



California State Board of Pharmacy

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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN, JR.

Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member
Ramón Castellblanch, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE

The Legislation and Regulation Committee did not meet during the last quarter.

AGENDA ITEM A: LEGISLATION REPORT

1. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

a. Regulation of Dangerous Drugs and Devices

1. SB 1329 (Simitian) Prescription Drugs: Collection and Distribution Program

Last Amend: March 29, 2012 (Introduced Feb. 23, 2012)

Location: SEN Com. on Business, Professions and Economic Development

2. SB 419 (Simitian) Solid Waste: Home Generated Sharps

Introduced: February 16, 2011

Location: In ASM. Ordered to Inactive File on Request of Assembly Member Allen (1/9/12)

Existing law permits hospitals and other entities to accept for disposal home-generated sharps, as specified. Currently a pharmaceutical manufacturer that sells or distributes a medication in California that is self-injected, as specified, is required to submit to the Department of Resource Recovery and Recycling a plan that describes what actions, if any, the manufacturer supports for the safe management of sharps. This bill would require that the manufacturers provide their reports to DRRR electronically and also make them readily accessible on the manufacturers websites.

3. SB 1301 (Hernandez) Prescription Drugs: 90-Day Supply

Last Amend: April 16, 2012

Location: Senate Business, Professions and Economic Development

This measure would specify conditions under which a pharmacist may dispense a 90-day supply of a dangerous drug, as specified, without first receiving authorization from the prescriber. The board's regulation at 16 CCR 1716 precludes a pharmacist from deviating from the requirements of a prescription, except as specified.

Status: Set for hearing. 4/23/12 in SEN BP&ED

4. AB 389 (Mitchell) Bleeding Disorders: Blood Clotting Products

Board Position: Oppose (*Ver. Jan. 17, 2012*)

Last Amend: January 17, 2012

Location: Senate Third Reading File (*3/29/12*)

AB 389 seeks to establish the Standards for Service for Providers of Blood Clotting Products for Home Use Act by imposing specified requirements on providers of blood clotting products for home use. The board has expressed its opposition to the bill, citing concerns regarding jurisdiction and challenges in enforcing some of the provisions. The January 17, 2012, version of the bill removed references to home nursing services. The board reaffirmed its position of Oppose at the January 2012 Board Meeting.

5. AB 1442 (Wieckowski) Common Carriers to Transport Pharmaceutical Waste

Last Amend: March 27, 2012

Board Position: None

AB 1442 amends the Medical Waste Management Act (under the jurisdiction of the CDPH) to define, for purposes of the act, “pharmaceutical waste” and “common carrier”; to provide for a pharmaceutical waste hauling exemption; to allow the use of common carriers to transport pharmaceutical waste for disposal, and to specify what information must be maintained regarding the disposal and transporting of pharmaceutical waste. The measure excludes from the definition of “pharmaceutical waste” drugs that must be returned via a reverse distributor pursuant to section 4040.5 of the Business and Professions Code. As amended, supplies of dangerous drugs would be able to be transported by common carriers.

Status: Set for hearing. 4/18/12 in Senate Appropriations

6. AB 2369 (Valadao) Prisoners: Pharmacy Services

Introduced: February 24, 2012

Location: ASM Business, Professions and Consumer Protection

Summary: Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for facilities under the jurisdiction of the DCR that is cost effective and efficient, and that may incorporate a requirement for the use of generic medications, when available, with certain exceptions. AB 2369 would instead *require* the use of generic medications, when available, with certain exceptions. AB 2369 does not seek to modify existing Pharmacy Law.

AB 2369 was heard in the Assembly Committee on Business, Professions and Consumer Protection on April 17th and failed passage. Reconsideration was granted, and the bill is again set for hearing for April 24, 2012

Status: Set for hearing 4/24/12

7. AB 2348 (Mitchell) Registered Nurses: Dispensing Oral Contraception in Clinics

Last Amend: March 29, 2012 (Introduced on 2/24/12)
Location: ASM Business, Professions and Consumer Protection

Summary: The Nursing Practice Act authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic. This bill would, in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a specified clinic.

Status: Set for hearing 4/24/12

b. **Sunset Review and Legislative Oversight**

SB 1237 (Price) Sunset Extension to 2017

Last Amend:
Board Position: Support

In November 2011, the Board provided its “Sunset Review Report 2011” to the Senate Committee on Business, Professions and Economic Development, and also made the report available on the board’s public website. The board last underwent sunset review in 2002. Board President Stan Weisser and Executive Officer Giny Herold testified before the Senate Committee on Business, Professions and Economic Development on March 19, 2012, and responded to the committee’s questions and comments. The committee is scheduled to continue its review of SB 1237 on April 23, 2012.

c. **Licensing and Pharmacy Operations**

1. SB 1095 (Rubio) Pharmacy: Surgical Clinics

Introduced: February 16, 2012
Location: Senate Appropriations

Summary: SB 1095 would expand the definition of a clinic in Section 4190 to include not only surgical clinics licensed by the CDPH under H&SC Section 1204, but also to accredited outpatient settings and to Medicare certified ambulatory surgical centers, as specified. SB 1095 would provide that board licensure is optional, and that the board is authorized to inspect only those clinics which are licensed by the board. A clinic licensed by the board would be able to come into the

drug stock of the clinic and would authorize the clinic to purchase drugs at wholesale. SB 1095 would provide that nothing in the article shall preclude a physician and surgeon from dispensing dangerous drugs as provided in B&PC Section 4170.

Status: No hearing set as of 4/16/12

2. SB 1481 (Negrete McLeod) Clinical Laboratories: Community Pharmacies

Introduced: February 24, 2012
Location: Senate Appropriations

This bill would exempt from clinical laboratory licensing requirements and regulations, specified tests performed by a pharmacist in a community pharmacy. These are the same tests that pharmacists are currently authorized to perform pursuant to Section 4052.4 in specified clinic settings. Tests deemed CLIA Waived are those tests approved by the FDA as over-the-counter tests. Proponents believe this measure will result in greater access to safe, simple and economic tests that will play a crucial role in improving drug therapy, and improve patient health.

Status: No hearing set as of 4/18/12

3. AB 377 (Solorio) Hospital Central Fill Pharmacies

Amended: April 14, 2011
Board Position: Support if Amended (Ver. 4/14/11)
Location: Senate Appropriations (8/15/11)

AB 377 provides for centralized pharmacy packaging in a hospital, allowing the pharmacy to be located outside of a hospital on either the same premises or separate premises that is regulated under a hospital's license. The bill exempts from the definition of manufacturing, repackaging a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital, as specified. The board has conveyed its concerns with the bill (to move the new centralized packaging provisions away from the definition of consolidated hospital license). The sponsor has agreed to make this amendment, and staff has been advised that the bill will be moving forward in 2012.

Status: No hearing date set as of 4/16/12

4. AB 1896 (Chesbro) Tribal Health Programs: Health Care Practitioners

Last Amend: March 27, 2012
Location: Assembly Third Reading File (4/18/12)

This measure seeks to codify into state law existing federal law (the Patient Protection and Affordable Care Act). This bill would specify that a healthcare professional employed by a tribal health program is exempt from state licensure if that health professional holds a license from another state.

5. AB 1904 (Block) Military Spouses: Temporary License

Introduced: February 22, 2012
Location: Assembly Appropriations Suspense File

This measure would allow the board to issue a temporary permit to an applicant that submits an application, fees, and fingerprints and satisfies specified requirements including proof of licensure in good standing in another state with similar requirements. It would require the board to expedite the processing for the purpose of issuing a temporary license, would specify the term that a temporary license would be valid, and authorize the board to promulgate regulations to implement the provisions. Staff anticipates that this may impact two primary license types: Pharmacist, and Pharmacy Technician.

d. **Other**

1. SB 1185 (Price) Centralized Intelligence Partnership Act

Last Amend: April 9, 2012
Location: Assembly Health

This bill would create a Centralized Intelligence Partnership consisting of various agencies, including the Department of Consumer Affairs, that would be charged with combating the underground economy, and would specify the general scope of the committee's process. This bill would allow information to be shared between committee participants and would provide that shared information would retain its confidential status as authorized by law.

Status: Scheduled for hearing April 24, 2012

2. SB 1195 (Price) Pharmacy Benefits: Audits

Last Amend: March 26, 2012
Location: Senate Committee on Health

SB 1195 would follow the direction of other states in an effort to establish fair auditing standards and procedural rights for pharmacies that undergo prescription claim audits performed by pharmacy benefit managers (PBMs). Pharmacy Benefit Managers are currently not regulated. Although the board does not have jurisdiction over the auditing of claims for reimbursement, board staff receive complaints on a somewhat routine basis from licensees complaining about the perceived unjust auditing practice of an auditing company receiving payment based on the number of claims rejected. This proposal would appear to address this issue.

Status: Scheduled for hearing in Senate Health on April 25, 2012

3. SB 1250 (Alquist) Medical Records: Confidentiality

Introduced: February 23, 2012
Location: Senate Judiciary

The Confidentiality of Medical Information Act specifies the confidentiality of information maintained in medical records by health care providers, health coverage plans, pharmaceutical companies and others. Section 56.35 of the Civil Code also provides for monetary penalties for individuals and entities that violate the act. This bill would specify that in addition to other legal remedies, a defendant may be required to pay for credit monitoring and reporting services for one year from the unauthorized release of medical information.

4. AB 2342 (Torres) Controlled Substances

Staff has been advised that AB 2342 in its current form will not be moving forward this year. No staff analysis is provided.

5. AB 1733 (Logue) Telehealth

AB 1733 impacts the coverage of telehealth benefits for health care service plans and programs. This bill would specify that the mandated in-person contact prohibition would also apply to health care service plan contracts with the Department of Health Care Services for services provided by the Medi-Cal program, other publicly supported programs, as well as to organizations implementing the California Program of All-Inclusive Care for the Elderly (PACE).

Agenda Item A.1

Legislation Report

- a. Regulation of Dangerous
Drugs and Devices

AMENDED IN SENATE MARCH 29, 2012

SENATE BILL

No. 1329

Introduced by Senator Simitian

February 23, 2012

An act to amend Sections 150201, 150202, 150204, and 150205 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

SB 1329, as amended, Simitian. Prescription drugs: collection and distribution program.

Existing law authorizes a county to establish, by ordinance, a repository and distribution program under which a pharmacy that is owned by or contracts with the county may distribute surplus unused medications, as defined, to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies. Existing law requires a county that has established a program to establish procedures to, among other things, ensure proper safety and management of any medications collected and maintained by a participating pharmacy. Existing law authorizes a skilled nursing facility, specified drug manufacturer, or pharmacy wholesaler to donate medications to the program. Existing law requires medication under the program to be dispensed to an eligible patient, destroyed, or returned to a reverse distributor, as specified. Except in cases of noncompliance, bad faith, or gross negligence, existing law prohibits certain people and entities from being subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program's provisions.

This bill would authorize a county to establish the program by action of the county board of supervisors or by action of a public health officer

of the county, as prescribed. This bill would *also* authorize ~~a primary care clinic dispensary, as defined, specified primary care clinics and pharmacies~~ to participate in the program. This bill would require a pharmacy or clinic seeking to participate in the program to inform the county health department in writing of its ~~intent, intent and prohibit the pharmacy or clinic from participating until~~ *and require* the county board of supervisors or public health officer to approve the pharmacy ~~or clinic~~ *health department has confirmed that it has received this notice.* This bill would require participating pharmacies and clinics to disclose specified information to the county health department and require the county board of supervisors or public health officer to make this information available upon request to the *California State Board of Pharmacy.* This bill would authorize the county board of supervisors, public health officer, and *California State Board of Pharmacy* to prohibit a pharmacy or clinic from participating in the program, under certain circumstances. This bill would authorize licensed health and care facilities, as specified, to donate unused medications to the program. ~~This bill would authorize medication under the program to be transferred to another participating pharmacy or primary care clinic.~~ This bill would also make other conforming changes to those 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 150201 of the Health and Safety Code
 2 is amended to read:
 3 150201. ~~(a) For purposes of this division, “medication”~~
 4 150201. *For purposes of this division:*
 5 (a) *“Eligible entity” means all of the following:*
 6 (1) *A licensed pharmacy, as defined in subdivision (a) of Section*
 7 *4037 of the Business and Professions Code, that is county owned*
 8 *or that contracts with the county pursuant to this division.*
 9 (2) *A licensed pharmacy, as defined in subdivision (a) of Section*
 10 *4037 of the Business and Professions Code, that is owned and*
 11 *operated by a licensed primary care clinic, as defined in Section*
 12 *1204.*
 13 (3) *A licensed primary care clinic, as defined in Section 1204,*
 14 *that is licensed to administer and dispense drugs pursuant to*

1 *subparagraph (A) of paragraph (1) of subdivision (a) of Section*
2 *4180 of the Business and Professions Code.*

3 (b) “Medication” or “medications” means a dangerous drug,
4 as defined in Section 4022 of the Business and Professions Code.

5 ~~(b) For purposes of this division, “primary care clinic~~
6 ~~dispensary” means a licensed primary care clinic, as defined in~~
7 ~~Section 1204, that is licensed to administer and dispense drugs~~
8 ~~pursuant to subparagraph (A) of paragraph (1) of subdivision (a)~~
9 ~~of Section 4180 of the Business and Professions Code.~~

10 (c) “Participating entity” means an eligible entity that has
11 received written or electronic documentation from the county
12 health department pursuant to paragraph (3) of subdivision (a) of
13 Section 150204 and that operates a repository and distribution
14 program pursuant to this division.

15 SEC. 2. Section 150202 of the Health and Safety Code is
16 amended to read:

17 150202. Notwithstanding any other provision of law, the
18 following health and care facilities may donate unused medications
19 under a program established pursuant to this division:

20 (a) A licensed general acute care hospital, as defined in Section
21 1250.

22 (b) A licensed acute psychiatric hospital, as defined in Section
23 1250.

24 (c) A licensed skilled nursing facility, as defined in Section
25 1250, including a skilled nursing facility designated as an
26 institution for mental disease.

27 (d) A licensed intermediate care facility, as defined in Section
28 1250.

29 (e) A licensed intermediate care facility/developmentally
30 disabled-habilitative facility, as defined in Section 1250.

31 (f) A licensed intermediate care facility/developmentally
32 disabled-nursing facility, as defined in Section 1250.

33 (g) A licensed correctional treatment center, as defined in
34 Section 1250.

35 (h) A licensed psychiatric health facility, as defined in Section
36 1250.2.

37 (i) A licensed chemical dependency recovery hospital, as defined
38 in Section 1250.3.

39 (j) A licensed residential care facility for the elderly, as defined
40 in Section 1569.2.

1 (k) A licensed residential care facility for persons with chronic,
 2 life-threatening illness, as defined in Section 1568.01.

3 (l) *An approved mental health rehabilitation center, as described*
 4 *in Section 5675 of the Welfare and Institutions Code.*

5 SEC. 3. Section 150204 of the Health and Safety Code is
 6 amended to read:

7 150204. (a) (1) A county may establish, by an action of the
 8 county board of supervisors or by an action of the public health
 9 officer of the county, as delegated by the county board of
 10 supervisors, a repository and distribution program for purposes of
 11 this division.

12 ~~(2) Only a pharmacy that is county-owned or that contracts with~~
 13 ~~the county pursuant to this division, or a primary care clinic~~
 14 ~~dispensary, as defined in subdivision (b) of Section 150201, is an~~
 15 ~~eligible entity, pursuant to subdivision (a) of Section 150201, may~~
 16 ~~participate in this program to dispense medication donated to the~~
 17 ~~drug repository and distribution program.~~

18 (3) ~~An eligible pharmacy or primary care clinic dispensary entity~~
 19 ~~that seeks to participate in the program shall inform the county~~
 20 ~~health department in writing of its intent to participate in the~~
 21 ~~program. An eligible pharmacy or primary care clinic dispensary~~
 22 ~~entity may not participate in the program unless it is approved by~~
 23 ~~the county board of supervisors or the public health officer of the~~
 24 ~~county until it has received written or electronic documentation~~
 25 ~~from the county health department confirming that the department~~
 26 ~~has received its notice of intent.~~

27 (4) (A) ~~A participating pharmacy or primary care clinic~~
 28 ~~dispensary entity shall disclose to the county health department~~
 29 ~~the name and location of the source of all donated medication it~~
 30 ~~receives.~~

31 (B) ~~A participating primary care clinic dispensary primary care~~
 32 ~~clinic, as described in paragraph (3) of subdivision (a) of Section~~
 33 ~~150201 shall disclose to the county health department the licensed~~
 34 ~~physician to who shall be accountable to the California State Board~~
 35 ~~of Pharmacy for the clinic’s program operations pursuant to this~~
 36 ~~division.~~

37 (C) The county board of supervisors or public health officer of
 38 the county shall, upon request, make available to the *California*
 39 *State Board of Pharmacy* the information in this paragraph.

1 (5) The county board of supervisors, the public health officer
2 of the county, and the *California State Board of Pharmacy* may
3 prohibit a ~~pharmacy or primary care clinic dispensary~~ *an eligible*
4 *or participating entity* from participating in the program if ~~the~~
5 ~~pharmacy or primary care clinic dispensary~~ *the entity* does not
6 comply with the provisions of the program, pursuant to this
7 division.

8 (b) A county that elects to establish a repository and distribution
9 program pursuant to this division shall establish procedures for,
10 at a minimum, all of the following:

11 (1) Establishing eligibility for medically indigent patients who
12 may participate in the program.

13 (2) Ensuring that patients eligible for the program shall not be
14 charged for any medications provided under the program.

15 (3) Developing a formulary of medications appropriate for the
16 repository and distribution program.

17 (4) Ensuring proper safety and management of any medications
18 collected by and maintained under the authority of a ~~county-owned~~
19 ~~or county-contracted, licensed pharmacy or primary care clinic~~
20 ~~dispensary~~ *participating entity*.

21 (5) Ensuring the privacy of individuals for whom the medication
22 was originally prescribed.

23 (c) Any medication donated to the repository and distribution
24 program shall comply with the requirements specified in this
25 division. Medication donated to the repository and distribution
26 program shall meet all of the following criteria:

27 (1) The medication shall not be a controlled substance.

28 (2) The medication shall not have been adulterated, misbranded,
29 or stored under conditions contrary to standards set by the United
30 States Pharmacopoeia (USP) or the product manufacturer.

31 (3) The medication shall not have been in the possession of a
32 patient or any individual member of the public, and in the case of
33 medications donated by a health or care facility, as described in
34 Section 150202, shall have been under the control of staff of the
35 health or care facility, as described in Section 150202.

36 (d) Only medication that is donated in unopened, tamper-evident
37 packaging or modified unit dose containers that meet USP
38 standards is eligible for donation to the repository and distribution
39 program, provided lot numbers and expiration dates are affixed.

1 Medication donated in opened containers shall not be dispensed
2 by the repository and distribution program.

3 (e) A pharmacist or physician shall use his or her professional
4 judgment in determining whether donated medication meets the
5 standards of this division before accepting or dispensing any
6 medication under the repository and distribution program.

7 (f) A pharmacist or physician shall adhere to standard pharmacy
8 practices, as required by state and federal law, when dispensing
9 all medications.

10 (g) Medication that is donated to the repository and distribution
11 program shall be handled in the following ways:

12 (1) Dispensed to an eligible patient.

13 (2) Destroyed.

14 (3) Returned to a reverse distributor.

15 (4) Transferred to another participating ~~pharmacy or primary~~
16 ~~care clinic dispensary~~ *entity* to be dispensed to eligible patients
17 pursuant to this division.

18 (h) Medication that is donated to the repository and distribution
19 program that does not meet the requirements of this division shall
20 not be distributed or transferred under this program and shall be
21 either destroyed or returned to a reverse distributor. This
22 medication shall not be sold, dispensed, or otherwise transferred
23 to any other entity.

24 (i) Medication donated to the repository and distribution program
25 shall be maintained in the donated packaging units until dispensed
26 to an eligible patient under this program, who presents a valid
27 prescription. When dispensed to an eligible patient under this
28 program, the medication shall be in a new and properly labeled
29 container, specific to the eligible patient and ensuring the privacy
30 of the individuals for whom the medication was initially dispensed.
31 Expired medication shall not be dispensed.

32 (j) Medication donated to the repository and distribution program
33 shall be segregated from the ~~pharmacy's or primary care clinic~~
34 ~~dispensary's~~ *participating entity's* other drug stock by physical
35 means, for purposes including, but not limited to, inventory,
36 accounting, and inspection.

37 (k) ~~The pharmacy or primary care clinic dispensary~~ *A*
38 *participating entity* shall keep complete records of the acquisition
39 and disposition of medication donated to, transferred, and dispensed
40 under the repository and distribution program. These records shall

1 be kept separate from the ~~pharmacy's or primary care clinic~~
2 ~~dispensary's participating entity's~~ other acquisition and disposition
3 records and shall conform to the Pharmacy Law (Chapter 9
4 (commencing with Section 4000) of Division 2 of the Business
5 and Professions Code), including being readily retrievable.

6 (l) Local and county protocols established pursuant to this
7 division shall conform to the Pharmacy Law regarding packaging,
8 transporting, storing, and dispensing all medications.

9 (m) County protocols established for packaging, transporting,
10 storing, and dispensing medications that require refrigeration,
11 including, but not limited to, any biological product as defined in
12 Section 351 of the Public Health and Service Act (42 U.S.C. Sec.
13 262), an intravenously injected drug, or an infused drug, shall
14 include specific procedures to ensure that these medications are
15 packaged, transported, stored, and dispensed at appropriate
16 temperatures and in accordance with USP standards and the
17 Pharmacy Law.

18 (n) Notwithstanding any other provision of law, a participating
19 ~~county-owned or county-contracted pharmacy or primary care~~
20 ~~clinic dispensary~~ entity shall follow the same procedural drug
21 pedigree requirements for donated drugs as it would follow for
22 drugs purchased from a wholesaler or directly from a drug
23 manufacturer.

24 SEC. 4. Section 150205 of the Health and Safety Code is
25 amended to read:

26 150205. The following persons and entities shall not be subject
27 to criminal or civil liability for injury caused when donating,
28 accepting, or dispensing prescription drugs in compliance with
29 this division:

30 (a) A prescription drug manufacturer, wholesaler, governmental
31 entity, ~~county-owned or county-contracted licensed pharmacy,~~ or
32 ~~primary care clinic dispensary participating entity.~~

33 (b) A pharmacist or health care professional who accepts or
34 dispenses prescription drugs.

35 (c) A health or care facility, as described in Section 150202.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NO.: SB 1329 **VERSION:** [A] Mar. 29, 2012

AUTHOR: Simitian **Committee
Recommendation:**

SUBJECT: Surplus Medication Collection and Distribution

Affected Sections: Health & Safety Code Sections **150201, 150202, 150204** and **150205**
Division 116. Surplus Medication Collection and Distribution
(§§ 150200-150207)

BILL STATUS:

April 12, 2012 – Passed out of SEN Committee on Health and Re-Referred to SEN Com. on Business, Professions and Economic Development. As of 4/17/12, no hearing date set.

EXISTING LAW:

Under existing ¹law, a county may voluntarily establish a Surplus Medication Collection and Distribution (SMCD) Program through a county-owned pharmacy or a pharmacy that contracts with the county for this purpose. Counties that elect to operate a program by ordinance of the County Board of Supervisors must establish criteria to determine who is eligible to receive drugs from the program; develop a formulary of medications appropriate for the program; ensure the privacy of individuals for whom the medication was originally prescribed; and ensure the safe storage and management of medications that are collected and dispensed under the program. No controlled drugs may be donated, and a pharmacist or physician and surgeon must dispense the medications to eligible patients.

Existing Pharmacy Law provides for the licensure and regulation of pharmacies, pharmacists, wholesalers of dangerous drugs or devices, and other individuals and entities.

THIS BILL WOULD:

- Also allow a county Public Health Officer to establish a Surplus Medication Collection and Distribution Program in a county.
- Expand the types of facilities/entities that may donate surplus medications to a SMCD Program, to include ²residential care facilities and ³mental health rehabilitation centers.
- Allow for the transfer of donated surplus medications between SMCD programs.
- Require that eligible programs disclose specified information to the county and that, upon request, make that information available to the board.
- Allow a physician to determine if donated medications meet specified standards, and to adhere to standard pharmacy practices when dispensing medications.
- Authorize the Board of Pharmacy to prohibit an entity from participating in a SMCD program.

¹ Division 116 of the Health and Safety Code, Sections 150200-150207

² Licensed by the Department of Social Services

³ Licensed by the Department of Mental Health, Welfare and Institutions Code § 5675

FOR DISCUSSION:

Patient Drugs – This measure is silent on the patient’s ownership of their drugs.

In various care settings, and with certain exceptions (i.e., such as a drug being returned for a pharmacy for credit for a Medicare and Medicaid patient) – once a drug is dispensed to a patient, the patient owns the drug – not the facility. This is true even if the drug is solely under the control of a facility’s healthcare staff for administration of the drug(s).

Donating Facilities [SEC. 2, H&SC 150202] – Existing law allows skilled nursing facilities (SNF), as defined, manufacturers and wholesalers to donate medications to a SMCD program. This bill would include eleven additional types of facilities that could donate unused medications to a drug repository and distribution program. SNFs are licensed by the Department of Public Health and in all cases the medications are under the control of health care staff. This bill would allow for the donation of drugs from some facilities that *may* allow the patient to maintain possession of the drugs (correctional, residential care, etc.).

Board Authority – This measure allows the Board of Pharmacy, a county board of supervisors, or a county public health officer to prohibit a “participating entity” from participating, if the entity does not comply with the provisions of the program. However, there is no board involvement in the establishment of such a program, nor are there provisions that require board approval to participate in such a program. How will the board go about “prohibiting” these “participating entities”?

Drug Storage & Transfer – Current law requires that donated drugs must be kept physically separate from a pharmacy’s or clinic’s other drug supply.

This bill allows for the permissive transfer of donated drugs from one approved program to another. According to the author, this would allow donated drugs to be directed where they are needed most. The bill specifies there shall be “complete records of the acquisition and disposition” of donated drugs. It is unclear what ‘complete records’ shall include. Likewise, SB 1329 is silent on how drugs transfers are to be made.

