CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 2756 **VERSION: Introduced: February 22, 2008**

AUTHOR: Duvall **SPONSOR: None – Spot Bill**

RECOMMENDED POSITION:

SUBJECT: Pharmacists: furnishing drugs during an emergency

EXISTING LAW:

Authorizes the pharmacists to, in good faith, furnish a dangerous drug or dangerous device in reasonable quanities without a prescription during a a federal, state or local emergency.

THIS BILL WOULD:

Make a nonsubstantive change to Section 4062 of the Business and Professions Code.

AUTHOR'S INTENT

To clarify Section 4062 of the Business and Professions Code to as it relates to Chapter 9, Division 2.

FISCAL IMPACT:

The board does not anticipate any substantial fiscal impact to its operations.

COMMENTS:

This is a spot bill.

HISTORY:

Dates	Actions
02/25/08	Feb. 25 Read first time.
02/24/08	Feb. 24 From printer. May be heard in committee March 25.
02/22/08	Feb. 22 Introduced. To print.

ASSEMBLY BILL No. 2756

Introduced by Assembly Member Duvall

February 22, 2008

An act to amend Section 4062 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 2756, as introduced, Duvall. Pharmacists: furnishing drugs during emergency.

Existing law authorizes a pharmacist to, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency.

This bill would make a nonsubstantive change to these provisions.

Vote: majority. 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 4062 of the Business and Professions
2 Code is amended to read:
3 4062. (a) Notwithstanding Section 4059 or any other provision
4 of law, a pharmacist may, in good faith, furnish a dangerous drug
5 or dangerous device in reasonable quantities without a prescription
6 during a federal, state, or local emergency, to further the health
7 and safety of the public. A record containing the date, name, and
8 address of the person to whom the drug or device is furnished, and
9 the name, strength, and quantity of the drug or device furnished
10 shall be maintained. The pharmacist shall communicate this

information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to ~~it~~ *this chapter* if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 963 **VERSION: As Amended on June 25, 2007**

AUTHOR: Ridley-Thomas **SPONSOR: BP& ED Committee**

BOARD POSITION: None

SUBJECT: Regulatory boards: Operations

EXISTING LAW:

1. States that all existing and proposed consumer-related boards or categories of licensed professionals shall be subject to review every four years to evaluate whether each board has demonstrated a public need for continued existence.
2. Provides that in the event the board becomes inoperative and is repealed, the Department of Consumer Affairs (DCA) shall succeed the board with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed.
3. Establishes the appointment of board members.
4. Establishes the authorization to appoint an executive officer.

THIS BILL WOULD:

1. Require the board to post annually on our Web site the number of reports received that year for criminal convictions, judgments, settlements, or arbitration as well as claims paid by a professional liability insurer caused by a licensees negligence, error or omission.
2. Provide the board with the authority to adopt regulations that provide an incentive to licensees to provide services within the scope of licensure, on a pro bono basis. The regulations could reduce the amount of renewal fee required for a licensee who demonstrates compliance with the pro bono requirements.
3. Require the board to adopt regulations for the number of staff required to adequately investigate and if necessary bring a disciplinary action against a licensee and specifies that the staff level shall at minimum be the number of staff per 1,000 persons regulated by the board and shall include the appropriate number of staff to complete all investigatory and disciplinary functions.

4. Require board members to disclose all ex parte communication at the board's next public meeting and that such communication will be recorded in the board's minutes. Defines "ex parte" communication.
5. State that it is the intent of the Legislature to be subject to ongoing and continuous review as well as a periodic thorough review when issues arise requiring that level of review and when such a review is requested by a Member of the Legislature or the Chief of the Office of the Consumer Advocate. The review shall evaluate and determine whether its operations are effectively protecting the public and that protection of the public is the highest priority of the board.
6. Provide that if the board is deemed deficient and its members removed, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed. Specify that the number of board members will remain the same and designates the appointing authorities for new members.
7. Require the board to enter into an agreement with the DCA to provide various administrative functions including personnel, information technology, examination and call centers. States that a board shall not enter into such an agreement if it would reduce the board's ability to comply with its duties prescribed in law.
8. Replace the duties of the Joint Committee on Boards, Commissions, and Consumer Protection with the Office of the Consumer Advocate to determine whether the highest priority of the licensing program is the protection of the public.
9. Make subject to approval of the DCA director as well as confirmation of the Senate, the appointment of an Executive Officer.
10. Require the board to post on our Web site minutes from public meetings within 10 days of the date of the meeting.
11. Require the board to adopt meaningful, measurable and manageable performance measures to include:
    - A comprehensive statement of the board's mission, goals, objectives and legal jurisdiction in protecting the health, safety and welfare of the public.
    - The board's enforcement priorities, complaint and enforcement data, budget expenditures with average and median cost per case, case aging data specific to post and preaccusation cases at the Attorney General's Office
    - The board's fund conditions, sources of revenues and expenditure categories for the last four fiscal years.

- Description of the board's licensing process including the time and cost required to implement and administer the licensing examination, ownership of the licensing examination, relevancy and validity of the licensing examination and passage rate and areas of examination.
- Board initiation of legislative efforts, budget change proposals and other initiatives it has taken to improve its legislative mandate.

12. Require the board to report to the director of DCA and the chief of the Office of the Consumer Advocate our performance measures on a quarterly basis as well as to post this information on the board's Web site. In addition, require the board to report this information annually to the Department of Finance, the Legislative Analyst's Office and the Legislature.
13. Require the chief of the Office of the Consumer Advocate in consultation with LAO to annually review the information provided and report to the Legislature if it determines that a board has failed to meet the performance measures established.
14. Require each board member to provide an annual report to the authority that appointed him or her the extent to which the member has achieved his or her goals and objectives that years as well as to report on goals and objectives for the upcoming year.
15. Require the board to post these reports on the board's Web site within 30 days of submission.
16. Require the department to report to the Legislature and the Governor when a board has been unable to schedule or convene a meeting because of a lack of a quorum caused by the absence of its members or by a vacancy in its membership.
17. Require the director of the DCA the work with the State Chief Information Officer to replace the department's existing information technology system and allow the director to change each of the board's systems on a pro rata basis for the costs of replacing the information technology system.
18. Require the director of DCA to annually report to the chairperson of fiscal committees for each house of the Legislature, as well as the Joint Legislative Budget Committee information specific information about the Office of the Consumer Advocate.
19. Require the board to submit all notices and final rulemaking records to the chief of the Office of the Consumer Advocate, in addition to the director of the DCA and specifies the timeframes and procedures for review and approval or disapproval.

20. Create the Office of the Consumer Advocate to promote the efficiency of each board that comprise the department and designate that the office is under the supervision and control of a chief. The chief will be appointed by the Governor and subject to Senate confirmation and will serve a four year term.
21. Require the chief to appointment of chief counsel of the office as well as adequate number of attorneys to carry out the provisions.
22. Specify the duties of the Office of the Consumer Advocate to serve as an independent monitor, and detail the powers given to the chief as well as the Office of the Consumer Advocate which includes allowing the office to appear at a board meeting and permitting participation in a disciplinary proceeding by the board whenever the chief determines that the appearance is required to promote and protect the interests of consumers.
23. Allow the office to exercise and perform functions, powers and duties as may be deemed appropriate to protect and promote the interests of consumers as directed by the Governor or the Legislature.
24. Require the chief to report annually to the Governor and appear annually before committees of the Legislature as specified.
25. Allow the chief to annually charge each board on a pro rata basis an amount sufficient to carry out the provisions.
26. Allow a board member to serve as a public member of more than one board at a time if not prohibited by another law.
27. Authorize a member of the Legislature or the chief to request the appropriate standing policy committee to conduct an analysis to evaluate a state board. This request must describe any perceived deficiencies in the operation of the board and the detailed reasons an analysis of its operations is requested.
28. Require the appropriate standing policy committee to investigate the perceived deficiencies, including holding public meetings. This committee may request the assistance from the Office of the Consumer Advocate.
29. Require determination by the committee if based on the information obtained during the course of the investigation if the highest priority of a board's operations is consumer protection.
30. Specify the types of issues the committee shall review and consider when making their determination.
31. Require the committee to report to the Joint Committee on Rules if a board is deemed deficient at which time each member of the board will be removed from office without a hearing within 10 business days and a successor board shall be appointed. In

addition, the Office of the Consumer Advocate will assume the duties of an independent monitor for the board and shall report to the Legislature within one year making recommendations for required reforms of the board.

AUTHOR'S INTENT

According to the author's office, the intent of this legislation is to develop a more effective method of continuing state licensing and regulation when the Legislature sunsets a licensing board. This bill is intended to perform the ongoing continuation of the licensing and regulation of a profession via a more independent board structure, than by a bureau operated by the Department.

FISCAL IMPACT

In its amended form, the Board of Pharmacy (board) will experience fiscal impact to cover the cost of additional staff allowed under this proposal as well as the new computer system and will most likely see a large increase in the amount of pro rata it pays to the department. Unfortunately board staff was unable to obtain information from the department in advance of this meeting to quantify these increases.

COMMENTS

This legislation was significantly amended on June 25, 2007 to become a new bill. Several of the functions assigned to the Office of the Consumer Advocate are already assigned to the DCA and its director as well as the Bureau of State Audits. It is unclear if the DCA's role will change as an oversight to board or if the board will now be subject to continual review by both the director as well as the chief.

The board currently provides weekly updates to the director's office detailing the board's work for the week as well as any pressing issues. A special report is required monthly. The board completes an annual Agency Statistical Profile documenting the workload of the board for the previous fiscal year.

Several of the public reporting requirements mandated in this legislation are already provided by the board already provides on a quarterly basis as part of its inherent committee structure and close adherence to the performance measures established in the board's strategic plan.

The board's record for consumer protection is solid and strong. The board continually demonstrates its commitment to consumer protection and as such further scrutiny by another office would not be problematic for the board, except potentially for an increase in reporting requirements and possible redirection of staff to complete the reports.

Should this bill become law, the board would need to seek additional staffing to comply with all the requirements and would need to seek a statutory fee increase to cover the increased expenditures for computer systems and pro rata charges.

There are a couple of items of concern:

1. Allowing only 10 days to post public meeting minutes on the board's Web site is not a reasonable time frame given the length of meetings, the complexity of the issues as well as turn around time for board members to vote on minutes. Moreover it eliminates the board's ability to review minutes,
2. The board could lose its ability to hire the executive officer of its choice, and rather this process could become very political in nature. Given the role of the executive officer, the board may want sole discretion in making this hiring decision.

Some benefits of this proposal include:

1. A legislative mandate to replace the board's very outdated computer system.
2. A legislative mandate to adopt by regulation the personnel needed to complete all investigatory and disciplinary functions. The ratio included in the legislation is one staff per 1,000 persons regulated.

HISTORY:

Date	Action
June 25	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B. & P.
June 21	To Com. on B. & P.
June 6	In Assembly. Read first time. Held at Desk.
June 6	Read third time. Passed. (Ayes 26. Noes 13. Page 1279.) To Assembly.
May 31	From committee: Do pass. (Ayes 10. Noes 4. Page 1224.) Read second time. To third reading.
May 25	Set for hearing May 31.
May 7	Placed on APPR. suspense file.
Apr. 25	Set for hearing May 7.
Apr. 24	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 6. Noes 2. Page 706.) Re-referred to Com. on APPR.

Apr. 16	From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.
Mar. 29	Set for hearing April 23.
Mar. 15	To Com. on B., P. & E.D.
Feb. 26	Read first time.
Feb. 25	From print. May be acted upon on or after March 27.
Feb. 23	Introduced. To Com. on RLS. for assignment. To print.

AMENDED IN ASSEMBLY JUNE 25, 2007

AMENDED IN SENATE APRIL 16, 2007

SENATE BILL No. 963

Introduced by Senator Ridley-Thomas

February 23, 2007

~~An act to amend Sections 4001 and 4003 of, and to repeal and add Section 101.1 of, the Business and Professions Code, relating to regulatory boards.~~ *An act to amend Sections 22, 102.3, 107, 108, 312, 313.1, 321, 1601.1, 1632.5, 1634.2, 1638.1, 1638.7, 1742, 1751, 2001, 2460, 2531, 2570.19, 2602, 2701, 2841, 2920, 3010.5, 3502.1, 3504, 3685, 3710, 4001, 4003, 4200.1, 4200.3, 4501, 4800, 4928, 4990, 5000, 5510, 5621, 5810, 5811, 6510, 6511, 6710, 7000.5, 7200, 7303, 7810, 8000, 8520, 8710, 9882, 18602, 18602.5, 18824, and 18882 of, to add Sections 27.5, 36, 37, 38, 101.5, 117, 117.5, 127.5, 156.7, and 450.1 to, to add Chapter 4.5 (commencing with Section 360) to Division 1 of, to add Division 1.3 (commencing with Section 474.20) to, to repeal Sections 2569, 4989, 4990.24, 7304, and 22259 of, to repeal Division 1.2 (commencing with Section 473) of, and to repeal and add Section 101.1 of, the Business and Professions Code, and to amend Sections 9148.8 and 9148.51 of, and to repeal Section 9148.52 of, the Government Code, relating to regulatory entities, and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 963, as amended, Ridley-Thomas. Regulatory boards: ~~termination~~ *operations.*

Existing law creates various regulatory boards, as defined, within the Department of Consumer Affairs and makes their funds separate accounts within the Professions and Vocations Fund. Under existing

law, the revenue in certain of these accounts is continuously appropriated to the board, other than fine and penalty revenues.

Existing law generally makes the regulatory boards inoperative on a specified date, unless that date is deleted or extended by subsequent legislation, and subjects these boards as well as other boards in state government, as specified, to review by the Joint Committee on Boards, Commissions, and Consumer Protection. Under existing law, that committee, following a specified procedure, recommends whether the board should be continued or its functions modified.

This bill would delete those provisions making the boards inoperative on a specified date and subjecting boards to review by the Joint Committee on Boards, Commissions, and Consumer Protection. The bill would instead make each of those boards subject to review by a standing policy committee of the Legislature upon request by a Member of the Legislature or the chief of the Office of the Consumer Advocate, which the bill would create in the Department of Consumer Affairs. The bill would, upon the committee's determination that a board is deficient, as specified, provide for the removal of all incumbent board members without a hearing and the appointment of a successor board, as specified. The bill would require the Office of the Consumer Advocate to serve as an independent monitor for a board that is found deficient. The bill would authorize the office to appear at meetings and to participate in disciplinary proceedings by a board within the department if required to promote or protect the interests of consumers, as defined, and would require the office to perform other specified duties. The bill would require the office to charge each board a fee to support the office's functions and would thereby make an appropriation by expanding the expenditure purposes of a continuously appropriated fund. The bill would create the Consumer Advocate Fund where these fees would be deposited and would be available to the office upon appropriation by the Legislature. The bill would require the director to report annually to the Governor and the Legislature, as specified, on the office's operations.

The bill would require boards within the department to enter into an agreement with the department for the performance of administrative and ministerial functions and would require the Director of Consumer Affairs, prior to January 1, 2010, to replace the existing technology system serving the department and its component boards and to charge each board its pro rata share of the cost to replace the system.

The bill would also require each board within the department to adopt performance measures, as specified, and report quarterly to the director and the chief of the Office of Consumer Advocate relating to those measures. The bill would also require boards to post the information on their Internet Web site and to report the information to the Legislative Analyst's Office, the Legislature, and the Department of Finance. The bill would require the Office of the Consumer Advocate to report to the Legislature if a board failed to meet its performance measures. The bill would also require those boards to post annually on their Internet Web sites the number of reports in specified categories that it received that year for its licensees.

The bill would allow a person to serve as the public member of more than one of these boards and would require all members of these boards, as well as bureau chiefs, to report annually to their appointing authority on their goals and objectives and success in achieving them, which would be posted on the board's Internet Web site. The bill would require the department to report to the Legislature and Governor if a board was unable to meet because of a lack of a quorum or vacancy. The bill would require members of these boards and other state boards to report ex parte communications, as defined, in the board's minutes. The bill would require boards within the department, the State Bar, the Office of Real Estate Appraisers, and other state boards that license professions or businesses to adopt regulations to provide incentives to licensees to provide services on a pro bono basis and to adopt regulations prior to June 30, 2009, establishing regulatory board staffing requirements.

~~Existing law creates the Department of Consumer Affairs within the State and Consumer Services Agency. Under existing law, the department consists of boards that license and regulate members of various professions and vocations. Existing law provides for the boards to become inoperative on a specified date unless that date is extended or deleted by the Legislature. Under existing law, when a board becomes inoperative, the department succeeds to and is vested with all the duties, powers, purposes, responsibilities, and jurisdiction of the board and its executive officer that are not otherwise repealed or made inoperative.~~

~~This bill would instead, when a board becomes inoperative, create a successor board in the Department of Consumer Affairs that succeeds to and is vested with all of the duties, powers, purposes, responsibilities, and jurisdiction of the board that are not otherwise repealed or made inoperative. The bill would provide for the successor board to have the~~

~~same number of members and composition as the prior board, would provide that its members be appointed by the same appointing authorities, for the same term, and with the same requirements as the prior board members, and would give the successor board the same authority to appoint an executive officer as the prior board had.~~

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

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

1 *SECTION 1. Section 22 of the Business and Professions Code*
2 *is amended to read:*
3 22. ~~(a)~~ "Board," as used in any provision of this code, refers
4 to the board in which the administration of the provision is vested,
5 and unless otherwise expressly provided, shall include "bureau,"
6 "commission," "committee," "department," "division," "examining
7 committee," "program," and "agency."
8 ~~(b) Whenever the regulatory program of a board that is subject~~
9 ~~to review by the Joint Committee on Boards, Commissions, and~~
10 ~~Consumer Protection, as provided for in Division 1.2 (commencing~~
11 ~~with Section 473), is taken over by the department, that program~~
12 ~~shall be designated as a "bureau."~~
13 *SEC. 2. Section 27.5 is added to the Business and Professions*
14 *Code, to read:*
15 *27.5. A board within the department shall annually post on its*
16 *Internet Web site the number of reports it received that year for*
17 *its licensees in each of the following categories:*
18 *(a) Criminal convictions.*
19 *(b) Judgments, settlements, or arbitration awards.*
20 *(c) Claims paid by a professional liability insurer caused by*
21 *the licensee's negligence, error, or omission.*
22 *SEC. 3. Section 36 is added to the Business and Professions*
23 *Code, to read:*
24 *36. A board within the department, the State Bar, the Office*
25 *of Real Estate Appraisers, and any other state board that issues*
26 *a license, certificate, or registration authorizing a person to engage*
27 *in a business or profession may adopt regulations that provide an*
28 *incentive to the holder to provide services within the scope of his*
29 *or her license, certificate, or registration on a pro bono basis. The*
30 *regulations may reduce the amount of the renewal fee for a*

licensee, certificate holder, or registrant who demonstrates compliance with the pro bono requirements set forth in the regulations.

