervise pharmacy technicians in greater ratios
2 than those described in subdivision (g).

3 SEC. 37. Section 4127.7 is added to the Business and
4 Professions Code, to read:

5 4127.7. On and after July 1, 2005, a pharmacy shall
6 compound sterile injectable products from one or more nonsterile
7 ingredients in one of the following environments:

8 ~~(1)~~

9 (a) An ISO class 5 laminar airflow hood within an ISO class 7
10 cleanroom. The cleanroom must have a positive air pressure
11 differential relative to adjacent areas.

12 ~~(2)~~

13 (b) An ISO class 5 cleanroom.

14 ~~(3)~~

15 (c) A barrier isolator that provides an ISO class 5 environment
16 for compounding.

17 SEC. 38. Section 4170.5 is added to the Business and
18 Professions Code, to read:

19 4170.5. (a) Veterinarians in a veterinary teaching hospital
20 operated by an accredited veterinary medical school may dispense
21 and administer dangerous drugs and devices and controlled
22 substances from a common stock.

23 (b) The veterinary teaching hospital shall designate a
24 pharmacist to be responsible for ordering the drugs for the
25 common stock and the designated pharmacist-in-charge shall be
26 professionally responsible to insure that inventories, security
27 procedures, training, protocol development, recordkeeping,
28 packaging, labeling, and dispensing occur in a manner that is
29 consistent with the promotion and protection of the health and
30 safety of the public.

31 (c) The veterinary teaching hospital's pharmacist-in-charge
32 shall develop policies, procedures, and guidelines that recognize
33 the unique relationship between the institution's pharmacists and
34 veterinarians in the control, management, dispensation, and
35 administration of drugs.

36 (d) The board may inspect a veterinary teaching hospital
37 dispensing or administering drugs pursuant to this section.

38 SEC. 39. Section 4200 of the Business and Professions Code
39 is amended to read:



1 4200. (a) The board may license as a pharmacist any
2 applicant who meets all the following requirements:

3 (1) Is at least 18 years of age.

4 (2) (A) Has graduated from a college of pharmacy or
5 department of pharmacy of a university recognized by the board;
6 or

7 (B) If the applicant graduated from a foreign pharmacy school,
8 the foreign-educated applicant has been certified by the Foreign
9 Pharmacy Graduate Examination Committee.

10 (3) Has completed at least 150 semester units of collegiate
11 study in the United States, or the equivalent thereof in a foreign
12 country. No less than 90 of those semester units shall have been
13 completed while in resident attendance at a school or college of
14 pharmacy.

15 (4) Has earned at least a baccalaureate degree in a course of
16 study devoted to the practice of pharmacy.

17 (5) Has completed 1,500 hours of pharmacy practice
18 experience or the equivalent in accordance with Section 4209.

19 (6) Has passed a written and practical examination given by the
20 board prior to December 31, 2003, or has passed the North
21 American Pharmacist Licensure Examination and the Multi-State
22 Pharmacy Jurisprudence Examination for California on or after
23 January 1, 2004.

24 (b) Proof of the qualifications of an applicant for licensure as
25 a pharmacist, shall be made to the satisfaction of the board and
26 shall be substantiated by affidavits or other evidence as may be
27 required by the board.

28 (c) Each person, upon application for licensure as a pharmacist
29 under this chapter, shall pay to the executive officer of the board,
30 the fees provided by this chapter. The fees shall be compensation
31 to the board for investigation or examination of the applicant.

32 SEC. 40. Section 4207 of the Business and Professions Code
33 is amended to read:

34 4207. (a) Upon receipt of an application for a license and the
35 applicable fee, the board shall make a thorough investigation to
36 determine whether the applicant is qualified for the license being
37 sought. The board shall also determine whether this article has
38 been complied with, and shall investigate all matters directly
39 related to the issuance of the license that may affect the public
40 welfare.



1 (b) The board shall not investigate matters connected with the
2 operation of a premises other than those matters solely related to
3 the furnishing of dangerous drugs or dangerous devices that might
4 adversely affect the public welfare.

5 (c) The board shall deny an application for a license if the
6 applicant does not qualify for the license being sought.

7 (d) Notwithstanding any other provision of law, the board may
8 request any information it deems necessary to complete the
9 application investigation required by this section, and a request for
10 information that the board deems necessary in carrying out this
11 section in any application or related form devised by the board
12 shall not be required to be adopted by regulation pursuant to the
13 Administrative Procedures Act (Chapter 3.5 (commencing with
14 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
15 Code).

16 SEC. 41. Section 4208 is added to the Business and
17 Professions Code, to read:

18 4208. (a) At the discretion of the board, an intern pharmacist
19 license may be issued for a period of:

20 (1) One to six years to a person who is currently enrolled in a
21 school of pharmacy recognized by the board.