Pedigree – The bill specifies that a recipient of donated medications shall follow the same pedigree requirements for a donated drug as it would for drugs purchased from a Wholesaler or Manufacturer. Under current law, pedigree stops when the drug is dispensed to a patient. [SEC. 3 (n)]

Physician Oversight – When determining if a donated drug meets the requirements of the division, this bill requires a physician to adhere to “standard pharmacy practices.” Pharmacy Law applies to pharmacists and those under the board’s jurisdiction. The Board does not have jurisdiction over physicians. [SEC. 3 H&SC 150204 (f)]

Drug Disposal – SB 1329 specifies that donated medications that are not eligible for redistribution shall be destroyed or returned to a *reverse distributor*. The author’s fact sheet states this measure would reduce needless *pharmaceutical waste*. Under current law, ⁴pharmaceutical waste is required to be disposed of in accordance with the Medical Waste Management Act (i.e., medical waste hauler). If a donated drug does not meet the standards of the division, should it be disposed of as pharmaceutical waste?

STAFF RECOMMENDATION: Oppose Unless Amended

⁴ Medical Waste Management Act, Health and Safety Code Section 117747

Introduced by Senator Simitian

February 16, 2011

An act to amend Sections 47115 and 47116 of the Public Resources Code, relating to solid waste.

LEGISLATIVE COUNSEL'S DIGEST

SB 419, as introduced, Simitian. Solid waste: home-generated sharps.

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

This bill would require the above plan to be submitted in an electronic format as prescribed by the department. The bill would require the manufacturer to post and maintain a copy of the plan in a readily accessible location on its Internet Web site.

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

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

1 SECTION 1. Section 47115 of the Public Resources Code is
2 amended to read:
3 47115. A pharmaceutical manufacturer that sells or distributes
4 a medication in California that is usually intended to be
5 self-injected at home through the use of a hypodermic needle, pen
6 needle, intravenous needle, or any other similar device, shall, on
7 or before July 1, 2010, and annually thereafter, submit to the ~~board,~~

1 ~~or its successor agency~~ *department*, a plan that describes how the
2 manufacturer supports the safe collection and proper disposal of
3 the waste devices. *The plan shall be submitted in an electronic*
4 *format as prescribed by the department.*

5 SEC. 2. Section 47116 of the Public Resources Code is
6 amended to read:

7 47116. (a) The manufacturer shall post and maintain a copy
8 of the plans required pursuant to Section 47115 *in a readily*
9 *accessible location* on its Internet Web site.

10 (b) ~~The board, or its successor agency,~~ *department* shall post
11 and maintain copies of the plans submitted by the manufacturers
12 pursuant to Section 47115 on its Internet Web site.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 419 **VERSION:** Introduced February 16, 2011

AUTHOR: Simitian **SPONSOR:**

BOARD POSITION: None

SUBJECT: Solid Waste: Home-Generated Sharps

Affected Sections: Amend Sections 47115 and 47116 of the Public Resources Code related to solid waste.

Current Status: On Assembly Inactive File (1/9/12)

EXISTING LAW:

Existing law requires a pharmaceutical manufacturer selling or distributing medication that is intended to be self-injected at home to submit, on an annual basis, to the Department of Resources and Recycling and Recovery a plan supporting the safe collection and proper disposal of specified waste devices. The manufacturer is required to post and maintain a copy of the plan on its Internet Web site.

THIS BILL:

Would require that a pharmaceutical manufacturer to submit the required report in an electronic format, and that the plan be in a readily accessible location on its Internet Web site.

COMMENTS:

Staff was recently advised that the author has no immediate plans for the bill.

FISCAL/ECONOMIC IMPACT:

No fiscal impact, as introduced.

HISTORY:

Date	Action
2012	
Jan. 9	Ordered to inactive file on request of Assembly Member Allen
2011	
Sep. 1	From inactive file. Ordered to third reading.
Aug. 31	Notice of intention to remove from inactive file given by Assembly Member Charles Calderon.
Aug. 15	From consent calendar. Ordered to third reading. Ordered to inactive file on request of Assembly Member Charles Calderon.
July 14	Read second time. Ordered to consent calendar.
July 13	From committee: Do pass. Ordered to consent calendar. (Ayes 16. Noes 0.)
June 28	From committee. Do pass and re-refer to Com. on APPR (Ayes 9. Noes 0.) Re-referred to Com. on APPR.
May 2	Referred to Com. on E.S. & T.M.
Apr. 25	In Assembly. Read first time. Held at Desk.
Apr. 25	Read third time. Passed. (Ayes 32. Noes 8. Page 708.) Ordered to the Assembly.
Apr. 12	Read second time. Ordered to third reading.
Apr. 11	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 1	Set for hearing April 11.
Mar. 22	From committee: Do pass and re-refer to Com. on APPR (Ayes 5. Noes 0. Page 414.) (March 21). Re-referred to Com. on APPR.
Mar. 10	Set for hearing March 21.
Feb. 24	Referred to Com. on E.Q.
Feb 17	From printer. May be acted upon on or after March 19.
Feb. 16	Introduced. Read first time. To Com. on RLS. for assignment. To print.

AMENDED IN SENATE MARCH 29, 2012

SENATE BILL

No. 1301

Introduced by Senator Hernandez
(Principal coauthor: Assembly Member Mitchell)
(Coauthor: Senator Emmerson)

February 23, 2012

An act to add Section 4064.5 to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1301, as amended, Hernandez. Prescription drugs: 90-day supply.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy. Existing law prohibits a person from furnishing a dangerous drug except upon the prescription of specified practitioners, except as specified. Existing law authorizes a pharmacist filling a prescription order for a drug product to substitute a generic drug product or 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. Existing law also authorizes a pharmacist to refill a prescription for a dangerous drug without the prescriber's authorization under specified circumstances.

This bill would authorize a pharmacist to dispense up to a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription if the pharmacist is exercising his or her professional judgment, he or she dispenses no more than the total amount prescribed, including refills, and the prescriber has not specified on the

prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

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

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

1 SECTION 1. Section 4064.5 is added to the Business and
2 Professions Code, to read:

3 4064.5. (a) A pharmacist may dispense up to a 90-day supply
4 of a dangerous drug other than a controlled substance pursuant to
5 a valid prescription that specifies the initial dispensing of a lesser
6 amount followed by periodic refills of that amount if all of the
7 following requirements are satisfied:

8 (a)

9 (1) The total quantity of dosage units dispensed does not exceed
10 the total quantity of dosage units authorized by the prescriber on
11 the prescription, including refills.

12 (b)

13 (2) The prescriber has not specified on the prescription that
14 dispensing the prescription in an initial amount followed by
15 periodic refills is medically necessary.

16 (c)

17 (3) The pharmacist is exercising his or her professional
18 judgment.

19 (b) *Nothing in this section shall be construed to require a health
20 care service plan, health insurer, workers' compensation insurance
21 plan, pharmacy benefits manager, or any other person or entity,
22 including, but not limited to, a state program or state employer,
23 to provide coverage for a dangerous drug in a manner inconsistent
24 with a beneficiary's plan benefit.*

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NO.: SB 1301 **VERSION:** A – April 16, 2012

AUTHOR: Hernandez **Committee**
 Coauthors: Mitchell **Recommendation:**
 and Emmerson

SUBJECT: Prescription Drugs: 90-Day Supply

Affected Sections: Add Section 4064.5 to the Business and Professions Code.

CURRENT STATUS:

April 23, 2012 – Set for hearing in SEN Committee on Business, Professions and Economic Development

EXISTING LAW:

1. B&PC § 4024 defines “Dispense” as the furnishing of drugs or devices upon a prescription from an authorized prescriber, and also refers to the furnishing of drugs or devices directly to a patient by a prescriber, as specified.
2. B&PC § 4063 specifies “No prescription for any dangerous drug or dangerous device may be refilled except upon authorization of the prescriber. The authorization may be given orally or at the time of giving the original prescription. No prescription for any dangerous drug that is a controlled substance may be designated refillable as needed.”
3. B&PC § 4064 provides for the emergency refilling of a prescription without prescriber authorization.
4. 16 CCR Section 1716 precludes a pharmacist from deviating from the requirements of a prescription, except upon consent of the prescriber, or to select another drug product in accordance with B&PC § 4063.

THIS BILL WOULD:

1. Add Section 4064.5 to the Business and Professions Code to specify limited circumstances by which a pharmacist may dispense not more than a 90-day supply of a dangerous drug (not a controlled substance) pursuant to a valid prescription for a lesser amount, with refills (such as 30-day supply), so long as specified requirements are met:
 - The patient has completed an initial 30-day supply of the drug, AND all of the following requirements are met:
 - i. The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.
 - ii. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary; and
 - iii. The pharmacist is exercising his or her professional judgment.

- The pharmacist notifies the prescriber of the change in the quantity of dosage units dispensed.
- The provisions would not apply to psychotropic medication or psychotropic drugs, as specified.

AUTHOR'S INTENT:

According to the author, SB 1301 would permit a pharmacist to dispense a refill prescription drug in a 90-day supply, unless the prescriber indicates otherwise on the prescription document. This could save a patient time and money and would aid in a patient's adherence to a prescribed medication therapy.

COMMENTS:

Under current law, a pharmacist may dispense a 90-day supply of a dangerous drug (other than a controlled substance) pursuant to a valid prescription for a lesser amount, so long as the pharmacist receives authorization from the prescriber. This measure would establish limited conditions by which a pharmacist can dispense a 90-day supply after the patient has completed a 30-day supply of that drug, and provided the pharmacist notifies the prescriber of the change in dosage units dispensed.

However, the board's regulation at 16 CCR 1716 specifies that a pharmacist **shall not** deviate from the requirements of a prescription, except as specified. If enacted, the board's regulation may require amendment so as to not conflict with the provisions of the bill.

SB 1301 is silent as to patient interaction. Thus, a pharmacist, complying with the provisions of the bill, would be able to dispense a 90-day supply of a prescription drug without knowing if the patient **wants** a 90-day supply. Board staff believes there should be some level of interaction with the patient to determine if the patient wants an amount greater than what the prescription is written for.

HISTORY:

2012

Date Action

- Apr. 13 Set for hearing April 23.
- Apr. 12 From committee: Do pass as amended and re-refer to Com. On B., P. & E.D.
- Mar 29 From committee with author's amendments. Read second time and amended. Re-referred to Com. on HEALTH.
- Mar. 27 Set for hearing April 11
- Mar. 22 Set, first hearing. Hearing canceled at the request of author.
- Mar. 13 Set for hearing March 28.
- Mar. 8 Referred to Coms. On HEALTH and B., P. & E.D.
- Feb. 24 From printer. May be acted upon on or after March 25.
- Feb. 23 Introduced. Read first time. To Com. On RLS for assignment. To print.

AMENDED IN SENATE JANUARY 17, 2012

AMENDED IN ASSEMBLY MARCH 30, 2011

AMENDED IN ASSEMBLY MARCH 15, 2011

AMENDED IN ASSEMBLY MARCH 7, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 389

Introduced by Assembly Member Mitchell
(Principal coauthor: Senator Pavley)

February 14, 2011

An act to add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code, relating to genetic diseases.

LEGISLATIVE COUNSEL'S DIGEST

AB 389, as amended, Mitchell. Bleeding disorders.

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, as described, whose products are used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia. This bill would require the California State Board of Pharmacy to administer and enforce 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 125286.10)
2 is added to Chapter 2 of Part 5 of Division 106 of the Health and
3 Safety Code, to read:

4
5 Article 5. Standards of Service for Providers of Blood Clotting
6 Products for Home Use Act

7
8 125286.10. This article shall be known, and may be cited, as
9 the Standards of Service for Providers of Blood Clotting Products
10 for Home Use Act.

11 125286.15. The Legislature hereby finds and declares all of
12 the following:

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

16 (b) Von Willebrand disease is a human bleeding disorder caused
17 by a hereditary deficiency or abnormality of the von Willebrand
18 factor in human blood, which is a protein that helps clot blood.
19 Von Willebrand disease is a chronic, lifelong, incurable, but
20 treatable, disease affecting at least 360,000 Californians.

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

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

32 (e) Pharmacies and other entities specializing in the delivery of
33 blood clotting products and related equipment, supplies, and
34 services for home use form a growing enterprise in California.

35 (f) Timely access to federally designated regional hemophilia
36 centers and appropriate products and services in the home,
37 including infusion of blood clotting products and related
38 equipment, and supplies and services for persons with hemophilia

1 and other bleeding disorders, reduces mortality and bleeding-related
2 hospitalizations according to the federal Centers for Disease
3 Control and Prevention and the Medical and Scientific Advisory
4 Council of the National Hemophilia Foundation.

5 (g) Eligible persons with hemophilia or other bleeding disorders
6 may receive treatment through the Genetically Handicapped
7 Persons Program, the California Children’s Services Program, and
8 the Medi-Cal program.

9 (h) For the benefit of persons with hemophilia or other bleeding
10 disorders, the purposes of this article are to do the following:

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

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

18 125286.20. Unless the context otherwise requires, the following
19 definitions shall apply for purposes of this article:

20 (a) “Assay” means the amount of a particular constituent of a
21 mixture or of the biological or pharmacological potency of a drug.

22 (b) “Ancillary infusion equipment and supplies” means the
23 equipment and supplies required to infuse a blood clotting product
24 into a human vein, including, but not limited to, syringes, needles,
25 sterile gauze, field pads, gloves, alcohol swabs, numbing creams,
26 tourniquets, medical tape, sharps or equivalent biohazard waste
27 containers, and cold compression packs.

28 (c) “Bleeding disorder” means a medical condition characterized
29 by a deficiency or absence of one or more essential blood clotting
30 proteins in the human blood, often called “factors,” including all
31 forms of hemophilia and other bleeding disorders that, without
32 treatment, result in uncontrollable bleeding or abnormal blood
33 clotting.

34 (d) “Blood clotting product” means an intravenously
35 administered medicine manufactured from human plasma or
36 recombinant biotechnology techniques, approved for distribution
37 by the federal Food and Drug Administration, that is used for the
38 treatment and prevention of symptoms associated with bleeding
39 disorders. Blood clotting products include, but are not limited to,
40 ~~Factor VII, Factor factor VII, factor VIIa, Factor factor VIII, and~~

1 ~~Factor~~ *factor* IX products, von Willebrand-~~Factor~~ *factor* products,
2 bypass products for patients with inhibitors, and activated
3 prothrombin complex concentrates.

4 (e) “Emergency” means care as defined in Section 1317.1.

5 (f) “Hemophilia” means a human bleeding disorder caused by
6 a hereditary deficiency of the ~~Factors~~ *factors* I, II, V, VIII, IX, XI,
7 XII, or XIII blood clotting protein in human blood.

8 (g) “Hemophilia treatment center” means a facility for the
9 treatment of bleeding disorders, including, but not limited to,
10 hemophilia, that receives funding specifically for the treatment of
11 patients with bleeding disorders from federal government sources,
12 including, but not limited to, the federal Centers for Disease
13 Control and Prevention and the federal Health Resources and
14 Services Administration (HRSA) of the United States Department
15 of Health and Human Services.

16 ~~(h) “Home nursing services” means specialized nursing care
17 provided in the home setting to assist a patient in the reconstitution
18 and administration of blood clotting products.~~

19 ~~(i)~~

20 (h) “Home use” means infusion or other use of a blood clotting
21 product in a place other than a state-recognized hemophilia
22 treatment center or other clinical setting. Places where home use
23 occurs include, without limitation, a home or other nonclinical
24 setting.

25 ~~(j)~~

26 (i) “Patient” means a person needing a blood clotting product
27 for home use.

28 ~~(k)~~

29 (j) (1) “Provider of blood clotting products for home use” means
30 all the following pharmacies, except as described in Section
31 125286.35, that dispense blood clotting factors for home use:

32 (A) Hospital pharmacies.

33 (B) Health system pharmacies.

34 (C) Pharmacies affiliated with hemophilia treatment centers.

35 (D) Specialty home care pharmacies.

36 (E) Retail pharmacies.

37 ~~(2) The providers described in this subdivision may also provide
38 home nursing services for persons with bleeding disorders.~~

39 ~~(3)~~

1 (2) The providers described in this subdivision shall include a
2 health care service plan and all its affiliated providers if the health
3 care service plan exclusively contracts with a single medical group
4 in a specified geographic area to provide professional services to
5 its enrollees.

6 125286.25. Each provider of blood clotting products for home
7 use shall meet all of the following requirements:

8 (a) Have sufficient knowledge and understanding of bleeding
9 disorders to accurately follow the instructions of the prescribing
10 physician and ensure high-quality service for the patient and the
11 medical and psychosocial management thereof, including, but not
12 limited to, home therapy.

13 (b) Have access to a provider with sufficient clinical experience
14 providing services to persons with bleeding disorders that enables
15 the provider to know when patients have an appropriate supply of
16 clotting factor on hand and about proper storage and refrigeration
17 of clotting factors.

18 (c) Maintain 24-hour on-call service seven days a week for
19 every day of the year, adequately screen telephone calls for
20 emergencies, acknowledge all telephone calls within one hour or
21 less, and have access to knowledgeable pharmacy staffing on call
22 24 hours a day, to initiate emergency requests for clotting factors.

23 (d) Have the ability to obtain all brands of blood clotting
24 products approved by the federal Food and Drug Administration
25 in multiple assay ranges (low, medium, and high, as applicable)
26 and vial sizes, including products manufactured from human
27 plasma and those manufactured with recombinant biotechnology
28 techniques, provided manufacturer supply exists and payer
29 authorization is obtained.

30 (e) Supply all necessary ancillary infusion equipment and
31 supplies with each prescription, as needed.

32 (f) Store and ship, or otherwise deliver, all blood clotting
33 products in conformity with all state and federally mandated
34 standards, including, but not limited to, the standards set forth in
35 the product's approved package insert (PI).

36 ~~(g) When home nursing services are necessary, as determined
37 by the treating physician, provide these services either directly or
38 through a qualified third party with experience in treating bleeding
39 disorders and coordinate pharmacy services with the third party
40 when one is used to provide home nursing services.~~

- 1 ~~(h)~~
2 (g) Upon receiving approved authorization for a nonemergency
3 prescription, provided manufacturer supply exists, ship the
4 prescribed blood clotting products and ancillary infusion equipment
5 and supplies to the patient within two business days or less for
6 established and new patients.
- 7 ~~(i)~~
8 (h) Upon receiving approved authorization to dispense a
9 prescription for an emergency situation, provided manufacturer
10 supply exists, deliver prescribed blood products, ancillary infusion
11 equipment and supplies, ~~medications, and home nursing services~~
12 *and medications* to the patient within 12 hours for patients living
13 within 100 miles of a major metropolitan airport, and within one
14 day for patients living more than 100 miles from a major
15 metropolitan airport.
- 16 ~~(j)~~
17 (i) Provide patients who have ordered their products with a
18 designated contact telephone number for reporting problems with
19 a delivery and respond to these calls within a reasonable time
20 period.
- 21 ~~(k)~~
22 (j) Provide patients with notification of Class 1 and Class 2
23 recalls and withdrawals of blood clotting products and ancillary
24 infusion equipment within 24 hours of the provider of blood
25 clotting products for home use receiving notification and participate
26 in the National Patient Notification System for blood clotting
27 product recalls.
- 28 ~~(l)~~
29 (k) Provide language interpretive services over the telephone
30 or in person, as needed by the patient.
- 31 ~~(m)~~
32 (l) Have a detailed plan for meeting the requirements of this
33 article in the event of a natural or manmade disaster or other
34 disruption of normal business operations.
- 35 ~~(n)~~
36 (m) Provide appropriate and necessary recordkeeping and
37 documentation as required by state and federal law and retain
38 copies of the patient's prescriptions.
- 39 ~~(o)~~

1 (n) Comply with the privacy and confidentiality requirements
2 of the federal Health Insurance Portability and Accountability Act
3 of 1996 (HIPAA).

4 125286.30. The California State Board of Pharmacy shall
5 administer and enforce this article.

6 125286.35. Nothing in this article shall apply to either hospital
7 pharmacies or health system pharmacies that dispense blood
8 clotting products due only to emergency, urgent care, or inpatient
9 encounters, or if an inpatient is discharged with a supply of blood
10 clotting products for home use.

O

Assembly Bill 389

Hemophilia – Standards for Clotting Factor in Home Setting

ISSUE

For people with hemophilia, and other bleeding disorders, it is often necessary that they receive intravenous injection or infusion of prescription blood clotting products several times a week. Most patients use these products at home.

Currently, pharmacies that provide clotting factor to patients on state programs: Medi-Cal, CA Children's Services (CCS) and Genetically Handicapped Persons Program (GHPP) must comply with standards that are included in written contracts with the State.

Because these standards are not established for pharmacy providers with patients on private insurance, patients have endured some difficulties in receiving their products. For example, clotting factor has been left on patients' front porches resulting in spoilage due to the heat. Clotting factor is lifesaving for patients and needs to be available on a regular and emergency basis. Additionally, spoilage causes financial hardship as it is an expensive biological product.

BACKGROUND

Currently, there are no standards in State law that governs the proper storage and delivery of blood clotting products for private patients.

THIS BILL

AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, and other bleeding disorders.

SUMMARY

AB 389 creates a uniform standard for both public and private pay patients who receive clotting factors. This bill will assure that both public and private pay patients receive the same standard of care.

SUPPORT

- Hemophilia Council of CA (sponsor)
- Accredo Health Group Inc.
- Baxter Healthcare
- California Academy of Family Physicians
- California Medical Association
- California Pharmacists Association
- California Society of Health System Pharmacists
- Community Healthcare Services
- CSL Behring
- DLA Piper
- DRG Pharmacy LLC
- Federal Hemophilia Treatment Centers Region XI
- Grifols, Inc.
- Hemophilia Foundation of Northern California
- Herndon Pharmacy
- Meyer Family Cellars
- National Cornerstone Healthcare Services, Inc.
- Pfizer
- Red Chip Enterprises
- Talecris Biotherapeutics
- UC Davis Medical Center
- Walgreens

OPPOSITION

None

VOTES

- | | |
|-------------------------|------|
| ▪ Senate Appropriations | 28-8 |
| ▪ Senate Health | 8-0 |

- Assembly Floor 78-0
- Assembly Appropriations 12-3
- Assembly Health 15-3
- Assembly BP &CP 9-0

FOR MORE INFORMATION

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(916) 319-2047





California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

August 18, 2011

The Honorable Holly Mitchell
Member, California State Assembly
State Capitol, Room 2176
Sacramento, CA 95816

RE: AB 389

Dear Assembly Member Mitchell:

I regret to advise you that the Board of Pharmacy has taken an oppose position on your AB 389. This bill would codify a number of current standards of practice for pharmacies that dispense blood clotting products to patients with bleeding disorders. I recognize the lateness of notification, and I apologize for the timing.

The board believes that pharmacies that service patients with bleeding disorders are typically specialized in providing such care, have close relationships with their patients and comply with all of the standards in this bill, with the exception of arranging for nursing services (which is usually outside the realm of pharmacy). We are not aware of any problems in the care provided by pharmacies to patients with bleeding disorders and cannot recall a situation were the board has received a complaint in this area.

As such, without a compelling need to establish specially codified provisions for a medical condition, the board is hesitant to endorse such requirements because they seem unnecessary and could lead to a plethora of additional specialized requirements in law for patients with other conditions. The result would be a more complex series of provisions that could actually impair patient care and compliance with the already extensive provisions in place to regulate pharmacy care.

I had the pleasure of meeting with Tiffany Jones of your staff and the sponsors of this bill early this summer, and I strongly encouraged them to file complaints with the board when they question the quality of pharmacy care or products provided to them. Without such complaints, the board finds it difficult to fulfill its consumer protection mandate. They agreed to do so in the future, and this will aid us in identifying and resolving issues for these patients should problems arise.

Please do not hesitate to contact me at (916) 574-7911 with questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold".

VIRGINIA HEROLD
Executive Officer

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 389 **VERSION:** Amended January 17, 2012
AUTHOR: Mitchell **SPONSOR:** Hemophilia Council of California
BOARD POSITION: Oppose (*Reaffirmed January 2012*)
SUBJECT: Bleeding Disorders: Blood Clotting Products

Affected Sections: Add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code

Current Status: In the Senate. On Third Reading File (4/19/12)

EXISTING LAW:

1. Establishes the Holden-Moscone-Garamendi Genetically Handicapped Person's Program within the Department of Health Care Services. [H&SC § 125125]
2. Requires the Director of Health Care Services to establish and administer a program for the medical care of persons with genetically disabling conditions, including hemophilia. [H&SC § 125130]
3. Requires the Division of Licensing of the Medical Board of California to establish continuing education requirements for physicians and surgeons as specified and sets forth the criteria that the division shall use in considering courses. [B&PC § 2191]

THIS BILL WOULD:

1. Add Article 5. Standards of Service for Providers of Blood Clotting Products for Home Use Act that includes the following:
 - a. Findings and declarations about bleeding disorders, history of and treatment of such disorders, pharmacies role in the delivery of products, identification of persons eligible for treatment through various programs, and states that this article is necessary for the benefit of persons with bleeding disorders to establish standards of service and to promote cost effective, life saving products for home use.
 - b. Defines various terms for purposes of this article including:
 - i. "assay"
 - ii. "ancillary infusion equipment and supplies"
 - iii. "bleeding disorder"
 - iv. "blood clotting product"
 - v. "emergency"

- vi. "hemophilia"
 - vii. "hemophilia treatment center"
 - viii. "home use"
 - ix. "patient"
 - x. "provider of blood clotting products" to mean specified pharmacies that dispense blood clotting factors for home use, unless excepted
 - 1. Hospital pharmacies
 - 2. Health system pharmacies
 - 3. Pharmacies affiliated with hemophilia treatment centers
 - 4. Specialty home care pharmacies
 - 5. Retail pharmacies
 - xi. And that the above providers shall include a health care service plan and all its affiliated providers if the health care service plan exclusively contracts with a single medical group in a specified geographic area to provide professional services to its enrollees.
- c. Requires that each provider, as defined above, meet the following requirements:
- i. Have sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescriber and ensure quality care.
 - ii. Have access to a provider with sufficient clinical experience providing services to persons with bleeding disorders that enables the provider to know when patients have an appropriate supply of product on hand as well and understanding about proper storage and refrigeration.
 - iii. Maintain 24-hour on-call service seven days a week, 365 days a year.
 - iv. Have the ability to obtain all brands of the products approved by the FDA in multiple assay ranges as specified.
 - v. Supply all necessary ancillary infusion equipment and supplies as needed.
 - vi. Store, ship, or otherwise deliver, all products in conformity with state and federally mandated standards.
 - vii. Ship product within two business days to a patient for a nonemergency prescription.
 - viii. For emergencies, deliver products, ancillary equipment, supplies and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, or within one day for patients living outside that area.
 - ix. Provide contact information to a patient to report problems with delivery.
 - x. Provide patient with product recall and withdrawal notifications within 24 hours.
 - xi. Provide language interpretive service via phone or in person, as needed.
 - xii. Have a detailed plan in the event of a natural or manmade disaster.
 - xiii. Provide appropriate record keeping.
 - xiv. Comply with HIPAA requirements.
2. Requires the California Board of Pharmacy to administer and enforce this article.