SEC. 4. Section 37 is added to the Business and Professions Code, to read:

37. A board within the department and any other state board that issues a license, certificate, or registration authorizing a person to engage in a business or profession shall adopt regulations prior to June 30, 2009, that establish requirements for the number of staff required to adequately investigate and, if appropriate, bring a disciplinary action against a licensee, certificate holder, or registrant regulated by the board. The staff level requirements shall, at a minimum, be the number of staff required per 1,000 persons regulated by the board and include the appropriate number of staff to complete all investigatory and disciplinary functions.

SEC. 5. Section 38 is added to the Business and Professions Code, to read:

38. A member of a board within the department and a member of a state board, as defined in Section 9148.2 of the Government Code, shall disclose all of his or her ex parte communications at the board's next public meeting, and the ex parte communications shall be recorded in the board's minutes. "Ex parte communication" means any oral or written communication concerning matters, other than purely procedural matters, under the board's jurisdiction that are subject to a vote by the board that occurred between the member and a person, other than another board member or an employee of the board or the department of which the board is a part, who intends to influence the decision of the member.

SEC. 6. Section 101.1 of the Business and Professions Code is repealed.

~~101.1. (a) It is the intent of the Legislature that all existing and proposed consumer-related boards or categories of licensed professionals be subject to a review every four years to evaluate and determine whether each board has demonstrated a public need for the continued existence of that board in accordance with enumerated factors and standards as set forth in Division 1.2 (commencing with Section 473).~~

~~(b) (1) In the event that any board, as defined in Section 477, becomes inoperative or is repealed in accordance with the act that added this section, or by subsequent acts, the Department of Consumer Affairs shall succeed to and is vested with all the duties, powers, purposes, responsibilities and jurisdiction not otherwise repealed or made inoperative of that board and its executive officer.~~

~~(2) Any provision of existing law that provides for the appointment of board members and specifies the qualifications and tenure of board members shall not be implemented and shall have no force or effect while that board is inoperative or repealed. Every reference to the inoperative or repealed board, as defined in Section 477, shall be deemed to be a reference to the department.~~

~~(3) Notwithstanding Section 107, any provision of law authorizing the appointment of an executive officer by a board subject to the review described in Division 1.2 (commencing with Section 473), or prescribing his or her duties, shall not be implemented and shall have no force or effect while the applicable board is inoperative or repealed. Any reference to the executive officer of an inoperative or repealed board shall be deemed to be a reference to the director or his or her designee.~~

~~(c) It is the intent of the Legislature that subsequent legislation to extend or repeal the inoperative date for any board shall be a separate bill for that purpose.~~

SEC. 7. Section 101.1 is added to the Business and Professions Code, to read:

101.1. (a) It is the intent of the Legislature that all existing and proposed consumer-related boards or categories of licensed professionals be subject to ongoing and continuous review as well as a periodic thorough review when issues arise requiring that level of review and such a review is requested by a Member of the Legislature or the chief of the Office of the Consumer Advocate as provided in Division 1.3 (commencing with Section 474.20). The review of a board shall evaluate and determine whether its operations are effectively protecting the public and that protection of the public is the highest priority of the board.

(b) Notwithstanding any other provision of law, if a board is deemed deficient and its members removed, as described in Section 474.21, a successor board shall be appointed that shall succeed to, and be vested with, all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made

inoperative of the board that it is succeeding. The successor board shall have the same number of members and composition as the board that it is succeeding, and those members shall be appointed by the same appointing authorities, for the same term, and with the same membership requirements as the members of the board it is succeeding. The successor board shall have the same authority to appoint an executive officer as the board that it is succeeding as of the date that board was found deficient. The successor board members shall be appointed within 10 business days of receipt by the Joint Committee on Rules of the deficiency report, as described in Section 474.21.

SEC. 8. Section 101.5 is added to the Business and Professions Code, to read:

101.5. (a) Each board within the department shall enter into an agreement with the department for the department to provide administrative and ministerial functions and services, including, but not limited to, personnel services, information technology, the administration of call centers, and the administration of examinations. The Legislature intends that these agreements shall achieve cost savings resulting from economies of scale and a more consistent delivery of services to California consumers and licensees.

(b) A board shall not enter into an agreement described in subdivision (a) if it would reduce the board's ability to comply with its duties prescribed by law.

SEC. 9. Section 102.3 of the Business and Professions Code is amended to read:

102.3. (a) The director may enter into an interagency agreement with an appropriate entity within the Department of Consumer Affairs as provided for in Section 101 to delegate the duties, powers, purposes, responsibilities, and jurisdiction that have been succeeded and vested with the department, of a board~~,~~ ~~as defined in Section 477, which~~ *that* became inoperative and was repealed in accordance with Chapter 908 of the Statutes of 1994.

(b) (1) ~~Where~~ *If*, pursuant to subdivision (a), an interagency agreement is entered into between the director and that entity, the entity receiving the delegation of authority may establish a technical committee to regulate, as directed by the entity, the profession subject to the authority that has been delegated. The entity may delegate to the technical committee only those powers

that it received pursuant to the interagency agreement with the director. The technical committee shall have only those powers that have been delegated to it by the entity.

(2) ~~Where~~ *If* the entity delegates its authority to adopt, amend, or repeal regulations to the technical committee, all regulations adopted, amended, or repealed by the technical committee shall be subject to the review and approval of the entity.

(3) The entity shall not delegate to a technical committee its authority to discipline a licentiate who has violated the provisions of the applicable chapter of the Business and Professions Code that is subject to the director's delegation of authority to the entity.

(c) An interagency agreement entered into, pursuant to subdivision (a), shall continue until ~~such time as~~ the licensing program administered by the technical committee has undergone a review by the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Office of the Consumer Advocate* to evaluate and determine whether the *highest priority of the* licensing program ~~has demonstrated a public need for its continued existence~~ *is the protection of the public*. Thereafter, at the ~~director's~~ discretion *of the chief of that office*, the interagency agreement may be renewed.

SEC. 10. Section 107 of the Business and Professions Code is amended to read:

107. *(a)* Pursuant to subdivision (e) of Section 4 of Article VII of the California Constitution, each board may appoint a person exempt from civil service and may fix his or her salary, with the approval of the Department of Personnel Administration pursuant to Section 19825 of the Government Code, who shall be designated as an executive officer unless the licensing act of the particular board designates the person as a registrar. *A person may be appointed as an executive officer or registrar for more than one board if approved by each of those boards and may serve in those capacities at the same time if practical and consistent with law and the respective board functions and duties.*

(b) Notwithstanding any other provision of law, all appointments of an executive officer or registrar shall be subject to the approval of the director and confirmation by the Senate.

SEC. 11. Section 108 of the Business and Professions Code is amended to read:

108. *(a)* Each of the boards comprising the department exists as a separate unit, and has the functions of setting standards,

holding meetings, and setting dates thereof, preparing and conducting examinations, passing upon applicants, conducting investigations of violations of laws under its jurisdiction, issuing citations and holding hearings for the revocation of licenses, and the imposing of penalties following ~~such~~ *those* hearings, in so far as these powers are given by statute to each respective board.

(b) The department shall develop a common method of maintaining, posting, and making available to the public minutes of the meetings of the boards comprising the department. Each of those boards shall use that method and shall post the minutes of its meetings on its Internet Web site within 10 days of the date of the meeting.

SEC. 12. Section 117 is added to the Business and Professions Code, to read:

117. (a) Each board within the department shall adopt meaningful, measurable, and manageable performance measures. Performance measures include, but are not limited to, the following information:

(1) A comprehensive statement of the board's mission, goals, objectives, and legal jurisdiction in protecting the health, safety, and welfare of the public.

(2) The board's enforcement priorities, complaint and enforcement data, budget expenditures with average- and median-costs per case, and case aging data specific to post and preaccusation cases at the Attorney General's office.

(3) The board's fund conditions, sources of revenues, and expenditure categories for the last four fiscal years by program component.

(4) The board's description of its licensing process including the time and costs required to implement and administer its licensing examination, ownership of the license examination, relevancy and validity of the licensing examination, and passage rate and areas of examination.

(5) The board's initiation of legislative efforts, budget change proposals, and other initiatives it has taken to improve its legislative mandate.

(b) Each board within the department shall report to the director and the chief of the Office of the Consumer Advocate its performance measures and data relating to those measures on a quarterly basis. Each board shall post quarterly on its Internet

Web site the information it reported pursuant to this subdivision and provide the information annually to the Department of Finance, the Legislative Analyst's Office, and the Legislature.

(c) The chief of the Office of the Consumer Advocate, in consultation with the Legislative Analyst's Office, shall annually review the information reported by boards pursuant to subdivision (b) and report to the Legislature if it determines that a board has failed to meet its performance measures.

(d) The department may adopt regulations pertaining to the requirements described in subdivision (a).

SEC. 13. Section 117.5 is added to the Business and Professions Code, to read:

117.5. (a) Each member of a board within the department and the chief of any bureau within the board shall annually report, on or before December 31 of each year, to the authority that appointed him or her the extent to which the member or chief achieved his or her goals and objectives that year and shall also report the goals and objectives he or she expects to achieve during the following calendar year.

(b) The board or bureau shall post the reports described in subdivision (a) submitted by its members chief on its Internet Web site within 30 days of their submission date.

SEC. 14. Section 127.5 is added to the Business and Professions Code, to read:

127.5. The department shall report to the Legislature and the Governor when a board within the department has been unable to schedule or convene a meeting of the board because of a lack of a quorum caused by the absence of its members or by a vacancy in its membership.

SEC. 15. Section 156.7 is added to the Business and Professions Code, to read:

156.7. (a) Prior to January 1, 2010, the director, in consultation with the State Chief Information Officer, shall replace the department's existing information technology system with a system that meets the requirements of the department and of the boards within the department.

(b) The director shall charge each of the boards on a pro rata share basis for the costs of replacing the information technology system. The charge shall be an administrative expense that may

be levied in advance against the funds of any of the boards pursuant to Section 201.

(c) Notwithstanding any other provision of this section, the procurement of the information technology system shall be made in accordance with Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code.

SEC. 16. Section 312 of the Business and Professions Code is amended to read:

312. *(a)* The director shall submit to the Governor and the Legislature on or before January 1, 2003, and annually thereafter, a report of programmatic and statistical information regarding the activities of the department and its constituent entities. The report shall include information concerning the director's activities pursuant to Section 326, including the number and general patterns of consumer complaints and the action taken on those complaints.

(b) On or before January 1 of each year, beginning in 2009, the director shall submit to the chairperson of the fiscal committee of each house of the Legislature and to the Joint Legislative Budget Committee all of the following information:

(1) The number of personnel years assigned to the Office of the Consumer Advocate.

(2) The total dollars expended by the Office of the Consumer Advocate in the prior year, the estimated total dollars expended in the current year, and the total dollars proposed for appropriation in the following budget year.

(3) Workload standards and measures for the Office of the Consumer Advocate.

SEC. 17. Section 313.1 of the Business and Professions Code is amended to read:

313.1. (a) Notwithstanding any other provision of law to the contrary, no rule or regulation, except those relating to examinations and qualifications for licensure, and no fee change proposed or promulgated by any of the boards, commissions, or committees within the department, shall take effect pending compliance with this section.

(b) The director *and the chief of the Office of the Consumer Advocate* shall be formally notified of and shall be provided a full opportunity to review, in accordance with the requirements of Article 5 (commencing with Section 11346) of Chapter 3.5 of Part

1 of Division 3 of Title 2 of the Government Code, and this section, all of the following:

(1) All notices of proposed action, any modifications and supplements thereto, and the text of proposed regulations.

(2) Any notices of sufficiently related changes to regulations previously noticed to the public, and the text of proposed regulations showing modifications to the text.

(3) Final rulemaking records.

(c) The submission of all notices and final rulemaking records to the director *and the chief of the Office of the Consumer Advocate* and the completion of ~~the director's~~ *their* review, as authorized by this section, shall be a precondition to the filing of any rule or regulation with the Office of Administrative Law. The Office of Administrative Law shall have no jurisdiction to review a rule or regulation subject to this section until after the completion of the director's review and only then if the director ~~has~~ *and the chief of the Office of the Consumer Advocate have* not disapproved it. The filing of any document with the Office of Administrative Law shall be accompanied by a certification that the board, commission, or committee has complied with the requirements of this section.

(d) Following the receipt of any final rulemaking record subject to subdivision (a), the director *and the chief of the Consumer Advocate* shall have the authority for a period of 30 days to disapprove a proposed rule or regulation on the ground that it is injurious to the public health, safety, or welfare.

(e) Final rulemaking records shall be filed with the director *and the chief of the Office of the Consumer Advocate* within the one-year notice period specified in Section 11346.4 of the Government Code. If necessary for compliance with this section, the one-year notice period may be extended, as specified by this subdivision.

(1) ~~In the event that~~ *If* the one-year notice period lapses during the ~~director's~~ 30-day review period, or within 60 days following the notice of ~~the director's~~ disapproval, it may be extended for a maximum of 90 days.

(2) If the director ~~approves~~ *and the chief approve* the final rulemaking record or declines to take action on it within 30 days, the board, commission, or committee shall have five days from the receipt of the record from the director *and the chief* within which to file it with the Office of Administrative Law.

(3) If the director *or the chief* disapproves a rule or regulation, it shall have no force or effect unless, within 60 days of the notice of disapproval, (A) the disapproval is overridden by a unanimous vote of the members of the board, commission, or committee, and (B) the board, commission, or committee files the final rulemaking record with the Office of Administrative Law in compliance with this section and the procedures required by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(f) Nothing in this section shall be construed to prohibit the director *or the chief of the Office of the Consumer Advocate* from affirmatively approving a proposed rule, regulation, or fee change at any time within the 30-day period after it has been submitted to him or her, in which event it shall become effective upon compliance with this section and the procedures required by Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

SEC. 18. Section 321 of the Business and Professions Code is amended to read:

321. Whenever it appears to the director *or the chief of the Office of Consumer Advocate* that the interests of the consumers of this state are being damaged, or may be damaged, by any person who engaged in, or intends to engage in, any acts or practices in violation of any law of this state, or any federal law, the director or any officer or employee designated by the director, or the Attorney General, may commence legal proceedings in the appropriate forum to enjoin ~~such~~ *those* acts or practices and may seek other appropriate relief on behalf of ~~such~~ *those* consumers.

SEC. 19. Chapter 4.5 (commencing with Section 360) is added to Division 1 of the Business and Professions Code, to read:

CHAPTER 4.5. OFFICE OF THE CONSUMER ADVOCATE

Article 1. General Provisions

360. This chapter shall be known and may be cited as the Office of the Consumer Advocate Act.

361. It is the intent of the Legislature and the purpose of this chapter to promote the efficiency of each of the boards that comprise the department by ensuring that each board properly

discharges its regulatory and disciplinary functions to protect the interests of consumers.

362. The following definitions apply for purposes of this chapter:

(a) "Board" means any entity listed in Section 101.

(b) "Chief" means the chief of the Office of the Consumer Advocate.

(c) "Interests of consumers" means the protection of the health, welfare, and safety of consumers by a board.

(d) "Office" means the Office of the Consumer Advocate.

Article 2. Administration

370. The Office of the Consumer Advocate is hereby established in the department.

371. The office is under the supervision and control of a chief. The chief shall be appointed by the Governor, subject to confirmation by the Senate pursuant to Section 1322 of the Government Code. The chief shall be appointed for a term of four years. Upon expiration of the chief's term, the chief shall continue to serve in the position until a new chief is appointed by the Governor. The director shall fix the amount of the chief's compensation in accordance with law. The Governor may remove the chief for any cause specified in Section 106.

372. The chief shall administer and enforce the provisions of this chapter. Every power granted or duty imposed upon the chief under this chapter may be exercised or performed in the name of the chief by an employee of the office, subject to any conditions and limitations the chief may prescribe.

373. (a) The chief, in accordance with the State Civil Service Act, shall appoint a chief counsel of the office and an adequate number of attorneys, as determined by the chief counsel, to carry out the provisions of this chapter.

(b) The chief, in accordance with the State Civil Service Act, may appoint and fix the compensation of clerical or other personnel as may be necessary to carry out the provisions of this chapter.

(c) All personnel appointed under this section shall perform their duties under the supervision and direction of the chief.

374. The chief may contract for the services of experts and consultants if necessary to carry out the provisions of this chapter

and may provide compensation and reimbursement of expenses for those experts and consultants in accordance with state law.

Article 3. Powers and Duties

380. (a) The office shall serve as an independent monitor pursuant to Section 474.22.

(b) The office shall review interagency agreements pursuant to Section 102.3.

381. The chief may establish through regulations a Consumer Participation Program to allow the office to award reasonable advocacy and witness fees to any person or organization that has made a substantial contribution on behalf of the interests of consumers either through the adoption of a regulation by a board or through an order or decision issued by a board in a disciplinary proceeding.

382. The office may appear at a meeting of a board and shall be permitted to participate as an amicus curiae in disciplinary proceedings by the board whenever the chief determines that the appearance or participation is required to promote or protect the interests of consumers. The office shall conform with the provisions of the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) in discharging these duties.

383. The chief shall have the following powers and it shall be his or her duty to take the following actions:

(a) Recommend and propose the enactment of legislation that is necessary to protect and promote the interests of consumers.

(b) Represent the interests of consumers before federal and state legislative and regulatory hearings.

(c) Assist, advise, and cooperate with federal, state, and local agencies and officials to protect and promote the interests of consumers.

(d) Study, investigate, research, and analyze matters affecting the interests of consumers.

(e) Hold public hearings, subpoena witnesses, take testimony, compel the production of books, papers, documents, and other evidence, and call upon state agencies for information.

(f) Propose and assist in the creation and development of consumer education programs.

(g) Promote ethical standards of conduct for business, professions, and consumers related to the interest of consumers.

(h) Advise the Governor and Legislature on all matters affecting the interests of consumers.

(i) Exercise and perform other functions, powers, and duties as may be deemed appropriate to protect and promote the interests of consumers as directed by the Governor or the Legislature.

(j) Maintain contact and liaison with consumer groups in California and nationally.

384. The chief shall report annually to the Governor and appear annually before the appropriate policy committees of the Legislature to report on the office's activities.

Article 4. Revenue

390. The office shall annually charge each board on a pro rata share basis an amount that is sufficient, as determined by the chief, to carry out the provisions of this chapter. The total amount of charges made pursuant to this section shall not exceed ____ million dollars ($____) annually.

391. All moneys collected pursuant to this article shall be deposited into the Consumer Advocate Fund, which is hereby created in the State Treasury. The revenue in this fund shall be expended solely for purposes of this chapter upon appropriation by the Legislature in the annual Budget Act.

SEC. 20. Section 450.1 is added to the Business and Professions Code, to read:

450.1. A person may serve as a public member of more than one board at the same time if not prohibited by any other law.

SEC. 21. Division 1.2 (commencing with Section 473) of the Business and Professions Code is repealed.

SEC. 22. Division 1.3 (commencing with Section 474.20) is added to the Business and Professions Code, to read:

DIVISION 1.3. LEGISLATIVE REVIEW OF STATE BOARDS AND BOARDS WITHIN THE DEPARTMENT OF CONSUMER AFFAIRS

474.20. (a) A Member of the Legislature or the chief of the Office of the Consumer Advocate may submit a written request to

the appropriate standing policy committee of the Legislature to conduct an analysis to evaluate any of the following entities:

(1) A board, as defined in Section 22.