22 (2) Two years to a person who is a graduate of a school of
23 pharmacy recognized by the board and who has applied to become
24 licensed as a pharmacist in California.

25 (3) Two years to a foreign graduate who has met educational
26 requirements described in paragraphs (1) to (4), inclusive, and (2)
27 of subdivision (a) of Section 4200.

28 (4) One year to a person who has failed the pharmacist
29 licensure examination four times and has reenrolled in a school of
30 pharmacy to satisfy the requirements of Section 4200.1.

31 (b) The board may issue an intern pharmacist license to an
32 individual for the period of time specified in a decision of
33 reinstatement adopted by the board.

34 (c) An intern pharmacist shall notify the board within 30 days
35 of any change of address.

36 (d) An intern pharmacist whose license has been issued
37 pursuant to paragraph (1) or paragraph (4) of subdivision (a) shall
38 return his or her license, by registered mail, within 30 days of no
39 longer being enrolled in a school of pharmacy. The intern
40 pharmacist license will be canceled by the board. Notwithstanding



1 subdivision (c), an intern pharmacist license may be reinstated if
2 the student reenrolls in a school of pharmacy recognized by the
3 board to fulfill the education requirements of paragraphs (1) to (4),
4 inclusive, of subdivision (a) of Section 4200.

5 SEC. 42. Section 4209 is added to the Business and
6 Professions Code, to read:

7 4209. (a) (1) An intern pharmacist shall complete 1,500
8 hours of pharmacy practice before applying for the pharmacist
9 licensure examination.

10 (~~1~~)

11 (2) This pharmacy practice shall comply with the Standards of
12 Curriculum established by the Accreditation Council for
13 Pharmacy Education or with regulations adopted by the board.

14 (b) An intern pharmacist shall submit proof of his or her
15 experience on board-approved affidavits, or another form
16 specified by the board, which shall be certified under penalty of
17 perjury by a pharmacist under whose supervision such experience
18 was obtained or by the pharmacist-in-charge at the pharmacy
19 while the pharmacist intern obtained the experience.

20 (c) An applicant for the examination who has been licensed as
21 a pharmacist in any state for at least one year, as certified by the
22 licensing agency of that state, may submit this certification to
23 satisfy the required 1,500 hours of intern experience. Certification
24 of an applicant's licensure in another state shall be submitted in
25 writing and signed, under oath, by a duly authorized official of the
26 state in which the license is held.

27 SEC. 43. Section 4409 of the Business and Professions Code
28 is amended to read:

29 4409. At the time a pharmacy license is renewed pursuant to
30 subdivision (a) of Section 4110 or a pharmacist license is renewed
31 pursuant to Section 4401, the pharmacy or pharmacist may make
32 a contribution of at least twenty-five dollars (\$25), to be submitted
33 to the board, for the sole purpose of funding the California
34 Pharmacist Scholarship and Loan Repayment Program
35 established pursuant to Article 2 (commencing with Section
36 128198) of Chapter 3 of Part 3 of Division 107 of the Health and
37 Safety Code. The contribution submitted pursuant to this section
38 shall be paid into the State Treasury and credited to the California
39 Pharmacist Scholarship and Loan Repayment Program Fund



1 established pursuant to Section 128198.5 of the Health and Safety
2 Code.

3 SEC. 44. Section 4980.395 of the Business and Professions
4 Code is amended to read:

5 4980.395. (a) A licensee who began graduate study prior to
6 January 1, 2004, shall complete a three-hour continuing education
7 course in aging and long-term care during his or her first renewal
8 period after the operative date of this section and shall submit to
9 the board evidence, acceptable to the board, of the person's
10 satisfactory completion of the course.

11 (b) The course shall include, but is not limited to, the
12 biological, social, and psychological aspects of aging.

13 (c) A person seeking to meet the requirements of subdivision
14 (a) of this section may submit to the board a certificate evidencing
15 completion of equivalent courses in aging and long-term care
16 taken prior to the operative date of this section, or proof of
17 equivalent teaching or practice experience. The board, in its
18 discretion, may accept that certification as meeting the
19 requirements of this section.

20 (d) The board may not renew an applicant's license until the
21 applicant has met the requirements of this section.

22 (e) Continuing education courses taken pursuant to this section
23 shall be applied to the 36 hours of approved continuing education
24 required in Section 4980.54.

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

26 SEC. 45. Section 4990.4 of the Business and Professions
27 Code is amended to read:

28 4990.4. "Accredited school of social work," within the
29 meaning of this chapter, is a school that is accredited by the
30 Commission on Accreditation of the Council on Social Work
31 Education.