AUTHOR'S INTENT:

According to the author's office, "AB 389 will establish standards of service for pharmacies that deliver blood clotting products and related equipment, supplies, and services for home use and would promote access to a full range of essential, cost effective, life-saving, blood clotting products and related equipment, supplies for home use for people who have hemophilia, von Willebrand disease and other bleeding disorders."

COMMENTS:

Many of these provisions in AB 389 are currently the standard of practice, but are not codified. This measure specifies that the Board of Pharmacy will enforce the provisions of this bill. The board could fulfill this mandate through routine inspections of pharmacies and others under the board's jurisdiction as well as investigation of consumer complaints received. The board would already have jurisdiction to investigate consumer complaints involving poor service or product delivery that resulted in either patient harm or the potential for harm. We are unaware of any such complaints received by the board.

There are potential challenges in enforcing some of these provisions. Specifically, the board may not be in a position to assess the clinical experience of the provider to ensure they have sufficient experience to know when patients have an appropriate supply of clotting factor on hand as required.

A previous version of this bill contained a provision requiring the Licensing Division of the Medical Board to consider requiring a continuing education course on bleeding disorders. This provision was amended out of the measure on March 30, 2011. Previous provisions related to the requirement that a provider provide home nursing services were amended out the measure on January 17, 2012.

PRIOR BOARD DISCUSSION and ACTION:

The board opposed the measure in August 2011. The board reaffirmed this position at the January 2012 Board Meeting.

In its letter of opposition (8/18/11), the board cited the lack of a compelling need to establish codified provisions for a medical condition which could result in a more complex series of provisions that could actually impair patient care and compliance with the already extensive provisions in place to regulate pharmacy care. The board also stated that it was not aware of any problems in the care provided by pharmacies to patients with bleeding disorders based on the lack of complaints in this area.

FISCAL/ECONOMIC IMPACT:

We anticipate a portion of an inspector PY will be necessary to ensure compliance with these provisions. This workload could possibly be absorbed if the board is able to fill all authorized inspector positions. However, because of the bill's specificity and the need for close monitoring of these provisions, the board would need to do frequent inspections. Because the specialty pharmacies are not required to have a separate license, nor are they required to notify the board that they provide such services, performing inspection on all pharmacies that provide these services would be a challenge.

PREVIOUS/RELATED LEGISLATION

SB 1594 (Steinberg, 2007) would have established standards for providers of blood clotting products. The board had a "Watch" position on the bill. The measure later died after being placed on the Senate Appropriations Suspense File and never passed out of the house of origin.

SB 971 (Pavely, 2010) introduced legislation similar to this proposal. The board did not have a position on this bill. This bill was vetoed by the governor.

"I am returning Senate Bill 971 without my signature. This bill is unnecessary and attempts to create additional standards that are already being adequately enforced through other regulatory and administrative mechanisms. Since the current standards of practice for blood clotting products and service are already being met through state and federal pharmacy laws, voluntary compliance and existing state contract provisions, it is unclear what problem this bill seeks to address. For these reasons, I am unable to sign this bill."

SUPPORT/OPPOSITION:

Support

Hemophilia Council of California (Sponsor)
Accredo Health Group Inc.
Baxter Healthcare
California Academy of Family Physicians
California Medical Association
California Pharmacists Association
California Society of Health System Pharmacists
Community Healthcare Services
CSL Behring
DLA Piper
DRG Pharmacy LLC

Federal Hemophilia Treatment Centers, Region XI
Grifols Inc.
Hemophilia Foundation of Northern California
Herndon Pharmacy
Meyer Family Cellars
National Cornerstone Healthcare Services Inc.
Pfizer Inc.
Red Chip Enterprises
Talecris Biotherapeutics
UC Davis Medical Center
Walgreens

Oppose

Board of Pharmacy

HISTORY:

Date Action

2012

Jan. 18 Read second time. Ordered to third reading.

Jan. 17 From inactive file. Ordered to second reading. Read second time and amended. Ordered to second reading.

2011

Sept. 1 From Special Consent Calendar pursuant to Joint Rule 22.2. Ordered to third reading. Ordered to inactive file at the request of Senator Pavley.

Aug. 31 Ordered to special consent calendar.

Aug. 23 Read second time. Ordered to third reading.

Aug. 22 From committee: Be placed on second reading file pursuant to Senate Rule 28.8.

Aug. 15 In committee: Hearing postponed by committee.

July 6 From committee: Do pass and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (July 6). Re-referred to Com. on APPR.

June 23 From committee: Do pass and re-refer to Com. on B., P. & E.D. with recommendation: to consent calendar. (Ayes 8. Noes 0.) (June 22). Re-referred to Com. on B., P. & E.D.

June 8 In committee: Hearing postponed by committee.

May 12 Referred to Coms. on HEALTH and B., P. & E.D.

Apr. 28 In Senate. Read first time. To Com. on RLS. for assignment.

Apr. 28 Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 1127.)

Apr. 14 Read second time. Ordered to third reading.

Apr. 13 From committee: Do pass. (Ayes 12. Noes 3.) (April 13).

Apr. 6 From committee: Do pass and re-refer to Com. on APPR. (Ayes 15. Noes 3.) (April 5). Re-referred to Com. on APPR.

Mar. 31 Re-referred to Com. on HEALTH.

Mar. 30 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.

Mar. 22 From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 9. Noes 0.) (March 22). Re-referred to Com. on HEALTH.

Mar. 16 Re-referred to Com. on B., P. & C.P.

Mar. 15 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.

Mar. 8 Re-referred to Com. on B., P. & C.P.

Mar. 7 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.

Feb. 24 Referred to Com. on B., P. & C.P.

Feb. 15 From printer. May be heard in committee March 17.

Feb. 14 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 27, 2012
AMENDED IN ASSEMBLY FEBRUARY 6, 2012
CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1442

Introduced by Assembly Member Wieckowski
(~~Coauthor: Coauthors: Assembly Member Members~~ Allen and Williams)

January 4, 2012

An act to amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and to add Sections 117637, 117748, and 118032 to, the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as amended, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would authorize a medical waste generator or parent organization that employs health care professionals who generate pharmaceuticals to apply to the enforcement agency for a pharmaceutical waste hauling exemption if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements *and if the facility receiving the medical*

waste retains specified documentation. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

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

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

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 117637 is added to the Health and Safety
2 Code, to read:

3 117637. “Common carrier” means either of the following:

4 (a) A person or company that has a United States Department
5 of Transportation number issued by the Federal Motor Carrier
6 Safety Administration and is registered with the Federal Motor
7 Carrier Safety Administration as a for-hire property carrier.

8 (b) A person or company that has a motor carrier of property
9 permit issued by the Department of Motor Vehicles pursuant to
10 the Motor Carriers of Property Permit Act (Division 14.85
11 (commencing with Section 34600) of the Vehicle Code) and, if
12 applicable, a carrier identification number issued by the Department
13 of the California Highway Patrol pursuant to Section 34507.5 of
14 the Vehicle Code.

15 SEC. 2. Section 117748 is added to the Health and Safety Code,
16 to read:

17 117748. (a) “Pharmaceutical waste” means any pharmaceutical,
18 as defined in Section 117747, that for any reason may no longer
19 be sold or dispensed for use as a drug.

20 (b) For purposes of this part, “pharmaceutical waste” does not
21 include any pharmaceutical that still has potential value to the
22 generator because it is being returned to a reverse distributor, as
23 defined in Section 4040.5 of the Business and Professions Code,
24 that is licensed both as a wholesaler of dangerous drugs by the

1 California State Board of Pharmacy pursuant to Section 4160 of
2 the Business and Professions Code and as a permitted transfer
3 station pursuant to Section 117775, for possible manufacturer
4 credit.

5 SEC. 3. Section 117935 of the Health and Safety Code is
6 amended to read:

7 117935. Any small quantity generator required to register with
8 the enforcement agency pursuant to Section 117930 shall file with
9 the enforcement agency a medical waste management plan, on
10 forms prescribed by the enforcement agency containing, but not
11 limited to, all of the following:

12 (a) The name of the person.

13 (b) The business address of the person.

14 (c) The type of business.

15 (d) The types, and the estimated average monthly quantity, of
16 medical waste generated.

17 (e) The type of treatment used onsite.

18 (f) The name and business address of the registered hazardous
19 waste hauler used by the generator for backup treatment and
20 disposal, for waste when the onsite treatment method is not
21 appropriate due to the hazardous or radioactive characteristics of
22 the waste,; the name of the registered hazardous waste hauler used
23 by the generator to have untreated medical waste removed for
24 treatment and disposal, and, if applicable, the name of the common
25 carrier used by the generator to transport pharmaceutical waste
26 offsite for treatment and disposal pursuant to Section 118032.

27 (g) A statement indicating that the generator is hauling the
28 medical waste generated in his or her business pursuant to Section
29 118030 and the name and any business address of the treatment
30 and disposal facilities to which the waste is being hauled, if
31 applicable.

32 (h) The name and business address of the registered hazardous
33 waste hauler service provided by the building management to
34 which the building tenants may subscribe or are required by the
35 building management to subscribe and the name and business
36 address of the treatment and disposal facilities used, if applicable.

37 (i) A statement certifying that the information provided is
38 complete and accurate.

39 SEC. 4. Section 117945 of the Health and Safety Code is
40 amended to read:

1 117945. Small quantity generators who are not required to
2 register pursuant to this chapter shall maintain on file in their office
3 all of following:

4 (a) An information document stating how the generator contains,
5 stores, treats, and disposes of any medical waste generated through
6 any act or process of the generator.

7 (b) Records of any medical waste transported offsite for
8 treatment and disposal, including the quantity of waste transported,
9 the date transported, the name of the registered hazardous waste
10 hauler or individual hauling the waste pursuant to Section 118030,
11 and, if applicable, the name of the common carrier transporting
12 pharmaceutical waste pursuant to Section 118032. The small
13 quantity generator shall maintain these records for not less than
14 two years.

15 SEC. 5. Section 117960 of the Health and Safety Code is
16 amended to read:

17 117960. Any large quantity generator required to register with
18 the enforcement agency pursuant to Section 117950 shall file with
19 the enforcement agency a medical waste management plan, on
20 forms prescribed by the enforcement agency containing, but not
21 limited to, all of the following:

22 (a) The name of the person.

23 (b) The business address of the person.

24 (c) The type of business.

25 (d) The types, and the estimated average monthly quantity, of
26 medical waste generated.

27 (e) The type of treatment used onsite, if applicable. For
28 generators with onsite medical waste treatment facilities, including
29 incinerators or steam sterilizers or other treatment facilities as
30 determined by the enforcement agency, the treatment capacity of
31 the onsite treatment facility.

32 (f) The name and business address of the registered hazardous
33 waste hauler used by the generator to have untreated medical waste
34 removed for treatment, if applicable, and, if applicable, the name
35 and business address of the common carrier transporting
36 pharmaceutical waste pursuant to Section 118032.

37 (g) The name and business address of the registered hazardous
38 waste hauler service provided by the building management to
39 which the building tenants may subscribe or are required by the
40 building management to subscribe, if applicable.

1 (h) The name and business address of the offsite medical waste
2 treatment facility to which the medical waste is being hauled, if
3 applicable.

4 (i) An emergency action plan complying with regulations
5 adopted by the department.

6 (j) A statement certifying that the information provided is
7 complete and accurate.

8 SEC. 6. Section 118000 of the Health and Safety Code is
9 amended to read:

10 118000. (a) Except as otherwise exempted pursuant to Section
11 118030 or 118032, all medical waste transported to an offsite
12 medical waste treatment facility shall be transported in accordance
13 with this chapter by a registered hazardous waste transporter issued
14 a registration certificate pursuant to Chapter 6 (commencing with
15 Section 118025) and Article 6.5 (commencing with Section
16 25167.1) of Chapter 6.5 of Division 20. A hazardous waste
17 transporter transporting medical waste shall have a copy of the
18 transporter's valid hazardous waste transporter registration
19 certificate in the transporter's possession while transporting
20 medical waste. The transporter shall show the certificate, upon
21 demand, to any enforcement agency personnel or authorized
22 employee of the Department of the California Highway Patrol.

23 (b) Except for small quantity generators transporting medical
24 waste pursuant to Section 118030 or small quantity generators or
25 common carriers transporting pharmaceutical waste pursuant to
26 Section 118032, medical waste shall be transported to a permitted
27 offsite medical waste treatment facility or a permitted transfer
28 station in leak-resistant and fully enclosed rigid secondary
29 containers that are then loaded into an enclosed cargo body.

30 (c) A person shall not transport medical waste in the same
31 vehicle with other waste unless the medical waste is separately
32 contained in rigid containers or kept separate by barriers from
33 other waste, or unless all of the waste is to be handled as medical
34 waste in accordance with this part.

35 (d) Medical waste shall only be transported to a permitted
36 medical waste treatment facility, or to a transfer station or another
37 registered generator for the purpose of consolidation before
38 treatment and disposal, pursuant to this part.

1 (e) Facilities for the transfer of medical waste shall be annually
2 inspected and issued permits in accordance with the regulations
3 adopted pursuant to this part.

4 (f) Any persons manually loading or unloading containers of
5 medical waste shall be provided by their employer at the beginning
6 of each shift with, and shall be required to wear, clean and
7 protective gloves and coveralls, changeable lab coats, or other
8 protective clothing. The department may require, by regulation,
9 other protective devices appropriate to the type of medical waste
10 being handled.

11 SEC. 7. Section 118032 is added to the Health and Safety Code,
12 to read:

13 118032. A medical waste generator or parent organization that
14 employs health care professionals who generate pharmaceutical
15 waste may apply to the enforcement agency for a pharmaceutical
16 waste hauling exemption if the generator, health care professional,
17 or parent organization meets all of the following requirements:

18 (a) The generator or parent organization has on file one of the
19 following:

20 (1) If the generator or parent organization is a small quantity
21 generator required to register pursuant to Chapter 4 (commencing
22 with Section 117915), a medical waste management plan prepared
23 pursuant to Section 117935.

24 (2) If the generator or parent organization is a small quantity
25 generator not required to register pursuant to Chapter 4
26 (commencing with Section 117915), the information document
27 maintained pursuant to subdivision (a) of Section 117945.

28 (3) If the generator or parent organization is a large quantity
29 generator, a medical waste management plan prepared pursuant
30 to Section 117960.

31 (b) The generator or health care professional who generated the
32 pharmaceutical waste transports the pharmaceutical waste himself
33 or herself, or directs a member of his or her staff to transport the
34 pharmaceutical waste to a parent organization or another health
35 care facility for the purpose of consolidation before treatment and
36 disposal, or contracts with a common carrier to transport the
37 pharmaceutical waste to a permitted medical waste treatment
38 facility or transfer station.

1 (c) Except as provided in subdivision (d), the generator
2 ~~maintains and the facility receiving the medical waste maintain a~~
3 tracking document, as specified in Section 118040.

4 (d) (1) Notwithstanding subdivision (c), if a health care
5 professional who generates pharmaceutical waste returns the
6 pharmaceutical waste to the parent organization *for the purpose*
7 *of consolidation before treatment and disposal over a period of*
8 *time*, a single-page form or multiple entry log may be substituted
9 for the tracking document, if the form or log contains all of the
10 following information:

11 (A) The name of the person transporting the pharmaceutical
12 waste.

13 (B) The number of containers of pharmaceutical waste. This
14 clause does not require any generator to maintain a separate
15 medical waste container for every patient or to maintain records
16 as to the specified source of the pharmaceutical waste in any
17 container.

18 (C) The date that the pharmaceutical waste was returned.

19 (2) *The form or log described in paragraph (1) shall be*
20 *maintained in the files of the health care professional who*
21 *generates the pharmaceutical waste and the parent organization*
22 *or another health care facility that receives the waste.*

23 ~~(2)~~

24 (3) This subdivision does not prohibit the use of a single
25 document to verify the return of more than one container to a parent
26 organization or another health care facility ~~for the purpose of~~
27 ~~consolidation before treatment and disposal over a period of time,~~
28 ~~if the form or log is maintained in the files of the parent~~
29 ~~organization or another health care facility that receives the waste~~
30 ~~once the form or log is completed, provided the form or log meets~~
31 *the requirements specified in paragraphs (1) and (2).*

32 SEC. 8. Section 118040 of the Health and Safety Code is
33 amended to read:

34 118040. (a) Except with regard to sharps waste consolidated
35 by a home-generated sharps consolidation point approved pursuant
36 to Section 117904, a hazardous waste transporter or generator
37 transporting medical waste shall maintain a completed tracking
38 document of all medical waste removed for treatment or disposal.
39 A hazardous waste transporter or generator who transports medical
40 waste to a facility, other than the final medical waste treatment

1 facility, shall also maintain tracking documents which show the
2 name, address, and telephone number of the medical waste
3 generator, for purposes of tracking the generator of medical waste
4 when the waste is transported to the final medical waste treatment
5 facility. At the time that the medical waste is received by a
6 hazardous waste transporter, the transporter shall provide the
7 medical waste generator with a copy of the tracking document for
8 the generator's medical waste records. The transporter or generator
9 transporting medical waste shall maintain its copy of the tracking
10 document for three years.

11 (b) The tracking document shall include, but not be limited to,
12 all of the following information:

13 (1) The name, address, telephone number, and registration
14 number of the transporter, unless transported pursuant to Section
15 118030.

16 (2) The type of medical waste transported and the quantity or
17 aggregate weight of medical waste transported.

18 (3) The name, address, and telephone number of the generator.

19 (4) The name, address, telephone number, permit number, and
20 the signature of an authorized representative of the permitted
21 facility receiving the medical waste.

22 (5) The date that the medical waste is collected or removed
23 from the generator's facility, the date that the medical waste is
24 received by the transfer station, the registered large quantity
25 generator, or point of consolidation, if applicable, and the date that
26 the medical waste is received by the treatment facility.

27 (c) Any hazardous waste transporter or generator transporting
28 medical waste in a vehicle shall have a tracking document in his
29 or her possession while transporting the medical waste. The
30 tracking document shall be shown upon demand to any
31 enforcement agency personnel or officer of the Department of the
32 California Highway Patrol. If the medical waste is transported by
33 rail, vessel, or air, the railroad corporation, vessel operator, or
34 airline shall enter on the shipping papers any information
35 concerning the medical waste that the enforcement agency may
36 require.

37 (d) A hazardous waste transporter or a generator transporting
38 medical waste shall provide the facility receiving the medical waste
39 with the original tracking document.

1 (e) Each hazardous waste transporter and each medical waste
2 treatment facility shall provide tracking data periodically and in a
3 format as determined by the department.

4 (f) Medical waste transported out of state shall be consigned
5 to a permitted medical waste treatment facility in the receiving
6 state. If there is no permitted medical waste treatment facility in
7 the receiving state or if the medical waste is crossing an
8 international border, the medical waste shall be treated in
9 accordance with Chapter 8 (commencing with Section 118215)
10 prior to being transported out of the state.

11 SEC. 9. Section 118165 of the Health and Safety Code is
12 amended to read:

13 118165. On and after April 1, 1991, all persons operating a
14 medical waste treatment facility shall maintain individual records
15 for a period of three years and shall report or submit to the
16 enforcement agency upon request, all of the following information:

17 (a) The type of treatment facility and its capacity.

18 (b) All treatment facility operating records.

19 (c) Copies of the tracking documents for all medical waste it
20 receives for treatment from offsite generators, hazardous waste
21 haulers, or, pursuant to Section 118032, common carriers.

22 SEC. 10. No reimbursement is required by this act pursuant to
23 Section 6 of Article XIII B of the California Constitution because
24 the only costs that may be incurred by a local agency or school
25 district will be incurred because this act creates a new crime or
26 infraction, eliminates a crime or infraction, or changes the penalty
27 for a crime or infraction, within the meaning of Section 17556 of
28 the Government Code, or changes the definition of a crime within
29 the meaning of Section 6 of Article XIII B of the California
30 Constitution.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1442 **VERSION:** Amended March 27, 2012

AUTHOR: Weickowski **SPONSOR:**

BOARD POSITION:

SUBJECT: Common Carriers to Transport Pharmaceutical Waste

Affected Sections: Add Article 5 (commencing with Section 125286.10) to Chapter 2 of Part 5 of Division 106 of the Health and Safety Code

Current Status: Referred to ASM Appropriations (3/28). As of 4/18/12, no hearing date has been set.

EXISTING LAW:

1. Establishes the Medical Waste Management Act (MWMA), administered by the State Department of Public Health (DPH) (Health and Safety Code § 117600 et seq.) to include
 - a. Requirements for Medical Waste / Small Quantity Generators (Health and Safety Code § 117915-117945), to include
 - i. Minimum information required to be contained in a small quantity generator's medical waste management plan (H&SC § 117935)
 - ii. Records that must be maintained by a small quantity generator that is not required to register (H&SC § 117945)
 - b. Requirements for Medical Waste / Large Quantity Generators (Health and Safety Code § 117950-117995)
 - c. The Licensing and Oversight of Medical Waste Haulers, requirements and exemptions (Health and Safety Code § 118000 et seq.)
 - d. Recordkeeping Requirements for the Medical Waste Treatment Facilities (Health and Safety Code § 118165)
2. Provides for the licensure and regulation of "reverse distributors" by the California State Board of Pharmacy (defined at Business and Professions Code § 4040.5)
3. Provides for the management of hazardous waste by the Department of Toxic Substances Control (Health and Safety Code Section 25100 et seq.) and related regulations (11 CCR starting at Section 6626.1)

THIS BILL WOULD:

1. Amend the Medical Waste Management Act to allow for the legal handling and transportation of pharmaceutical waste by a common carrier.
Specifically, AB 1442 would
 - a. Add a definition of “common carrier.” [SEC.1. Section 117637]
 - b. Add a definition of “pharmaceutical waste” as any pharmaceutical (defined at H&SC 117747) that for any reason may no longer be sold or dispensed for use as a drug, excluding those pharmaceuticals that are being returned to a reverse distributor (licensed by the Board) and that also is licensed as permitted transfer station (under H&SC § 117775). [SEC.2. Section 117748]
 - c. Change provisions related to Small Quantity Generators, to include
 - i. For a small quantity generator that is required to register pursuant to the MWMA, that its medical waste management plan registered with the enforcement agency also include the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal. [SEC.3. Section 17935(f)]
 - ii. For a small quantity generator that is not required to register pursuant to the MWMA, that files maintained in their office also include the name of the common carrier transporting the pharmaceutical waste. [SEC.4. Section 117945(b)]
 - d. Change provisions related to Large Quantity Generators, to include
 - i. Require that a large quantity generator’s medical waste management plan, also include the name *and business address* of the common carrier transporting pharmaceutical waste. [SEC.5, Section 117960 (f)]
 - e. Exempt from requirements that specify the manner in which medical waste shall be transported to a medical waste treatment facility or permitted transfer station, those with a pharmaceutical waste hauling exemption, a small quantity generator transporting pharmaceutical waste, or a common carrier transporting pharmaceutical waste, as specified. [SEC.6. Section 118000(a) and (b)]
 - f. Specify requirements under which a medical waste generator or parent organization that generates pharmaceutical waste may apply for a “pharmaceutical waste hauling exemption” to include specified recordkeeping requirements [SEC.7. Section 118032]
 - g. Specify that tracking documents of a hazardous waste transporter or generator of medical waste also specify the quantity or aggregate weight of medical waste transported. [SEC.8, Section 118040 §(b)(2)]
 - h. Require that the records kept and maintained by Medical Waste Treatment Facilities also include tracking documents for generators of pharmaceutical waste. [Sec.9. Section 118165(c)]

Technical issues:

Proposed Section 118032 references various documents, or medical waste management plans. With the establishment of the term “pharmaceutical waste,” technical amendments may be need to so that the section specifies documents or plans that include provisions specific to ‘pharmaceutical waste’ (as proposed at H&S 117748).

AUTHOR’S INTENT:

According to the author, AB 1442 would allow healthcare facilities to ship all non-dispensable (unwanted) pharmaceuticals designated as “medical waste” via common carriers. The author states that a substantial portion of unwanted pharmaceuticals at healthcare facilities (not designated as ‘hazardous’ under federal law) must be handled as medical waste under state law, and the transportation costs associated with the disposal of that waste “encourages healthcare facilities to illegally dispose of the pharmaceuticals via the trash or sewer system.” The author further states that allowing healthcare facilities to utilize common carriers for the transportation of “all unwanted pharmaceuticals” simply makes sense.

COMMENTS:

The Medical Waste Management Act (MWMA) currently requires pharmaceutical waste to be managed as “medical waste” which includes such material as infectious and biohazardous waste and other types of waste that have posed a potential harm to public health and safety and the environment if not managed properly. The MWMA establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements. While this is appropriate for large scale medical waste, the management of pharmaceutical waste needs a protective, yet different approach.

This proposal would make amendments to the MWMA to define pharmaceutical waste and to allow for such waste to be transported by a common carrier, yet staff is concerned that the manifesting requirements and tracking of the pharmaceutical waste may not be sufficient to ensure the drugs will not be diverted, scavenged to be sold illegally, or otherwise re-enter the drug supply chain.