(2) A state board, as defined in Section 9148.2 of the Government Code.

(b) The request made pursuant to subdivision (a) shall describe any perceived deficiencies in the operation of the board and the detailed reasons an analysis of its operation is requested that may include, but not be limited to, the issues subject to investigation under subdivision (c) of Section 474.21.

474.21. (a) (1) The appropriate standing policy committee of the Legislature shall, through its oversight function, investigate the perceived deficiencies described in the request submitted pursuant to Section 474.20 and hold public hearings on the matter. The committee may request the Office of the Consumer Advocate to assist in the investigation. The committee shall complete these functions within a 60-day period during the regular legislative session, with the period commencing on the date of the committee's receipt of the request.

(2) Notwithstanding paragraph (1), if, in the two-year period prior to the committee's receipt of the request, public hearings relating to the same board named in the request were held by a standing policy committee of the Legislature that determined no deficiencies exist, the committee may refuse to conduct additional hearings and investigation of the board.

(b) The committee may find, on the basis of the information it obtained during its investigation, whether a question exists as to the highest priority of the operations of the board being the protection of the public when exercising its licensing, regulatory, and disciplinary functions, and whether the board is effectively protecting the public.

(c) In determining whether a question exists under subdivision (b), the committee shall review the information and allegations made in the request submitted pursuant to Section 474.20 and any related information and allegations. The committee may review issues such as the following:

(1) Whether regulation by the board is necessary to protect the public health, safety, and welfare.

(2) Whether the initial reasons for licensing or regulating a practice or profession have changed.

(3) Whether other conditions have occurred that would warrant increased, decreased, or the same amount of regulation by the board.

(4) If regulation of the profession or practice is necessary, whether existing statutes and regulations establish the least restrictive form of regulation consistent with the public interest, considering other available regulatory mechanisms, and whether the board's rules promote the public interest and are within the scope of legislative intent.

(5) Whether the board operates and enforces its regulatory responsibilities in the public interest and whether its regulatory mission is impeded or enhanced by existing statutes, regulations, policies, practices, or any other circumstances, including budgetary, resources, and personnel matters.

(6) Whether an analysis of the board's operations indicates that the entity performs its statutory duties efficiently and effectively.

(7) Whether the composition of the board adequately represents the public interest and whether the board encourages public participation in its decisions rather than participation only by the profession or vocation and the individuals it regulates.

(8) Whether the board and its laws or regulations stimulate or restrict competition and the extent of the economic impact the board's regulatory practices have on the state's business and technological growth.

(9) Whether complaint investigation, intervention, and disciplinary procedures adequately protect the public and whether the final disposition of complaints, investigations, restraining orders, and disciplinary actions are in the public interest or these procedures are, instead, self-serving to the profession, vocation, or individuals being regulated by the board.

(10) Whether the scope of practice of the regulated profession or vocation contributes to the highest utilization of personnel and whether the entry requirements for the profession or vocation encourage affirmative action.

(11) Whether administrative and statutory changes are necessary to improve the board's operations to promote the public interest.

(d) The standing policy committee shall determine if a board is deficient. The committee shall report its deficiency determination to the Joint Committee on Rules. Notwithstanding any other

provision of law, if a board is found deficient, each incumbent member of the board shall be removed from office without a hearing within 10 business days of receipt of the committee's deficiency report by the Joint Committee on Rules, and successor board members shall be appointed within that timeframe pursuant to Section 101.1.

474.22. (a) Within 10 business days of the date the Joint Committee on Rules receives the deficiency report described in Section 474.21, the Office of the Consumer Advocate shall assume the duties of an independent monitor for the board.

(b) Within one year of the date it assumes the duties of an independent monitor, the Office of the Consumer Advocate shall report its findings to the Governor, and the Legislature may make recommendations for required reforms of the board.

SEC. 23. Section 1601.1 of the Business and Professions Code is amended to read:

1601.1. (a) There shall be in the Department of Consumer Affairs the Dental Board of California in which the administration of this chapter is vested. The board shall consist of eight practicing dentists, one registered dental hygienist, one registered dental assistant, and four public members. Of the eight practicing dentists, one shall be a member of a faculty of any California dental college and one shall be a dentist practicing in a nonprofit community clinic. The appointing powers, described in Section 1603, may appoint to the board a person who was a member of the prior board. The board shall be organized into standing committees dealing with examinations, enforcement, and other subjects as the board deems appropriate.

(b) For purposes of this chapter, any reference in this chapter to the Board of Dental Examiners shall be deemed to refer to the Dental Board of California.

(c) The board shall have all authority previously vested in the existing board under this chapter. The board may enforce all disciplinary actions undertaken by the previous board.

~~(d) This section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute that is enacted before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 24. Section 1632.5 of the Business and Professions Code is amended to read:

1632.5. (a) Prior to implementation of paragraph (2) of subdivision (c) of Section 1632, the department's Office of Examination Resources shall review the Western Regional Examining Board examination to assure compliance with the requirements of Section 139 and to certify that the examination process meets those standards. If the department determines that the examination process fails to meet those standards, paragraph (2) of subdivision (c) of Section 1632 shall not be implemented. The review of the Western Regional Examining Board examination shall be conducted during or after the Dental Board of California's occupational analysis scheduled for the 2004–05 fiscal year, but not later than September 30, 2005. However, an applicant who successfully completes the Western Regional Examining Board examination on or after January 1, 2005, shall be deemed to have met the requirements of subdivision (c) of Section 1632 if the department certifies that the Western Regional Examining Board examination meets the standards set forth in this subdivision.

(b) The Western Regional Examining Board examination process shall be regularly reviewed by the department pursuant to Section 139.

(c) The Western Regional Examining Board examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) ~~As part of its next scheduled review by the Joint Committee on Boards, Commissions, and Consumer Protection, the~~ *The* Dental Board of California shall report *on or before July 1, 2008,* to ~~that committee and~~ the department *and the Office of the Consumer Advocate* on the pass rates of applicants who sat for the Western Regional Examining Board examination, compared with the pass rates of applicants who sat for the state clinical and written examination administered by the Dental Board of California. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 25. Section 1634.2 of the Business and Professions Code is amended to read:

1634.2. (a) An advanced education program's compliance with subdivision (c) of Section 1634.1 shall be regularly reviewed by the department pursuant to Section 139.

(b) An advanced education program described in subdivision (c) of Section 1634.1 shall meet the requirements of subdivision (a) of Section 12944 of the Government Code.

(c) The clinical residency program completion certification required by subdivision (c) of Section 1634.1 shall include a list of core competencies commensurate to those found in the board's examinations. The board, together with the department's Office of Examination Resources, shall ensure the alignment of the competencies stated in the clinical residency program completion certification with the board's current occupational analysis. The board shall implement use of the clinical residency program completion certification form and use of the core competency list through the adoption of emergency regulations by January 1, 2008.

(d) ~~As part of its next scheduled review after January 1, 2007, by the Joint Committee on Boards, Commissions and Consumer Protection, the~~ *The* board shall report to ~~that committee and to~~ the department *and the Office of the Consumer Advocate on or before January 1, 2010,* the number of complaints received for those dentists who have obtained licensure by passing the state clinical examination and for those dentists who have obtained licensure through an advanced education program. The report shall also contain tracking information on these complaints and their disposition. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 26. Section 1638.1 of the Business and Professions Code is amended to read:

1638.1. (a) (1) A person licensed pursuant to Section 1634 who wishes to perform elective facial cosmetic surgery shall first apply for and receive a permit to perform elective facial cosmetic surgery from the board.

(2) A permit issued pursuant to this section shall be valid for a period of two years and must be renewed by the permitholder at the time his or her license is renewed. Every six years, prior to renewal of the permitholder's license and permit, the permitholder shall submit evidence acceptable to the credentialing committee

that he or she has maintained continued competence to perform the procedures authorized by the permit. The credentialing committee may limit a permit consistent with paragraph (1) of subdivision (e) if it is not satisfied that the permitholder has established continued competence.

(b) The board may adopt regulations for the issuance of the permit that it deems necessary to protect the health, safety, and welfare of the public.

(c) A licensee may obtain a permit to perform elective facial cosmetic surgery by furnishing all of the following information on an application form approved by the board:

(1) Proof of successful completion of an oral and maxillofacial surgery residency program accredited by the Commission on Dental Accreditation of the American Dental Association.

(2) Proof that the applicant has satisfied the criteria specified in either subparagraph (A) or (B):

(A) (i) Is certified, or is a candidate for certification, by the American Board of Oral and Maxillofacial Surgery.

(ii) Submits to the board a letter from the program director of the accredited residency program, or from the director of a postresidency fellowship program accredited by the Commission on Dental Accreditation of the American Dental Association, stating that the licensee has the education, training, and competence necessary to perform the surgical procedures that the licensee has notified the board he or she intends to perform.

(iii) Submits documentation to the board of at least 10 operative reports from residency training or proctored procedures that are representative of procedures that the licensee intends to perform from both of the following categories:

(I) Cosmetic contouring of the osteocartilaginous facial structure, which may include, but is not limited to, rhinoplasty and otoplasty.

(II) Cosmetic soft tissue contouring or rejuvenation, which may include, but is not limited to, facelift, blepharoplasty, facial skin resurfacing, or lip augmentation.

(iv) Submits documentation to the board showing the surgical privileges the applicant possesses at any licensed general acute care hospital and any licensed outpatient surgical facility in this state.

(B) (i) Has been granted privileges by the medical staff at a licensed general acute care hospital to perform the surgical procedures set forth in paragraph (A) at that hospital.

(ii) Submits to the board the documentation described in clause (iii) of subparagraph (A).

(3) Proof that the applicant is on active status on the staff of a general acute care hospital and maintains the necessary privileges based on the bylaws of the hospital to maintain that status.

(d) The application shall be accompanied by an application fee of five hundred dollars ($500) for an initial permit. The fee to renew a permit shall be two hundred dollars ($200).

(e) (1) The board shall appoint a credentialing committee to review the qualifications of each applicant for a permit. Upon completion of the review of an applicant, the committee shall make a recommendation to the board on whether to issue or not issue a permit to the applicant. The permit may be unqualified, entitling the permitholder to perform any facial cosmetic surgical procedure authorized by this section, or it may contain limitations if the credentialing committee is not satisfied that the applicant has the training or competence to perform certain classes of procedures, or if the applicant has not requested to be permitted for all procedures authorized by this section.

(2) The credentialing committee shall be comprised of five members, as follows:

(A) A physician and surgeon with a specialty in plastic and reconstructive surgery who maintains active status on the staff of a licensed general acute care hospital in this state.

(B) A physician and surgeon with a specialty in otolaryngology who maintains active status on the staff of a licensed general acute care hospital in this state.

(C) Three oral and maxillofacial surgeons licensed by the board who are board certified by the American Board of Oral and Maxillofacial Surgeons, and who maintain active status on the staff of a licensed general acute care hospital in this state, at least one of whom shall be licensed as a physician and surgeon in this state. Two years after the effective date of this section, any oral and maxillofacial surgeon appointed to the committee who is not licensed as a physician and surgeon shall hold a permit pursuant to this section.

(3) The board shall solicit from the following organizations input and recommendations regarding members to be appointed to the credentialing committee:

(A) The Medical Board of California.

(B) The California Dental Association.

(C) The California Association of Oral and Maxillofacial Surgeons.

(D) The California Medical Association.

(E) The California Society of Plastic Surgeons.

(F) Any other source that the board deems appropriate.

(4) The credentialing committee shall meet at a time and place directed by the board to evaluate applicants for permits. A quorum of three members shall be required for the committee to consider applicants and make recommendations to the board.

(f) A licensee may not perform any elective, facial cosmetic surgical procedure except at a general acute care hospital, a licensed outpatient surgical facility, or an outpatient surgical facility accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the American Association for Ambulatory Health Care (AAAHC), the Medicare program, or an accreditation agency approved by the Medical Board of California pursuant to subdivision (g) of Section 1248.1 of the Health and Safety Code.

(g) For purposes of this section, the following terms shall have the following meanings:

(1) "Elective cosmetic surgery" means any procedure defined as cosmetic surgery in subdivision (d) of Section 1367.63 of the Health and Safety Code, and excludes any procedure that constitutes reconstructive surgery, as defined in subdivision (c) of Section 1367.63 of the Health and Safety Code.

(2) "Facial" means those regions of the human body described in Section 1625 and in any regulations adopted pursuant to that section by the board.

(h) A holder of a permit issued pursuant to this section shall not perform elective facial cosmetic surgical procedures unless he or she has malpractice insurance or other financial security protection that would satisfy the requirements of Section 2216.2 and any regulations adopted thereunder.

(i) A holder of a permit shall comply with the requirements of subparagraph (D) of paragraph (2) of subdivision (a) of Section 1248.15 of the Health and Safety Code, and the reporting

requirements specified in Section 2240, with respect to any surgical procedure authorized by this section, in the same manner as a physician and surgeon.

(j) Any violation of this section constitutes unprofessional conduct and is grounds for the revocation or suspension of the person's permit, license, or both, or the person may be reprimanded or placed on probation. Proceedings initiated by the board under this section shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted therein.

(k) On or before January 1, 2009, and every four years thereafter, the board shall report to the ~~Joint Committee on Boards, Commissions and Consumer Protection~~ *Legislature and the Office of the Consumer Advocate* on all of the following:

(1) The number of persons licensed pursuant to Section 1634 who apply to receive a permit to perform elective facial cosmetic surgery from the board pursuant to subdivision (a).

(2) The recommendations of the credentialing committee to the board.

(3) The board's action on recommendations received by the credentialing committee.

(4) The number of persons receiving a permit from the board to perform elective facial cosmetic surgery.

(5) The number of complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery.

(6) Action taken by the board resulting from complaints filed by or on behalf of patients who have received elective facial cosmetic surgery by persons who have received a permit from the board to perform elective facial cosmetic surgery.

SEC. 27. Section 1638.7 of the Business and Professions Code is amended to read:

1638.7. The next occupational analysis of dental licensees and oral and maxillofacial facial surgeons pursuant to Section 139 shall include a survey of the training and practices of oral and maxillofacial surgeons and, upon completion of that analysis, a report shall be made to the ~~Joint Committee on Boards,~~

~~Commissions, and Consumer Protection~~ *Legislature and the Office of the Consumer Advocate* regarding the findings.

SEC. 28. Section 1742 of the Business and Professions Code is amended to read:

1742. (a) There is within the jurisdiction of the board a Committee on Dental Auxiliaries.

(b) The Committee on Dental Auxiliaries shall have the following areas of responsibility and duties:

(1) The committee shall have the following duties and authority related to education programs and curriculum:

(A) Shall evaluate all dental auxiliary programs applying for board approval in accordance with board rules governing the programs.

(B) May appoint board members to any evaluation committee. Board members so appointed shall not make a final decision on the issue of program or course approval.

(C) Shall report and make recommendations to the board as to whether a program or course qualifies for approval. The board retains the final authority to grant or deny approval to a program or course.

(D) Shall review and document any alleged deficiencies that might warrant board action to withdraw or revoke approval of a program or course, at the request of the board.

(E) May review and document any alleged deficiencies that might warrant board action to withdraw or revoke approval of a program or course, at its own initiation.

(2) The committee shall have the following duties and authority related to applications:

(A) Shall review and evaluate all applications for licensure in the various dental auxiliary categories to ascertain whether a candidate meets the appropriate licensing requirements specified by statute and board regulations.

(B) Shall maintain application records, cashier application fees, and perform any other ministerial tasks as are incidental to the application process.

(C) May delegate any or all of the functions in this paragraph to its staff.

(D) Shall issue auxiliary licenses in all cases, except where there is a question as to a licensing requirement. The board retains final authority to interpret any licensing requirement. If a question arises

in the area of interpreting any licensing requirement, it shall be presented by the committee to the board for resolution.

(3) The committee shall have the following duties and authority regarding examinations:

(A) Shall advise the board as to the type of license examination it deems appropriate for the various dental auxiliary license categories.

(B) Shall, at the direction of the board, develop or cause to be developed, administer, or both, examinations in accordance with the board's instructions and periodically report to the board on the progress of those examinations. The following shall apply to the examination procedure:

(i) The examination shall be submitted to the board for its approval prior to its initial administration.

(ii) Once an examination has been approved by the board, no further approval is required unless a major modification is made to the examination.

(iii) The committee shall report to the board on the results of each examination and shall, where appropriate, recommend pass points.

(iv) The board shall set pass points for all dental auxiliary licensing examinations.

(C) May appoint board members to any examination committee established pursuant to subparagraph (B).

(4) The committee shall periodically report and make recommendations to the board concerning the level of fees for dental auxiliaries and the need for any legislative fee increase. However, the board retains final authority to set all fees.

(5) The committee shall be responsible for all aspects of the license renewal process, which shall be accomplished in accordance with this chapter and board regulations. The committee may delegate any or all of its functions under this paragraph to its staff.

(6) The committee shall have no authority with respect to the approval of continuing education providers and the board retains all of this authority.

(7) The committee shall advise the board as to appropriate standards of conduct for auxiliaries, the proper ordering of enforcement priorities, and any other enforcement-related matters that the board may, in the future, delegate to the committee. The board shall retain all authority with respect to the enforcement

actions, including, but not limited to, complaint resolution, investigation, and disciplinary action against auxiliaries.

(8) The committee shall have the following duties regarding regulations:

(A) To review and evaluate all suggestions or requests for regulatory changes related to dental auxiliaries.

(B) To report and make recommendations to the board, after consultation with departmental legal counsel and the board's executive officer.

(C) To include in any report regarding a proposed regulatory change, at a minimum, the specific language of the proposed changes and the reasons for and facts supporting the need for the change. The board has the final rulemaking authority.

~~(c) This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute which becomes effective on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the committee subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 29. Section 1751 of the Business and Professions Code, as amended by Section 8 of Chapter 621 of the Statutes of 2005, is amended to read:

1751. (a) The board, upon recommendation of the committee, shall adopt regulations governing the procedures that dental assistants, registered orthodontic assistants, registered surgery assistants, registered restorative assistants, registered dental assistants, registered restorative assistants in extended functions, and registered dental assistants in extended functions are authorized to perform consistent with and necessary to implement the provisions of this article, and the settings within which each may practice.

(b) The board shall conduct an initial review of the procedures, supervision level, settings under which they may be performed, and utilization of extended functions dental auxiliaries by January 1, 2012. The board shall submit the results of its review to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Legislature and the Office of the Consumer Advocate*. After the initial review, a review shall be conducted at least once every five to seven years thereafter, and the board shall update regulations as necessary to keep them current with the state of dental practice.

(c) This section shall become operative on January 1, 2008.

SEC. 30. Section 2001 of the Business and Professions Code is amended to read:

2001. There is in the Department of Consumer Affairs a Medical Board of California that consists of 21 members, nine of whom shall be public members.