32 SEC. 46. Section 4996.18 of the Business and Professions
33 Code is amended to read:

34 4996.18. (a) A person who wishes to be credited with
35 experience toward licensure requirements shall register with the
36 board as an associate clinical social worker prior to obtaining that
37 experience. The application shall be made on a form prescribed by
38 the board and shall be accompanied by a fee of seventy-five dollars
39 (\$75). An applicant for registration shall (1) possess a master's
40 degree from an accredited school or department of social work,



1 (e) “Disqualified person” means a licensed person who for any
2 reason becomes legally disqualified (temporarily or permanently)
3 to render the professional services that the particular professional
4 corporation or foreign professional corporation of which he or she
5 is an officer, director, shareholder, or employee is or was
6 rendering.

7 SEC. 51. Section 11159.1 of the Health and Safety Code is
8 amended to read:

9 11159.1. An order for controlled substances furnished to a
10 patient in a clinic which has a permit issued pursuant to Article 13
11 (commencing with Section 4180) of Chapter 9 of Division 2 of the
12 Business and Professions Code, except an order for a Schedule II
13 controlled substance, shall be exempt from the prescription
14 requirements of this article and shall be in writing on the patient’s
15 record, signed by the prescriber, dated, and shall state the name and
16 quantity of the controlled substance ordered and the quantity
17 actually furnished. The record of the order shall be maintained as
18 a clinic record for a minimum of seven years. This section shall
19 apply only to a clinic that has obtained a permit under the
20 provisions of Article 13 (commencing with Section 4180) of
21 Chapter 9 of Division 2 of the Business and Professions Code.

22 Clinics that furnish controlled substances shall be required to
23 keep a separate record of the furnishing of those drugs which shall
24 be available for review and inspection by all properly authorized
25 personnel.

26 SEC. 52. Section 11207 of the Health and Safety Code is
27 amended to read:

28 11207. (a) No person other than a pharmacist as defined in
29 Section 4036 of the Business and Professions Code or an intern
30 pharmacist, as defined in Section 4030 of the Business and
31 Professions Code, who is under the personal supervision of a
32 pharmacist, shall compound, prepare, fill or dispense a
33 prescription for a controlled substance.

34 (b) Notwithstanding subdivision (a), a pharmacy technician
35 may perform those tasks permitted by Section 4115 of the Business
36 and Professions Code when assisting a pharmacist dispensing a
37 prescription for a controlled substance.

38 ~~SEC. 53. Section 111625 of the Health and Safety Code is~~
39 ~~amended to read:~~



1 ~~111625. (a) A license application shall be completed~~
2 ~~annually and accompanied by an application fee as prescribed in~~
3 ~~Section 111630. This fee is not refundable if the license is refused.~~
4 ~~(b) A manufacturer licensed pursuant to this article may not~~
5 ~~operate without employing sufficient, qualified supervision to~~
6 ~~adequately safeguard and protect the public health. Either a~~
7 ~~pharmacist licensed pursuant to Section 4200 of the Business and~~
8 ~~Professions Code or an individual issued a certificate of exemption~~
9 ~~pursuant to Section 4053 of the Business and Professions Code~~
10 ~~shall be deemed qualified to provide sufficient, qualified~~
11 ~~supervision, as required by this subdivision.~~

12 ~~SEC. 54.~~

13 *SEC. 53.* No reimbursement is required by this act pursuant
14 to Section 6 of Article XIII B of the California Constitution
15 because the only costs that may be incurred by a local agency or
16 school district will be incurred because this act creates a new crime
17 or infraction, eliminates a crime or infraction, or changes the
18 penalty for a crime or infraction, within the meaning of Section
19 17556 of the Government Code, or changes the definition of a
20 crime within the meaning of Section 6 of Article XIII B of the
21 California Constitution.



Attachment 15

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Legislation and Regulation Committee
Strategic Plan Update for July 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:	<ol style="list-style-type: none"> 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. <u>Advocacy:</u> AB 320, AB 1826, AB 1960, AB 2184, AB 2660, AB 2682, SB 1159, AB 1196, SB 1427, SB 1563, SB 1735, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774 <u>Technical Assistance:</u> 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, SB 1333 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 held on March 30, 2004. 8. Sponsor legislation to strengthen consumer protections in wholesale transactions. January 2004 - Board approved draft legislation. February 2004 - SB 1307 Introduced. May 2004 - SB 1307 Passed Senate