The board is not aware of circumstances where healthcare facilities are illegally disposing of pharmaceuticals via the trash or sewer system. While a reasonable approach may be needed for the adequate handling and transportation of pharmaceutical waste, it is imperative that the health and safety of Californian’s not be placed at risk through access to discarded drugs.

PRIOR BOARD DISCUSSION and ACTION:

In the previous session, Senator Simitian authored SB 26, which sought to implement provisions for common carriers to pick up and transport pharmaceutical waste (drugs returned to the pharmacy by patients).

In dealing with drug take-back issues, the board has in the past sought amendments to Pharmacy Law that would have allowed pharmaceutical waste to be transported by a licensed integrated waste hauler, given sufficient recordkeeping. The board’s proposal specified that a reverse distributor shall not accept the return of dangerous drugs that have been dispensed to patients, which are later returned by the patient to the pharmacy, and would also specify that – if these drugs were accepted by the pharmacy – the drugs shall only be handled by a licensed integrated waste hauler. The board’s proposal specified recordkeeping requirements for drugs that were returned to a wholesaler or provided to a reverse distributor, to include:

- the quantity or weight of drugs returned
- the date the drugs were returned
- the names of the reverse distributors or wholesalers to whom the drugs were provided.

Also, records of drugs returned to a licensed integrated waste hauler shall specify

- the volume in weight or measurement of the pharmaceutical waste
- the date
- the name of the licensed integrated waste hauler

As AB 1442, as amended, would apply to a “parent organization that employs health care professionals” it could be interpreted that the provisions could apply to pharmacies who chose to collect unwanted drugs from patients.

SUPPORT/OPPOSITION:

Support

EXP Pharmaceutical Services Corp.
Fremont Chamber of Commerce

HISTORY:

Date Action

2012

Mar. 22 Referred to Com. on RLS.

Feb. 27 Read first time.

Feb. 25 From printer. May be acted upon on or after March 26.

Feb. 24 Introduced. To Com. on RLS. for assignment. To print.

AB 1442 (Wieckowski)

Co-Authors: Assemblymembers Allen and Williams

Common Carriers

PROBLEM

Under existing law, pharmaceutical drugs can be sent to healthcare facilities (HCFs) through standard common carriers, or standard shipping means. Unused drugs can sometimes be returned to the manufacturer for credit, via a common carrier. Expired and non-dispensable drugs must be shipped as "Medical Waste", requiring expensive hazardous waste shipping, instead of common carrier. This is unnecessarily expensive for pharmacies, hospitals, and other health care facilities, who are simply returning the exact same drug that was shipped to them by common carrier.

THIS BILL

The proposed changes to the California Medical Waste Management Act (MWMA) (Health and Safety Code Sections 117600-118360) would allow HCFs to ship all non-dispensable (unwanted) pharmaceuticals designated as "Medical Waste" under the MWMA to permitted Medical Waste Transfer Stations or Treatment Facilities via common carriers for proper processing in accordance with all applicable federal, state and local laws. Presently a substantial portion of unwanted pharmaceuticals at HCF's that are not designated as hazardous under federal law must be handled as Medical Waste under state law. This substantially increases the processing and transportation costs associated with disposing of the unwanted pharmaceuticals and encourages HCF's to illegally dispose of the pharmaceuticals via the trash or sewer system.

SUMMARY

In short, under the MWMA, HCF's must process the same unwanted pharmaceutical in different ways and at substantially different costs depending on whether the pharmaceutical drug may be returned to the manufacturer for credit. In light of the risk to the California water supply and environment, allowing HCF's to utilize common carriers for the transportation of all unwanted pharmaceuticals simply makes sense.

FACTS

- Reverse distribution helps business and healthcare facilities save money by returning drugs to pharmaceutical companies for recycling/disposal.
- Reverse distribution helps the environment and water supply by encouraging proper disposal instead of drugs ending up in trash or the sewer system.

STATUS

Introduced January 4th, 2012

Assembly Committee on Environmental Safety & Toxic Materials- March 20, 2012

SUPPORT

EXP Pharmaceutical Services Corp.
Fremont Chamber of Commerce

OPPOSITION

None on File

FOR MORE INFORMATION

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ASSEMBLY BILL

No. 2369

Introduced by Assembly Member Valadao

February 24, 2012

An act to amend Section 5024.2 of the Penal Code, relating to prisoners.

LEGISLATIVE COUNSEL'S DIGEST

AB 2369, as introduced, Valadao. Prisoners: pharmacy services.

Existing law authorizes the Department of Corrections and Rehabilitation to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient, that may incorporate a requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

This bill would instead require the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

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

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

- 1 SECTION 1. Section 5024.2 of the Penal Code is amended to
2 read:
3 5024.2. (a) The Department of Corrections and Rehabilitation
4 is authorized to maintain and operate a comprehensive pharmacy
5 services program for those facilities under the jurisdiction of the

1 department that is both cost effective and efficient, and may
2 incorporate the following:

3 (1) A statewide pharmacy administration system with direct
4 authority and responsibility for program administration and
5 oversight.

6 (2) Medically necessary pharmacy services using professionally
7 and legally qualified pharmacists, consistent with the size and the
8 scope of medical services provided.

9 (3) Written procedures and operational practices pertaining to
10 the delivery of pharmaceutical services.

11 (4) A multidisciplinary, statewide Pharmacy and Therapeutics
12 Committee responsible for all of the following:

13 (A) Developing and managing a department formulary.

14 (B) Standardizing the strengths and dosage forms for
15 medications used in department facilities.

16 (C) Maintaining and monitoring a system for the review and
17 evaluation of corrective actions related to errors in prescribing,
18 dispensing, and administering medications.

19 (D) Conducting regular therapeutic category reviews for
20 medications listed in the department formulary.

21 (E) Evaluating medication therapies and providing input to the
22 development of disease management guidelines used in the
23 department.

24 ~~(5) A requirement for the use of generic medications, when~~
25 ~~available, unless an exception is reviewed and approved in~~
26 ~~accordance with an established nonformulary approval process.~~

27 ~~(6)~~

28 (5) Use of an enterprise-based pharmacy operating system that
29 provides management with information on prescription workloads,
30 medication utilization, prescribing data, and other key pharmacy
31 information.

32 *(b) The comprehensive pharmacy services program shall require*
33 *the use of generic medications, when available, unless an exception*
34 *is reviewed and approved in accordance with an established*
35 *nonformulary approval process.*

36 ~~(b)~~

37 (c) The department is authorized to operate and maintain a
38 centralized pharmacy distribution center to provide advantages of
39 scale and efficiencies related to medication purchasing, inventory
40 control, volume production, drug distribution, workforce utilization,

1 and increased patient safety. It is the intent of the Legislature that
2 the centralized pharmacy distribution center and institutional
3 pharmacies be licensed as pharmacies by the California State Board
4 of Pharmacy meeting all applicable regulations applying to a
5 pharmacy.

6 (1) To the extent it is cost effective and efficient, the centralized
7 pharmacy distribution center should include systems to do the
8 following:

9 (A) Order and package bulk pharmaceuticals and prescription
10 and stock orders for all department correctional facilities.

11 (B) Label medications as required to meet state and federal
12 prescription requirements.

13 (C) Provide barcode validation matching the drug to the specific
14 prescription or floor stock order.

15 (D) Sort completed orders for shipping and delivery to
16 department facilities.

17 (2) Notwithstanding any other requirements, the department
18 centralized pharmacy distribution center is authorized to do the
19 following:

20 (A) Package bulk pharmaceuticals into both floor stock and
21 patient-specific packs.

22 (B) Reclaim, for reissue, unused and unexpired medications.

23 (C) Distribute the packaged products to department facilities
24 for use within the state corrections system.

25 (3) The centralized pharmacy distribution center should maintain
26 a system of quality control checks on each process used to package,
27 label, and distribute medications. The quality control system may
28 include a regular process of random checks by a licensed
29 pharmacist.

30 ~~(e)~~

31 *(d)* The department may investigate and initiate potential
32 systematic improvements in order to provide for the safe and
33 efficient distribution and control of, and accountability for, drugs
34 within the department's statewide pharmacy administration system,
35 taking into account factors unique to the correctional environment.

36 ~~(e)~~

37 *(e)* The department should ensure that there is a program
38 providing for the regular inspection of all department pharmacies
39 in the state to verify compliance with applicable law, rules,

1 regulations, and other standards as may be appropriate to ensure
2 the health, safety, and welfare of the department's inmate patients.

3 (e)

4 (f) On March 1, 2012, and each March 1 thereafter, the
5 department shall report all of the following to the Joint Legislative
6 Budget Committee, the Senate Committee on Appropriations, the
7 Senate Committee on Budget and Fiscal Review, the Senate
8 Committee on Health, the Senate Committee on Public Safety, the
9 Assembly Committee on Appropriations, the Assembly Committee
10 on Budget, the Assembly Committee on Health, and the Assembly
11 Committee on Public Safety:

12 (1) The extent to which the Pharmacy and Therapeutics
13 Committee has been established and achieved the objectives set
14 forth in this section, as well as the most significant reasons for
15 achieving or not achieving those objectives.

16 (2) The extent to which the department is achieving the objective
17 of operating a fully functioning and centralized pharmacy
18 distribution center, as set forth in this section, that distributes
19 pharmaceuticals to every adult prison under the jurisdiction of the
20 department, as well as the most significant reasons for achieving
21 or not achieving that objective.

22 (3) The extent to which the centralized pharmacy distribution
23 center is achieving cost savings through improved efficiency and
24 distribution of unit dose medications.

25 (4) A description of planned or implemented initiatives to
26 accomplish the next 12 months' objectives for achieving the goals
27 set forth in this section, including a fully functioning and
28 centralized pharmacy distribution center that distributes
29 pharmaceuticals to every adult facility under the jurisdiction of
30 the department.

31 (5) The costs for prescription pharmaceuticals for the previous
32 fiscal year, both statewide and at each adult prison under the
33 jurisdiction of the department, and a comparison of these costs
34 with those of the prior fiscal year.

35 (f)

36 (g) The requirement for submitting a report imposed under
37 subdivision ~~(e)~~ (f) is inoperative on March 1, 2016, pursuant to
38 Section 10231.5 of the Government Code.

O

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 2369 **VERSION:** Introduced February 24, 2012

AUTHOR: Valadao **SPONSOR:** Author

BOARD POSITION:

SUBJECT: Prisoners: Pharmacy Services

Affected Sections: Amend Section 5024.2 of the Penal Code

Current Status: 4/17/12 – First hearing in AS Business Professions and Consumer Protection. Failed passage. Reconsideration granted.

EXISTING LAW:

1. Requires the Department of Corrections and Rehabilitation's (CDCR) to maintain and operate a comprehensive pharmacy services program for those facilities under the jurisdiction of the department that is both cost effective and efficient.
2. Permits the CDCR to incorporate a number of components into its comprehensive pharmacy services program, to include a requirement for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.
3. Pharmacy Law, Section 4073 of the Business and Professions Code, authorizes a pharmacist filling a prescription order to 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 specified, of those drugs having the same active chemical ingredient.

THIS BILL:

1. Would amend the provisions of Section 5024.2 to require that the comprehensive pharmacy services program include a *requirement* for the use of generic medications, when available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process.

AUTHOR'S INTENT:

The author states "as management of prison health care services transitions out of the control of the federal Receiver and back to the jurisdiction of CDCR, it is critical that fiscal responsibility

is maintained while upholding quality patient care.” The author further states that generic medications are an excellent way to maintain fiscal responsibility as they have the equivalent active ingredient as the brand name versions and must work under the same safety and effectiveness standards as approved by the FDA, yet the cost is significantly less.

COMMENTS:

As introduced, no impact to Pharmacy Law.

SUPPORT/OPPOSITION:

According to the ASM Com. on Business Professions and Consumer Protection (4/17):

Support

Peace Officers Research Association of California

Oppose

BayBio

Mental Health America of California

HISTORY:

Date Action

2012

Mar. 22 Referred to Coms. on B., P. & C.P. and HEALTH.

Feb. 27 Read first time.

Feb. 26 From printer. May be heard in committee March 27.

Feb. 24 Introduced. To print.

AB 2369 (Valadao)

Department of Corrections & Rehabilitation: Pharmacy Services

SUMMARY

AB 2369 would require the Department of Corrections and Rehabilitation (CDCR) to use generic medications in their pharmacy services program for inmates. There will still be an exception approval process for brand name medications under the acting physician's care, or if a generic version of the prescribed medication is unavailable.

PROBLEM

As management of prison health care services transitions out of the control of the federal Receiver and back to the jurisdiction of CDCR, it is critical that fiscal responsibility is maintained while upholding quality patient care.

Generic medications are an excellent way to maintain fiscal responsibility as they have the equivalent active ingredient as the brand name versions and must work under the same safety and effectiveness standards as approved by the FDA, yet the cost is significantly less. However, there is no current requirement to use generic medications within the penal code.

EXISTING LAW

Under Penal Code section 5024.2, CDCR is currently *authorized* to maintain and operate a comprehensive pharmacy services program that may incorporate a requirement for use of generic medications.

THE SOLUTION

Strengthening the current code to make generic drugs mandatory when prescribing drugs to inmates (except in special physician-approved circumstances), is a common sense policy that should be adopted in order to keep health care costs lower.

FISCAL EFFECT

Unknown at this time.

SPONSOR

Author

For more information:

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AMENDED IN ASSEMBLY MARCH 29, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 2348

**Introduced by Assembly Member Mitchell
(Principal coauthor: Assembly Member Chesbro)**

February 24, 2012

An act to amend Section 2725.1 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 2348, as amended, Mitchell. Registered nurses: dispensation of drugs.

Existing law, the Nursing Practice Act, authorizes a registered nurse to dispense drugs or devices upon an order by a licensed physician and surgeon if the nurse is functioning within a specified clinic.

This bill would ~~make a nonsubstantive change to these provisions,~~ in addition, authorize a registered nurse to dispense drugs or devices upon an order issued by a certified nurse-midwife, nurse practitioner, or physician assistant if the nurse is functioning within a specified clinic. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures, if the nurse is functioning within a specified clinic.

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 2725.1 of the Business and Professions
- 2 Code is amended to read:

1 2725.1. (a) Notwithstanding any other provision of law, a
2 registered nurse may dispense drugs or devices upon an order by
3 a licensed physician and surgeon *or an order issued by a certified*
4 *nurse-midwife, nurse practitioner, or physician assistant* if the
5 nurse is functioning within a licensed primary care clinic as defined
6 in ~~paragraphs (1) and (2)~~ of subdivision (a) of Section 1204 of, or
7 within a clinic as defined in subdivision (b) or (c) of Section 1206;
8 of, the Health and Safety Code.

9 (b) *Notwithstanding any other provision of law, a registered*
10 *nurse may dispense hormonal contraceptives pursuant to*
11 *standardized procedures developed in compliance with subdivision*
12 *(c) of Section 2725 if the nurse is functioning within a licensed*
13 *primary care clinic as defined in subdivision (a) of Section 1204*
14 *of, or within a clinic as defined in subdivision (b), (c), or (h) of*
15 *Section 1206 of, the Health and Safety Code.*

16 (c) No clinic shall employ a registered nurse to perform
17 dispensing duties exclusively. No registered nurse shall dispense
18 drugs in a pharmacy, keep a pharmacy, open shop, or drugstore
19 for the retailing of drugs or poisons. No registered nurse shall
20 compound drugs. Dispensing of drugs by a registered nurse, except
21 a certified nurse-midwife who functions pursuant to a standardized
22 procedure or protocol described in Section 2746.51 or a nurse
23 practitioner who functions pursuant to a standardized procedure
24 described in Section 2836.1, or protocol, shall not include
25 substances included in the California Uniform Controlled
26 Substances Act (Division 10 (commencing with Section 11000)
27 of the Health and Safety Code). Nothing in this section shall
28 exempt a clinic from the provisions of Article 13 (commencing
29 with Section 4180) of Chapter 9.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 2348 **VERSION:** Introduced February 24, 2012
AUTHOR: Mitchell **SPONSORS:** Planned Parenthood Affiliates of Ca.
California Family Health Council
BOARD POSITION:
SUBJECT: Registered nurses: dispensation of drugs

Affected Sections: Amend Section 5024.2 of the Penal Code

Current Status: 4/17/12 – First hearing in ASM Committee on Business, Professions and Consumer Protection. Failed passage. Reconsideration granted.

EXISTING LAW:

1. Provides for the scope of practice of a Registered Nurse under the authority of the Nursing Practice Act, administered by the Board of Registered Nursing (Business and Professions Code Section 2700 et seq.).
2. A registered nurse is authorized to dispense drugs or devices in a clinic licensed pursuant to Sections 1204 or 1206, as specified. With limited exceptions, a nurse shall not dispense controlled substances. (Business and Professions Code Section 2725.1)
3. The following clinics are specified in the Health and Safety Code:
 - a. § 1204(a) – Primary Care Clinics, which include “community clinics” and “free clinics” (Licensed by Department of Public Health)
The following clinics are exempt from licensure by the Department of Public Health:
 - b. § 1206(b) – A government operated clinic, as specified.
 - c. § 1206(c) – A clinic operated by a federally recognized Indian tribe or tribal organization, as specified.
 - d. § 1206(h) – A clinic that is operated by a primary care community or free clinic that is operated as an “intermittent clinic” (one with limited hours of service, as specified).

THIS BILL WOULD:

1. Specify that in a clinic licensed pursuant to Section 1204(a) or Section 1206(b) or (c) a nurse may dispense drugs or devices upon an order by a licensed physician and surgeon *or on order issued by a certified nurse-midwife, nurse practitioner, or physician assistant*, as specified.
2. Specify that a registered nurse may dispense hormonal contraceptives in a primary care clinic (defined at Section 1204(a) of the Health and Safety Code) or in a clinic (defined at Section 1206 (b) (c) or (h) of the Health and Safety Code pursuant to an established protocol.

AUTHOR'S INTENT:

According to the author, utilizing a standardized procedure (protocol) would allow a Registered Nurse with the ability to provide hormonal contraceptives to patients after the RN conducts a patient assessment pursuant to approved medical guidelines. This includes reviewing basic health indicators like age and blood pressure, and analyzing the patient's health history. Further, the author states that AB 2348 will expand access to birth control by allowing RNs to dispense these drugs under a protocol, thereby helping to meet the needs of women.

COMMENTS:

As introduced, no impact to Pharmacy Law.

SUPPORT/OPPOSITION:

Support

Planned Parenthood Affiliates of California (Sponsor)
California Family Health Council (Sponsor)
American Nurses Association of CA

Oppose

HISTORY:

Date Action
2012

Apr. 9 Re-referred to Com. on B., P. & C.P.

Mar. 29 Referred to Com. on B., P. & C.P. From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.

Feb. 27 Read first time.

Feb. 26 From printer. May be heard in committee March 27.

Feb. 24 Introduced. To print.

Assembly Bill 2348

Access to Birth Control

Assemblymember Holly Mitchell (D – 47)

ISSUE

Across California, many women lack access to birth control, leaving them at significant risk of unintended pregnancy. In some parts of the state, patients of community health clinics cannot access hormonal contraceptives because of the limited supply of prescribers and others who are legally authorized to order or furnish these medications. Lack of enough appropriate staff can result in health centers closing or reducing hours, compounding many communities' unmet family planning needs. For a woman in need of birth control these types of shortages can mean waiting long periods of time to schedule a health center appointment, sitting in a waiting room for hours before being seen, or driving long distances to see a provider. All of these barriers place her at greater risk of unintended pregnancy.

BACKGROUND

While the Family PACT program serves 1.82 million women annually, overall only 71% of the women in need of family planning received services through Family PACT or Medi-Cal. Unmet need for family planning varies widely by county, of the 10 counties with the highest need, the proportion who accessed services ranged from 46% in San Bernardino to 75% in San Diego, with the greatest need in rural areas.

Need for the program has increased 12% since FY 2005-06, yet the percentage of patients in need who accessed services has dropped by 6% (FPACT Program Report, 2009-10). This gap is likely to become increasingly acute with the addition of the estimated 5-6 million California residents to be insured under national health reform.

Women with unintended pregnancies are more likely to receive later or no prenatal care, to smoke and consume alcohol during pregnancy (Contraception, 2009), to be depressed during pregnancy, to experience domestic violence during pregnancy, and have a higher rate of maternal death. The health consequences for the newborn are dire, including preterm birth and low birth weight, both associated with infant mortality.

An essential component of comprehensive reproductive health care for women, hormonal contraceptives are among the safest medications available today. Many respected medical institutions, including the World Health Organization (WHO), the American College of Obstetricians and Gynecologists (ACOG) and Planned Parenthood Federation of America (PPFA), have developed evidence-based guidelines for hormonal contraceptive use based on a self-reported medical history and measurement of blood pressure. All of these guidelines acknowledge that hormonal contraception can be safely provided and utilized without requiring a pelvic examination.

The Institute of Medicine (IOM) Committee on Women's Health Research recently reported a universal need for making contraceptives more available, accessible, and acceptable (IOM, 2010b). There are several barriers that women often face that keep them from being able to successfully and correctly utilize their birth control method, among these are expensive co-pays, insurance coverage limitations on prescriptions, and the difficulty or delay when scheduling an office visit.

EXISTING LAW

Current law allows for the prescribing or furnishing of drugs, including birth control, by physicians and surgeons, nurse practitioners, certified nurse

midwives, and physician's assistants. RNs in community clinics have the authority to dispense drugs based on an order from a physician or surgeon, they currently serve in this capacity by dispensing birth control to community clinic patients.

THIS BILL

This bill would build on current law by allowing RNs to dispense hormonal contraceptives, including birth control pills, transdermal contraceptive patch, and vaginal contraceptive ring, pursuant to a standardized procedure.

The Nurse Practice Act (B&P Code §2725) specifies that a standardized procedure must be developed collaboratively by the nurses, physician, and administration of a health center. Because of this interdisciplinary collaboration, there is accountability on several levels for the activities to be performed by the registered nurse.

Utilizing a standardized procedure would allow RNs to provide hormonal contraceptives to patients after the RN conducts a patient assessment based on approved medical guidelines. This includes reviewing basic health indicators like age and blood pressure and analyzing the patient's health history including history of smoking and relevant cancers in order to dispense the appropriate birth control for the patient.

SUMMARY

This bill will expand access to birth control, an essential component of women's preventive health care, by allowing RNs to dispense hormonal birth control under a standardized procedure. Increasing access while maintaining the safety of current medical guidelines will help address the significant unmet need faced by across the state.

SUPPORT

- Planned Parenthood Affiliates of California (Sponsor)
- California Family Health Council (Sponsor)

- American Nurses Association of CA

OPPOSITION

None at this time

FOR MORE INFORMATION

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Agenda Item A.1

Legislation Report

b. Sunset Review and Legislative Oversight

AMENDED IN SENATE APRIL 16, 2012

SENATE BILL

No. 1237

Introduced by Senator Price

February 23, 2012

An act to amend Sections 4001, 4003, 8000, ~~and 8005, 8027, 8030.2, and 8030.5~~ of the Business and Professions Code, relating to professions, *and making an appropriation therefor.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1237, as amended, Price. Professions: pharmacists ~~and~~, court ~~reporters: reporters, and Transcript Reimbursement Fund:~~ sunset dates.

(1) Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, pharmacists, pharmacy technicians, wholesalers of dangerous drugs or devices, and others by the California State Board of Pharmacy. Existing law authorizes the board to appoint an executive officer. Under existing law, the board and its authority to appoint an executive officer will be repealed on January 1, 2013. Under existing law, boards scheduled for repeal are required to be evaluated by the Joint Sunset Review Committee.

This bill would extend the operation of the California State Board of Pharmacy and its authority to appoint an executive officer until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

(2) Existing law provides for the licensure and regulation of court reporters by the Court Reporters Board of California within the Department of Consumer Affairs. Existing law authorizes this board to appoint an executive officer and committees as necessary. Existing law repeals these provisions on January 1, 2013.

This bill would extend the operation of these provisions until January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

Existing law requires, until January 1, 2013, certain fees and revenues collected by the board to be deposited into the Transcript Reimbursement Fund, to be available to provide reimbursement for the cost of providing shorthand reporting services to low-income litigants in civil cases. Existing law authorizes, until January 1, 2013, low-income persons appearing pro se to apply for funds from the Transcript Reimbursement Fund, subject to specified requirements and limitations. Existing law requires the board, until January 1, 2013, to publicize the availability of the fund to prospective applicants. Existing law requires the unencumbered funds remaining in the Transcript Reimbursement Fund as of January 1, 2013, to be transferred to the Court Reporters' Fund.

This bill would extend the operation of these provisions until January 1, 2017, and would make a technical change to these provisions. By extending the operation of the Transcript Reimbursement Fund, which is a continuously appropriated fund, the bill would make an appropriation.

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 4001 of the Business and Professions
2 Code is amended to read:
3 4001. (a) There is in the Department of Consumer Affairs a
4 California State Board of Pharmacy in which the administration
5 and enforcement of this chapter is vested. The board consists of
6 13 members.
7 (b) The Governor shall appoint seven competent pharmacists
8 who reside in different parts of the state to serve as members of
9 the board. The Governor shall appoint four public members, and
10 the Senate Committee on Rules and the Speaker of the Assembly
11 shall each appoint a public member who shall not be a licensee of
12 the board, any other board under this division, or any board referred
13 to in Section 1000 or 3600.
14 (c) At least five of the seven pharmacist appointees to the board
15 shall be pharmacists who are actively engaged in the practice of

1 pharmacy. Additionally, the membership of the board shall include
2 at least one pharmacist representative from each of the following
3 practice settings: an acute care hospital, an independent community
4 pharmacy, a chain community pharmacy, and a long-term health
5 care or skilled nursing facility. The pharmacist appointees shall
6 also include a pharmacist who is a member of a labor union that
7 represents pharmacists. For the purposes of this subdivision, a
8 “chain community pharmacy” means a chain of 75 or more stores
9 in California under the same ownership, and an “independent
10 community pharmacy” means a pharmacy owned by a person or
11 entity who owns no more than four pharmacies in California.

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

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

22 (f) This section shall remain in effect only until January 1, 2017,
23 and as of that date is repealed, unless a later enacted statute, that
24 is enacted before January 1, 2017, deletes or extends that date.
25 Notwithstanding any other provision of law, the repeal of this
26 section renders the board subject to review by the appropriate
27 policy committees of the Legislature.