The Governor shall appoint 19 members to the board, subject to confirmation by the Senate, seven of whom shall be public members. The Senate Rules Committee and the Speaker of the Assembly shall each appoint a public member, and their initial appointment shall be made to fill, respectively, the first and second public member vacancies that occur on or after January 1, 1983.

~~This section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 31. Section 2460 of the Business and Professions Code is amended to read:

2460. There is created within the jurisdiction of the Medical Board of California and its divisions the California Board of Podiatric Medicine. ~~This section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the California Board of Podiatric Medicine subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 32. Section 2531 of the Business and Professions Code is amended to read:

2531. There is in the Department of Consumer Affairs a Speech-Language Pathology and Audiology Board in which the enforcement and administration of this chapter is vested. The Speech-Language Pathology and Audiology Board shall consist of nine members, three of whom shall be public members.

~~This section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2009, deletes or extends the inoperative and repeal dates. The repeal of this section renders~~

~~the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 33. Section 2569 of the Business and Professions Code is repealed.

~~2569. The powers and duties of the board, as set forth in this chapter, shall be subject to the review required by Division 1.2 (commencing with Section 473). The review shall be performed as if this chapter were scheduled to become inoperative on July 1, 2003, and would be repealed as of January 1, 2004, as described in Section 473.1.~~

SEC. 34. Section 2570.19 of the Business and Professions Code is amended to read:

2570.19. (a) There is hereby created a California Board of Occupational Therapy, hereafter referred to as the board. The board shall enforce and administer this chapter.

(b) The members of the board shall consist of the following:

(1) Three occupational therapists who shall have practiced occupational therapy for five years.

(2) One occupational therapy assistant who shall have assisted in the practice of occupational therapy for five years.

(3) Three public members who shall not be licentiates of the board or of any board referred to in Section 1000 or 3600.

(c) The Governor shall appoint the three occupational therapists and one occupational therapy assistant to be members of the board. The Governor, the Senate Rules Committee, and the Speaker of the Assembly shall each appoint a public member. Not more than one member of the board shall be appointed from the full-time faculty of any university, college, or other educational institution.

(d) All members shall be residents of California at the time of their appointment. The occupational therapist and occupational therapy assistant members shall have been engaged in rendering occupational therapy services to the public, teaching, or research in occupational therapy for at least five years preceding their appointments.

(e) The public members may not be or have ever been occupational therapists or occupational therapy assistants or in training to become occupational therapists or occupational therapy assistants. The public members may not be related to, or have a household member who is, an occupational therapist or an occupational therapy assistant, and may not have had, within two

years of the appointment, a substantial financial interest in a person regulated by the board.

(f) The Governor shall appoint two board members for a term of one year, two board members for a term of two years, and one board member for a term of three years. Appointments made thereafter shall be for four-year terms, but no person shall be appointed to serve more than two consecutive terms. Terms shall begin on the first day of the calendar year and end on the last day of the calendar year or until successors are appointed, except for the first appointed members who shall serve through the last calendar day of the year in which they are appointed, before commencing the terms prescribed by this section. Vacancies shall be filled by appointment for the unexpired term. The board shall annually elect one of its members as president.

(g) The board shall meet and hold at least one regular meeting annually in the Cities of Sacramento, Los Angeles, and San Francisco. The board may convene from time to time until its business is concluded. Special meetings of the board may be held at any time and place designated by the board.

(h) Notice of each meeting of the board shall be given in accordance with the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

(i) Members of the board shall receive no compensation for their services, but shall be entitled to reasonable travel and other expenses incurred in the execution of their powers and duties in accordance with Section 103.

(j) The appointing power shall have the power to remove any member of the board from office for neglect of any duty imposed by state law, for incompetency, or for unprofessional or dishonorable conduct.

(k) A loan is hereby authorized from the General Fund to the Occupational Therapy Fund on or after July 1, 2000, in an amount of up to one million dollars ($1,000,000) to fund operating, personnel, and other startup costs of the board. Six hundred ten thousand dollars ($610,000) of this loan amount is hereby appropriated to the board to use in the 2000–01 fiscal year for the purposes described in this subdivision. In subsequent years, funds from the Occupational Therapy Fund shall be available to the board upon appropriation by the Legislature in the annual Budget Act.

The loan shall be repaid to the General Fund over a period of up to five years, and the amount paid shall also include interest at the rate accruing to moneys in the Pooled Money Investment Account. The loan amount and repayment period shall be minimized to the extent possible based upon actual board financing requirements as determined by the Department of Finance.

~~(l) This section shall become inoperative on July 1, 2013, and, as of January 1, 2014, is repealed, unless a later enacted statute that is enacted before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 35. Section 2602 of the Business and Professions Code is amended to read:

2602. The Physical Therapy Board of California, hereafter referred to as the board, shall enforce and administer this chapter. ~~This section shall become inoperative on July 1, 2013, and, as of January 1, 2014, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2014, deletes or extends the dates on which it becomes inoperative and is repealed.~~

~~The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 36. Section 2701 of the Business and Professions Code is amended to read:

2701. There is in the Department of Consumer Affairs the Board of Registered Nursing consisting of nine members.

Within the meaning of this chapter, board, or the board, refers to the Board of Registered Nursing. Any reference in state law to the Board of Nurse Examiners of the State of California or California Board of Nursing Education and Nurse Registration shall be construed to refer to the Board of Registered Nursing.

~~This section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 37. Section 2841 of the Business and Professions Code is amended to read:

2841. There is in the Department of Consumer Affairs a Board of Vocational Nursing and Psychiatric Technicians of the State of California, consisting of 11 members.

Within the meaning of this chapter, board, or the board, refers to the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

~~This section shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2009, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 38. Section 2920 of the Business and Professions Code is amended to read:

2920. The Board of Psychology shall enforce and administer this chapter. The board shall consist of nine members, four of whom shall be public members.

~~This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 39. Section 3010.5 of the Business and Professions Code is amended to read:

3010.5. (a) There is in the Department of Consumer Affairs a State Board of Optometry in which the enforcement of this chapter is vested. The board consists of 11 members, five of whom shall be public members.

Six members of the board shall constitute a quorum.

(b) The board shall, with respect to conducting investigations, inquiries, and disciplinary actions and proceedings, have the authority previously vested in the board as created pursuant to Section 3010. The board may enforce any disciplinary actions undertaken by that board.

~~(c) This section shall remain in effect only until July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends that date.~~

SEC. 40. Section 3502.1 of the Business and Professions Code is amended to read:

3502.1. (a) In addition to the services authorized in the regulations adopted by the board, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons authorized by law to supervise a physician assistant, a physician assistant may administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt, or adopt, a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. The drugs listed shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.

(b) "Drug order" for purposes of this section means an order for medication which is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription or order of the supervising physician, (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by physician assistants pursuant to authority granted by their supervising physicians, and (3) the signature of a physician assistant on a drug order shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(c) A drug order for any patient cared for by the physician assistant that is issued by the physician assistant shall either be based on the protocols described in subdivision (a) or shall be

1 approved by the supervising physician before it is filled or carried
2 out.
3 (1) A physician assistant shall not administer or provide a drug
4 or issue a drug order for a drug other than for a drug listed in the
5 formulary without advance approval from a supervising physician
6 and surgeon for the particular patient. At the direction and under
7 the supervision of a physician and surgeon, a physician assistant
8 may hand to a patient of the supervising physician and surgeon a
9 properly labeled prescription drug prepackaged by a physician and
10 surgeon, manufacturer as defined in the Pharmacy Law, or a
11 pharmacist.
12 (2) A physician assistant may not administer, provide or issue
13 a drug order for Schedule II through Schedule V controlled
14 substances without advance approval by a supervising physician
15 and surgeon for the particular patient.
16 (3) Any drug order issued by a physician assistant shall be
17 subject to a reasonable quantitative limitation consistent with
18 customary medical practice in the supervising physician and
19 surgeon's practice.
20 (d) A written drug order issued pursuant to subdivision (a),
21 except a written drug order in a patient's medical record in a health
22 facility or medical practice, shall contain the printed name, address,
23 and phone number of the supervising physician and surgeon, the
24 printed or stamped name and license number of the physician
25 assistant, and the signature of the physician assistant. Further, a
26 written drug order for a controlled substance, except a written drug
27 order in a patient's medical record in a health facility or a medical
28 practice, shall include the federal controlled substances registration
29 number of the physician assistant. The requirements of this
30 subdivision may be met through stamping or otherwise imprinting
31 on the supervising physician and surgeon's prescription blank to
32 show the name, license number, and if applicable, the federal
33 controlled substances number of the physician assistant, and shall
34 be signed by the physician assistant. When using a drug order, the
35 physician assistant is acting on behalf of and as the agent of a
36 supervising physician and surgeon.
37 (e) The medical record of any patient cared for by a physician
38 assistant for whom the supervising physician and surgeon's
39 Schedule II drug order has been issued or carried out shall be

reviewed and countersigned and dated by a supervising physician and surgeon within seven days.

(f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).

(g) The committee shall consult with the Medical Board of California and report ~~during its sunset review required by Division 1.2 (commencing with Section 473)~~ *to the Legislature and the Office of the Consumer Advocate periodically, as necessary, on* the impacts of exempting Schedule III and Schedule IV drug orders from the requirement for a physician and surgeon to review and countersign the affected medical record of a patient.

SEC. 41. Section 3504 of the Business and Professions Code is amended to read:

3504. There is established a Physician Assistant Committee of the Medical Board of California. The committee consists of nine members. ~~This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the committee subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 42. Section 3685 of the Business and Professions Code is amended to read:

3685. ~~(a)~~ The provisions of Article 8 (commencing with Section 3680) shall become operative on January 1, 2004, but the remaining provisions of this chapter shall become operative on July 1, 2004. It is the intent of the Legislature that the initial implementation of this chapter be administered by fees collected in advance from applicants. Therefore, the bureau shall have the power and authority to establish fees and receive applications for licensure or intents to file application statements on and after January 1, 2004. The department shall certify that sufficient funds are available prior to implementing this chapter. Funds from the General Fund may not be used for the purpose of implementing this chapter.

~~(b) This chapter shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute~~

~~that is enacted before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this chapter renders the bureau subject to the review required by Division 1.2 (commencing with Section 473).~~

~~(c) The bureau shall prepare the report required by Section 473.2 no later than September 1, 2008.~~

SEC. 43. Section 3710 of the Business and Professions Code is amended to read:

3710. The Respiratory Care Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

~~This section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.~~

~~The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 44. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent

community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

~~(f) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 45. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.

~~(c) In accordance with Sections 101.1 and 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 46. Section 4200.1 of the Business and Professions Code is amended to read:

4200.1. (a) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination four times, and may take the Multi-State Pharmacy Jurisprudence Examination for California four times.

(b) Notwithstanding Section 135, an applicant may take the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California four additional times each if he or she successfully completes, at minimum, 16 additional semester units of education in pharmacy as approved by the board.

(c) The applicant shall comply with the requirements of Section 4200 for each application for reexamination made pursuant to subdivision (b).

(d) An applicant may use the same coursework to satisfy the additional educational requirement for each examination under subdivision (b), if the coursework was completed within 12 months of the date of his or her application for reexamination.

(e) For purposes of this section, the board shall treat each failing score on the pharmacist licensure examination administered by the board prior to January 1, 2004, as a failing score on both the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.

(f) From January 1, 2004, to July 1, 2008, inclusive, the board shall collect data on the applicants who are admitted to, and take, the licensure examinations required by Section 4200. The board shall report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Legislature and the Office of the Consumer Advocate* before September 1, 2008, regarding the impact on those applicants of the examination limitations imposed by this section. The report shall include, but not be limited to, the following information:

(1) The number of applicants taking the examination and the number who fail the examination for the fourth time.

(2) The number of applicants who, after failing the examination for the fourth time, complete a pharmacy studies program in California or another state to satisfy the requirements of this section and who apply to take the licensure examination required by Section 4200.

(3) To the extent possible, the school from which the applicant graduated and the school's location and the pass/fail rates on the examination for each school.

(g) This section shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.

SEC. 47. Section 4200.3 of the Business and Professions Code is amended to read:

4200.3. (a) The examination process shall be regularly reviewed pursuant to Section 139.

(b) The examination process shall meet the standards and guidelines set forth in the Standards for Educational and Psychological Testing and the Federal Uniform Guidelines for Employee Selection Procedures. The board shall work with the Office of Examination Resources of the department or with an equivalent organization who shall certify at minimum once every five years that the examination process meets these national testing standards. If the department determines that the examination process fails to meet these standards, the board shall terminate its use of the North American Pharmacy Licensure Examination and shall use only the written and practical examination developed by the board.

(c) The examination shall meet the mandates of subdivision (a) of Section 12944 of the Government Code.

(d) The board shall work with the Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

(e) The board shall annually publish the pass and fail rates for the pharmacist's licensure examination administered pursuant to Section 4200, including a comparison of historical pass and fail rates before utilization of the North American Pharmacist Licensure Examination.

(f) The board shall *annually* report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Legislature, the Office of the Consumer Advocate,* and the department ~~as part of its next scheduled review~~, the pass rates of applicants who sat for the national examination compared with the pass rates of applicants who sat for the prior state examination. This report shall be a component of the evaluation of the examination process that is based on psychometrically sound principles for establishing minimum qualifications and levels of competency.

SEC. 48. Section 4501 of the Business and Professions Code is amended to read:

4501. ~~(a)~~ "Board," as used in this chapter, means the Board of Vocational Nursing and Psychiatric Technicians.

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

SEC. 49. Section 4800 of the Business and Professions Code is amended to read:

4800. There is in the Department of Consumer Affairs a Veterinary Medical Board in which the administration of this chapter is vested. The board consists of seven members, three of whom shall be public members.

~~This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.~~

~~The repeal of this section renders the board subject to the review provided for by Division 1.2 (commencing with Section 473).~~

SEC. 50. Section 4928 of the Business and Professions Code is amended to read:

4928. The Acupuncture Board, which consists of seven members, shall enforce and administer this chapter. The appointing powers, as described in Section 4929, may appoint to the board a person who was a member of the prior board prior to the repeal of that board on January 1, 2006.

~~This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed.~~

~~The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 51. Section 4989 of the Business and Professions Code is repealed.

~~4989. The powers and duties of the board, as set forth in this chapter, shall be subject to the review required by Division 1.2 (commencing with Section 473). The review shall be performed as if this chapter were scheduled to become inoperative on July 1, 2005, and would be repealed as of January 1, 2006, as described in Section 473.1.~~

SEC. 52. Section 4990 of the Business and Professions Code is amended to read:

4990. (a) There is in the Department of Consumer Affairs, a Board of Behavioral Sciences that consists of 11 members composed as follows:

(1) Two state licensed clinical social workers.

(2) One state licensed educational psychologist.

(3) Two state licensed marriage and family therapists.

(4) Six public members.

(b) Each member, except the six public members, shall have at least two years of experience in his or her profession.

(c) Each member shall reside in the State of California.

(d) The Governor shall appoint four of the public members and the five licensed members with the advice and consent of the Senate. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(e) Each member of the board shall be appointed for a term of four years. A member appointed by the Speaker of the Assembly or the Senate Committee on Rules shall hold office until the appointment and qualification of his or her successor or until one year from the expiration date of the term for which he or she was appointed, whichever first occurs. Pursuant to Section 1774 of the Government Code, a member appointed by the Governor shall hold office until the appointment and qualification of his or her successor or until 60 days from the expiration date of the term for which he or she was appointed, whichever first occurs.

(f) A vacancy on the board shall be filled by appointment for the unexpired term by the authority who appointed the member whose membership was vacated.

(g) Not later than the first of June of each calendar year, the board shall elect a chairperson and a vice chairperson from its membership.

(h) Each member of the board shall receive a per diem and reimbursement of expenses as provided in Section 103.

~~(i) This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 53. Section 4990.24 of the Business and Professions Code is repealed.

~~4990.24. The powers and duties of the board, as set forth in this chapter, shall be subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 54. Section 5000 of the Business and Professions Code is amended to read:

5000. There is in the Department of Consumer Affairs the California Board of Accountancy, which consists of 15 members, seven of whom shall be licensees, and eight of whom shall be public members who shall not be licentiates of the board or registered by the board. The board has the powers and duties conferred by this chapter.

The Governor shall appoint four of the public members, and the seven licensee members as provided in this section. The Senate ~~Rules Committee~~ *Committee on Rules* and the Speaker of the Assembly shall each appoint two public members. In appointing the seven licensee members, the Governor shall appoint members representing a cross section of the accounting profession with at least two members representing a small public accounting firm. For the purposes of this chapter, a small public accounting firm shall be defined as a professional firm that employs a total of no more than four licensees as partners, owners, or full-time employees in the practice of public accountancy within the State of California.

~~This section shall become inoperative on July 1, 2011, and as of January 1, 2012, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2012, deletes or extends the dates on which this section becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

~~However, the review of the board shall be limited to reports or studies specified in this chapter and those issues identified by the Joint Committee on Boards, Commissions, and Consumer Protection and the board regarding the implementation of new licensing requirements.~~

SEC. 55. Section 5510 of the Business and Professions Code is amended to read:

5510. There is in the Department of Consumer Affairs a California Architects Board which consists of 10 members.

Any reference in law to the California Board of Architectural Examiners shall mean the California Architects Board.

~~This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 56. Section 5621 of the Business and Professions Code is amended to read:

5621. (a) There is hereby created within the jurisdiction of the board, a Landscape Architects Technical Committee, hereinafter referred to in this chapter as the landscape architects committee.

(b) The landscape architects committee shall consist of five members who shall be licensed to practice landscape architecture in this state. The Governor shall appoint three of the members. The Senate Committee on Rules and the Speaker of the Assembly shall appoint one member each.

(c) The initial members to be appointed by the Governor are as follows: one member for a term of one year; one member for a term of two years; and one member for a term of three years. The Senate Committee on Rules and the Speaker of the Assembly shall initially each appoint one member for a term of four years. Thereafter, appointments shall be made for four-year terms, expiring on June 1 of the fourth year and until the appointment and qualification of his or her successor or until one year shall have elapsed whichever first occurs. Vacancies shall be filled for the unexpired term.

(d) No person shall serve as a member of the landscape architects committee for more than two consecutive terms.

~~(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 57. Section 5810 of the Business and Professions Code is amended to read:

5810. ~~(a)~~ This chapter shall be subject to the ~~review required by Division 1.2 (commencing with Section 473)~~ *process described in Division 1.3 (commencing with Section 474.20).*

~~(b) This chapter shall remain in effect only until January 1, 2010, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2010, deletes or extends that date.~~

SEC. 58. Section 5811 of the Business and Professions Code is amended to read:

5811. An interior design organization issuing stamps under Section 5801 shall provide to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Legislature and the Office of the Consumer Advocate* by September 1, 2008, a report that reviews and assesses the costs and benefits associated with the California Code and Regulations Examination and explores feasible alternatives to that examination.