	<p>9. Sponsor legislation to address licensing issues related to the UC Davis Veterinary Medical Teaching Hospital. July 2003 – Board approves draft language. May 2004 – Language added to SB 1913</p>
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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:	<ol style="list-style-type: none"> 1. Strengthen standards for compounding sterile injectable drug products. In process. Rulemaking approved by board in October 2003. February 2004 – Rulemaking Submitted to OAL April 2004 – Rulemaking Disapproved by OAL May 2004 – 15 day notice published 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. April 2004 – Board Adopted May 2004 – Submitted to DCA 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. September 2003 - Informational hearing held. February 2004 - Rulemaking Notice Published. April 2004 – Board Adopted May 2004 – Submitted to DCA 5. Update pharmacy self-assessment form. 6. Allow central filling by hospital pharmacies. September 2003 - Informational hearing held. February 2004 – Rulemaking Notice Published. April 2004 – Board Adopted May 2004 – Submitted to DCA 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. April 2004 – Board Adopted May 2004 – Submitted to DCA 8. Modify patient notification provision of the quality assurance regulation to require notification only if the error results in the medication being administered to the patient or a clinically significant delay in therapy.
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	<p>July 2003 – Informational hearing held. February 2004 – Rulemaking Notice Published. April 2004 – Board Adopted May 2004 – Submitted to DCA</p> <p>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. April 2004 – Board Adopted May 2004 – Submitted to DCA</p> <p>10. Update pharmacy technician regulations to conform to SB 361. September 2003 – Informational hearing held. February 2004 – Rulemaking Notice Published. April 2004 – Board Adopted May 2004 – Submitted to DCA</p> <p>11. Update pharmacist licensure regulations to conform to SB 361. September 2003 – Informational hearing held. February 2004 – Rulemaking Notice Published. April 2004 – Board Adopted May 2004 – Submitted to DCA</p> <p>12. Complete a Section 100 filing to clean up regulations in conformity with recent legislation.</p>
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<p>Objective 3.3:</p>	<p>Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.</p>
<p>Measure:</p>	<p>Number of areas of pharmacy law reviewed</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 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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Attachment 16

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

Legislation and Regulation Committee
400 R Street, Suite 4070
Sacramento, CA

Meeting Minutes
June 14, 2004

Via Teleconference
8 a.m. – 9:05 a.m.

Present: **Andrea Zinder, Chairperson**
 Dave Fong, Pharm.D., Board Member
 Patricia Harris, Executive Officer
 Virginia Herold, Assistant Executive Officer

Call to Order

Chairperson Zinder called the meeting to order at 8 a.m.

Regulation Update

The committee discussed the status of regulations adopted at April 2004 Board Meeting. The following rulemaking files have been submitted to the Department of Consumer Affairs for review. The department has 30 days to review the files, but because of workload and staff shortages may take longer. Following approval by the Department of Consumer Affairs, the rulemaking files will be provided to the Office of Administrative Law, which has 30 working days to review the files.

1. Section 1709.1 -- Pharmacist-in-Charge
2. Section 1793.3 -- Clerk Typist
3. Section 1710 -- Hospital Central Fill
4. Section 1711 -- Notification of a Prescription Error
5. Section 1717.1 -- Common Electronic Files
6. Section 1717.4 -- Authentication of Prescriptions
7. Section 1720 -- Pharmacist License Process
8. Section 1721 -- Pharmacist Examination
9. Section 1723.1 -- Confidentiality of Exam Questions
10. Section 1724 -- Passing Score
11. Sections 1749 and 1793 et seq. -- Pharmacy Technicians

The committee discussed the 15-day comment period underway on the compounding regulations (Section 1751 et. Seq.). This rulemaking was disapproved by the Office of Administrative Law in April because the regulation contained building standards that had not been adopted by the California Building Standards Commission. To remedy the problem, the building components will be added to the board's omnibus bill (SB 1913), for enactment by the legislature. The rest of the language for the sterile compounding requirements have been renoticed for a 15-day comment period, which will end in June.

The committee noted that this was an action item for the July board meeting.

The committee noted the several regulations that have not been publicly noticed or finalized by staff: The board's inspectors will provide updates to the Pharmacy Self Assessment forms (Section 1715) during a June inspectors meeting. Staff will later this year submit a number of technical changes to conform board regulations with new statutory requirements (or "Section 100 Changes"). This rulemaking does not need to be publicly noticed.

Legislation Update

The committee discussed board-sponsored legislation. Ms. Harris provided an update on amendments made to SB 1307 (wholesalers) to resolve opposition. She added that AB 2682 will be amended to include provisions for nonresident wholesalers.

The committee also briefly discussed the status and new provisions in the board's omnibus bill (SB 1913).

The committee then discussed the status of the 13 other bills where the board has a position or has asked to be kept advised. There was discussion regarding the board's non-position on the Canadian drug bills (specifically SB 1149 and AB 1957), given that these bills continue to move through the Legislature.

Adjournment

There being no other business, the meeting was adjourned at 9:05 a.m.