28 SEC. 2. Section 4003 of the Business and Professions Code is
29 amended to read:

30 4003. (a) The board, with the approval of the director, may
31 appoint a person exempt from civil service who shall be designated
32 as an executive officer and who shall exercise the powers and
33 perform the duties delegated by the board and vested in him or her
34 by this chapter. The executive officer may or may not be a member
35 of the board as the board may determine.

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

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

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

9 (e) This section shall remain in effect only until January 1, 2017,
10 and as of that date is repealed, unless a later enacted statute, that
11 is enacted before January 1, 2017, deletes or extends that date.

12 SEC. 3. Section 8000 of the Business and Professions Code is
13 amended to read:

14 8000. (a) There is in the Department of Consumer Affairs a
15 Court Reporters Board of California, which consists of five
16 members, three of whom shall be public members and two of
17 whom shall be holders of certificates issued under this chapter
18 who have been actively engaged as shorthand reporters within this
19 state for at least five years immediately preceding their
20 appointment.

21 (b) This section shall remain in effect only until January 1, 2017,
22 and as of that date is repealed, unless a later enacted statute, that
23 is enacted before January 1, 2017, deletes or extends that date.

24 (c) Notwithstanding any other provision of law, the repeal of
25 this section renders the board subject to review by the appropriate
26 policy committees of the Legislature.

27 SEC. 4. Section 8005 of the Business and Professions Code is
28 amended to read:

29 8005. The Court Reporters Board of California is charged with
30 the executive functions necessary for effectuating the purposes of
31 this chapter. It may appoint committees as it deems necessary or
32 proper. The board may appoint, prescribe the duties, and fix the
33 salary of an executive officer. Except as provided by Section 159.5,
34 the board may also employ other employees as may be necessary,
35 subject to civil service and other provisions of law.

36 This section shall remain in effect only until January 1, 2017,
37 and as of that date is repealed, unless a later enacted statute, that
38 is enacted before January 1, 2017, deletes or extends that date.

39 SEC. 5. Section 8027 of the Business and Professions Code is
40 amended to read:

1 8027. (a) As used in this section, “school” means a court
2 reporter training program or an institution that provides a course
3 of instruction approved by the board and the Bureau for Private
4 Postsecondary and Vocational Education, is a public school in this
5 state, or is accredited by the Western Association of Schools and
6 Colleges.

7 (b) A court reporting school shall be primarily organized to train
8 students for the practice of shorthand reporting, as defined in
9 Sections 8016 and 8017. Its educational program shall be on the
10 postsecondary or collegiate level. It shall be legally organized and
11 authorized to conduct its program under all applicable laws of the
12 state, and shall conform to and offer all components of the
13 minimum prescribed course of study established by the board. Its
14 records shall be kept and shall be maintained in a manner to render
15 them safe from theft, fire, or other loss. The records shall indicate
16 positive daily and clock-hour attendance of each student for all
17 classes, apprenticeship and graduation reports, high school
18 transcripts or the equivalent or self-certification of high school
19 graduation or the equivalent, transcripts of other education, and
20 student progress to date, including all progress and counseling
21 reports.

22 (c) Any school intending to offer a program in court reporting
23 shall notify the board within 30 days of the date on which it
24 provides notice to, or seeks approval from, the State Department
25 of Education, the Bureau for Private Postsecondary and Vocational
26 Education, the Office of the Chancellor of the California
27 Community Colleges, or the Western Association of Schools and
28 Colleges, whichever is applicable. The board shall review the
29 proposed curriculum and provide the school tentative approval, or
30 notice of denial, within 60 days of receipt of the notice. The school
31 shall apply for provisional recognition pursuant to subdivision (d)
32 within no more than one year from the date it begins offering court
33 reporting classes.

34 (d) The board may grant provisional recognition to a new court
35 reporting school upon satisfactory evidence that it has met all of
36 the provisions of subdivision (b) and this subdivision. Recognition
37 may be granted by the board to a provisionally recognized school
38 after it has been in continuous operation for a period of no less
39 than three consecutive years from the date provisional recognition
40 was granted, during which period the school shall provide

1 satisfactory evidence that at least one person has successfully
2 completed the entire course of study established by the board and
3 complied with the provisions of Section 8020, and has been issued
4 a certificate to practice shorthand reporting as defined in Sections
5 8016 and 8017. The board may, for good cause shown, extend the
6 three-year provisional recognition period for not more than one
7 year. Failure to meet the provisions and terms of this section shall
8 require the board to deny recognition. Once granted, recognition
9 may be withdrawn by the board for failure to comply with all
10 applicable laws and regulations.

11 (e) Application for recognition of a court reporting school shall
12 be made upon a form prescribed by the board and shall be
13 accompanied by all evidence, statements, or documents requested.
14 Each branch, extension center, or off-campus facility requires
15 separate application.

16 (f) All recognized and provisionally recognized court reporting
17 schools shall notify the board of any change in school name,
18 address, telephone number, responsible court reporting program
19 manager, owner of private schools, and the effective date thereof,
20 within 30 days of the change. All of these notifications shall be
21 made in writing.

22 (g) A school shall notify the board in writing immediately of
23 the discontinuance or pending discontinuance of its court reporting
24 program or any of the program's components. Within two years
25 of the date this notice is sent to the board, the school shall
26 discontinue its court reporting program in its entirety. The board
27 may, for good cause shown, grant not more than two one-year
28 extensions of this period to a school. If a student is to be enrolled
29 after this notice is sent to the board, a school shall disclose to the
30 student the fact of the discontinuance or pending discontinuance
31 of its court reporting program or any of its program components.

32 (h) The board shall maintain a roster of currently recognized
33 and provisionally recognized court reporting schools, including,
34 but not limited to, the name, address, telephone number, and the
35 name of the responsible court reporting program manager of each
36 school.

37 (i) The board shall maintain statistics that display the number
38 and passing percentage of all first-time examinees, including, but
39 not limited to, those qualified by each recognized or provisionally

1 recognized school and those first-time examinees qualified by
2 other methods as defined in Section 8020.

3 (j) Inspections and investigations shall be conducted by the
4 board as necessary to carry out this section, including, but not
5 limited to, unannounced site visits.

6 (k) All recognized and provisionally recognized schools shall
7 print in their school or course catalog the name, address, and
8 telephone number of the board. At a minimum, the information
9 shall be in 8-point bold type and include the following statement:

10

11 “IN ORDER FOR A PERSON TO QUALIFY FROM A
12 SCHOOL TO TAKE THE STATE LICENSING EXAMINATION,
13 THE PERSON SHALL COMPLETE A PROGRAM AT A
14 RECOGNIZED SCHOOL. FOR INFORMATION CONCERNING
15 THE MINIMUM REQUIREMENTS THAT A COURT
16 REPORTING PROGRAM MUST MEET IN ORDER TO BE
17 RECOGNIZED, CONTACT: THE COURT REPORTERS
18 BOARD OF CALIFORNIA; (ADDRESS); (TELEPHONE
19 NUMBER).”

20

21 (l) Each court reporting school shall file with the board, not
22 later than June 30 of each year, a current school catalog that shows
23 all course offerings and staff, and for private schools, the owner,
24 except that where there have been no changes to the catalog within
25 the previous year, no catalog need be sent. In addition, each school
26 shall also file with the board a statement certifying whether the
27 school is in compliance with all statutes and the rules and
28 regulations of the board, signed by the responsible court reporting
29 program manager.

30 (m) A school offering court reporting shall not make any written
31 or verbal claims of employment opportunities or potential earnings
32 unless those claims are based on verified data and reflect current
33 employment conditions.

34 (n) If a school offers a course of instruction that exceeds the
35 board’s minimum requirements, the school shall disclose orally
36 and in writing the board’s minimum requirements and how the
37 course of instruction differs from those criteria. The school shall
38 make this disclosure before a prospective student executes an
39 agreement obligating that person to pay any money to the school

1 for the course of instruction. The school shall also make this
2 disclosure to all students enrolled on January 1, 2002.

3 (o) Private and public schools shall provide each prospective
4 student with all of the following and have the prospective student
5 sign a document that shall become part of that individual's
6 permanent record, acknowledging receipt of each item:

7 (1) A student consumer information brochure published by the
8 board.

9 (2) A list of the school's graduation requirements, including the
10 number of tests, the pass point of each test, the speed of each test,
11 and the type of test, such as jury charge or literary.

12 (3) A list of requirements to qualify for the state-certified
13 shorthand reporter licensing examination, including the number
14 of tests, the pass point of each test, the speed of each test, and the
15 type of test, such as jury charge or literary, if different than those
16 requirements listed in paragraph (2).

17 (4) A copy of the school's board-approved benchmarks for
18 satisfactory progress as identified in subdivision (u).

19 (5) A report showing the number of students from the school
20 who qualified for each of the certified shorthand reporter licensing
21 examinations within the preceding two years, the number of those
22 students that passed each examination, the time, as of the date of
23 qualification, that each student was enrolled in court reporting
24 school, and the placement rate for all students that passed each
25 examination.

26 (6) On and after January 1, 2005, the school shall also provide
27 to prospective students the number of hours each currently enrolled
28 student who has qualified to take the next licensing test, exclusive
29 of transfer students, has attended court reporting classes.

30 (p) All enrolled students shall have the information in
31 subdivisions (n) and (o) on file no later than June 30, 2005.

32 (q) Public schools shall provide the information in subdivisions
33 (n) and (o) to each new student the first day he or she attends theory
34 or machine speed class, if it was not provided previously.

35 (r) Each enrolled student shall be provided written notification
36 of any change in qualification or graduation requirements that is
37 being implemented due to the requirements of any one of the
38 school's oversight agencies. This notice shall be provided to each
39 affected student at least 30 days before the effective date of the
40 change and shall state the new requirement and the name, address,

1 and telephone number of the agency that is requiring it of the
2 school. Each student shall initial and date a document
3 acknowledging receipt of that information and that document, or
4 a copy thereof, shall be made part of the student's permanent file.

5 (s) Schools shall make available a comprehensive final
6 examination in each academic subject to any student desiring to
7 challenge an academic class in order to obtain credit towards
8 certification for the state licensing examination. The points required
9 to pass a challenge examination shall not be higher than the
10 minimum points required of other students completing the
11 academic class.

12 (t) An individual serving as a teacher, instructor, or reader shall
13 meet the qualifications specified by regulation for his or her
14 position.

15 (u) Each school shall provide a substitute teacher or instructor
16 for any class for which the teacher or instructor is absent for two
17 consecutive days or more.

18 (v) The board has the authority to approve or disapprove
19 benchmarks for satisfactory progress which each school shall
20 develop for its court reporting program. Schools shall use only
21 board-approved benchmarks to comply with the provisions of
22 paragraph (4) of subdivision (o) and subdivision (u).

23 (w) Each school shall counsel each student a minimum of one
24 time within each 12-month period to identify the level of attendance
25 and progress, and the prognosis for completing the requirements
26 to become eligible to sit for the state licensing examination. If the
27 student has not progressed in accordance with the board-approved
28 benchmarks for that school, the student shall be counseled a
29 minimum of one additional time within that same 12-month period.

30 (x) The school shall provide to the board, for each student
31 qualifying through the school as eligible to sit for the state licensing
32 examination, the number of hours the student attended court
33 reporting classes, both academic and machine speed classes,
34 including theory.

35 (y) The pass rate of first-time examination takers for each school
36 offering court reporting shall meet or exceed the average pass rate
37 of all first-time test takers for a majority of examinations given
38 for the preceding three years. Failure to do so shall require the
39 board to conduct a review of the program. In addition, the board
40 may place the school on probation and may withdraw recognition

1 if the school continues to place below the above-described standard
2 on the two examinations that follow the three-year period.

3 (z) A school shall not require more than one 10-minute
4 qualifying examination, as defined in the regulations of the board,
5 for a student to be eligible to sit for the state certification
6 examination.

7 (aa) A school shall provide the board the actual number of hours
8 of attendance for each applicant the school qualifies for the state
9 licensing examination.

10 (ab) The board shall, by December 1, 2001, do the following
11 by regulation as necessary:

12 (1) Establish the format that shall be used by schools to report
13 tracking of all attendance hours and actual timeframes for
14 completed coursework.

15 (2) Require schools to provide a minimum of 10 hours of live
16 dictation class each school week for every full-time student.

17 (3) Require schools to provide students with the opportunity to
18 read back from their stenographic notes a minimum of one time
19 each day to his or her instructor.

20 (4) Require schools to provide students with the opportunity to
21 practice with a school-approved speed-building audio recording,
22 or other assigned material, a minimum of one hour per day after
23 school hours as a homework assignment and provide the notes
24 from this audio recording to their instructor the following day for
25 review.

26 (5) Develop standardization of policies on the use and
27 administration of qualifier examinations by schools.

28 (6) Define qualifier examination as follows: the qualifier
29 examination shall consist of 4-voice testimony of 10-minute
30 duration at 200 words per minute, graded at 97.5 percent accuracy,
31 and in accordance with the guidelines followed by the board.
32 Schools shall be required to date and number each qualifier and
33 announce the date and number to the students at the time of
34 administering the qualifier. All qualifiers shall indicate the actual
35 dictation time of the test and the school shall catalog and maintain
36 the qualifier for a period of not less than three years for the purpose
37 of inspection by the board.

38 (7) Require schools to develop a program to provide students
39 with the opportunity to interact with professional court reporters

1 to provide skill support, mentoring, or counseling that they can
2 document at least quarterly.

3 (8) Define qualifications and educational requirements required
4 of instructors and readers that read test material and qualifiers.

5 (ac) The board shall adopt regulations to implement the
6 requirements of this section not later than September 1, 2002.

7 (ad) The board may recover costs for any additional expenses
8 incurred under the enactment amending this section in the 2001–02
9 Regular Session of the Legislature pursuant to its fee authority in
10 Section 8031.

11 *SEC. 6. Section 8030.2 of the Business and Professions Code*
12 *is amended to read:*

13 8030.2. (a) To provide shorthand reporting services to
14 low-income litigants in civil cases, who are unable to otherwise
15 afford those services, funds generated by fees received by the board
16 pursuant to subdivision (c) of Section 8031 in excess of funds
17 needed to support the board’s operating budget for the fiscal year
18 in which a transfer described below is made shall be used by the
19 board for the purpose of establishing and maintaining a Transcript
20 Reimbursement Fund. The Transcript Reimbursement Fund shall
21 be established by a transfer of funds from the Court Reporters’
22 Fund in the amount of three hundred thousand dollars (\$300,000)
23 at the beginning of each fiscal year. Notwithstanding any other
24 provision of this article, a transfer to the Transcript Reimbursement
25 Fund in excess of the fund balance established at the beginning of
26 each fiscal year shall not be made by the board if the transfer will
27 result in the reduction of the balance of the Court Reporters’ Fund
28 to an amount less than six months’ operating budget.

29 (b) All moneys held in the Court Reporters’ Fund on the
30 effective date of this section in excess of the board’s operating
31 budget for the 1996–97 fiscal year shall be used as provided in
32 subdivision (a).

33 (c) Refunds and unexpended funds that are anticipated to remain
34 in the Transcript Reimbursement Fund at the end of the fiscal year
35 shall be considered by the board in establishing the fee assessment
36 pursuant to Section 8031 so that the assessment shall maintain the
37 level of funding for the Transcript Reimbursement Fund, as
38 specified in subdivision (a), in the following fiscal year.

39 (d) The Transcript Reimbursement Fund is hereby created in
40 the State Treasury. Notwithstanding Section 13340 of the

1 Government Code, moneys in the Transcript Reimbursement Fund
2 are continuously appropriated for the purposes of this chapter.

3 (e) (1) Applicants, including applicants pursuant to Section
4 8030.5, who have been reimbursed pursuant to this chapter for
5 services provided to litigants and who are awarded court costs or
6 attorney's fees by judgment or by settlement agreement shall refund
7 the full amount of that reimbursement to the fund within 90 days
8 of receipt of the award or settlement.

9 (2) An applicant pursuant to Section 8030.5 who has been
10 reimbursed for services provided to litigants under this chapter
11 shall refund the full amount reimbursed if a court orders the
12 applicant's fee waiver withdrawn or denied retroactively pursuant
13 to Section 68636 of the Government Code, within 90 days of the
14 court's order withdrawing or denying the fee waiver.

15 (f) Subject to the limitations of this chapter, the board shall
16 maintain the fund at a level that is sufficient to pay all qualified
17 claims. To accomplish this objective, the board shall utilize all
18 refunds, unexpended funds, fees, and any other moneys received
19 by the board.

20 (g) Notwithstanding Section 16346 of the Government Code,
21 all unencumbered funds remaining in the Transcript
22 Reimbursement Fund as of January 1, ~~2013~~, 2017, shall be
23 transferred to the Court Reporters' Fund.

24 (h) This section shall remain in effect only until January 1, ~~2013~~,
25 2017, and as of that date is repealed, unless a later enacted statute,
26 that is enacted before January 1, ~~2013~~, 2017, deletes or extends
27 that date.

28 *SEC. 7. Section 8030.5 of the Business and Professions Code*
29 *is amended to read:*

30 8030.5. (a) Notwithstanding subdivision (e) of Section 8030.4,
31 as used in this chapter the term "applicant" also means an indigent
32 person, as defined in subdivision (f) of Section 8030.4, appearing
33 pro se to represent himself or herself at any stage of the case and
34 applying to receive funds from the Transcript Reimbursement
35 Fund established by this chapter.

36 (b) Notwithstanding Section 8030.6, total disbursements to
37 cover the cost of providing transcripts to all applicants pursuant
38 to this section shall not exceed thirty thousand dollars (\$30,000)
39 annually and shall not exceed one thousand five hundred dollars
40 (\$1,500) per case.

1 (c) The board shall provide a report to the Senate and Assembly
2 Committees on Judiciary by March 1, 2012, that includes a
3 summary of the expenditures and claims relating to this article,
4 including the initial fund balance as of January 1, 2011; all funds
5 received, including the amount of, and reason for, any refunds
6 pursuant to subdivision (e) of Section 8030.2; all claims received,
7 including the type of case, court involved, service for which
8 reimbursement was sought, amount paid, and amount denied, if
9 any, and the reason for denial; and all administrative fees. This
10 report shall be provided using existing resources.

11 (d) The Legislature finds and declares that there are funds
12 available for indigent pro se parties under this article only because
13 the Transcript Reimbursement Fund has not been fully utilized in
14 recent years by the eligible applicants for whom its use has been
15 intended, despite the evident financial need among legal services
16 organizations and pro bono attorneys. Accordingly, the board shall,
17 using existing resources, undertake further efforts to publicize the
18 availability of the Transcript Reimbursement Fund to prospective
19 applicants, as defined in subdivision (e) of Section 8030.4, through
20 appropriate entities serving these applicants, including the State
21 Bar of California, the California Commission on Access to Justice,
22 and the Legal Aid Association of California. These efforts shall
23 be described in the report required by subdivision (c).

24 (e) This section shall remain in effect only until January 1, ~~2013~~,
25 2017, and as of that date is repealed, unless a later enacted statute
26 that is enacted before January 1, ~~2013~~, 2017, deletes or extends
27 that date.

The Senate Committee on Business, Professions and Economic Development held an oversight hearing on March 19, 2012, at which Board President Stan Weisser and Executive Officer Virginia (Giny) Herold testified on a variety of issues, including the following topics:

- Effectiveness of the Board's Substance Abuse Recovery Program
- Drug Diversion and Prescription Monitoring Program (CURES)
- E-Pedigree
- Implementation of Patient-Centered Prescription Label Requirements
- Drug Take-Back and reuse Program

STAFF RECOMMENDATION:

Board staff recommends a **SUPPORT** position for SB 1237.



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

April 16, 2012

The Honorable Curren Price
Chair,
Senate Business, Professions and Economic Development Committee
State Capitol, Room 2057
Sacramento, CA 95814

RE: Senate Bill 1237

Dear Senator Price:

On behalf of the California State Board of Pharmacy, thank you for authoring Senate Bill 1237, which would extend the board's sunset date for four years.

The board is grateful for the committee's support over the years for the our consumer protection activities. We look forward to responding to any inquiries members may have about our operations, activities and achievements as this bill moves through the Capitol. We will be in attendance in all legislative committee hearings.

Please do not hesitate to contact me with questions at (916) 574-7911.

Sincerely,

A handwritten signature in black ink, appearing to read "Virginia Herold", written over the typed name and title.

VIRGINIA HEROLD
Executive Officer

Agenda Item A.1

Legislation Report

c. Licensing and Pharmacy Operations

Introduced by Senator RubioFebruary 16, 2012

An act to amend Sections 4190 and 4195 of, and to amend the heading of Article 14 (commencing with Section 4190) of Chapter 9 of Division 2 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1095, as introduced, Rubio. Pharmacy: clinics.

Existing law, the Pharmacy Law, provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy and makes a knowing violation of its provisions a crime. Existing law authorizes a surgical clinic, as defined, that is licensed by the board to purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the surgical clinic. Existing law prohibits a surgical clinic from operating without a license issued by the board. Existing law requires these surgical clinics to comply with various regulatory requirements and to maintain specified records. Existing law authorizes the board to inspect a surgical clinic at any time in order to determine whether a surgical clinic is operating in compliance with certain requirements.

This bill would expand these provisions to additionally authorize an outpatient setting or an ambulatory surgical center, as specified, to purchase drugs at wholesale for administration or dispensing, subject to the requirements applicable to surgical clinics. The bill would delete the requirement that a surgical clinic be licensed by the board but would require the clinics described above to be licensed in order to receive the benefits of these provisions. The bill would specify that the board is authorized to inspect only a clinic that is licensed by the board.

Because a knowing violation of these requirements by outpatient settings and ambulatory surgical centers would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

1 SECTION 1. This act shall be known and may be cited as the
2 California Outpatient Pharmacy Patient Safety and Improvement
3 Act.

4 SEC. 2. The heading of Article 14 (commencing with Section
5 4190) of Chapter 9 of Division 2 of the Business and Professions
6 Code is amended to read:

7
8 Article 14. ~~Surgical~~Clinics
9

10 SEC. 3. Section 4190 of the Business and Professions Code is
11 amended to read:

12 4190. (a) *For the purposes of this article, "clinic" means a*
13 *surgical clinic licensed pursuant to paragraph (1) of subdivision*
14 *(b) of Section 1204 of the Health and Safety Code, an outpatient*
15 *setting accredited by an accreditation agency, as defined in Section*
16 *1248 of the Health and Safety Code, or an ambulatory surgical*
17 *center certified to participate in the Medicare Program under Title*
18 *XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et*
19 *seq.).*

20 (a)
21 (b) Notwithstanding any provision of this chapter, a ~~surgical~~
22 ~~clinic, as defined in paragraph (1) of subdivision (b) of Section~~
23 ~~1204 of the Health and Safety Code~~ clinic may purchase drugs at
24 wholesale for administration or dispensing, under the direction of
25 a physician *and surgeon*, to patients registered for care at the clinic,
26 as provided in subdivision ~~(b)~~ (c). The clinic shall keep records of
27 the kind and amounts of drugs purchased, administered, and

1 dispensed, and the records shall be available and maintained for
2 a minimum of three years for inspection by all properly authorized
3 personnel.

4 ~~(b)~~

5 (c) The drug distribution service of a ~~surgical~~ clinic shall be
6 limited to the use of drugs for administration to the patients of the
7 ~~surgical~~ clinic and to the dispensing of drugs for the control of
8 pain and nausea for patients of the clinic. Drugs shall not be
9 dispensed in an amount greater than that required to meet the
10 patient's needs for 72 hours. Drugs for administration shall be
11 those drugs directly applied, whether by injection, inhalation,
12 ingestion, or any other means, to the body of a patient for his or
13 her immediate needs.

14 ~~(e)~~

15 (d) No ~~surgical~~ clinic shall ~~operate without a license issued by~~
16 ~~the board nor shall it~~ be entitled to the benefits of this section until
17 it has obtained a license from the board. A separate license shall
18 be required for each clinic location. A clinic *licensed by the board*
19 shall notify the board of any change in the clinic's address on a
20 form furnished by the board.

21 ~~(d) Any~~

22 (e) *If a clinic is licensed by the board, any proposed change in*
23 *ownership or beneficial interest in the licensee shall be reported*
24 *to the board, on a form to be furnished by the board, at least 30*
25 *days prior to the execution of any agreement to purchase, sell,*
26 *exchange, gift or otherwise transfer any ownership or beneficial*
27 *interest or prior to any transfer of ownership or beneficial interest,*
28 *whichever occurs earlier.*

29 (f) *Nothing in this section shall limit the ability of a physician*
30 *and surgeon or a group medical practice to prescribe, dispense,*
31 *administer, or furnish drugs at a clinic as provided in Sections*
32 *2241.5, 2242, and 4170.*

33 SEC. 4. Section 4195 of the Business and Professions Code is
34 amended to read:

35 4195. The board shall have the authority to inspect a clinic *that*
36 *is licensed pursuant to this article* at any time in order to determine
37 whether ~~a the~~ clinic is, or is not, operating in compliance with this
38 article and all other provisions of the law.

39 SEC. 5. No reimbursement is required by this act pursuant to
40 Section 6 of Article XIII B of the California Constitution because

1 the only costs that may be incurred by a local agency or school
2 district will be incurred because this act creates a new crime or
3 infraction, eliminates a crime or infraction, or changes the penalty
4 for a crime or infraction, within the meaning of Section 17556 of
5 the Government Code, or changes the definition of a crime within
6 the meaning of Section 6 of Article XIII B of the California
7 Constitution.

O

AUTHOR'S INTENT:

According to the author's office, SB 1095 would expand the term "clinic" to include accredited or Medicare certified Ambulatory Surgical Centers (ASCs) and would allow these ASCs to obtain a license from the board so that they can purchase drugs at wholesale. This measure is intended to provide a solution for clinics seeking board licensure following *Capen v. Shewry* which prohibited CDPH from issuing licenses to surgical clinics that were either partially or fully owned by a physician(s). Also according to the author, approximately 90 percent of ASCs have some form of physician ownership.

FISCAL IMPACT:

The initial application fee for a clinic license is \$400; annual renewal is \$250. Any increase in staff processing of applications would be offset by the application/renewal fees.