SEC. 59. Section 6510 of the Business and Professions Code is amended to read:

6510. (a) There is within the jurisdiction of the department the Professional Fiduciaries Bureau. The bureau is under the supervision and control of the director. The duty of enforcing and administering this chapter is vested in the chief of the bureau, who is responsible to the director. Every power granted or duty imposed upon the director under this chapter may be exercised or performed in the name of the director by a deputy director or by the chief, subject to conditions and limitations as the director may prescribe.

(b) The Governor shall appoint, subject to confirmation by the Senate, the chief of the bureau, at a salary to be fixed and determined by the director with the approval of the Director of Finance. The chief shall serve under the direction and supervision of the director and at the pleasure of the Governor.

~~(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed.~~

~~The repeal of this section renders the bureau subject to the review required by Division 1.2 (commencing with Section 473).~~

~~Notwithstanding any other provision of law, upon the repeal of this section, the responsibilities and jurisdiction of the bureau shall be transferred to the Professional Fiduciaries Advisory Committee, as provided by Section 6511.~~

SEC. 60. Section 6511 of the Business and Professions Code is amended to read:

6511. (a) There is within the bureau a Professional Fiduciaries Advisory Committee. The committee shall consist of seven members; three of whom shall be licensees actively engaged as professional fiduciaries in this state, and four of whom shall be public members. One of the public members shall be a member of a nonprofit organization advocating on behalf of the elderly, and one of the public members shall be a probate court investigator.

(b) Each member of the committee shall be appointed for a term of four years, and shall hold office until the appointment of his or her successor or until one year shall have elapsed since the expiration of the term for which he or she was appointed, whichever first occurs.

(c) Vacancies shall be filled by the appointing power for the unexpired portion of the terms in which they occur. No person shall serve as a member of the committee for more than two consecutive terms.

(d) The Governor shall appoint the member from a nonprofit organization advocating on behalf of the elderly, the probate court investigator, and the three licensees. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member.

(e) Every member of the committee shall receive per diem and expenses as provided in Sections 103 and 113.

(f) The committee shall do all of the following:

(1) Examine the functions and policies of the bureau and make recommendations with respect to policies, practices, and regulations as may be deemed important and necessary by the director or the chief to promote the interests of consumers or that otherwise promote the welfare of the public.

(2) Consider and make appropriate recommendations to the bureau in any matter relating to professional fiduciaries in this state.

(3) Provide assistance as may be requested by the bureau in the exercise of its powers or duties.

(4) Meet at least once each quarter. All meetings of the committee shall be public meetings.

(g) The bureau shall meet and consult with the committee regarding general policy issues related to professional fiduciaries.

~~(h) Notwithstanding any other provision of law, if the bureau becomes inoperative or is repealed in accordance with Section 6510, or by subsequent acts, the committee shall succeed to and is vested with all the duties, powers, purposes, responsibilities, and jurisdiction, not otherwise repealed or made inoperative, of the bureau and its chief. The succession of the committee to the functions of the bureau as provided in this subdivision shall establish the committee as the Professional Fiduciaries Committee in the department within the meaning of Section 22, and all references to the bureau in this code shall be considered as references to the committee.~~

SEC. 61. Section 6710 of the Business and Professions Code is amended to read:

6710. (a) There is in the Department of Consumer Affairs a Board for Professional Engineers and Land Surveyors, which consists of 13 members.

(b) Any reference in any law or regulation to the Board of Registration for Professional Engineers and Land Surveyors is deemed to refer to the Board for Professional Engineers and Land Surveyors.

~~(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 62. Section 7000.5 of the Business and Professions Code is amended to read:

7000.5. ~~(a)~~ There is in the Department of Consumer Affairs a Contractors' State License Board, which consists of 15 members.

~~(b) The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473). However, the review of this board by the department shall be~~

~~limited to only those unresolved issues identified by the Joint Committee on Boards, Commissions, and Consumer Protection.~~

~~(c) This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 63. Section 7200 of the Business and Professions Code is amended to read:

7200. ~~(a)~~ There is in the Department of Consumer Affairs a State Board of Guide Dogs for the Blind in whom enforcement of this chapter is vested. The board shall consist of seven members appointed by the Governor. One member shall be the Director of Rehabilitation or his or her designated representative. The remaining members shall be persons who have shown a particular interest in dealing with the problems of the blind, and at least two of them shall be blind persons who use guide dogs.

~~(b) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 64. Section 7303 of the Business and Professions Code is amended to read:

7303. (a) Notwithstanding Article 8 (commencing with Section 9148) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code, there is in the Department of Consumer Affairs the State Board of Barbering and Cosmetology in which the administration of this chapter is vested.

(b) The board shall consist of nine members. Five members shall be public members and four members shall represent the professions. The Governor shall appoint three of the public members and the four professions members. The Senate Committee on Rules and the Speaker of the Assembly shall each appoint one public member. Members of the board shall be appointed for a term of four years, except that of the members appointed by the Governor, two of the public members and two of the professions members shall be appointed for an initial term of two years. No board member may serve longer than two consecutive terms.

(c) The board shall appoint an executive officer who is exempt from civil service. The executive officer shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The appointment of the executive officer is subject to the approval of the director. In the event that a newly authorized board replaces an existing or previous bureau, the director may appoint an interim executive officer for the board who shall serve temporarily until the new board appoints a permanent executive officer.

(d) The executive officer shall provide examiners, inspectors, and other personnel necessary to carry out the provisions of this chapter.

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

SEC. 65. Section 7304 of the Business and Professions Code is repealed.

~~7304. The board shall be subject to review pursuant to Division 1.2 (commencing with Section 473).~~

SEC. 66. Section 7810 of the Business and Professions Code is amended to read:

7810. The Board for Geologists and Geophysicists is within the department and is subject to the jurisdiction of the department. Except as provided in this section, the board shall consist of eight members, five of whom shall be public members, two of whom shall be geologists, and one of whom shall be a geophysicist.

Each member shall hold office until the appointment and qualification of the member's successor or until one year has elapsed from the expiration of the term for which the member was appointed, whichever occurs first. Vacancies occurring prior to the expiration of the term shall be filled by appointment for the remainder of the unexpired term.

Each appointment shall be for a four-year term expiring June 1 of the fourth year following the year in which the previous term expired. No person shall serve as a member of the board for more than two consecutive terms.

The Governor shall appoint three of the public members and the three members qualified as provided in Section 7811. The Senate Committee on Rules and the Speaker of the Assembly shall each

appoint a public member, and their initial appointment shall be made to fill, respectively, the first and second public member vacancies that occurred on or after January 1, 1983.

At the time the first vacancy is created by the expiration of the term of a public member appointed by the Governor, the board shall be reduced to consist of seven members, four of whom shall be public members, two of whom shall be geologists, and one of whom shall be a geophysicist. Notwithstanding any other provision of law, the term of that member shall not be extended for any reason, except as provided in this section.

~~This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 67. Section 8000 of the Business and Professions Code is amended to read:

8000. There is in the Department of Consumer Affairs a Court Reporters Board of California, which consists of five members, three of whom shall be public members and two of whom shall be holders of certificates issued under this chapter who have been actively engaged as shorthand reporters within this state for at least five years immediately preceding their appointment.

~~This section shall become inoperative on July 1, 2009, and, as of January 1, 2010, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed.~~

SEC. 68. Section 8520 of the Business and Professions Code is amended to read:

8520. (a) There is in the Department of Consumer Affairs a Structural Pest Control Board, which consists of seven members.

(b) Subject to the jurisdiction conferred upon the director by Division 1 (commencing with Section 100) of this code, the board is vested with the power to and shall administer the provisions of this chapter.

(c) It is the intent of the Legislature that consumer protection is the primary mission of the board.

~~(d) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute,~~

~~which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 69. Section 8710 of the Business and Professions Code is amended to read:

8710. (a) The Board for Professional Engineers and Land Surveyors is vested with power to administer the provisions and requirements of this chapter, and may make and enforce rules and regulations that are reasonably necessary to carry out its provisions.

(b) The board may adopt rules and regulations of professional conduct that are not inconsistent with state and federal law. The rules and regulations may include definitions of incompetence and negligence. Every person who holds a license or certificate issued by the board pursuant to this chapter, or a license or certificate issued to a civil engineer pursuant to Chapter 7 (commencing with Section 6700), shall be governed by these rules and regulations.

~~(c) This section shall become inoperative on July 1, 2011, and, as of January 1, 2012, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2012, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section shall render the board subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 70. Section 9882 of the Business and Professions Code is amended to read:

9882. ~~(a)~~ There is in the Department of Consumer Affairs a Bureau of Automotive Repair under the supervision and control of the director. The duty of enforcing and administering this chapter is vested in the chief who is responsible to the director. The director may adopt and enforce those rules and regulations that he or she determines are reasonably necessary to carry out the purposes of this chapter and declaring the policy of the bureau, including a system for the issuance of citations for violations of this chapter as specified in Section 125.9. These rules and regulations shall be adopted pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

~~(b) In 2003 and every four years thereafter, the Joint Committee on Boards, Commissions, and Consumer Protection shall hold a public hearing to receive testimony from the Director of Consumer Affairs and the bureau. In those hearings, the bureau shall have~~

~~the burden of demonstrating a compelling public need for the continued existence of the bureau and its regulatory program, and that its function is the least restrictive regulation consistent with the public health, safety, and welfare. The committee shall evaluate and review the effectiveness and efficiency of the bureau based on factors and minimum standards of performance that are specified in Section 473.4. The committee shall report its findings and recommendations as specified in Section 473.5. The bureau shall prepare an analysis and submit a report to the committee as specified in Section 473.2.~~

SEC. 71. Section 18602 of the Business and Professions Code is amended to read:

18602. (a) Except as provided in this section, there is in the Department of Consumer Affairs the State Athletic Commission, which consists of seven members. Five members shall be appointed by the Governor, one member shall be appointed by the Senate ~~Rules~~ Committee *on Rules*, and one member shall be appointed by the Speaker of the Assembly.

The members of the commission appointed by the Governor are subject to confirmation by the Senate pursuant to Section 1322 of the Government Code.

No person who is currently licensed, or who was licensed within the last two years, under this chapter may be appointed or reappointed to, or serve on, the commission.

(b) In appointing commissioners under this section, the Governor, the Senate ~~Rules~~ Committee *on Rules*, and the Speaker of the Assembly shall make every effort to ensure that at least four of the members of the commission shall have experience and demonstrate expertise in one of the following areas:

(1) A licensed physician or surgeon having expertise or specializing in neurology, neurosurgery, head trauma, or sports medicine. Sports medicine includes, but is not limited to, physiology, kinesiology, or other aspects of sports medicine.

(2) Financial management.

(3) Public safety.

(4) Past experience in the activity regulated by this chapter, either as a contestant, a referee or official, a promoter, or a venue operator.

(c) Each member of the commission shall be appointed for a term of four years. All terms shall end on January 1. Vacancies

occurring prior to the expiration of the term shall be filled by appointment for the unexpired term. No commission member may serve more than two consecutive terms.

(d) Notwithstanding any other provision of this chapter, members first appointed shall be subject to the following terms:

(1) The Governor shall appoint two members for two years, two members for three years, and one member for four years.

(2) The Senate Committee on Rules shall appoint one member for four years.

(3) The Speaker of the Assembly shall appoint one member for four years.

(4) The appointing powers, as described in subdivision (a), may appoint to the commission a person who was a member of the prior commission prior to the repeal of that commission on July 1, 2006.

~~(e) This section shall become inoperative on July 1, 2009, and as of January 1, 2010, is repealed, unless a later enacted statute, which becomes operative on or before January 1, 2010, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the commission subject to the review required by Division 1.2 (commencing with Section 473).~~

SEC. 72. Section 18602.5 of the Business and Professions Code is amended to read:

18602.5. (a) The commission shall adopt and submit a strategic plan to the Governor and the Legislature on or before September 30, 2008. The commission shall also submit a report to the Governor and the Legislature on the status of the adoption of the strategic plan ~~during the commission's next regularly scheduled sunset review after January 1, 2007~~ *on or before March 1, 2008.* The strategic plan shall include, but shall not be limited to, efforts to resolve prior State Athletic Commission deficiencies in the following areas:

(1) Regulation of the profession, what fees should be paid for this regulation, and the structure and equity of the fees charged.

(2) The effect and appropriateness of contracts made pursuant to Section 18828.

(3) Costs to train ringside physicians, referees, timekeepers, and judges.

(4) Steps that need to be taken to ensure sufficient sources of revenue and funding.

(5) Necessity for review and modification of organizational procedures, the licensing process, and the complaint process.

(6) Outdated information technology.

(7) Unorganized and improper accounting.

(8) Miscalculations at events, a lack of technology to record proper calculations, and funding issues.

(9) The health and safety of the participants and the public in attendance at events regulated under this chapter, including costs of examinations under Section 18711.

(b) The commission shall solicit input from the public, the State Auditor, the Little Hoover Commission, the Center for Public Interest Law, and others as necessary in preparing and adopting the strategic plan.

(c) The commission shall report on progress in implementing the strategic plan to the Director of Consumer Affairs, the Governor, and the Legislature on or before September 30, 2009.

SEC. 73. Section 18824 of the Business and Professions Code is amended to read:

18824. (a) Except as provided in Sections 18646 and 18832, every person who conducts a contest or wrestling exhibition shall, within five working days after the determination of every contest or wrestling exhibition for which admission is charged and received, furnish to the commission the following:

(1) A written report executed under penalty of perjury by one of the officers, showing the amount of the gross receipts, not to exceed two million dollars ($2,000,000), and the gross price for the contest or wrestling exhibition charged directly or indirectly and no matter by whom received, for the sale, lease, or other exploitation of broadcasting and television rights of the contest or wrestling exhibition, and without any deductions, except for expenses incurred for one broadcast announcer, telephone line connection, and transmission mobile equipment facility, which may be deducted from the gross taxable base when those expenses are approved by the commission.

(2) A fee of 5 percent, exclusive of any federal taxes paid thereon, of the amount paid for admission to the contest or wrestling exhibition, except that for any one contest, the fee shall not exceed the amount of one hundred thousand dollars ($100,000). The commission shall report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Legislature and the Office*

1 *of the Consumer Advocate* on the fiscal impact of the one hundred
2 thousand dollar ($100,000) limit on fees collected by the
3 commission for admissions revenues.
4 (A) The amount of the gross receipts upon which the fee
5 provided for in paragraph (2) is calculated shall not include any
6 assessments levied by the commission under Section 18711.
7 (B) (i) If the fee for any one boxing contest exceeds seventy
8 thousand dollars ($70,000), the amount in excess of seventy
9 thousand dollars ($70,000) shall be paid one-half to the commission
10 and one-half to the Boxers' Pension Fund.
11 (ii) If the report required by subdivision (b) of Section 18618
12 recommends that the Boxers' Pension Fund shall be expanded to
13 include all athletes licensed under this chapter, the commission,
14 by regulation, shall require, for all contests where the fee exceeds
15 seventy thousand dollars ($70,000), the amount in excess of
16 seventy thousand dollars ($70,000) shall be paid one-half to the
17 commission and one-half to the Boxers' Pension Fund only if all
18 athletes licensed under this chapter are made eligible for the
19 Boxers' Pension Fund.
20 (C) The fee shall apply to the amount actually paid for admission
21 and not to the regular established price.
22 (D) No fee is due in the case of a person admitted free of charge.
23 However, if the total number of persons admitted free of charge
24 to a boxing, kickboxing, or martial arts contest, or wrestling
25 exhibition exceeds 33 percent of the total number of spectators,
26 then a fee of one dollar ($1) per complimentary ticket or pass used
27 to gain admission to the contest shall be paid to the commission
28 for each complimentary ticket or pass that exceeds the numerical
29 total of 33 percent of the total number of spectators.
30 (E) The minimum fee for an amateur contest or exhibition shall
31 not be less than five hundred dollars ($500).
32 (3) A fee of up to 5 percent, to be established by the commission
33 through regulations to become operative on or before July 1, 2008,
34 and updated periodically as needed, of the gross price, exclusive
35 of any federal taxes paid thereon, for the sale, lease, or other
36 exploitation of broadcasting or television rights thereof, except
37 that in no case shall the fee be less than one thousand dollars
38 ($1,000) or more than twenty-five thousand dollars ($25,000).
39 (b) As used in this section, "person" includes a promoter, club,
40 individual, corporation, partnership, association, or other

organization, and "wrestling exhibition" means a performance of wrestling skills and techniques by two or more individuals, to which admission is charged or which is broadcast or televised, in which the participating individuals are not required to use their best efforts in order to win, and for which the winner may have been selected before the performance commences.

SEC. 74. Section 18882 of the Business and Professions Code is amended to read:

18882. (a) At the time of payment of the fee required by Section 18824, a promoter shall pay to the commission all amounts scheduled for contribution to the pension plan. If the commission, in its discretion, requires pursuant to Section 18881, that contributions to the pension plan be made by the boxer and his or her manager, those contributions shall be made at the time and in the manner prescribed by the commission.

(b) All contributions to finance the pension plan shall be deposited in the State Treasury and credited to the Boxers' Pension Fund, which is hereby created. Notwithstanding the provisions of Section 13340 of the Government Code, all moneys in the Boxers' Pension Fund are hereby continuously appropriated to be used exclusively for the purposes and administration of the pension plan.

(c) The Boxers' Pension Fund is a retirement fund, and no moneys within it shall be deposited or transferred to the General Fund.

(d) The commission has exclusive control of all funds in the Boxers' Pension Fund. No transfer or disbursement in any amount from this fund shall be made except upon the authorization of the commission and for the purpose and administration of the pension plan.

(e) Except as otherwise provided in this subdivision, the commission or its designee shall invest the money contained in the Boxers' Pension Fund according to the same standard of care as provided in Section 16040 of the Probate Code. The commission has exclusive control over the investment of all moneys in the Boxers' Pension Fund. Except as otherwise prohibited or restricted by law, the commission may invest the moneys in the fund through the purchase, holding, or sale of any investment, financial instrument, or financial transaction that the commission in its informed opinion determines is prudent.

(f) The administrative costs associated with investing, managing, and distributing the Boxers' Pension Fund shall be limited to no more than 20 percent of the average annual contribution made to the fund in the previous two years, not including any investment income derived from the corpus of the fund. Diligence shall be exercised by administrators in order to lower the fund's expense ratio as far below 20 percent as feasible and appropriate. The commission shall report to the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Legislature and the Office of the Consumer Advocate* on the impact of this provision ~~during the next regularly scheduled sunset review after January 1, 2007~~ *on or before March 1, 2008.*

SEC. 75. Section 22259 of the Business and Professions Code is repealed.

~~22259. This chapter shall be subject to the review required by Division 1.2 (commencing with Section 473).~~

~~This chapter shall become inoperative on July 1, 2008, and, as of January 1, 2009, is repealed, unless a later enacted statute, which becomes effective on or before January 1, 2009, deletes or extends that date on which it becomes inoperative and is repealed.~~

SEC. 76. Section 9148.8 of the Government Code is amended to read:

9148.8. (a) The ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Office of the Consumer Advocate*, acting pursuant to a request from the chairperson of the appropriate policy committee, shall evaluate a plan prepared pursuant to Section 9148.4 or 9148.6.

(b) Evaluations prepared by the ~~Joint Committee on Boards, Commissions, and Consumer Protection~~ *Office of the Consumer Advocate* pursuant to this section shall be provided to the respective policy and fiscal committees of the Legislature pursuant to rules adopted by each committee for this purpose.

SEC. 77. Section 9148.51 of the Government Code is amended to read:

9148.51. (a) It is the intent of the Legislature that all existing and proposed state boards be subject to review ~~every four years~~ *upon request by a Member of the Legislature or the chief of the Office of the Consumer Advocate, as provided in Division 1.3 (commencing with Section 474.20) of the Business and Professions Code,* to evaluate and determine whether ~~each has demonstrated~~

~~a public need for its continued existence in accordance with enumerated factors and standards as set forth in Chapter 2 (commencing with Section 474) of Division 1.2 of the Business and Professions Code~~ *the highest priority of each board is the protection of the public.*

(b) ~~In the event that~~ *If* any state board ~~becomes inoperative or is repealed in accordance with the act that added this section, any provision of existing law that provides for the appointment of board members and specifies the qualifications and tenure of board members shall not be implemented and shall have no force or effect while that state board is inoperative or repealed~~ *is determined to be deficient pursuant to Section 474.21 of the Business and Professions Code, the incumbent members of the board shall be removed from office without a hearing as described in Section 474.21 of the Business and Professions Code, and a successor board shall be appointed pursuant to Section 101.1 of the Business and Professions Code.*

~~(c) Any provision of law authorizing the appointment of an executive officer by a state board subject to the review described in Chapter 2 (commencing with Section 474) of Division 1.2 of the Business and Professions Code, or prescribing his or her duties, shall not be implemented and shall have no force or effect while the applicable state board is inoperative or repealed.~~

~~(d) It is the intent of the Legislature that subsequent legislation to extend or repeal the inoperative date for any state board shall be a separate bill for that purpose.~~

SEC. 78. Section 9148.52 of the Government Code is repealed.

~~9148.52. (a) The Joint Committee on Boards, Commissions, and Consumer Protection established pursuant to Section 473 of the Business and Professions Code shall review all state boards, as defined in Section 9148.2, other than a board subject to review pursuant to Chapter 1 (commencing with Section 473) of Division 1.2 of the Business and Professions Code, every four years.~~

~~(b) The committee shall evaluate and make determinations pursuant to Chapter 2 (commencing with Section 474) of Division 1.2 of the Business and Professions Code.~~

~~SECTION 1. Section 101.1 of the Business and Professions Code is repealed.~~

~~SEC. 2. Section 101.1 is added to the Business and Professions Code, to read:~~

~~101.1. In the event that any board, as defined in Section 477, becomes inoperative or is repealed, a successor board shall be created in the Department of Consumer Affairs that shall succeed to and is vested with all the duties, powers, purposes, responsibilities, and jurisdiction not otherwise repealed or made inoperative of the board that it is succeeding. The successor board shall have the same number of members and composition as the board that it is succeeding, and those members shall be appointed by the same appointing authorities, for the same term, and with the same membership requirements as the members of that board. The successor board shall also have the same authority to appoint an executive officer as was possessed by the board that it is succeeding on the date upon which that board became inoperative.~~

~~SEC. 3. Section 4001 of the Business and Professions Code is amended to read:~~

~~4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.~~

~~(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.~~

~~(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.~~

~~(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.~~

~~(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.~~

~~(f) In accordance with Section 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed, unless a later enacted statute, that becomes effective on or before January 1, 2011, deletes or extends the dates on which it becomes inoperative and is repealed. The repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473).~~

~~SEC. 4. Section 4003 of the Business and Professions Code is amended to read:~~

~~4003. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter. The executive officer may or may not be a member of the board as the board may determine.~~

~~(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of his or her duties.~~

~~(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.~~

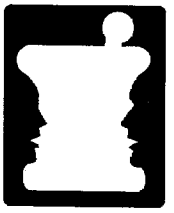
~~(d) The executive officer shall give receipts for all money received by him or her and pay it to the Department of Consumer Affairs, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of him or her by the board.~~

~~(e) In accordance with Section 473.1, this section shall become inoperative on July 1, 2010, and, as of January 1, 2011, is repealed,~~

1 ~~unless a later enacted statute, that becomes effective on or before~~
2 ~~January 1, 2011, deletes or extends the dates on which it becomes~~
3 ~~inoperative and is repealed.~~

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 1096 **VERSION: As introduced January 14, 2008**

AUTHOR: Calderon **SPONSOR: Adheris, Inc.**

BOARD POSITION: Oppose

SUBJECT: Medical Information

EXISTING LAW:

1. Prohibits a provider of health care, health care service plan or contractor from disclosing medical information regarding a patient without first obtaining an authorization from the patient.
2. Makes exceptions that include allowing for the disclosure of patient medical information without authorization if compelled by a court, board, commission or administrative agency under specified conditions or pursuant to a subpoena as specified or pursuant to a search warrant lawfully issued.
3. Specifies that a provider of health care a health care service plan can also disclose medical information without prior approval for purposes of diagnosis or treatment of a patient, for paying for health care services rendered and may disclose information to public agencies, clinical investigators or healthcare institutions for research purposes.
4. Provides additional exemptions and details the limitations and parameters under which the exemptions apply.

THIS BILL WOULD:

1. Allow for written communication to be mailed to a patient by a pharmacy if deemed to be necessary to provide health care services to the patient and will not require prior authorization if all of the following are met:
    - The written communication encourages the patient to adhere to the prescribed course of medical treatment as prescribed.
    - The written communication pertains only to the prescribed course of medication treatment and does not describe or mention any other pharmaceutical products.
    - All product-related information shall be consistent with the current federal Food and Drug Administration (FDA) approved product package insert.
    - A copy of each written communication version shall be submitted to the FDA.

- Evidence-based or consensus-based practice guidelines shall be the basis of any information that is provided to patients in order to improve their overall health.
- All personally identifiable medical information collected, used and disclosed shall be confidential as specified.
- If the written communication is paid for, in whole or in part by a manufacturer, distributor or provider of a health care product, the communication must disclose whether the pharmacy receives direct or indirect remuneration in a typeface no smaller than 14-point type.
- The communication contains instructions in a typeface no smaller than 14-point font describing how the patient may opt out of future communications.

AUTHOR'S INTENT

According to the author, allowing communication with pharmacy patients about the importance of following treatment prescribed by their doctors, including refill reminders, has proven benefits to individual patients and public health.

COMMENTS

While the intent of this legislation is good, the mechanism by which the goal is to be achieved appears to be violation a patient's confidentiality. Further, this bill would provide consumers with potentially unnecessary marketing information disguised as medication information sponsored by drug manufacturers.

It is also of concern that a pharmacy could receive direct or indirect remuneration from a third party for providing the written communication. This could potentially discredit the health care provider role of a pharmacist, even if the pharmacy does not receive remuneration from the message's sponsor.

Patients receive a significant amount of information at the time a prescription is dispensed, both on the prescription label itself, through supplemental drug inserts, as well as through direct patient counseling. This information is provided to improve patient adherence to medication therapy. Patients receiving additional sponsored information at the time of dispensing could be particularly vulnerable to marketing messages. Moreover, it can make the other, essential health care information about how to take the medicine also appear as an advertisement.

There is nothing to prohibit a pharmacy from directing communication to a patient that may have transferred the prescription to another pharmacy.

Staff requested an analysis by the DCA legal office to determine if this proposal would constitute a violation of HIPAA.

PRIOR HISTORY/RELATED BILLS

SB 843 (Calderon) contained similar provisions to those contained in this proposal. Staff was advised that this proposal would not move in its current form.

FISCAL IMPACT

The board does not anticipate any major fiscal impact to the board however could experience an increase in consumer calls and complaints. This minor impact could most likely be absorbed with existing resources.

SUPPORT/OPPOSITION

Support

None on file

Opposition

CA Alliance for Retired Americans
CMA
Consumer Federations of CA
Consumer Union
Gray Panthers
Privacy Right Clearinghouse
World Privacy Forum

HISTORY:

Dates	Actions
01/15/08	Jan. 15 From print. May be acted upon on or after February 14.
01/14/08	Jan. 14 Introduced. Read first time. To Com. on RLS. for assignment. To print.

SENATE BILL No. 1096

Introduced by Senator Calderon

January 14, 2008

An act to amend Section 56.10 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 1096, as introduced, Calderon. Medical information.

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

This bill would, under those provisions, allow a pharmacy to mail specified written communications to a patient, without the patient's authorization under specified conditions. Those conditions include, among other things, that the written communication shall pertain only to the prescribed course of medical treatment, that it may not mention any other pharmaceutical products, that a copy of each version shall be submitted to the federal Food and Drug Administration, and that it shall include specified disclosures regarding whether the pharmacy receives direct or indirect remuneration for making that written communication.

Vote: majority. 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 56.10 of the Civil Code is amended to
2 read:
3 56.10. (a) No provider of health care, health care service plan,
4 or contractor shall disclose medical information regarding a patient
5 of the provider of health care or an enrollee or subscriber of a
6 health care service plan without first obtaining an authorization,
7 except as provided in subdivision ~~(b) or (c)~~ *(b), (c), or (d)*.
8 (b) A provider of health care, a health care service plan, or a
9 contractor shall disclose medical information if the disclosure is
10 compelled by any of the following:
11 (1) By a court pursuant to an order of that court.
12 (2) By a board, commission, or administrative agency for
13 purposes of adjudication pursuant to its lawful authority.
14 (3) By a party to a proceeding before a court or administrative
15 agency pursuant to a subpoena, subpoena duces tecum, notice to
16 appear served pursuant to Section 1987 of the Code of Civil
17 Procedure, or any provision authorizing discovery in a proceeding
18 before a court or administrative agency.
19 (4) By a board, commission, or administrative agency pursuant
20 to an investigative subpoena issued under Article 2 (commencing
21 with Section 11180) of Chapter 2 of Part 1 of Division 3 of Title
22 2 of the Government Code.
23 (5) By an arbitrator or arbitration panel, when arbitration is
24 lawfully requested by either party, pursuant to a subpoena duces
25 tecum issued under Section 1282.6 of the Code of Civil Procedure,
26 or any other provision authorizing discovery in a proceeding before
27 an arbitrator or arbitration panel.
28 (6) By a search warrant lawfully issued to a governmental law
29 enforcement agency.
30 (7) By the patient or the patient's representative pursuant to
31 Chapter 1 (commencing with Section 123100) of Part 1 of Division
32 106 of the Health and Safety Code.
33 (8) By a coroner, when requested in the course of an
34 investigation by the coroner's office for the purpose of identifying
35 the decedent or locating next of kin, or when investigating deaths
36 that may involve public health concerns, organ or tissue donation,
37 child abuse, elder abuse, suicides, poisonings, accidents, sudden
38 infant deaths, suspicious deaths, unknown deaths, or criminal

deaths, or when otherwise authorized by the decedent's representative. Medical information requested by the coroner under this paragraph shall be limited to information regarding the patient who is the decedent and who is the subject of the investigation and shall be disclosed to the coroner without delay upon request.

(9) When otherwise specifically required by law.

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

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

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

(3) The information may be disclosed to a person or entity that provides billing, claims management, medical data processing, or other administrative services for providers of health care or health care service plans or for any of the persons or entities specified in

paragraph (2). However, no information so disclosed shall be further disclosed by the recipient in any way that would violate this part.

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

(5) The information in the possession of a provider of health care or health care service plan may be reviewed by a private or public body responsible for licensing or accrediting the provider of health care or health care service plan. However, no patient-identifying medical information may be removed from the premises except as expressly permitted or required elsewhere by law, nor shall that information be further disclosed by the recipient in any way that would violate this part.

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

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

(8) A provider of health care or health care service plan that has created medical information as a result of employment-related health care services to an employee conducted at the specific prior

written request and expense of the employer may disclose to the employee's employer that part of the information that:

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

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

(9) Unless the provider of health care or health care service plan is notified in writing of an agreement by the sponsor, insurer, or administrator to the contrary, the information may be disclosed to a sponsor, insurer, or administrator of a group or individual insured or uninsured plan or policy that the patient seeks coverage by or benefits from, if the information was created by the provider of health care or health care service plan as the result of services conducted at the specific prior written request and expense of the sponsor, insurer, or administrator for the purpose of evaluating the application for coverage or benefits.

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

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

(12) The information relevant to the patient's condition and care and treatment provided may be disclosed to a probate court

investigator in the course of any investigation required or authorized in a conservatorship proceeding under the Guardianship-Conservatorship Law as defined in Section 1400 of the Probate Code, or to a probate court investigator, probation officer, or domestic relations investigator engaged in determining the need for an initial guardianship or continuation of an existent guardianship.

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

(14) The information may be disclosed when the disclosure is otherwise specifically authorized by law, including, but not limited to, the voluntary reporting, either directly or indirectly, to the federal Food and Drug Administration of adverse events related to drug products or medical device problems.

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

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

(17) For purposes of disease management programs and services as defined in Section 1399.901 of the Health and Safety Code, information may be disclosed as follows: (A) to an entity contracting with a health care service plan or the health care service plan's contractors to monitor or administer care of enrollees for a covered benefit, if the disease management services and care are authorized by a treating physician, or (B) to a disease management organization, as defined in Section 1399.900 of the Health and Safety Code, that complies fully with the physician authorization requirements of Section 1399.902 of the Health and Safety Code,

if the health care service plan or its contractor provides or has provided a description of the disease management services to a treating physician or to the health care service plan's or contractor's network of physicians. Nothing in this paragraph shall be construed to require physician authorization for the care or treatment of the adherents of a well-recognized church or religious denomination who depend solely upon prayer or spiritual means for healing in the practice of the religion of that church or denomination.

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

(19) The information may be disclosed, consistent with applicable law and standards of ethical conduct, by a psychotherapist, as defined in Section 1010 of the Evidence Code, if the psychotherapist, in good faith, believes the disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a reasonably foreseeable victim or victims, and the disclosure is made to a person or persons reasonably able to prevent or lessen the threat, including the target of the threat.

(20) The information may be disclosed as described in Section 56.103.

(d) Except to the extent expressly authorized by the patient or enrollee or subscriber or as provided by subdivisions (b) and (c), no provider of health care, health care service plan, contractor, or corporation and its subsidiaries and affiliates shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient. *For purposes of this section, a written communication mailed to a patient by a pharmacy shall be deemed to be necessary to provide health care services to the patient and shall not require prior authorization, if all of the following conditions are met:*

(1) The written communication encourages the patient to adhere to the prescribed course of medical treatment as prescribed by a licensed health care professional and may include information

about that particular pharmaceutical drug as authorized in this section.

(2) The written communication pertains only to the prescribed course of medical treatment, and does not describe or mention any other pharmaceutical products.

(3) All product-related information in the written communication shall be consistent with the current federal Food and Drug Administration (FDA) approved product package insert, and provide fair and balanced information regarding the product's benefits and risks in accordance with the FDA requirements and policies.

(4) A copy of each written communication version shall be submitted to the FDA Center for Drug Evaluation and Research, Division of Drug Marketing, Advertising and Communications, prior to program implementation.

(5) Evidence-based or consensus-based practice guidelines shall be the basis of any information that is provided to patients in order to improve their overall health, prevent clinical exacerbations or complications, or promote patient self-management strategies.

(6) All personally identifiable medical information collected, used, and disclosed pursuant to this subdivision shall be confidential and shall be used solely to deliver the written communication to the patient. Access to the information shall be limited to authorized persons. Any entity that receives the information pursuant to this subdivision shall comply with existing requirements, including Sections 56.101 and 1798.84, concerning confidentiality and security of information. The pharmacy must have a written agreement with any entity that receives the information. The written agreement shall require the entity to maintain the confidentiality of the information it receives from the pharmacy and prohibit the entity from disclosing or using the information for any purpose other than to deliver to the patient the written communication that is the subject of the written agreement.

(7) If the written communication is paid for, in whole or in part, by a manufacturer, distributer, or provider of a health care product or service, the written communication shall disclose whether the pharmacy receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic

benefits from a third party for making the written communication and shall disclose, in a clear and conspicuous location, the source of any sponsorship in a typeface no smaller than 14-point type.

(8) The communication contains instructions in a typeface no smaller than 14-point type describing how the patient may opt out of future communications by, for example, calling a toll-free number or visiting a Web site, and no further sponsored message is made to the individual after 30 calendar days from the date the individual makes the opt out request.

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

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1270 **VERSION: As Amended March 27, 2008**

AUTHOR: Cedillo **SPONSOR: Pharmaceutical industry**

RECOMMENDED POSITION:

SUBJECT: Pharmacy: dangerous drug and devices pedigree

EXISTING LAW:

1. On or after January 1, 2009 requires an electronic pedigree to accompany each distribution of a dangerous drug.
2. Prohibits a wholesaler or pharmacy from selling, trading, transferring, or acquiring a dangerous drug without a pedigree.
3. Authorizes the board to extend the compliance date for these pedigree requirements to January 1, 2011.
4. Provides exceptions from the pedigree requirements for certain transactions.

THIS BILL WOULD:

1. As amended, delete the pedigree provisions and would instead require the certification or pedigree of distributors or persons who distribute dangerous drugs manufactured on or after January 1, 2009, outside the normal chain of distribution, as specified.
2. Authorize the board to require verification of specific transactions.
3. Prohibit a wholesaler from selling, trading, transferring, or acquiring a dangerous drug without complying with this requirement.
4. Commencing January 1, 2011, prohibit a pharmacy from acquiring, selling, trading, or transferring a dangerous drug without complying with this requirement.

AUTHOR'S INTENT:

COMMENTS:

This is currently a spot bill sponsored by the pharmaceutical industry to amend the board's electronic pedigree requirements. As amended, this bill deletes the pedigree requirements.

HISTORY:

Dates	Actions
03/27/08	Mar. 27 From committee with author's amendments. Read second time. Amended. Re-referred to Com. on B., P. & E.D.
03/13/08	Mar. 13 Set for hearing April 7.
02/28/08	Feb. 28 To Com. on B., P. & E.D.
02/20/08	Feb. 20 From print. May be acted upon on or after March 21.
02/19/08	Feb. 19 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE MARCH 27, 2008

SENATE BILL No. 1270

Introduced by Senator Cedillo

February 19, 2008

An act to amend Sections ~~4034, 4163, and 4163.5 of~~ *4034 and 4163 of, and to repeal Sections 4163.1 and 4163.5 of,* the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1270, as amended, Cedillo. Pharmacy: dangerous drug and device pedigrees.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy and the sale of dangerous drugs or dangerous devices by the California State Board of Pharmacy, in the Department of Consumer Affairs. On and after January 1, 2009, existing law requires a pedigree, as defined, to accompany each distribution of a dangerous drug, and prohibits a wholesaler or pharmacy from selling, trading, transferring, or acquiring a dangerous drug without a pedigree. Existing law authorizes the board to extend the compliance date for these pedigree requirements to January 1, 2011, in specified circumstances. Existing law provides exceptions from the pedigree requirements for certain transactions. *A knowing violation of the Pharmacy Law is a crime.*

This bill would ~~instead impose the pedigree requirement and the prohibition against selling, trading, transferring, or acquiring a dangerous drug without a pedigree on an unspecified date, authorize the board to extend the compliance date to an unspecified date in those specified circumstances, and make conforming changes~~ *delete the pedigree provisions and would instead require the certification or pedigree of*

distributors or persons who distribute dangerous drugs manufactured on or after January 1, 2009, outside of the normal chain of distribution, as defined. The bill would authorize the board to require verification of specific transactions. The bill would prohibit a wholesaler from selling, trading, transferring, or acquiring a dangerous drug without complying with this requirement, and would, commencing January 1, 2011, prohibit a pharmacy from acquiring, selling, trading, or transferring a dangerous drug without complying with this requirement. The bill would exempt specified transactions from these requirements.