The board would require one additional Board Inspector to inspect new applicant/facilities and to conduct annual inspections of those clinics to ensure the compliance with Pharmacy laws and regulations. Personnel costs for one Board Inspector would be \$164,000 per fiscal year.

Capen v. Shewry (2007) 155 Cal.App.4th 378, 384-385

In response to a lawsuit that the California Department of Public Health was involved in regarding the regulation of a physician-owned ambulatory surgical clinic, several legislative remedies have been offered. Past remedies have generally expanded the conditions for licensure to allow the board to license surgical clinics that participate in the Medicare Program as well as those that were accredited by an approved agency. A summary of the lawsuit is provided below.

The California Court of Appeal interpreted the Health and Safety Code exclusion highlighted above to "...exclude physician owned and operated surgical clinics from licensing by the Department, leaving them, when using general anesthesia, to accreditation and regulation by the Medical Board." (*Capen v. Shewry* (2007) 155 Cal.App.4th 378, 384-385.) In short, this ruling means that ambulatory surgical clinics owned and operated by physicians do not qualify as "surgical clinics" within the meaning of Health and Safety Code section 1204(b)(1).

Consequently, pursuant to the "*Capen* decision," the California Department of Public Health (CDPH) no longer issues their licenses to physician-owned (either in whole or in part) ambulatory surgical clinics. Although the Court opined that the Medical Board was the appropriate regulator of these physician-owned clinics, the Medical Board does not have statutory authority to regulate these facilities, only the physicians practicing in them. The Medical Board only has authority to approve the agencies that accredit outpatient surgery centers where general anesthesia will be used. (Business and Professions Code section 2216; Health and Safety Code section 1248.1.)

As a result of the ruling, the California State Board of Pharmacy could no longer issue permits to ambulatory surgical clinics (ASCs) with physician ownership.

PREVIOUS LEGISLATION

AB 847 (Lowenthal) was significantly similar to SB 1095. The board had an Oppose Unless Amended position, stating that board licensure should be required. The measure died in ASM Committee on Health without being heard.

AB 2292 (Lowenthal) of 2010 contained provisions that would have expanded the conditions under which the board can issue a clinic license including surgical clinics licensed by the Department of Public Health, those certified to participate in the Medicare Program and those accredited by an approved agency. The board had a support position on this bill that was subsequently vetoed by Governor Schwarzenegger with the following veto message.

“This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California.”

AB 1574 (Plescia) of 2008 would have expended the board’s licensing authority to issue a (surgical) clinic permit to clinics that are Medicare certified or accredited by a recognized accreditation agency, require the board to perform inspections within 120 days of issuing a clinic license (and at least annually thereafter), and establish a self-assessment requirement. AB 1574 was vetoed by the Governor who stated that the bill failed to address the larger issue concerning the Capen v. Shewry ruling. The board had a Support position on this bill.

AB 2122 (Plescia) of 2008 would have required surgical clinics to meet prescribed licensing requirements and standards, including compliance with Medicare conditions of participation, and also contained provisions nearly identical to those proposed in AB 1574. AB 2122 died in Assembly Appropriations Committee. The board did not have a position on this bill.

AB 543 (Plescia) of 2007 also would have required surgical clinics to meet specified operating and staffing standards, to limit surgical procedures, as specified, and to develop and implement policies and procedures consistent with Medicare conditions of participation, including interpretive guidelines. AB 543 was vetoed by the Governor who stated that the bill did not establish appropriate time limits for performing surgery under general anesthesia,

inappropriately restricted administrative flexibility, and created fiscal pressure during ongoing budget challenges. The board had a Support position on this bill.

AB 2308 (Plescia) of 2006 – This bill was vetoed by the governor. The veto message stated. “While I recognize the need for the Department of Health Services to develop clear licensing standards for surgical clinics, I am unable to support Assembly Bill 2308 because it does not establish such standards, but rather statutorily mandates creation of another advisory committee and provides an unrealistic timeframe to operate within. I am directing the Department of Health Services to work with stakeholders to develop standards that will effectively promote quality care in these facilities and to pursue legislation, as needed, to provide licensing standards for surgical clinics in a timely manner.” The board had no position on this bill.

COMMENTS:

Following *Capen*, the board has consistently supported measures that allowed the board to expand its licensing of clinics to also include accredited outpatient settings (as specified), or to those that are Medicare certified.

Board licensure allows a clinic to purchase drugs at wholesale and allows for a common drug supply from which prescribers may dispense in amounts to meet the patient’s needs for a 72 hour period. Equally important is the regulatory oversight to ensure that a clinic complies with applicable laws and regulations related to drug distribution, to ensure that inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are carried out in a manner that is consistent with the promotion and protection of the health and safety of the public. This includes the requirement that a clinic have a professional director and the requirement to retain a consulting pharmacist who is responsible for approving the policies and procedures in conjunction with the director.

SEC.3 (starting on p. 2. line 12)

This bill would allow expand the definition of a “clinic” to include all of the following:

- A surgical clinic licensed per H&SC 1204 (b)(1) [*these are licensed by CDPH/current law*]
- An outpatient setting accredited by an accreditation agency, as defined at H&SC 1248 [this includes in vitro fertilization clinics]
- An ambulatory surgical center that is Medicare certified

SB 1095 makes this licensure permissive – not mandatory. This would be the case even for surgical clinics that are currently licensed by the board. For those entities that are not required by to be licensed by the Department of Public Health – and for those or others who would not seek licensure from the board – there may be a lack of regulatory oversight of a clinic’s drug stock to ensure it is consistent with the promotion and protection of the health and safety of the public.

SEC.3 (starting at p. 3, line 15)

SB 1095 would amend existing subdivision (c) of Section 4190 to strike the requirement that a surgical clinic be licensed by the board. The board has consistently supported measures that allow the board to expand its authority to license clinics. The board, however, has also opposed provisions that make board licensure optional (AB 847).

SEC.3 (p. 3, line 29)

SB 1095 seeks to amend Section 4190 to add a subdivision (f) which would re-state the right of a physician and surgeon to dispense drugs as provided in B&PC Section 4170. Board staff feels this amendment is unnecessary. B&PC 4170 stands as current law. To say “*Nothing in this section shall limit...*” could cause concern that drug distribution in a clinic may not be limited to an amount needed to meet the patient’s needs for a 72-hour period.

SEC.4 (starting on p. 3, line 35)

SB 1095 would amend Section 4195 to specify that the board shall have the authority to inspect *only those clinics* that are licensed by the board. Should the board feel that board licensure for these clinics be mandatory, these amendments would not be necessary.

STAFF RECOMMENDATION

Based on the comments provided and the board’s positions on previous measures related to the licensing of surgical clinics, staff recommends an **Oppose Unless Amended** position to address the following:

- Strike proposed amendments that make board licensure optional, and related amendments to Section 4195.
- Strike the proposed language at Section 4190, subdivision (f), as it is unnecessary.

SUPPORT/OPPOSITION

According to the author, the following entities support SB 1095 *(as of 4/3/12)*:

Ca. Ambulatory Surgery Association (sponsor)	Oasis Surgery Center
Advanced Eye Surgery Center	Orthopaedic Surgery Center
Airport Endoscopy Center	OtayLakes Surgery Center
AmSurg Corp	Outpatient Surgery Center of La Jolla
Antelope Valley Surgery Center	Pain Diagnostic and Treatment Center
ASD Management	Parkway Endoscopy Center
Aspen Surgery Center	Physicians Plaza Surgical Center
Brentwood Surgery Center	Pleasanton Surgery Center
Carlsbad Surgery Center	Rancho Bernardo Surgery Center
Central California Endoscopy Center	Redding Endoscopy Center
Coast Surgery Center	Riverside Surgery Center
East Bay Endosurgery	Roseville Surgery Center
El Camino Surgery Center	San Luis Obispo Surgery Center
Glendale Eye Surgery Center	San Mateo Surgery Center
Glendora Digestive Disease Institute	Skyway Surgery Center
Golden Triangle Surgicenter	Southwest Surgical Center
Hacienda Surgery Center	Surgery Center of Santa Monica
Hope Square Surgical Center	Surgery Center of the Pacific
Inland Surgery Center	Surgical Care Affiliates
La Jolla Endoscopy Center	Temecula Valley Endoscopy Center
Millennium Surgery Center	Templeton Endoscopy Center
Monterey Peninsula Surgery Centers	The Oaks Surgery Center
Monterey Peninsula Surgery Centers	The Surgery Center of Santa Rosa
National Surgical Hospitals	United Surgical Partners
North Coast Surgery Center	Valley Digestive Health Center

Opposition:

None known as of 4/16/2012

HISTORY:

2012

Apr. 9 From committee (SEN BP&ED): Do pass and re-refer to Com. on APPR.
(Ayes 8. Noes 0.) (April 9). Re-referred to Com. on APPR.

Mar. 21 Set for hearing April 9.

Mar. 1 Referred to Com. on B., P. & E.D.

Feb. 17 From printer. May be acted upon on or after March 18.

Feb. 16 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Introduced by Senator Negrete McLeod

February 24, 2012

An act to amend Sections 1241 and 4052.4 of the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

SB 1481, as introduced, Negrete McLeod. Clinical laboratories: community pharmacies.

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, subject to certain exceptions. Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA).

This bill would exempt a community pharmacy that solely provides certain tests classified as waived under CLIA from the clinical laboratory regulations, provided that the tests are performed by a pharmacist, as specified, and the pharmacy obtains a certificate of waiver and complies with all other requirements under CLIA.

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

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

- 1 SECTION 1. Section 1241 of the Business and Professions
- 2 Code is amended to read:

1 1241. (a) This chapter applies to all clinical laboratories in
2 California or receiving biological specimens originating in
3 California for the purpose of performing a clinical laboratory test
4 or examination, and to all persons performing clinical laboratory
5 tests or examinations or engaging in clinical laboratory practice
6 in California or on biological specimens originating in California,
7 except as provided in subdivision (b).

8 (b) This chapter shall not apply to any of the following clinical
9 laboratories, or to persons performing clinical laboratory tests or
10 examinations in any of the following clinical laboratories:

11 (1) Those owned and operated by the United States of America,
12 or any department, agency, or official thereof acting in his or her
13 official capacity to the extent that the Secretary of the federal
14 Department of Health and Human Services has modified the
15 application of CLIA requirements to those laboratories.

16 (2) Public health laboratories, as defined in Section 1206.

17 (3) Those that perform clinical laboratory tests or examinations
18 for forensic purposes only.

19 (4) Those that perform clinical laboratory tests or examinations
20 for research and teaching purposes only and do not report or use
21 patient-specific results for the diagnosis, prevention, or treatment
22 of any disease or impairment of, or for the assessment of the health
23 of, an individual.

24 (5) Those that perform clinical laboratory tests or examinations
25 certified by the National Institutes on Drug Abuse only for those
26 certified tests or examinations. However, all other clinical
27 laboratory tests or examinations conducted by the laboratory are
28 subject to this chapter.

29 (6) Those that register with the State Department of Health
30 Services pursuant to subdivision (c) to perform blood glucose
31 testing for the purposes of monitoring a minor child diagnosed
32 with diabetes if the person performing the test has been entrusted
33 with the care and control of the child by the child’s parent or legal
34 guardian and provided that all of the following occur:

35 (A) The blood glucose monitoring test is performed with a blood
36 glucose monitoring instrument that has been approved by the
37 federal Food and Drug Administration for sale over the counter to
38 the public without a prescription.

39 (B) The person has been provided written instructions by the
40 child’s health care provider or an agent of the child’s health care

1 provider in accordance with the manufacturer’s instructions on the
2 proper use of the monitoring instrument and the handling of any
3 lancets, test strips, cotton balls, or other items used during the
4 process of conducting a blood glucose test.

5 (C) The person, receiving written authorization from the minor’s
6 parent or legal guardian, complies with written instructions from
7 the child’s health care provider, or an agent of the child’s health
8 care provider, regarding the performance of the test and the
9 operation of the blood glucose monitoring instrument, including
10 how to determine if the results are within the normal or therapeutic
11 range for the child, and any restriction on activities or diet that
12 may be necessary.

13 (D) The person complies with specific written instructions from
14 the child’s health care provider or an agent of the child’s health
15 care provider regarding the identification of symptoms of
16 hypoglycemia or hyperglycemia, and actions to be taken when
17 results are not within the normal or therapeutic range for the child.
18 The instructions shall also contain the telephone number of the
19 child’s health care provider and the telephone number of the child’s
20 parent or legal guardian.

21 (E) The person records the results of the blood glucose tests and
22 provides them to the child’s parent or legal guardian on a daily
23 basis.

24 (F) The person complies with universal precautions when
25 performing the testing and posts a list of the universal precautions
26 in a prominent place within the proximity where the test is
27 conducted.

28 (7) Those individuals who perform clinical laboratory tests or
29 examinations, approved by the federal Food and Drug
30 Administration for sale to the public without a prescription in the
31 form of an over-the-counter test kit, on their own bodies or on their
32 minor children or legal wards.

33 (8) Those certified emergency medical technicians and licensed
34 paramedics providing basic life support services or advanced life
35 support services as defined in Section 1797.52 of the Health and
36 Safety Code who perform only blood glucose tests that are
37 classified as waived clinical laboratory tests under CLIA, if the
38 provider of those services obtains a valid certificate of waiver and
39 complies with all other requirements for the performance of waived
40 clinical laboratory tests under applicable federal regulations.

1 (9) A community pharmacy that is providing only those tests
2 identified in Section 1246.5, provided that both of the following
3 requirements are satisfied:

4 (A) The pharmacy obtains a valid certificate of waiver and
5 complies with all other requirements for the performance of waived
6 clinical laboratory tests under applicable federal regulations.

7 (B) The tests are performed by a pharmacist, as defined in
8 Section 4036, in the course of performing routine patient
9 assessment procedures in compliance with Section 4052.4.

10 (c) Any place where blood glucose testing is performed pursuant
11 to paragraph (6) of subdivision (b) shall register by notifying the
12 State Department of Health Services in writing no later than 30
13 days after testing has commenced. Registrants pursuant to this
14 subdivision shall not be required to pay any registration or renewal
15 fees nor shall they be subject to routine inspection by the State
16 Department of Health Services.

17 SEC. 2. Section 4052.4 of the Business and Professions Code
18 is amended to read:

19 4052.4. Notwithstanding Section 2038 or any other provision
20 of law, a pharmacist may perform skin puncture in the course of
21 performing routine patient assessment procedures or in the course
22 of performing any procedure authorized under Section 1206.5 or
23 paragraph (9) of subdivision (b) of Section 1241. For purposes of
24 this section, "routine patient assessment procedures" means: (a)
25 procedures that a patient could, with or without a prescription,
26 perform for himself or herself, or (b) clinical laboratory tests that
27 are classified as waived pursuant to the federal Clinical Laboratory
28 Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the
29 regulations adopted thereunder by the federal Health Care
30 Financing Administration, as authorized by paragraph (11) of
31 subdivision (a) of Section 1206.5 or paragraph (9) of subdivision
32 (b) of Section 1241. A pharmacist performing these functions shall
33 report the results obtained from a test to the patient and any
34 physician designated by the patient. Any pharmacist who performs
35 the service authorized by this section shall not be in violation of
36 Section 2052.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NO.:	SB 1481	VERSION:	I – Feb. 24, 2012
AUTHOR:	Negrete McLeod	Committee Recommendation:	
SUBJECT:	Clinical Laboratories: Community Pharmacies (CLIA Waived Tests)		

Affected Sections: Amend Sections 1241 and 4052.4 of the Business and Professions Code

CURRENT STATUS:

In Senate Appropriations. As of 4/18/12, no hearing date set.

On 4/9/12, passed out of SEN Committee on Business, Professions and Economic Development

EXISTING LAW:

Existing law provides for the licensure and regulation of clinical laboratories and various clinical laboratory personnel by the State Department of Public Health, Laboratory Field Services (CDPH-LFS), subject to certain exceptions. Health and Safety Code section 1246.5 specifies tests that may be conducted pursuant to that section. Those tests are approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test.

The provisions of Section 1241 of the Health and Safety Code applies to all clinical laboratories in California or those receiving biological specimens originating in California for the purpose of performing a clinical laboratory test, to all persons performing clinical laboratory tests, or engaging in clinical laboratory practice, with specified exceptions. Among those that the provisions of Section 1241 do not apply to, include emergency medical technicians and paramedics who perform blood glucose tests that are classified as waived under CLIA, so long as the provider obtains a valid certificate of waiver and complies with other requirements for the performance of waived tests under federal regulations.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy and authorizes a pharmacist to perform skin puncture in the course of performing clinical laboratory tests in a clinic, as specified. These tests include clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) (see B&PC 4052.4).

The federal Centers for Medicare & Medicaid Services (CMS) grants CLIA Waivers to entities that conduct only those tests which are deemed 'waived' by CMS. These are tests which are determined to be so simple that there is little risk of error.

THIS BILL WOULD:

Exempt from the licensure and regulation of clinical laboratories a community pharmacy that provides specified tests that are classified as waived under CLIA from the clinical laboratory regulations, provided that the tests are performed by a pharmacist, as specified, and the pharmacy obtains a certificate of waiver and complies with all other requirements under CLIA. This bill would make conforming changes to Section 4052.4 of the business and professions code, which currently authorizes a pharmacist to conduct these tests in specified settings.

AUTHOR'S INTENT:

According to the author, there is a growing need for consumers to have access to basic laboratory tests that are related to medication therapy. The New England Healthcare Institute states that "poor medication adherence is exacting a heavy toll in the form of unnecessary illness, disability and premature mortality, particularly among the burgeoning number of chronically ill patients in the U.S. Poor medication adherence in all its manifestations costs the U.S. upwards of \$290 billion per year in unnecessary health care spending. There are commercially available tests that can help patients and their medical providers monitor therapy and disease. With the results of these tests, appropriate adjustments to treatment can be made in a timely manner.

"Passage of this legislation will result in easier access to safe, simple, and economic tests – especially for low income individuals – less crowding in physicians' offices, and an improved ability of pharmacists to provide meaningful feedback to their patients when providing drug consultations required by law."

COMMENTS:

This bill would allow a pharmacist in a community pharmacy to perform only specific tests which are "waived" by CLIA – the same tests that a pharmacist is currently authorized to conduct in a clinic setting, pursuant to Section 4052.4. The California Legislature has declared that the practice of pharmacy is a dynamic patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.

STAFF RECOMMENDATION:

Support

BILL HISTORY

2012

- Apr. 9 From committee: Do pass and re-refer to Com. on APPR. (Ayes 8.
Noes 0. Page 3087.) (April 9). Re-referred to Com. on APPR.
- Mar. 27 Set for hearing April 9.
- Mar. 22 Referred to Com. on B., P. & E.D.
- Feb. 27 Read first time.
- Feb. 25 From printer. May be acted upon on or after March 26.
- Feb. 24 Introduced. To Com. on RLS. for assignment. To print.

Senate Bill 1481 (Negrete McLeod)

Pharmacy: CLIA Waived Tests

PURPOSE

This narrowly crafted bill would allow pharmacists to perform specific CLIA-waived tests, such as glucose level or cholesterol tests, without the need to hire a laboratory director.

BACKGROUND

There is a growing need for consumers to have access to basic laboratory tests that are related to medication therapy. The New England Healthcare Institute states that “poor medication adherence is exacting a heavy toll in the form of unnecessary illness, disability and premature mortality, particularly among the burgeoning number of chronically ill patients in the U.S. Poor medication adherence in all its manifestations costs the U.S. upwards of \$290 billion per year in unnecessary health care spending.”¹ There are many commercially available tests that can help patients and their medical providers monitor therapy and disease. With the results of these tests, appropriate adjustments to treatment can be made in a timely manner.

NEED FOR THE BILL

Passage of this legislation will result in greater access to safe, simple and economical tests that will play a crucial role in improving drug therapy, especially for patients with complex and chronic conditions, and improve public health.

SUPPORT

California Pharmacists Association

OPPOSITION

None Known

KEY CONTACTS

Missy Johnson
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AMENDED IN ASSEMBLY APRIL 14, 2011

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 377

Introduced by Assembly Member Solorio

February 14, 2011

An act to amend Sections 4029 and 4033 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 377, as amended, Solorio. Pharmacy.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies, including hospital pharmacies, by the California State Board of Pharmacy, and makes a knowing violation of that law a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location. Under existing law, a hospital pharmacy, as defined, includes a pharmacy located outside of the hospital in another physical plant. However, as a condition of licensure by the board for these pharmacies, pharmaceutical services may only be provided to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located and those services must be directly related to the services or treatment plan administered in the physical plant. Existing law imposes various requirements on manufacturers, as defined, and states that a manufacturer does not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription.

This bill would provide that a hospital pharmacy also includes a pharmacy, licensed by the board, that may be located outside of the hospital in either another physical plant on the same premises or on a separate premises, located within a 100-mile radius of the hospital, that is regulated under a hospital's license, *but would impose limitations on the services provided by a centralized hospital pharmacy*. The bill would eliminate the conditions of licensure by the board that limit the services provided by the pharmacy in the other physical plant, but would require that any unit-dose medication produced by a hospital pharmacy under common ownership be barcoded to be readable at the patient's bedside. The bill would authorize a hospital pharmacy to prepare and store a limited quantity of unit-dose medications in advance of a patient-specific prescription under certain circumstances. The bill would also provide that a "manufacturer" does not mean a pharmacy compounding or repackaging a drug for parenteral therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership in order to dispense or administer the drug to the patient or patients pursuant to a prescription or order. The bill would require a pharmacy compounding or repackaging a drug pursuant to this provision to notify the board of the location of the compounding or repackaging within a specified period of time. Because a knowing violation of the bill's requirements would be a crime, the bill would impose a state-mandated local program.

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

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

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

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

- 1 SECTION 1. Section 4029 of the Business and Professions
- 2 Code is amended to read:
- 3 4029. (a) "Hospital pharmacy" means and includes a pharmacy,
- 4 licensed by the board, located within any licensed hospital,
- 5 institution, or establishment that maintains and operates organized
- 6 facilities for the diagnosis, care, and treatment of human illnesses
- 7 to which persons may be admitted for overnight stay and that meets

1 all of the requirements of this chapter and the rules and regulations
2 of the board.

3 (b) A hospital pharmacy also includes a pharmacy, licensed by
4 the board, that may be located outside of the hospital, in either
5 another physical plant on the same premises or on a separate
6 premises, located within a ~~100-mile~~ 100-mile radius of the hospital,
7 that is regulated under a hospital’s license. *A centralized hospital*
8 *pharmacy may only provide pharmaceutical services to its own*
9 *patients who are either admitted or registered patients of a hospital*
10 *within the same health care system.* Nothing in this subdivision
11 shall be construed to restrict or expand the services that a hospital
12 pharmacy may provide.

13 (c) Any unit-dose medication produced by a hospital pharmacy
14 under common ownership, as described in Section 4033, shall be
15 barcoded to be readable at the patient’s bedside.

16 (d) A hospital pharmacy may prepare and store a limited quantity
17 of unit-dose medications in advance of receipt of a patient-specific
18 prescription in a quantity as is necessary to ensure continuity of
19 care for an identified population of patients of the hospital based
20 on a documented history of prescriptions for that patient population.

21 (e) Nothing in this section shall limit the obligation of a hospital
22 pharmacy, hospital, or pharmacist to comply with all applicable
23 federal and state laws.

24 SEC. 2. Section 4033 of the Business and Professions Code is
25 amended to read:

26 4033. (a) (1) “Manufacturer” means and includes every person
27 who prepares, derives, produces, compounds, or repackages any
28 drug or device except a pharmacy that manufactures on the
29 immediate premises where the drug or device is sold to the ultimate
30 consumer.

31 (2) Notwithstanding paragraph (1), “manufacturer” shall not
32 mean a pharmacy compounding or repackaging a drug for
33 parenteral therapy or oral therapy in a hospital for delivery to
34 another pharmacy or hospital under common ownership for the
35 purpose of dispensing or administering the drug, pursuant to a
36 prescription or order, to the patient or patients named in the
37 prescription or order. A pharmacy compounding or repackaging
38 a drug as described in this paragraph shall notify the board in
39 writing of the location where the compounding or repackaging is
40 being performed within 30 days of initiating the compounding or

1 repackaging. The pharmacy shall report any change in that
2 information to the board in writing within 30 days of the change.

3 (3) Notwithstanding paragraph (1), “manufacturer” shall not
4 mean a pharmacy that, at a patient’s request, repackages a drug
5 previously dispensed to the patient, or to the patient’s agent,
6 pursuant to a prescription.

7 (b) Notwithstanding subdivision (a), as used in Sections 4034,
8 4163, 4163.1, 4163.2, 4163.3, 4163.4, and 4163.5, “manufacturer”
9 means a person who prepares, derives, manufactures, produces,
10 or repackages a dangerous drug, as defined in Section 4022, device,
11 or cosmetic. Manufacturer also means the holder or holders of a
12 New Drug Application (NDA), an Abbreviated New Drug
13 Application (ANDA), or a Biologics License Application (BLA),
14 provided that such application has been approved; a manufacturer’s
15 third-party logistics provider; a private label distributor (including
16 colicensed partners) for whom the private label distributor’s
17 prescription drugs are originally manufactured and labeled for the
18 distributor and have not been repackaged; or the distributor agent
19 for the manufacturer, contract manufacturer, or private label
20 distributor, whether the establishment is a member of the
21 manufacturer’s affiliated group (regardless of whether the member
22 takes title to the drug) or is a contract distributor site.

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

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 377 **VERSION:** **As Amended April 14, 2011**
AUTHOR: Solorio **SPONSOR:** **California Hospital Association and
California Society of Health Systems Pharmacists**

BOARD POSITION: Support if Amended *(May 2011)*

SUBJECT: Pharmacies: Centralized Hospital Packaging

AFFECTED SECTIONS: Amend Sections 4029 and 4033 of the Business and Professions Code

CURRENT STATUS: Last location: Senate Appropriations Committee (8/15/11).
Hearing postponed by committee.