Because this bill would impose new requirements under the Pharmacy Law, the knowing 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: ~~no~~ *yes*.

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

1 ~~SECTION 1. Section 4034 of the Business and Professions~~
2 ~~Code is amended to read:~~
3 ~~4034. (a) "Pedigree" means a record, in electronic form,~~
4 ~~containing information regarding each transaction resulting in a~~
5 ~~change of ownership of a given dangerous drug, from sale by a~~
6 ~~manufacturer, through acquisition and sale by one or more~~
7 ~~wholesalers, manufacturers, or pharmacies, until final sale to a~~
8 ~~pharmacy or other person furnishing, administering, or dispensing~~
9 ~~the dangerous drug. The pedigree shall be created and maintained~~
10 ~~in an interoperable electronic system, ensuring compatibility~~
11 ~~throughout all stages of distribution.~~
12 ~~(b) A pedigree shall include all of the following information:~~
13 ~~(1) The source of the dangerous drug, including the name, the~~
14 ~~federal manufacturer's registration number or a state license~~
15 ~~number as determined by the board, and principal address of the~~
16 ~~source.~~

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

~~(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.~~

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

~~(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.~~

~~(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the pharmacy or another person furnishing, administering, or dispensing the dangerous drug.~~

~~(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.~~

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

~~(g) The following transactions are not required to be recorded on a pedigree:~~

~~(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.~~

~~(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity~~

~~directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.~~

~~(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, ____, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, ____. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.~~

~~(h) If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge. This subdivision shall apply to any dangerous drug that has been sold or distributed in or through this state.~~

~~(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.~~

~~(j) The application of the pedigree requirement in pharmacies shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.~~

~~(k) This section shall become operative on January 1, ____. However, the board may extend the date for compliance with this~~

~~section and Section 4163 until January 1, ____, in accordance with Section 4163.5.~~

SECTION 1. Section 4034 of the Business and Professions Code is amended to read:

~~4034. (a) "Pedigree" means a record, in electronic form, containing information regarding each transaction resulting in a change of ownership of a given dangerous drug, from sale by a manufacturer, through acquisition and sale by one or more wholesalers, manufacturers, or pharmacies, until final sale to a pharmacy or other person furnishing, administering, or dispensing the dangerous drug. The pedigree shall be created and maintained in an interoperable electronic system, ensuring compatibility throughout all stages of distribution.~~

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

~~(1) The source of the dangerous drug, including the name, the federal manufacturer's registration number or a state license number as determined by the board, and principal address of the source.~~

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

~~(3) The business name, address, and the federal manufacturer's registration number or a state license number as determined by the board, of each owner of the dangerous drug, and the dangerous drug shipping information, including the name and address of each person certifying delivery or receipt of the dangerous drug.~~

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

~~(c) A single pedigree shall include every change of ownership of a given dangerous drug from its initial manufacture through to its final transaction to a pharmacy or other person for furnishing, administering, or dispensing the drug, regardless of repackaging or assignment of another National Drug Code (NDC) Directory number.~~

~~(d) A pedigree shall track each dangerous drug at the smallest package or immediate container distributed by the manufacturer, received and distributed by the wholesaler, and received by the~~

~~pharmacy or another person furnishing, administering, or dispensing the dangerous drug.~~

~~(e) Any return of a dangerous drug to a wholesaler or manufacturer shall be documented on the same pedigree as the transaction that resulted in the receipt of the drug by the party returning it.~~

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

~~(g) The following transactions are not required to be recorded on a pedigree:~~

~~(1) The provision of samples of dangerous drugs by a manufacturer's employee to an authorized prescriber, provided the samples are dispensed to a patient of the prescriber without charge.~~

~~(2) An injectable dangerous drug that is delivered by the manufacturer directly to an authorized prescriber or other entity directly responsible for administration of the injectable dangerous drug, only for an injectable dangerous drug that by law may only be administered under the professional supervision of the prescriber or other entity directly responsible for administration of the drug. Injectable dangerous drugs exempted from the pedigree requirement by this paragraph may not be dispensed to a patient or a patient's agent for self-administration, and shall only be administered to the patient, as defined in Section 4016, by the prescriber or other authorized entity that received the drug directly from the manufacturer.~~

~~(3) The exemption in paragraph (2) shall expire and be inoperative on January 1, 2010, unless prior to that date the board receives, at a public hearing, evidence that entities involved in the distribution of the injectable dangerous drugs subject to that paragraph are not able to provide a pedigree in compliance with all of the provisions of California law, and the board votes to extend the expiration date for the exemption until January 1, 2011. The decision as to whether to extend the expiration date shall be within the sole discretion of the board, and shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of the Government Code.~~

4034. (a) The board shall require certification or pedigree of those distributors or persons who distribute dangerous drugs outside of the normal chain of distribution. The board shall adopt certification or pedigree requirements that provide the protections afforded by the normal chain of distribution. The certification or pedigree may be required to be in electronic form and may require verification of each specific transaction from the time a product leaves the manufacturer or authorized distributor by sale, trade, or transfer. This subdivision shall not apply to pharmacies until January 1, 2011, as specified in subdivision (e) of Section 4163.

(b) Manufacturers of a dangerous drug sold, traded, or transferred in the state of California shall not be required to comply with subdivision (a) with regard to any dangerous drug that passes through the normal chain of distribution from the manufacturer to an authorized distributor of record.

(c) For purposes of this section, "normal chair of distribution" means any of the following chains of custody for a dangerous drug, whether sent directly or by drop shipment:

(1) From a manufacturer of the dangerous drug to any of the following:

(A) A pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(B) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(C) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(D) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to the patient.

(E) An authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the dangerous drug to the patient.

(F) An authorized distributor to a pharmacy or other person licensed to dispense or administer the dangerous drug.

(2) From a manufacturer of the drug to the manufacturer's colicensed partner to any of the following:

(A) A pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(B) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(C) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(D) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to the patient.

(E) An authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the dangerous drug to the patient.

(F) An authorized distributor to a pharmacy or other person licensed to dispense or administer the dangerous drug.

(3) From a manufacturer of the drug to the manufacturer's third-party logistics provider to any of the following.

(A) A pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(B) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(C) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(D) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to the patient.

(E) An authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the dangerous drug to the patient.

(F) An authorized distributor to a pharmacy or other person licensed to dispense or administer the dangerous drug.

(4) From a manufacturer of the drug to the manufacturer's authorized distributor of record to any of the following:

(A) A pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(B) A wholesale distributor to a pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(C) A wholesale distributor to a chain pharmacy warehouse to that chain pharmacy warehouse's intracompany pharmacy to a patient or other designated person authorized by law to dispense or administer the dangerous drug to a patient.

(D) A chain pharmacy warehouse to the chain pharmacy warehouse's intracompany pharmacy or other designated person authorized by law to dispense or administer the dangerous drug to the patient.

(E) An authorized distributor of record to one other authorized distributor of record to an office-based health care practitioner authorized by law to dispense or administer the dangerous drug to the patient.

(F) An authorized distributor to a pharmacy or other person licensed to dispense or administer the dangerous drug.

(d) For purposes of this section, "authorized distributor of record" means a distributor with whom a manufacturer has established an ongoing relationship by written agreement under which the distributor is authorized to distribute the manufacturer's products for a period of time or for a number of shipments. If the distributor is not authorized to distribute a manufacturer's entire product line, the written agreement shall identify the specific dangerous drug products that the distributor is authorized to distribute.

(e) This section does not apply to the provision of samples of dangerous drugs by a manufacturer's representative to an authorized prescriber, provided that the samples are dispensed to a patient of the prescriber without charge.

(f) This section does not apply to any dangerous drugs that are manufactured before January 1, 2009.

(g) For the purposes of this section, a dangerous drug does not include those drugs intended for use in nonhumans.

~~(i) "Interoperable electronic system" as used in this chapter means an electronic track and trace system for dangerous drugs that uses a unique identification number, established at the point of manufacture, contained within a standardized nonproprietary data format and architecture, that is uniformly used by manufacturers, wholesalers, and pharmacies for the pedigree of a dangerous drug.~~

~~(j)~~

(i) The application of ~~the pedigree requirement in pharmacies~~ *this section* shall be subject to review during the board's sunset review to be conducted as described in subdivision (f) of Section 4001.

~~(k) This section shall become operative on January 1, 2009. However, the board may extend the date for compliance with this section and Section 4163 until January 1, 2011, in accordance with Section 4163.5.~~

SEC. 2. Section 4163 of the Business and Professions Code is amended to read:

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

(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. When the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

~~(c) Except as otherwise provided in Section 4163.5, commencing~~ *(c) Commencing* on January 1, ~~____~~ *2009*, a wholesaler or pharmacy may not sell, trade, or transfer a dangerous drug at wholesale without ~~providing a pedigree~~ *complying with the requirements of Section 4034*.

(d) Except as otherwise provided in Section 4163.5, commencing on January 1, ~~____~~ *2009*, a wholesaler or pharmacy may not acquire a dangerous drug without ~~receiving a pedigree~~ *complying with the requirements of Section 4034*.

~~SEC. 3. Section 4163.5 of the Business and Professions Code is amended to read:~~

~~4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Sections 4034 and 4163~~

~~until January 1, ____, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.~~

(e) Commencing on January 1, 2011, a pharmacy may not acquire, sell, trade, or transfer a dangerous drug without complying with the requirements of subdivision (a) of Section 4034.

SEC. 3. Section 4163.1 of the Business and Professions Code is repealed.

~~4163.1. It is the intent of the Legislature that commencing on January 1, 2007, and continuing through the full implementation of the pedigree requirements specified by Section 4163, manufacturers and wholesalers shall use best efforts to provide in the most readily accessible form possible, information regarding the manufacturer's specific relationships in the distribution of dangerous drugs with wholesalers.~~

SEC. 4. Section 4163.5 of the Business and Professions Code is repealed.

~~4163.5. The board may extend the date for compliance with the requirement for a pedigree set forth in Sections 4034 and 4163 until January 1, 2011, if it determines that manufacturers or wholesalers require additional time to implement electronic technologies to track the distribution of dangerous drugs within the state. A determination by the board to extend the deadline for providing pedigrees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.~~

SEC. 5. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

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

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1504 **VERSION: As Amended April 3, 2008**

AUTHOR: Ridley-Thomas **SPONSOR: Epilepsy Foundation of California**

RECOMMENDED POSITION:

SUBJECT: Antiepileptic drug products: substitution

EXISTING LAW:

1. Authorizes a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name to substitute a generic drug product, subject to specified conditions.
2. Authorizes a pharmacist filling a prescription order for a drug product to substitute a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, subject to specified requirements.

THIS BILL WOULD:

1. Prohibit a pharmacist filling a prescription order for an antiepileptic drug or formulation of an antiepileptic drug, prescribed by its trade, brand or generic name for the treatment or prevention of epileptic seizures, from substituting a drug product pursuant to those provisions without prior notification of the prescriber and the signed consent of the patient or the patient's parent, legal guardian or spouse.
2. Impose a new prohibition under the Pharmacy Law, the violation of which would be a crime.

AUTHOR'S INTENT:

The board is awaiting a response from the author's office.

COMMENTS: This bill would amend section 4052.5 of the Business and Professions Code and add subdivision (f) as it relates to the filling of a prescription order for an antiepileptic drug.

HISTORY:

Dates	Actions
03/05/08	Mar. 5 To Com. on B., P. & E.D.
02/22/08	Feb. 22 From print. May be acted upon on or after March 23.
02/21/08	Feb. 21 Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE APRIL 3, 2008

SENATE BILL No. 1504

Introduced by Senator Ridley-Thomas

February 21, 2008

An act to amend Sections 4052.5 and 4073 of the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

SB 1504, as amended, Ridley-Thomas. Antiepileptic drug products: substitution.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy, and makes a knowing violation of the act a crime. Existing law authorizes a pharmacist filling a prescription order for a drug product prescribed by its trade or brand name to substitute a generic drug product, subject to specified requirements. Existing law authorizes a pharmacist filling a prescription order for a drug product to substitute a drug product with a different form of medication having the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product, subject to specified requirements.

This bill would prohibit a pharmacist filling a prescription order for an antiepileptic drug or formulation of an antiepileptic drug, prescribed by its trade, brand, or generic name for the treatment or prevention of epileptic seizures, from substituting a drug product pursuant to those provisions without prior notification of the prescriber and the signed consent of the patient or the patient's parent, legal guardian, or spouse.

Because this bill would impose a new prohibition 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 4052.5 of the Business and Professions
2 Code is amended to read:
3 4052.5. (a) In addition to the authority allowed under Section
4 4073, but subject to the express prohibition set forth in subdivision
5 (f) of Section 4073, a pharmacist filling a prescription order for a
6 drug product may select a different form of medication with the
7 same active chemical ingredients of equivalent strength and
8 duration of therapy as the prescribed drug product when the change
9 will improve the ability of the patient to comply with the prescribed
10 drug therapy.
11 (b) In no case shall a selection be made pursuant to this section
12 if the prescriber personally indicates, either orally or in his or her
13 own handwriting, "Do not substitute" or words of similar meaning.
14 Nothing in this subdivision shall prohibit a prescriber from
15 checking a box on a prescription marked "Do not substitute" if the
16 prescriber personally initials the box or checkmark.
17 (c) Selection pursuant to this section is within the discretion of
18 the pharmacist, except as provided in subdivision (b). The
19 pharmacist who selects the drug product to be dispensed pursuant
20 to this section shall assume the same responsibility for selecting
21 the dispensed drug product as would be incurred in filling a
22 prescription for a drug product using the prescribed form of
23 medication. There shall be no liability on the prescriber for an act
24 or omission by a pharmacist in selecting, preparing, or dispensing
25 a drug product pursuant to this section.
26 (d) This section shall apply to all prescriptions, including those
27 presented by or on behalf of persons receiving assistance from the
28 federal government or pursuant to the California Medical
29 Assistance Program set forth in Chapter 7 (commencing with

Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.

(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.

SEC. 2. Section 4073 of the Business and Professions Code is amended to read:

4073. (a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivisions (b) and (f). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There

shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

(f) In no case shall a pharmacist filling a prescription order for an antiepileptic drug, or formulation of an antiepileptic drug prescribed by its trade, brand, or generic name for the treatment or prevention of epileptic seizures, substitute a drug product pursuant to this section or subdivision (a) of Section 4052.5 without prior notification of the prescriber and the signed consent to the substitution from the patient or the patient's parent, legal guardian, or spouse.

For purposes of this subdivision, the following definitions apply:

(1) "Antiepileptic drug" means any drug approved by the United States Food and Drug Administration (FDA) for the treatment of epilepsy or the treatment or prevention of epileptic seizures.

(2) "Epilepsy" means a neurological condition characterized by recurrent seizures.

(3) "Seizure" means an acute clinical change secondary to a brief disturbance in the electrical activity of the brain.

(4) ~~"Substitute"~~ *"Select," "selection," "substitute,"* or "substitution" means the substitution for an antiepileptic drug originally prescribed ~~of a~~ *with any other* version of the same ~~antiepileptic drug, including a generic version for the prescribed generic version, a generic version by one manufacturer for a generic version by a different manufacturer, or a different formulation of~~

~~the prescribed antiepileptic drug.~~ *antiepileptic drug, including, but not limited to, any of the following:*

(A) A generic version for the prescribed trade or brand name drug.

(B) A trade or brand name drug for the prescribed generic version.

(C) A generic drug produced by one manufacturer for a generic drug produced by a different manufacturer.

(D) Any dosage form of that prescribed antiepileptic drug that differs from the dosage form originally prescribed by the prescriber.

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

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 1594 **VERSION: Introduced February 22, 2008**

AUTHOR: Steinberg **SPONSOR: Hemophilia Council of California**

RECOMMENDED POSITION:

SUBJECT: Bleeding disorders: blood clotting products

EXISTING LAW:

1. Requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

THIS BILL WOULD:

1. Would impose specified requirements on providers of blood clotting products for home use used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia.
2. Would also authorize the State Department of Health Care Services to adopt regulations necessary to implement these provisions.

AUTHOR'S INTENT:

According to the author, intravenous injection or infusion of prescribed blood clotting products, coupled with case management and specialized medical care, is the preferred method of treatment of hemophilia. The author states that the number of providers delivering blood clotting products and related equipment, supplies, and services for home use is rising. The author states that, while these providers are either pharmacies licensed by the state, or providers located in federally designated HTCs, there are currently no formal standards of service in California for providers of blood clotting products for home use. The author states that this bill will enact those standards for the benefit of persons with hemophilia and other bleeding disorders, and will maintain the current cost effective model of hemophilia care for future generations.

COMMENTS:

Imposes requirements on providers of blood clotting products for home use that are used to treat hemophilia and other bleeding disorders.

SUPPORT/OPPOSITION:

Support

Hemophilia Council of California (sponsor)
Accredo Health Group, Inc.
American Federation of State, County, and Municipal Employees
Critical Care Systems, Inc.
Herndon Pharmacy
Plasma Protein Therapeutics Association
Walgreens Home Care
Two individuals

Opposition

None

HISTORY:

Date	Actions
03/13/08	Mar. 13 Set for hearing April 2.
03/06/08	Mar. 6 To Com. on HEALTH.
02/25/08	Feb. 25 Read first time.
02/24/08	Feb. 24 From print. May be acted upon on or after March 25.
02/22/08	Feb. 22 Introduced. To Com. on RLS. for assignment. To print.

SENATE BILL No. 1594

Introduced by Senator Steinberg

February 22, 2008

An act to add Article 5 (commencing with Section 125286.1) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to bleeding disorders.

LEGISLATIVE COUNSEL'S DIGEST

SB 1594, as introduced, Steinberg. Bleeding disorders: blood clotting products.

Existing law, the Holden-Moscone-Garamendi Genetically Handicapped Person's Program, requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically handicapping conditions, including hemophilia.

This bill would impose specified requirements on providers of blood clotting products for home use used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would also authorize the State Department of Health Care Services to adopt regulations necessary to implement these provisions.