EXISTING LAW:

1. Defines a hospital pharmacy as a pharmacy licensed by the board that is located inside a hospital as specified.
2. Allows a hospital pharmacy to be located outside of the hospital building if the hospital pharmacy is on the California Department of Public Health's consolidated license and if the pharmacy is only providing pharmacy services to inpatients of the hospital.
3. Defines "manufacturer" and exempts compounding, as specified from the definition.

THIS BILL WOULD:

1. Specify a hospital pharmacy may be located outside of a hospital on either the same premises or separate premises, located within 100 mile radius, which is regulated under a hospital's license.
2. Specify that these services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.
3. Specify that unit-dose medication produced from a centralized pharmacy location for hospitals under common ownership must be bar-coded to be readable at the patient's bedside.
4. Allow for anticipatory unit-dose packaging as specified to ensure continuity of patient care.
5. Exempt from the definition of manufacturing, repackaging of a drug for parenteral therapy, or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership for purposes of administering medication pursuant to a prescription order.
6. Require a pharmacy performing such services to notify the board in writing within 30 days of initiating prepackaging or compounding from a centralized location, as well as within 30 days of any change in the information.

AUTHOR'S INTENT:

According to the author, "technology is now capable of providing hospitals with a method to deliver barcoded unit-doses to in-patients' bedsides. However, the cost of this technology renders it virtually impossible for hospitals to do within the structures of the current hospital pharmacy. In addition, because the new central pharmacy would serve multiple hospitals (though the hospitals are under

common ownership), currently lawful hospital pharmacy activities might run afoul of the manufacturing law." The author notes that the potential to finally and effectively address in-patient medication errors is greatly expanded by this proposal.

FISCAL IMPACT:

Board staff does not anticipate any significant impact. Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:

Amendments to this measure clarify that the centralized pharmacy services can only be provided to its own patients who are either admitted or registered patients of a hospital within the same health care system.

This proposal appears consistent with the board's mission statement "The Board of Pharmacy protects and promotes the health and safety of Californians by pursuing the highest quality of pharmacist's care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement." This proposal would allow a hospital to leverage existing technology to prepare unit-dose medications that include bar-coding technology that must be readable at the patient's bedside.

Recent Update

CSHP indicated that it anticipates amendments being incorporated into this measure in July 2012. According to CSHP, the amendments will address the board's concerns raised last year.

Background

Over the years the board has evaluated the issue of medication errors and reviewed materials and heard presentations from experts on what can be done to reduce such errors. Bar-coding technology has been identified as one tool that can be used to reduce medication errors. In 2004, the FDA established bar code label requirements for human drug and biological products (21 CFR Parts 201, 606, et al.) The FDA included in its guidance document, "Bar codes will allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. This new system is intended to help reduce the number of medication errors that occur in hospitals and health care settings." (Hospitals are exempt from the FDA requirement to barcode unit-dose packages.) In 2004, the FDA also noted that hospitals that were using bar-coding at that time avoided 50% of the adverse drug events caused by errors in the distribution and administration of prescriptions.

A summary from a study published in 2006, "Medication Dispensing Errors and Potential Adverse Drug Events before and after Implementing Bar Code Technology in the Pharmacy, Poon et. Al," included:

"...our study results suggest that bar code technology in a hospital pharmacy may substantially reduce serious dispensing errors. In particular, it may target several types of dispensing errors that may frequently harm patients, including wrong medication, wrong dose, or wrong formulation errors. However, the scanning technology should be configured to ensure that all doses are scanned at least once during the dispensing process. If optimally configured, this technology may be an important addition to the medication safety armamentarium."

Further, a portion of the discussion from this study also included:

“The rates of target dispensing errors and potential ADEs substantially decreased after the implementation of bar code technology: The target dispensing error rate decreased by 85%, and the rate of all dispensing-related potential ADEs decreased by more than 60%.”

As this measure does not currently specify the requirements of the bar-coding, the board may want to consider offering an amendment to clarify what information should be contained within bar-code. The board may want to consider the FDA requirement elements established in 21 CFR Parts 201, 606, et al.

PRIOR BOARD DISCUSSION and ACTION:

During the May 2011 Board Meeting, the board spoke in support of this measure. Technical issues were raised by counsel during this discussion about some clarity issues. As a result, the board voted to establish a Support if Amended position. Following the meeting, board staff conveyed the board’s position to CSHP and discussed the changes being sought.

PREVIOUS LEGISLATION:

The board previously supported AB 1370 (Solorio, 2009) which contained provisions similar to this bill.

The board previously supported AB 2077 (Solorio, 2010) which contained provisions similar to this bill. This bill was vetoed by the governor.

“This bill potentially places vulnerable patients at risk of medication error or exposure to adulterated or misbranded drugs. Without maintaining strict adherence to federal Food and Drug Administration requirements, there is a greater likelihood of product mix-up, loss of product identity, contamination and cross-contamination, and lack of adequate control systems. Current law clearly outlines the regulatory oversight functions for the Department of Public Health and the Board of Pharmacy. I see no reason to change these well-defined regulatory roles in California.”

SUPPORT/OPPOSITION:

Support:

California Hospital Association (sponsor)
California Pharmacists Association
Antelope Valley Hospital
California Society of Health-System Pharmacists
Mercy General Hospital
Sharp
St. Joseph's Medical Center, Pharmacy Department
Touro University, College of Pharmacy
Individual Pharmacists

Opposition:

None of file

HISTORY:

Date Action

2011

Aug. 15 In committee: Hearing postponed by committee.

July 5 In committee: Set, second hearing. Hearing canceled at the request of author.

June 21 In committee: Set, first hearing. Hearing cancelled at the request of author.
June 14 From committee: Do pass and re-refer to Com. on APPR. (Ayes 9. Noes. 0.) (June 13). Re-referred to Com. on APR.
May 26 Referred to Com. on B., P. & E.D.
May 12 In Senate. Read first time. To Com. on RLS. for assignment.
May 12 Read third time. Passed. Ordered to the Senate. (Ayes 70. Noes 0. Page 1356.)
May 9 Read second time. Ordered to consent calendar.
May 5 From committee: Do pass. To consent calendar. (Ayes 17. Noes 0.) (May 4).
Apr. 26 From committee: Do pass and re-refer to Com. on APPR. With recommendation: to consent calendar. (Ayes 9. Noes 0.) (April 26). Re-referred to Com. on APPR.
Apr. 25 Re-referred to Com. on B., P. & C.P.
Apr. 14 From committee chair, with author's amendments: Amend, and re-refer to Com. on B., P. & C.P. Read second time and amended.
Apr. 12 From committee: Do pass and re-refer to Com. on B., P. & C.P. (Ayes 19. Noes 0.) (April 12). Re-referred to Com. on B., P. & C.P.
Mar. 7 Referred to Coms. on HEALTH and B., P. & C.P.
Feb. 15 From printer. May be heard in committee March 17.
Feb. 14 Read first time. To print.

AMENDED IN ASSEMBLY MARCH 27, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1896

Introduced by Assembly Member Chesbro

February 22, 2012

An act to amend the heading of Article 10 (commencing with Section 710) of Chapter 1 of Division 2 of, and to add Section 719 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 1896, as amended, Chesbro. Tribal health programs: health care practitioners.

Under existing federal law, licensed health professionals employed by a tribal health program are required to be exempt, if licensed in any state, from the licensing requirements of the state in which the tribal health program performs specified services. A tribal health program is defined as an Indian tribe or tribal organization that operates any health program, service, function, activity, or facility funded, in whole or part, by the Indian Health Service.

Existing law provides for the licensure and regulation of health care practitioners by various healing arts boards *within the Department of Consumer Affairs*.

This bill would codify that federal requirement by specifying that a *person who is licensed as a health care practitioner in any other state and is employed by a tribal health program is exempt from any state licensing requirement with respect to acts authorized under the person's license where the tribal health program performs specified services.*

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. The heading of Article 10 (commencing with
2 Section 710) of Chapter 1 of Division 2 of the Business and
3 Professions Code is amended to read:

4

5 Article 10. Federal Personnel and Tribal Health Programs

6

7 SEC. 2. Section 719 is added to the Business and Professions
8 Code, to read:

9 719. (a) *A person who is licensed as a health care practitioner*
10 *in any other state and is employed by a tribal health program, as*
11 *defined in Section 1603 of Title 25 of the United States Code, shall*
12 *be exempt from any licensing requirement described in this division*
13 *with respect to acts authorized under the person’s license where*
14 *the tribal health program performs the services described in the*
15 *contract or compact of the tribal health program under the Indian*
16 *Self-Determination and Education Assistance Act (25 U.S.C. Sec.*
17 *450 et seq.).*

18 (b) For purposes of this section, “health care practitioner” means
19 any person who engages in acts that are the subject of licensure
20 or regulation under ~~this division or any initiative act referred to in~~
21 ~~this division~~ *the law of any other state.*

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1896 **VERSION:** Amended March 27, 2012

AUTHOR: Chesbro **SPONSORS:**

BOARD POSITION:

SUBJECT: Healing Arts: Tribal Health Programs: Healthcare Practitioners

Affected Sections: Amends the heading of Article 10, and Amends Section 719 of the Business and Professions Code

Current Status: 4/18/12 – On ASM Third Reading File
Passed out of ASM Committee on Business, Professions and Consumer Protection on 4/10/12

EXISTING LAW:

1. Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.
2. Allows a hospital to enter into an agreement with the Armed Forces of U.S. to authorize a physician and surgeon, physician assistant, or registered nurse to provide medical care in the hospital under specified conditions, including that the practitioner holds a valid license in good standing to provide medical care in the D.C. or any state or territory of the U.S., and that the practitioner registers with the appropriate California licensing board, as specified.
3. Under current federal law, a health care professional, as defined, is able to practice his or her profession in any state or territory without licensure by that state if he or she has a current license to practice the profession and is performing authorized duties for the Department of Defense.
4. Under current federal law, the Patient Protection and Affordable Care Act (PPACA), licensed health professionals employed by a tribal health program shall be exempt, if licensed in any state, from the licensing requirement of the state in which the tribal health program performs the services described in the contract or compact of the tribal health program under the ISDEAA.

THIS BILL:

1. Seeks to codify existing federal law into state law to specify that a health care professional employed by tribal health program is exempt from state licensure if that health care professional holds a license from another state.
2. Would defines “health care practitioner” to mean any person who engages in acts that are the subject of licensure or regulation under the law of any other state.

AUTHOR’S INTENT:

According to the author, the bill is important to help address a longstanding and increasingly severe shortage of physicians in Tribal Health Clinics that exists in underserved, rural areas. The goal is to increase the number of doctors practicing in rural areas resulting in increased health care access for communities served by Tribal Health Clinics.

To address the problem of staff shortages in Tribal Health Clinics, the U.S. Congress adopted language in the Federal Affordable Care Act. This act would allow health care providers employed by Tribal Health Programs to work in States without licensure as long as they hold a license from another State. AB 1896 will align the Federal Affordable Care Act provisions with California State statute and codifying Federal Law.

COMMENTS:

If current federal law (the Patient Protection and Affordable Care Act) already exempts health care professionals that are employed by a tribal health program so long as they are licensed in another state, is it necessary to codify the provision in State law?

SUPPORT/OPPOSITION:

According to the ASM Committee on Business, Professions and Consumer Protection

Support

California Rural Indian Health Board

California Rural Indian Health Board, Tribal Governments Consultation Committee

Oppose**HISTORY:**

Date Action
2012

Apr. 12 Read second time. Ordered to third reading.

Apr. 11 From committee: Do pass. (Ayes 9. Noes 0.) (April 10).

Mar. 28 Re-referred to Com. on B., P. & C.P.

Mar. 27 In committee: Set, first hearing. Hearing canceled at the request of author. From committee chair, with author's amendments: Amend,

and re-refer to Com. on B., P. & C.P. Read second time and amended.
Mar. 8 Referred to Com. on B., P. & C.P.
Feb. 23 From printer. May be heard in committee March 24.
Feb. 22 Read first time. To print.

AB 1896 (CHESBRO)

Affordable Care Act Alignment

Background

California's Tribal Health Programs are not-for-profit medical practices and medical research groups that provide primary care services, general dentistry, substance abuse counseling and mental health services. In California we have 31 Tribal Health Programs that operate 57 ambulatory clinics in primarily rural regions. These critically important safety net facilities serve over 130,000 American Indian/Alaska Native patients and multiple Medi-Cal patients on an annual basis.

Problem

Tribal Health Clinics have a severe shortage of physicians in underserved and rural areas. This lack of doctors places an undue burden on the existing provider network, risks a high turnover rate for current doctors, disrupts the continuity of care and challenges patient safety. This makes it difficult to recruit and retain health care providers willing to live and work in remote locations and overworked providers in the Indian health care delivery system with quickly developed burnout. The problem is especially acute in remote tribal and other rural communities, which lack the usual conveniences with which providers are familiar.

Solution

To address the problem of staff shortages in Tribal Health Clinics, the U.S. Congress adopted language in the Federal Affordable Care Act. This act allows health care providers employed by Tribal Health Programs to work in States without licensure as long as they hold a license from another State. AB 1896 will align the Federal Affordable Care Act provisions with California State statute and codifying Federal Law.

The bill is important to help address a longstanding and increasingly severe shortage of physicians in Tribal Health Clinics that exists in underserved, rural areas. The goal is to increase the number of doctors practicing in rural areas resulting in increased health care access for communities served by Tribal Health Clinics.

Contact

Robb Layne
Office of Assemblymember Chesbro
(916) 319-2001

Mark LeBeau
California Rural Indian Health Board
(916) 929-9761

ASSEMBLY BILL

No. 1904

Introduced by Assembly Members Block, Butler, and Cook

February 22, 2012

An act to add Section 115.5 to the Business and Professions Code, relating to professions and vocations, and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

AB 1904, as introduced, Block. Professions and vocations: military spouses: temporary licenses.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law provides for the issuance of reciprocal licenses in certain fields where the applicant, among other requirements, has a license to practice within that field in another jurisdiction, as specified. Under existing law, licensing fees imposed by certain boards within the department are deposited in funds that are continuously appropriated.

This bill would authorize a board within the department to issue a temporary license to an applicant who, among other requirements, holds an equivalent license in another jurisdiction, as specified, and is married to, or in a legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in California under official active duty military orders. The bill would require a board to expedite the process for issuing these temporary licenses. The bill would require the applicant to pay any fees required by the board and would require that those fees be deposited in the fund used by the board to administer its licensing program. To the extent that the bill would

increase the amount of money deposited into a continuously appropriated fund, the bill would make an appropriation.

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

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

- 1 SECTION 1. Section 115.5 is added to the Business and
- 2 Professions Code, to read:
- 3 115.5. (a) A board within the department may issue a
- 4 temporary license to an applicant who meets all of the following
- 5 requirements:
- 6 (1) Submits an application in the manner prescribed by the
- 7 board.
- 8 (2) Supplies evidence satisfactory to the board that the applicant
- 9 is married to, or in a domestic partnership or other legal union
- 10 with, an active duty member of the Armed Forces of the United
- 11 States who is assigned to a duty station in this state under official
- 12 active duty military orders.
- 13 (3) Holds a current license in another state, district, or territory
- 14 of the United States with the requirements that the board determines
- 15 are substantially equivalent to those established under this code
- 16 for that occupation.
- 17 (4) Has not committed an act in any jurisdiction that would have
- 18 constituted grounds for denial, suspension, or revocation of the
- 19 license under this code at the time the act was committed.
- 20 (5) Has not been disciplined by a licensing entity in another
- 21 jurisdiction and is not the subject of an unresolved complaint,
- 22 review procedure, or disciplinary proceeding conducted by a
- 23 licensing entity in another jurisdiction.
- 24 (6) Pays any fees required by the board. Those fees shall be
- 25 deposited in the applicable fund or account used by the board to
- 26 administer its licensing program.
- 27 (7) Submits fingerprints and any applicable fingerprinting fee
- 28 in the manner required of an applicant for a regular license.
- 29 (b) A board shall expedite the procedure for issuing a temporary
- 30 license pursuant to this section.
- 31 (c) A temporary license issued under this section shall be valid
- 32 for 180 days, except that the license may, at the discretion of the

- 1 board, be extended for an additional 180-day period on application
- 2 of the license holder.
- 3 (d) A board may adopt regulations necessary to administer this
- 4 section.

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Agenda Item A.1

Legislation Report

d. Other

AMENDED IN SENATE APRIL 9, 2012

SENATE BILL

No. 1185

Introduced by Senator Price

February 22, 2012

An act to add Part 12.2 (commencing with Section 15910) to Division 3 of Title 2 of, *and to repeal Section 15923 of*, the Government Code, relating to the Centralized Intelligence Partnership Act.

LEGISLATIVE COUNSEL'S DIGEST

SB 1185, as amended, Price. Centralized Intelligence Partnership Act.

Existing law requires various state entities, including, but not limited to, the State Board of Equalization, the Franchise Tax Board, and the Department of Justice, to enforce laws relating to the taxation and legal operation of businesses throughout the state under their respective jurisdictions.

This bill would create a multiagency partnership *consisting of specified state entities*, to be known as the Centralized Intelligence Partnership, to collaborate in combating illegal underground operations by, among other activities, providing a central intake process and organizational structure, with an administrator and support staff, to document, review, and evaluate data and complaints. ~~This~~ *The* bill would create an advisory committee, comprised of one representative from each entity ~~participating~~ in the partnership, to provide guidance on the activities and operations of the partnership. ~~This~~ *The* bill would *require the advisory committee to the partnership to determine the appropriate agency to house the processing center for the partnership. The bill would authorize duly authorized representatives of members of the partnership to exchange information for the purpose of*

investigating illegal underground operations. The bill would require the partnership, starting on or before July 1, 2014, to annually report to the Legislature and entities ~~belonging to~~ participating in the partnership on its activities. The bill would require an additional report to be filed with the Legislature by December 1, 2018, to include the number of complaints received by the partnership and cases investigated or prosecuted, as specified.

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

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

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

3 (a) According to the Employment Development Department's
4 analysis of findings made by the Internal Revenue Service, the
5 underground economy in California is estimated to be between
6 ~~\$60 billion~~ *sixty billion dollars (\$60,000,000,000)* and ~~\$140 billion~~
7 *one hundred forty billion dollars (\$140,000,000,000)* each year.

8 (b) According to the State Board of Equalization, an average
9 of ~~\$8 billion~~ *eight billion dollars (\$8,000,000,000)* in corporate,
10 personal, and sales and use taxes goes uncollected in California
11 each year, with unreported and underreported economic activity
12 responsible for the vast majority of that total.

13 (c) The underground economy hurts all Californians. Revenues
14 to support government services are lost, workers are forced to go
15 without basic employment protections, and legitimate businesses
16 are confronted with unfair competition. ~~Furthermore, the presence~~
17 ~~of the underground economy allows human traffickers to operate~~
18 ~~and victimize individuals who are trapped into forced labor~~
19 ~~conditions. Regrettably, California is reported to be one of the top~~
20 ~~four human trafficking destination states in the United States.~~

21 (d) Since the activities of many operating in the underground
22 economy span across multiple jurisdictions, various joint agency
23 enforcement efforts have been undertaken to combat the
24 underground economy, including, but not limited to, the creation
25 of the Joint Enforcement Strike Force *on the Underground*
26 *Economy* in 1993, and the creation of the Economic and
27 Employment Enforcement Coalition in 2005. Furthermore, various
28 individual agency efforts have been created, including, but not

1 limited to, the State Board of Equalization’s Statewide Compliance
2 and Outreach Program and the Contractors’ State License Board’s
3 Statewide Investigative Fraud Team. Thus, investigative
4 collaboration among state agencies is not a new concept in
5 California. Many collaborative efforts are already under way,
6 pursuant to which investigators periodically meet to discuss current
7 investigations, collaborate to conduct sting operations, and develop
8 best practices policies.

9 (e) Despite significant statewide efforts, California continues
10 to lose billions of dollars in annual revenue due to the underground
11 economy.

12 (f) The Legislature intends this act to enhance existing efforts
13 to combat the underground economy by institutionalizing
14 collaboration among state agencies through a Centralized
15 Intelligence Partnership that acquires relevant data for collaborative
16 data analysis, economic threat assessment, strategic planning, and
17 provides a referral tracking and value-added referral disbursement
18 process *to monitor the progress and measure the success of the*
19 *partnership activities*. This collaborative effort to combat the
20 underground economy will, in turn, further aid the state in its
21 progress toward preventing human trafficking. The Legislature
22 recognizes that the state needs to comprehensively address the
23 underground economy and capitalize on each agency’s enforcement
24 efforts and investigative resources by creating the Centralized
25 Intelligence Partnership. A key element of this effort is to authorize
26 and facilitate data and intelligence sharing among the Centralized
27 Intelligence Partnership and state agencies. It is the intent of the
28 Legislature in enacting this act to focus on the criminal *and civil*
29 prosecution of those operating in the underground economy in
30 flagrant violation of *the* law. Businesses that are in compliance
31 with state employment, safety, licensing, and tax laws that are
32 found to have committed minor or inadvertent violations of existing
33 law are to be addressed through other administrative procedures.

34 (g) It is the intent of the Legislature that this act be part of
35 ongoing efforts by the Legislature to combat the underground
36 economy in this state through legislation.

37 SEC. 2. Part 12.2 (commencing with Section 15910) is added
38 to Division 3 of Title 2 of the Government Code, to read:

1 PART 12.2. CENTRALIZED INTELLIGENCE PARTNERSHIP
2 ACT

3
4 15910. This part shall be known, and may be cited, as the
5 Centralized Intelligence Partnership Act.

6 15912. (a) The Centralized Intelligence Partnership is hereby
7 established in state government.

8 (b) For purposes of this part, the term “partnership” shall refer
9 to the Centralized Intelligence Partnership.

10 15914. ~~(a)~~The partnership shall include all of the following
11 state entities:

- 12 ~~(1)~~
- 13 (a) California Health and Human Services Agency.
- 14 ~~(2)~~
- 15 (b) Department of Consumer Affairs.
- 16 ~~(3)~~
- 17 (c) Department of Industrial Relations.
- 18 ~~(4)~~
- 19 (d) Department of Insurance.
- 20 ~~(5)~~
- 21 (e) Department of Justice.
- 22 ~~(6)~~
- 23 (f) Department of Motor Vehicles.
- 24 ~~(7)~~
- 25 (g) Employment Development Department.
- 26 ~~(8)~~
- 27 (h) Franchise Tax Board.
- 28 ~~(9)~~
- 29 (i) State Board of Equalization.

30 ~~(b) The Centralized Intelligence Partnership may include any~~
31 ~~other state or local entity that chooses to participate.~~

32 15916. (a) The advisory committee to the Centralized
33 Intelligence Partnership is hereby established to provide guidance
34 to, and advice on, the activities and operations of the partnership.

35 (b) The advisory committee is comprised of one representative
36 from each of the entities ~~participating~~ in the partnership. Each
37 representative shall be appointed by the head of the entity
38 ~~participating~~ in the partnership and serve at the pleasure of the
39 appointing authority.

1 (c) The advisory committee shall meet as needed but at least
2 quarterly to conduct its business.

3 15918. (a) To serve the best interests of the state by combating
4 the underground economy, the partnership shall do all of the
5 following to combat illegal underground operations:

6 (1) Provide a central intake process and organizational structure
7 to document, review, and evaluate data and complaints.

8 (2) Establish a processing center to receive and analyze data,
9 share complaints, and research leads from the input of each
10 impacted agency, ~~including, but not limited to, federal and local~~
11 ~~law enforcement agencies.~~

12 (3) Provide participating and nonparticipating agencies with
13 value-added investigative leads where collaboration opportunities
14 exist for felony-level criminal investigations, including, but not
15 limited to, referring leads to agencies with appropriate enforcement
16 jurisdiction.

17 (4) Provide that each participating and nonparticipating agency
18 retain jurisdictional authority over whether to pursue partnership
19 strategies or collaborative investigative leads based upon the
20 direction of their respective governing structures or available
21 resources.

22 (5) Document and provide intake data analysis, analytic data
23 findings, referrals, collaborative opportunities, outcomes, emerging
24 evasion trends, lessons learned, as well as additional enforcement,
25 administrative, and legislative opportunities.

26 (b) The scope of activities and projects undertaken by the
27 partnership shall be consistent with the amount of funds
28 appropriated by the Legislature.

29 ~~The Department of Justice~~ *advisory committee to the*
30 *partnership shall determine the appropriate agency to house the*
31 *processing center for the partnership.*

32 (d) The partnership may hire an administrator and staff.

33 ~~15920. Notwithstanding any other law, duly authorized~~
34 ~~representatives of members of the partnership may exchange~~
35 ~~intelligence, data, documents, information, complaints, or lead~~
36 ~~referrals for the purpose of investigating illegal underground~~
37 ~~operations. Information exchanged pursuant to this section shall~~
38 ~~retain its confidential status.~~

39 *15920. Duly authorized representatives of members of the*
40 *partnership may exchange intelligence, data, documents,*

1 *information, complaints, or lead referrals for the purpose of*
2 *investigating illegal underground operations. Any member or*
3 *ex-member of the partnership, any agent employed by any member*
4 *of the partnership, or any person who has at any time obtained*
5 *such knowledge from any of the foregoing partners or persons,*
6 *shall not divulge, or make known in any manner not provided by*
7 *law, any of the confidential information received by, or reported*
8 *to, the partnership. Information exchanged pursuant to this section*
9 *shall retain its confidential status and shall remain subject to the*
10 *confidentiality provisions contained in the following provisions:*

11 *(a) Department of Consumer Affairs: Section 30 of the Business*
12 *and Professions Code and Section 56.29 of the Civil Code.*

13 *(b) Department of Justice: Section 11183 of the Government*
14 *Code.*

15 *(c) Department of Motor Vehicles: Sections 1808.2, 1808.4,*
16 *1808.5, 1808.6, 1808.21, 1808.24, and 12800.5 of the Vehicle*
17 *Code.*

18 *(d) Employment Development Department: Sections 1094 and*
19 *1095 of the Unemployment Insurance Code.*

20 *(e) Franchise Tax Board: Sections 19542, 19542.1, and 19542.3*
21 *of the Revenue and Taxation Code.*

22 *(f) State Board of Equalization: Section 15619 of the*
23 *Government Code, Section 42464.8 of the Public Resources Code,*
24 *and Sections 7056, 7056.5, 8255, 9255, 9255.1, 30455, 38705,*
25 *38706, 43651, 45981, 45982, 45983, 45984, 46751, 50159, 50160,*
26 *50161, 55381, 60608, and 60609 of the Revenue and Taxation*
27 *Code.*

28 15922. On or before July 1, 2014, and annually thereafter, the
29 partnership shall report on its activities and accomplishments to
30 the Legislature and each ~~participating member~~ entity in the
31 partnership.