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. Article 5 (commencing with Section 125286.1)
2 is added to Chapter 2 of Part 5 of Division 106 of the Health and
3 Safety Code, to read:

Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act

125286.1. This article shall be known and may be cited as the Standards of Service for Providers of Blood Clotting Products for Home Use Act.

125286.2. The Legislature hereby finds and declares all of the following:

(a) Hemophilia is a rare, hereditary, bleeding disorder affecting at least 4,000 persons in California and is a chronic, lifelong, and incurable, but treatable, disease.

(b) Until the 1970's, people with severe hemophilia suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a shortened lifespan. More recently, the production of highly purified blood clotting factors have provided people with hemophilia and other bleeding disorders with the opportunity to lead normal lives, free of pain and crippling arthritis.

(c) The preferred method of treatment of hemophilia today is intravenous injection, or infusion, of prescription blood clotting products several times per week, along with case management and specialized medical care at a federally designated regional hemophilia treatment center.

(d) Pharmacies and other entities specializing in the delivery of blood clotting products and related equipment, supplies, and services for home use form a growing enterprise in California. Some of these entities are licensed by the state or are located at federally designated regional hemophilia treatment centers, or both, but many of these entities are neither licensed nor located at hemophilia treatment centers.

(e) Timely access to federally designated regional hemophilia centers and appropriate products and services in the home, including infusion of blood clotting products and related equipment, and supplies and services for persons with hemophilia and other bleeding disorders, reduces mortality and bleeding-related hospitalizations, and is extremely cost effective, according to the federal Centers for Disease Control and Prevention and the Medical and Scientific Advisory Council of the National Hemophilia Foundation.

(f) Eligible persons with hemophilia or other bleeding disorders may receive treatment through the Genetically Handicapped

Persons Program, the California Children's Services Program, and Medi-Cal. Access to quality blood clotting products for home use and related equipment, supplies, and services for people with hemophilia or other bleeding disorders promotes cost containment in each of these publicly funded programs as well as in the health insurance and health care industries more generally.

(g) For the benefit of persons with hemophilia or other bleeding disorders, as well as for cost containment in health care, the purposes of this article are to do the following:

(1) Establish standards of service for entities that deliver blood clotting products and related equipment, supplies, and services for home use.

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.

125286.3. Unless context otherwise requires, the following definitions shall apply for purposes of this article:

(a) "340B Program" means an outpatient pharmacy licensed to dispense blood clotting products in California and that is conditionally or fully designated as a covered entity under the Veterans Health Care Act of 1992 (Public Law 102-585), which enacted Section 340B of the Public Health Service Act (41 U.S.C. Sec. 201 et seq.).

(b) "Assay" means the amount of a particular constituent of a mixture or of the biological or pharmacological potency of a drug.

(c) "Ancillary infusion equipment and supplies" means the equipment and supplies required to infuse a blood clotting product into a human vein, including, but not limited to, syringes, needles, cyro cuffs, sterile gauze, field pads, gloves, alcohol swabs, numbing creams, tourniquets, medical tape, sharps or equivalent biohazard waste containers, and cold compression packs.

(d) "Bleeding disorder" means a medical condition characterized by a severe deficiency or absence of one or more essential blood clotting proteins in the human blood, often called "factors," including all forms of hemophilia and other bleeding disorders that result in uncontrollable bleeding or abnormal blood clotting.

(e) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution

by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, Factor VII, Factor VIIa, Factor VIII, and Factor IX products, von Willebrand Factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(f) "Consumer" means a person needing a blood clotting product for home use.

(g) "Emergency" means a situation in which a prudent layperson could reasonably believe that the consumer's condition requires immediate medical attention.

(h) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the Factors I, VII, VIII, IX, XI, or XII blood clotting protein in human blood.

(i) "Hemophilia treatment center" means a facility for the treatment of bleeding disorders, including, but not limited to, hemophilia, that receives funding from the federal government sources, including, but not limited to, the federal Centers for Disease Control and Prevention and the federal Health Resources and Services Administration (HRSA) of the United States Department of Health and Human Services.

(j) "Home nursing services" means specialized nursing care provided in the home setting to assist a patient in the reconstitution and administration of blood clotting products.

(k) "Home use" means infusion or other use of a blood clotting product in a place other than a state-recognized hemophilia treatment center. Places where home use occurs include, without limitation, a home, hospital, emergency room, clinic, or other physician office.

(*l*) "Provider of blood clotting products for home use" means a seller and provider of blood clotting products, ancillary infusion equipment, home nursing services, and patient assistance for the management of bleeding disorders for home use. These providers include, without limitation, 340 programs, other pharmacies, and, when treatment is not provided onsite, hemophilia treatment centers.

125286.4. Each provider of blood clotting products for home use shall meet all of the following requirements:

(a) Have sufficient knowledge and understanding of bleeding disorders and the medical and psychosocial management thereof, including, but not limited to, home therapy.

(b) Have sufficient experience providing services to persons with bleeding disorders.

(c) Ensure that its customer service staff meets the requirements of subdivisions (a) and (b).

(d) Have a pharmacist available at all times, 24 hours a day, seven days a week, every day of the year, either onsite or on call, to fill prescriptions for blood clotting products.

(e) Supply blood clotting products and home nursing services, as prescribed by the consumer's treating physician, and not make any substitutions of blood clotting products or assay amounts without the prior written approval of the treating physician.

(f) Ask the prescribing physician which specific blood clotting product is intended whenever a prescription does not indicate the specific product and then use the product named in the physician's response.

(g) Supply all brands of blood clotting products approved by the federal Food and Drug Administration in multiple assay ranges (low, medium, and high, as applicable) and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques.

(h) Supply all needed ancillary infusion equipment and supplies with each prescription.

(i) Maintain adequate stocks of blood clotting products and ancillary infusion equipment and supplies.

(j) Store and ship, or otherwise deliver, all blood clotting products in conformity with all federally mandated standards.

(k) When home nursing services are prescribed by the treating physician, provide these services either directly or through a reliable third party and coordinate pharmacy services with the third party when one is used to provide home nursing services.

(*l*) Upon receiving a nonemergency prescription, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the consumer within:

(1) Forty-eight hours or less for established consumers.

(2) Three business days or less for new consumers.

(m) Upon receiving a prescription for an emergency situation, deliver prescribed blood products, ancillary infusion equipment

and supplies, medications, and home nursing services to the consumer within three hours after receipt of the prescription.

(n) Maintain 24-hour oncall service seven days a week for every day of the year, adequately screen phone calls for emergencies, and respond to all phone calls within one hour or less.

(o) Provide consumers who have ordered their products with a designated contact phone number for reporting problems with a delivery and respond to these calls immediately.

(p) Provide patients with notification of recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours and participate in the National Patient Notification System for blood clotting product recalls.

(q) Provide language translation services, both over the phone and in person, as needed by the consumer.

(r) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(s) Provide for proper collection, removal, and disposal of hazardous waste pursuant to state and federal law, including, but not limited to, sharps containers for the removal and disposal of medical waste.

(t) Clearly inform the consumer of his or her copay, deductible, and coinsurance payment responsibilities each time he or she orders a blood clotting product.

(u) Provide consumers with a copy of all billing invoices.

(v) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law, including, but not limited to:

(1) Documenting the pedigree of all concentrates of blood clotting products so that the path of a bottle of any product can be traced from the time it left the manufacturer to the time it is delivered to the consumer.

(2) Having prescriptions available for treating physicians and consumers.

(w) Comply with the privacy and confidentiality requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

125286.5. A pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of

1 the Business and Professions Code, shall be deemed to meet the
2 requirements of Section 125286.4.
3 125286.6. The State Department of Health Care Services may
4 adopt regulations necessary to implement this article in accordance
5 with the rulemaking provisions of the Administrative Procedure
6 Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of
7 Division 3 of Title 2 of the Government Code).

O

AMENDED IN ASSEMBLY MARCH 24, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 2122

Introduced by Assembly Member Plescia
(Principal coauthor: Assembly Member Jones)

February 20, 2008

An act to amend Section 4190 of the Business and Professions Code, and to add Section 1212.5 to the Health and Safety Code, relating to clinics.

LEGISLATIVE COUNSEL'S DIGEST

AB 2122, as amended, Plescia. Surgical clinics: licensure.

Existing law, with certain exceptions, provides for the licensure and regulation of clinics, including specialty clinics, by the State Department of Public Health. Existing law defines a specialty clinic to include a surgical clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. A violation of these provisions is a crime.

This bill would enact the California Outpatient Surgery Patient Safety and Improvement Act, which would require, on or after January 1, 2009, any person, firm, association, partnership, or corporation desiring a license for a surgical clinic, except specified surgical clinics, in addition to other prescribed licensing requirements, to meet prescribed operational, staffing, and procedural standards. The bill would require the department to perform ~~initial~~ *periodic* inspections of ~~a~~ surgical ~~clinic within 45 calendar days of an application approval, and to perform periodic inspections~~ *clinics* at least once every 3 years ~~thereafter~~.

~~The bill would require the department, until January 1, 2016, if sufficient funds are made available for this purpose, as determined by~~

~~the department, pursuant to an appropriation in the annual Budget Act or other statute, to establish a program for the training of ambulatory surgical center inspection personnel, and would require the department to prepare a comprehensive report on the training program, as provided. By~~

By imposing new licensure requirements on surgical clinics, a violation of which would be a crime, the bill would impose a state-mandated local program.

Existing law provides that a surgical clinic may not operate and is not entitled to the benefits of specified provisions of the Pharmacy Law without a license issued by the California State Board of Pharmacy. Existing law authorizes the board to inspect a clinic at any time.

This bill would, instead, provide that a surgical clinic that is licensed by the State Department of Public Health, accredited by an accreditation agency, or certified to participate in the Medicare program is not entitled to the above-described benefits without a license issued by the board. It would also specify board inspection requirements for the accredited or certified surgical clinics, and would require self-assessments by any clinic licensed by the board.

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. This act shall be known, and may be cited, as the
2 California Outpatient Surgery Patient Safety and Improvement
3 Act.
4 SEC. 2. Section 4190 of the Business and Professions Code is
5 amended to read:
6 4190. (a) Notwithstanding any provision of this chapter, a
7 surgical clinic, licensed pursuant to paragraph (1) of subdivision
8 (b) of Section 1204 and Section 1212.5 of the Health and Safety
9 Code, accredited by an accreditation agency, as defined in
10 subdivision (d) of Section 1248 of the Health and Safety Code, or
11 certified to participate in the Medicare program under Title XVIII

of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.), may purchase drugs at wholesale for administration or dispensing, under the direction of a physician, to patients registered for care at the clinic, as provided in subdivision (b). The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) The drug distribution service of a surgical clinic shall be limited to the use of drugs for administration to the patients of the surgical clinic and to the dispensing of drugs for the control of pain and nausea for patients of the clinic. Drugs shall not be dispensed in an amount greater than that required to meet the patient's needs for 72 hours. Drugs for administration shall be those drugs directly applied, whether by injection, inhalation, ingestion, or any other means, to the body of a patient for his or her immediate needs.

(c) No surgical clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

(d) Any proposed change in ownership or beneficial interest in the licensee shall be reported to the board, on a form to be furnished by the board, at least 30 days prior to the execution of any agreement to purchase, sell, exchange, gift or otherwise transfer any ownership or beneficial interest or prior to any transfer of ownership or beneficial interest, whichever occurs earlier.

(e) The board shall inspect a surgical clinic that is accredited by an accreditation agency or is certified to participate in the Medicare program, as specified in subdivision (a), but is not licensed pursuant to Sections 1204 and 1212.5 of the Health and Safety Code, within 120 days of the issuance of a clinic licensed pursuant to this article, and at least annually thereafter.

(f) Every surgical clinic issued a license pursuant to this article shall complete a self-assessment within 30 days of opening and at least 30 days before each license renewal pursuant to this article. The completed self-assessment form shall be retained at the licensed premises for a period of three years.

SEC. 3. Section 1212.5 is added to the Health and Safety Code, to read:

1212.5. (a) In addition to other licensing requirements of this chapter, any person, firm, association, partnership, or corporation desiring a license for a surgical clinic shall meet the following standards:

(1) Comply with the Medicare conditions of coverage for ambulatory surgical centers, as set forth in Subpart C (commencing with Section 416.40) of Part 416 of Title 42 of the Code of Federal Regulations, including interpretive guidelines issued by the Centers for Medicare and Medicaid Services as those guidelines pertain to that subpart.

(2) Limit surgical procedures to those that:

(A) Do not result in extensive blood loss.

(B) Do not require major or prolonged invasion of body cavities.

(C) Do not directly involve major blood vessels.

(D) Do not constitute an emergency or are not life threatening in nature.

(3) Establish and implement policies and procedures consistent with the Medicare conditions of coverage set forth in Subpart C (commencing with Section 416.40) of Part 416 of Title 42 of the Code of Federal Regulations, including interpretive guidelines issued by the Centers for Medicare and Medicaid Services as those guidelines pertain to that subpart, including, but not limited to:

(A) Physician services, policies, and procedures, including surgical and anesthesia services.

(B) Nursing services, policies, and procedures.

(C) Infection control policies and procedures.

(D) Pharmaceutical services, policies, and procedures.

(E) Housekeeping services, policies, and procedures that include provisions for maintenance of a safe and clean environment.

(F) Laboratory and radiology services.

(G) Patient health records policies and procedures, which shall be developed with the assistance of a person skilled in records maintenance and preservation.

(H) Personnel policies and procedures.

(b) Notwithstanding subdivision (c) of Section 1228, the department shall perform ~~initial inspections of a surgical clinic within 45 calendar days of the date the completed application is received and approved by the department. Periodic inspections~~

~~shall occur at least once every three years thereafter.~~ *periodic inspections of surgical clinics at least once every three years.*

(c) The department may contract with licensed physicians and surgeons to serve as surveyors to perform inspections of surgical clinics for compliance with the licensure requirements of this chapter and in a manner that is consistent with department inspections pursuant to Section 1279.

~~(d) If sufficient funds are made available for this purpose, pursuant to an appropriation in the annual Budget Act or other statute, the department shall, until January 1, 2016, establish a program for training of surgical clinic inspection personnel. The goal of this program shall be to provide a sufficient number of qualified persons to facilitate the timely performance of the department's duties and responsibilities relating to initial and periodic licensing inspections of surgical clinics, in order to ensure compliance with this chapter.~~

~~(e) (1) The department shall prepare a comprehensive report on the training program setting forth its goals, objectives, and structure. The report shall assess processing time for initial and periodic licensing inspections of surgical clinics and include information on all of the following:~~

~~(A) The number of surgical clinic inspection personnel to be trained annually.~~

~~(B) A timeline for completion of training.~~

~~(C) A process for gathering information to evaluate the training program's efficiency that includes dropout and retention rates.~~

~~(D) A mechanism to annually assess the need for the training program to continue.~~

~~(2) The report required by paragraph (1) shall be submitted to the Joint Legislative Budget Committee no later than July 1, 2009, and no later than July 1 of each year thereafter, through July 1, 2014.~~

~~(f)~~

(d) (1) This section shall not apply to any surgical clinic that is any of the following:

(A) Accredited by an accreditation agency as defined in Section 1248.

(B) Certified to participate in the Medicare program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

(C) Exempt from licensure pursuant to Section 1206.

(2) An entity exempt from the requirements of this section pursuant to paragraph (1) may, at its option, apply for licensure as a surgical clinic.

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

AMENDED IN ASSEMBLY APRIL 1, 2008

CALIFORNIA LEGISLATURE—2007–08 REGULAR SESSION

ASSEMBLY BILL No. 2425

Introduced by Assembly Member Coto

February 21, 2008

~~An act relating to health.~~ *An act to add and repeal Chapter 6.62 (commencing with Section 25255) of Division 20 of the Health and Safety Code, relating to water quality.*

LEGISLATIVE COUNSEL'S DIGEST

AB 2425, as amended, Coto. State Department of Public Health: ~~study.~~ *water quality: pharmaceuticals.*

Existing law prohibits any person in the course of doing business from knowingly discharging or releasing a chemical known to the state to cause cancer or reproductive toxicity into water or onto or into land where such chemical passes or probably will pass into any source of drinking water, except as specified.

This bill would, by July 1, 2009, require every pharmaceutical manufacturer that does business with the state and whose pharmaceutical products have been detected in the drinking water supplies within the state to file a specified report with the State Public Health Officer. The bill would repeal this reporting requirement on January 1, 2014.

~~Existing law provides for the administration of various programs addressing public health by the State Department of Public Health.~~

~~This bill would require the department to conduct a study of the use of pharmaceuticals by vulnerable segments of the California population and the consequential adverse health effects, including the effects of~~

~~unintentional misuse of prescription drugs, and to report the results of the study to the appropriate committees of the Legislature.~~

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

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

1 *SECTION. 1. The Legislature hereby finds and declares all of*
2 *the following:*
3 *(a) In the course of a major study conducted and reported by*
4 *the Associated Press, pharmaceutical drugs have been detected*
5 *in the drinking water supplies of 24 major metropolitan areas of*
6 *the country, including southern California.*
7 *(b) The federal government does not require safety testing of*
8 *pharmaceutical products in drinking water. Some local water*
9 *providers screen only for one or two pharmaceutical products,*
10 *but not other pharmaceutical products that can cause harm.*
11 *(c) An official of the United States Environmental Protection*
12 *Agency has acknowledged that pharmaceutical "contamination*
13 *in water supplies is a growing concern and that government has*
14 *some catching up to do."*
15 *(d) In California, prescription drug spending totaled over $188*
16 *billion in 2004, a $14 billion dollar per year spending increase*
17 *from 1984.*
18 *(e) It is the purpose of this act to address the issue of*
19 *prescription drugs in public drinking water systems.*
20 *SEC. 2. Chapter 6.62 (commencing with Section 25255) is*
21 *added to Division 20 of the Health and Safety Code, to read:*
22
23 *CHAPTER 6.62. WATER CONTAMINATION FROM*
24 *PHARMACEUTICALS*
25
26 *25255. For purposes of this chapter, the following definitions*
27 *shall apply:*
28 *(a) "Pharmaceuticals" means any drug that is sold over the*
29 *counter and any drug that is required to bear the legend, "Caution:*
30 *Federal law prohibits dispensing without a prescription," "RX*
31 *only," or words of similar import.*
32 *(b) "Pharmaceutical manufacturer" means a drug manufacturer*
33 *as defined in Section 4033 of the Business and Professions Code.*

25256. On or before July 1, 2009, every pharmaceutical manufacturer that does business with the state, and whose pharmaceutical products have been detected by their chemical signatures in the drinking water supplies within the state, shall file with the State Public Health Officer a report that includes the following:

(a) An analysis of how these pharmaceuticals entered the drinking water supply of the state.

(b) Identification of the methods of preventing and removing pharmaceutical contaminants from the drinking water supplies of the state.

25257. This chapter shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

~~SECTION 1. The State Department of Public Health shall conduct a study of the use of pharmaceuticals by vulnerable segments of the California population and their consequential adverse health effects, including the effects of unintentional misuse of prescription drugs, and to report the results of the study to the appropriate committees of the Legislature.~~

O