32 15923. (a) The partnership shall submit to the Legislature on
33 or before December 1, 2018, a report that includes, but is not
34 limited to, the following information:

35 (1) The number of leads or complaints received by the
36 partnership.

37 (2) The number of cases investigated or prosecuted through
38 civil action or criminal prosecution.

39 (3) Recommendations for modifying, eliminating, or continuing
40 the operation of any or all of the provisions of this part.

1 ***(b) This section shall remain in effect only until January 1, 2020,***
2 ***and as of that date is repealed, unless a later enacted statute, that***
3 ***is enacted before January 1, 2020, deletes or extends that date.***

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1185

VERSION: As Amended April 9, 2012

AUTHOR: Price

SPONSOR: State Board of Equalization

BOARD POSITION:

SUBJECT: Centralized Intelligence Partnership Act

AFFECTED SECTIONS: Amend Section 1374.13 of the Health and Safety Code and add Section 14594 to the Welfare and Institutions Code

CURRENT STATUS: Assembly Health Committee hearing scheduled for April 24, 2012

EXISTING LAW:

1. Establishes several different government entities responsible for oversight, regulation and enforcement of various businesses and individuals doing business in California including:
 - a. California Health and Human Services Agency
 - b. Department of Consumer Affairs
 - c. Department of Industrial Relations
 - d. Department of Insurance
 - e. Department of Justice
 - f. Department of Motor Vehicles
 - g. Employment Development Department
 - h. Franchise Tax Board
 - i. State Board of Equalization
2. B&PC Section 110 specifies that the department (DCA) has possession and control of all records etc. held for use by all bodies, offices and officers comprised within the department.

THIS BILL WOULD:

1. Create the Centralized Intelligence Partnership consisting of the above agencies and establish an advisory committee with membership from each agency.
2. Specify that the advisory committee is charged with combating the underground economy and specifies the general scope of the committee's process.
3. Allow for the sharing of information between the members of the advisory committee and provides that information shared via this process will retain its confidential status as authorized by law.
4. Establish reporting requirements for this advisory committee.
5. Establish a January 1, 2020 sunset date.

AUTHOR’S INTENT:

The author’s fact sheet indicates that this measure “seeks to address the problems caused by California’s underground economy. This legislation establishes a multiagency collaboration, which will be known as the Centralized Intelligence Partnership (CIP). The CIP will facilitate consumer complaints, perform research that will assist in the recapturing of unreported taxes, aide in exposing employers who exploit workers and assist in efforts to investigate and prosecute violations.”

COMMENTS:

It is unclear what role, if any the board would play in the advisory committee. In its current form, it appears that only the department would be involved.

The board has working relationships with several other regulatory agencies including the Department of Public Health, Department of Health Care Services as well as local, state and federal enforcement agencies. Board inspectors participate in joint investigations on a fairly routine basis.

Further, board staff recommends that at minimum amendments be offered to the author’s office to include specific reference to two Government Code sections that relate to access to board records.

FISCAL IMPACT:

Board staff is not certain what the fiscal impact could be. The measure authorizes positions to work for the advisory committee, but is silent on the funding.

SUPPORT/OPPOSITION:

Support

- State Board of Equalization (sponsor)
- Taxpayers Association
- California Chamber of Commerce
- California Spa and Pool Industry Association
- California Building Industry Association
- California Healthcare Institute
- City of Southgate

Opposition

None

HISTORY:

Date	Action
2012	
Apr. 17	Re-referred to Com. on HEALTH.
Apr. 16	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 27	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 1	Referred to Com. on HEALTH.

Feb. 17 From printer. May be heard in committee March 18.
Feb. 16 Read first time. To print.

AMENDED IN SENATE MARCH 26, 2012

SENATE BILL

No. 1195

Introduced by Senator Price

February 22, 2012

An act to ~~amend Section 6253.3 of the Government Code, relating to public records~~ *add Part 6.01 (commencing with Section 12665) to Division 2 of the Insurance Code, relating to health care coverage.*

LEGISLATIVE COUNSEL'S DIGEST

SB 1195, as amended, Price. ~~California Public Records Act. Audits of pharmacy benefits.~~

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies by the California State Board of Pharmacy. Existing law provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and for the regulation of health insurers by the Department of Insurance. Existing law requires health care service plan contracts and health insurance policies to provide coverage for specified benefits and requires contracts between plans or insurers and providers to contain provisions requiring a fast, fair, and cost-effective dispute resolution mechanism.

This bill would require a contract entered into between a pharmacy and a health insurer, health care service plan, or pharmacy benefit manager, as defined, for the provision of pharmacy services to beneficiaries of a health benefit plan, to include policies and procedures for any audits under the contract, and would impose specified requirements on those audits. Among other things, the bill would prohibit the entity conducting the audit from receiving payment on any basis tied to the amount claimed or recovered from the pharmacy and would require the entity to deliver a preliminary audit report to the

pharmacy and to give the pharmacy an opportunity to respond to the report. The bill would require the entity to deliver a final audit report to the pharmacy and to establish a process for appealing the findings of that report, as specified. The bill would prohibit the entity from using extrapolation, as defined, in calculating penalties or amounts to be recouped from a pharmacy and would prohibit a pharmacy from being subject to recoupment of funds for a clerical or recordkeeping error. The bill would enact other related provisions.

~~The California Public Records Act requires state and local agencies to make public records available for inspection by the public, subject to specified criteria, and with specified exceptions. The act prohibits a state or local agency from allowing another party to control the disclosure of information otherwise subject to disclosure pursuant to the act.~~

~~This bill would make a technical, nonsubstantive change to this provision.~~

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. Part 6.01 (commencing with Section 12665) is
2 added to Division 2 of the Insurance Code, to read:

3
4 PART 6.01. AUDITS OF PHARMACY BENEFITS

5
6 12665. For purposes of this article, the following definitions
7 shall apply:

8 (a) "Carrier" means a health care service plan, as defined in
9 Section 1345 of the Health and Safety Code, or a health insurer
10 that issues policies of health insurance, as defined in Section 106.

11 (b) "Clerical or recordkeeping error" includes, but is not limited
12 to, a typographical error, scrivener's error, or computer error in
13 a required document or record.

14 (c) "Extrapolation" means the practice of inferring a frequency
15 or dollar amount of overpayments, underpayments, nonvalid
16 claims, or other errors on any portion of claims submitted, based
17 on the frequency or dollar amount of overpayments,
18 underpayments, nonvalid claims, or other errors actually measured
19 in a sample of claims.

1 (d) “Health benefit plan” means any plan or program that
2 provides, arranges, pays for, or reimburses the cost of health
3 benefits. “Health benefit plan” includes, but is not limited to, a
4 health care service plan contract issued by a health care service
5 plan, as defined in Section 1345 of the Health and Safety Code,
6 and a policy of health insurance, as defined in Section 106, issued
7 by a health insurer.

8 (e) “Pharmacy” has the same meaning provided in Section
9 4037 of the Business and Professions Code.

10 (f) “Pharmacy audit” means an audit, either onsite or remotely,
11 of any records of a pharmacy conducted by or on behalf of a
12 carrier or a pharmacy benefits manager, or a representative
13 thereof, for prescription drugs that were dispensed by that
14 pharmacy to beneficiaries of a health benefit plan pursuant to a
15 contract with the health benefit plan or the issuer or administrator
16 thereof.

17 (g) “Pharmacy benefit manager” means a person, business, or
18 other entity that, pursuant to a contract or under an employment
19 relationship with a carrier, health benefit plan sponsor, or other
20 third-party payer, either directly or through an intermediary,
21 manages the prescription drug coverage provided by the carrier,
22 plan sponsor, or other third-party payer, including, but not limited
23 to, the processing and payment of claims for prescription drugs,
24 the performance of drug utilization review, the processing of drug
25 prior authorization requests, the adjudication of appeals or
26 grievances related to prescription drug coverage, contracting with
27 network pharmacies, and controlling the cost of covered
28 prescription drugs.

29 12665.1. (a) Nothing in this article shall apply to an audit
30 conducted because a pharmacy benefit manager, carrier, health
31 benefit plan sponsor, or other third-party payer has evidence or
32 a significant suspicion that criminal wrongdoing, willful
33 misrepresentation, or fraud has occurred.

34 (b) Nothing in this article shall apply to an audit conducted by
35 the California State Board of Pharmacy, the State Department of
36 Health Care Services, or the State Department of Public Health.

37 12665.2. Notwithstanding any other provision of law, a contract
38 that is issued, amended, or renewed on or after January 1, 2013,
39 between a pharmacy and a carrier or a pharmacy benefit manager
40 to provide pharmacy services to beneficiaries of a health benefit

1 *plan shall include policies and procedures for any audits performed*
2 *under the contract. The policies and procedures shall be consistent*
3 *with generally accepted auditing practices and shall comply with*
4 *the provisions of this part.*

5 *12665.3. (a) An entity conducting a pharmacy audit shall not*
6 *receive payment or any other consideration on any basis that is*
7 *tied to the amount claimed or actual amount recovered from the*
8 *pharmacy that is the subject of the audit.*

9 *(b) An entity conducting a pharmacy audit shall not use*
10 *extrapolation in calculating penalties or amounts to be recouped*
11 *from a pharmacy. Any findings of overpayment or underpayment*
12 *to a pharmacy shall be based solely on documented instances of*
13 *overpayment or underpayment to the pharmacy and shall not be*
14 *based on an estimate or projection based on the number of patients*
15 *served having a similar diagnosis or on the number of similar*
16 *orders or refills for similar drugs.*

17 *(c) Any calculation of overpayment to a pharmacy determined*
18 *pursuant to a pharmacy audit shall not include the portion of any*
19 *payment that constitutes dispensing fees.*

20 *(d) A pharmacy shall not be subject to recoupment of funds for*
21 *a clerical or recordkeeping error, unless there is proof of intent*
22 *to commit fraud or that the error resulted in actual financial harm*
23 *to the pharmacy benefit manager, the carrier, or the beneficiary*
24 *of a health benefit plan.*

25 *12665.4. (a) Except as otherwise prohibited by state or federal*
26 *law, an entity conducting a pharmacy audit shall keep confidential*
27 *any information collected during the course of the audit and shall*
28 *not share any information with any person other than the carrier,*
29 *pharmacy benefit manager, or third-party payer for which the*
30 *audit is being performed. An entity conducting a pharmacy audit*
31 *shall have access only to previous audit reports relating to a*
32 *particular pharmacy conducted by or on behalf of the same entity.*
33 *Nothing in this subdivision shall be construed to authorize access*
34 *to information that is otherwise prohibited by law.*

35 *(b) An entity that is not a carrier or pharmacy benefit manager*
36 *and that is conducting a pharmacy audit on behalf of a carrier or*
37 *pharmacy benefit manager shall, prior to conducting the audit,*
38 *provide the pharmacy with an attestation that the entity and the*
39 *carrier or pharmacy benefit manager have executed a business*

1 *associate agreement or other agreement as required under state*
2 *and federal privacy laws.*

3 *(c) An entity conducting a pharmacy audit shall, prior to leaving*
4 *a pharmacy at the end of an onsite portion of the audit, provide*
5 *the pharmacist in charge with a complete list of records reviewed*
6 *to allow the pharmacy to account for disclosures as required by*
7 *state and federal privacy laws.*

8 *12665.5. (a) An entity conducting a pharmacy audit shall not*
9 *initiate or schedule a pharmacy audit during the first five business*
10 *days of any calendar month, unless it is expressly agreed to by the*
11 *pharmacy being audited.*

12 *(b) An entity conducting an onsite pharmacy audit shall provide*
13 *the pharmacy at least one week's prior written notice before*
14 *conducting an initial audit.*

15 *12665.6. (a) A pharmacy audit that involves clinical judgment*
16 *shall be conducted by a pharmacist licensed pursuant to Chapter*
17 *9 (commencing with Section 4000) of Division 2 of the Business*
18 *and Professions Code.*

19 *(b) An entity conducting a pharmacy audit shall make all*
20 *determinations regarding the legal validity of a prescription or*
21 *other record consistent with determinations made pursuant to*
22 *Article 4 (commencing with Section 4070) of Chapter 9 of Division*
23 *2 of the Business and Professions Code and shall accept as valid*
24 *electronically stored images of prescriptions, electronically created*
25 *annotations, and other related supporting documentation.*

26 *(c) An entity conducting a pharmacy audit shall accept paper*
27 *or electronic signature logs that indicate the delivery of pharmacy*
28 *services as valid proof of receipt of those services by a health*
29 *benefit plan beneficiary.*

30 *12665.7. The time period covered by a pharmacy audit shall*
31 *not exceed a 24-month period beginning no more than 24 months*
32 *prior to the initial date of the onsite portion of the audit, and the*
33 *audit shall encompass only claims that were submitted to or*
34 *adjudicated by the carrier or pharmacy benefit manager during*
35 *that 24-month period.*

36 *12665.8. (a) (1) An entity conducting a pharmacy audit shall*
37 *deliver a preliminary audit report to the pharmacy before issuing*
38 *a final audit report. This preliminary report shall be issued no*
39 *later than 60 days after conclusion of the audit.*

1 (2) A pharmacy shall be provided a time period of no less than
2 30 days following receipt of the preliminary audit report under
3 paragraph (1) to respond to the findings in the report, including
4 addressing any alleged mistakes or discrepancies and producing
5 documentation to that effect.

6 (3) A pharmacy may use the records of a health facility,
7 physician and surgeon, or other authorized practitioner of the
8 healing arts involving drugs, medicinal supplies, or medical devices
9 written or transmitted by any means of communication for purposes
10 of validating the pharmacy record with respect to orders or refills
11 of a dangerous drug or device.

12 (4) Prior to issuing a final audit report, an entity conducting a
13 pharmacy audit shall take into consideration any response by the
14 pharmacy to the preliminary audit report.

15 (b) (1) An entity conducting a pharmacy audit shall deliver a
16 final audit report to the pharmacy no later than 90 days after the
17 conclusion of the audit or 30 days after receipt of a pharmacy's
18 response to the preliminary audit report, as applicable.

19 (2) An entity conducting a pharmacy audit shall establish a
20 process for appealing the findings in a final audit report that
21 complies with the following requirements:

22 (A) A pharmacy shall be provided a time period of no less than
23 60 days following receipt of the final audit report to file an appeal
24 with the entity identified in the appeal process.

25 (B) A pharmacy may use the records of a hospital, physician
26 and surgeon, or other authorized practitioner of the healing arts
27 involving drugs, medicinal supplies, or medical devices written or
28 transmitted by any means of communication for purposes of
29 validating the pharmacy record with respect to orders or refills
30 of a dangerous drug or device.

31 (C) An entity conducting a pharmacy audit shall provide the
32 pharmacy with a written determination of appeal issued by the
33 entity identified in the appeal process, which shall be appended
34 to the final audit report, and a copy of the determination shall be
35 sent to the carrier, health benefit plan sponsor, or other third-party
36 payer.

37 (D) The appeals process may include a dispute resolution option
38 as long as the pharmacy retains the right to file a written appeal
39 and obtain a written determination pursuant to this subdivision.

1 (c) An entity conducting a pharmacy audit, a carrier, a health
2 benefit plan sponsor, or other third-party payer, or any person
3 acting on behalf of those entities, shall not attempt to make
4 chargebacks or seek recoupment from a pharmacy, or assess or
5 collect penalties from a pharmacy, until the time period for filing
6 an appeal to a final audit report has passed, or until the appeal
7 process has been exhausted, whichever is later.

8 (d) An entity conducting a pharmacy audit, a carrier, a health
9 benefit plan sponsor, or other third-party payer, or any person
10 acting on behalf of those entities, shall not charge interest during
11 the audit or appeal period.

12 (e) If, following final disposition of a pharmacy audit pursuant
13 to this section, an entity conducting a pharmacy audit, a carrier,
14 a health benefit plan sponsor, or other third-party payer, or any
15 person acting on behalf of those entities, finds that an audit report
16 or any portion thereof is unsubstantiated, the entity shall dismiss
17 the audit report or the unsubstantiated portion thereof without the
18 necessity of any further proceedings and shall return any moneys
19 recouped as a result of the lack of substantiation, as applicable.

20 ~~SECTION 1. Section 6253.3 of the Government Code is~~
21 ~~amended to read:~~

22 ~~6253.3. A state or local agency may not allow another party~~
23 ~~to control the disclosure of information otherwise subject to~~
24 ~~disclosure pursuant to this chapter.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1195

VERSION: As Amended March 26, 2012

AUTHOR: Price

SPONSOR: California Pharmacists Association

BOARD POSITION:

SUBJECT: Audits of pharmacy benefits

AFFECTED SECTIONS: Add Part 6.01 (commencing with Section 12665) to Division 2 of the Insurance Code

CURRENT STATUS: Senate Health Committee hearing scheduled for April 24, 2012

EXISTING LAW:

1. Provides for the regulation of pharmacy services through the California State Board of Pharmacy.
2. Provides for the regulation of health care services plans by the Department of Managed Health Care.
3. Provides for the regulation of health insurers by the Department of Insurance.

THIS BILL WOULD:

1. Specify that an audit conducted by or on behalf of a pharmacy benefit manager shall be consistent with generally accepted auditing practices and in conformance with the provisions specified.
2. Prohibit an entity performing an audit from receiving payment or other considerations on any basis that is tied to an amount claimed or actual amount recovered from a pharmacy that is subject to an audit.
3. Specify how calculations can be used to determine overpayment and underpayment of claims.
4. Provide the parameters around confidentiality, contract agreements, clerical and recordkeeping errors, notice requirements and timeframes.
5. Set forth an appeal process.

AUTHOR'S INTENT:

This legislation will follow the direction of other states in an effort to establish fair auditing standards and procedural rights for pharmacies that undergo prescription claim audits performed by pharmacy benefit managers, or "PBMs."

COMMENTS:

Pharmacy Benefit Managers are currently not regulated. Although the board does not have jurisdiction over the auditing of claims for reimbursement, board staff receive complaints on a somewhat routine basis from licensees complaining about the perceived unjust auditing practice

of an auditing company receiving payment based on the number of claims rejected. This proposal would appear to address this issue.

FISCAL IMPACT:

Board staff does not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Date Action

2012

Apr. 10 Set for hearing April 24.

Apr. 9 Set, first hearing. Hearing canceled at the request of author.

Apr. 5 Set for hearing April 18.

Mar. 29 Re-referred to Coms. on HEALTH and RLS.

Mar. 26 From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.

Mar. 1 Referred to Com. on RLS.

Feb. 23 From printer. May be acted upon on or after March 24.

Feb. 22 Introduced. Read first time. To Com. on RLS. for assignment. To print.



April 10, 2012

Senator Ed Hernandez, Chair
Senate Health Committee
State Capitol, Room 2191
Sacramento, CA 95814

Re: **SB 1195 – SUPPORT**

Dear Senator Hernandez:

The California Pharmacists Association is proud to sponsor SB 1195 (Price). This legislation will follow the direction of other states in an effort to establish fair auditing standards and procedural rights for pharmacies that undergo prescription claim audits performed by pharmacy benefit managers, or “PBMs.”

PBMs are intermediaries between payers and pharmacies that are responsible for processing and paying prescription drug claims, developing and maintaining drug formularies, contracting with pharmacies, and negotiating discounts and rebates with drug manufacturers. Most health plans and insurers contract the administration of their prescription drug benefits to PBMs and in the course and scope of their employment a pharmacy is given very little leeway in dealing with these largely unregulated entities. Until recently there were three major PBMs doing the lion’s share of the business and reaping billions in profits – now, they are eating their own and there are two major PBMs.

We do not dispute that, as claims adjudicators, PBMs have a necessary role in auditing pharmacy claims. In fact, we support responsible auditing and a strict adherence to legal and ethical standards for everyone who provides medications to California consumers.

However, PBM pharmacy audits have in many instances evolved away from their legitimate purpose and embraced a profit-seeking game of “gotcha” against pharmacies. Pharmacists are being driven from the workplace or placed unnecessarily in precarious financial corners due to aggressive PBM audits that retroactively deny pharmacy claims based on trivial issues and non-substantive technicalities where no fraud exists, there are no questions that the right drug was provided to the right patient, and the plan was billed the correct amount.

PBMs often contract with auditing firms on a contingency fee basis for the amount the audit firm recoups, thereby creating an enormous incentive for auditors to aggressively err on the side of the PBM and harshly punish minor clerical issues that no objective individual would consider “fraud.” The consequences of these reversals is that the retroactive claim denial

becomes an uncovered benefit for the patient, thereby forcing the pharmacy to bill the patient for what has been deemed an invalid claim.

When a PBM invalidates a claim after an audit, the PBM recoups the amount paid for that claim from the pharmacy, including both the drug ingredient cost and the pharmacy dispensing fee....*even if no fraud has been committed and the patient has received the appropriate medication.*

Abusive PBM audits result in patients and pharmacies footing the bill for prescription drugs that are covered benefits, medically necessary, and legitimately prescribed, while the PBM reaps the benefit of a weighted, unfair system that allows them to profit by overly punitive responses.

Again, we are not opposed to audits. However, SB 1195 would put an end to abusive PBM audits by establishing common sense, fair standards for all audits and prohibiting a number of unjust practices while allowing PBMs the continued appropriate role of finding and penalizing true fraud, waste, and abuse against pharmacies. For example, this bill would define a “valid” prescription as one consistent with what the California Board of Pharmacy considers valid, require PBMs to have a documented standardized appeals process, prohibit claims from being invalidated because of minor typographical errors, and prohibit PBMs that hire auditing firms from paying them on a head-hunter contingency basis.

SB 1195 expressly does not protect pharmacies that are engaging in fraud, does not prevent PBMs from collecting legitimate overpayments, and does not encourage fraudulent activities. This bill establishes fair and reasonable standards and due process rights for pharmacy audits to return a reasonable level of integrity to this process. California is not the first to recognize the problem. Similar protections have been negotiated between the stakeholders and enacted in dozens of other states with great success.

For these reasons, **we ask for your AYE vote on SB 1195**. If you have any questions, please do not hesitate to contact me at (916) 779-4517.

Sincerely,



Brian Warren
Director, Government and Professional Affairs

cc: Members, Senate Health Committee

Introduced by Senator Alquist

February 23, 2012

An act to amend Section 56.36 of the Civil Code, relating to medical records.

LEGISLATIVE COUNSEL'S DIGEST

SB 1250, as introduced, Alquist. Medical records: confidentiality.

The Confidentiality of Medical Information Act requires that every provider of health care, health care service plan, pharmaceutical company, and contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical records do so in a manner that preserves the confidentiality of the information contained in the records, and provides that negligence in conducting these activities may result in damages or an administrative fine or civil penalty, as specified.

This bill would provide that negligence in conducting these activities may result in the defendant being required to provide each person who is the subject of the medical records with access to a credit monitoring and reporting service for one year.

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 56.36 of the Civil Code is amended to
2 read:
3 56.36. (a) Any violation of ~~the provisions of~~ this part that
4 results in economic loss or personal injury to a patient is punishable
5 as a misdemeanor.

1 (b) In addition to any other remedies available at law, any
2 individual may bring an action against any person or entity ~~who~~
3 *that* has negligently released confidential information or records
4 concerning him or her in violation of this part, for *access, at the*
5 *defendant's expense, to a nationally recognized credit monitoring*
6 *and reporting service for one year from the date of release of any*
7 *medical information and* either or both of the following:

8 (1) Nominal damages of one thousand dollars (\$1,000). In order
9 to recover under this paragraph, it shall not be necessary that the
10 plaintiff suffered or was threatened with actual damages.

11 (2) The amount of actual damages, if any, sustained by the
12 patient.

13 (c) (1) In addition, any person or entity that negligently
14 discloses medical information in violation of the provisions of this
15 part shall also be liable, irrespective of the amount of damages
16 suffered by the patient as a result of that violation, for an
17 administrative fine or civil penalty not to exceed two thousand
18 five hundred dollars (\$2,500) per violation.

19 (2) (A) Any person or entity, other than a licensed health care
20 professional, who knowingly and willfully obtains, discloses, or
21 uses medical information in violation of this part shall be liable
22 for an administrative fine or civil penalty not to exceed twenty-five
23 thousand dollars (\$25,000) per violation.

24 (B) Any licensed health care professional, who knowingly and
25 willfully obtains, discloses, or uses medical information in violation
26 of this part shall be liable on a first violation, for an administrative
27 fine or civil penalty not to exceed two thousand five hundred
28 dollars (\$2,500) per violation, or on a second violation for an
29 administrative fine or civil penalty not to exceed ten thousand
30 dollars (\$10,000) per violation, or on a third and subsequent
31 violation for an administrative fine or civil penalty not to exceed
32 twenty-five thousand dollars (\$25,000) per violation. Nothing in
33 this subdivision shall be construed to limit the liability of a health
34 care service plan, a contractor, or a provider of health care that is
35 not a licensed health care professional for any violation of this
36 part.

37 (3) (A) Any person or entity, other than a licensed health care
38 professional, who knowingly or willfully obtains or uses medical
39 information in violation of this part for the purpose of financial
40 gain shall be liable for an administrative fine or civil penalty not

1 to exceed two hundred fifty thousand dollars (\$250,000) per
2 violation and shall also be subject to disgorgement of any proceeds
3 or other consideration obtained as a result of the violation.

4 (B) Any licensed health care professional, who knowingly and
5 willfully obtains, discloses, or uses medical information in violation
6 of this part for financial gain shall be liable on a first violation, for
7 an administrative fine or civil penalty not to exceed five thousand
8 dollars (\$5,000) per violation, or on a second violation for an
9 administrative fine or civil penalty not to exceed twenty-five
10 thousand dollars (\$25,000) per violation, or on a third and
11 subsequent violation for an administrative fine or civil penalty not
12 to exceed two hundred fifty thousand dollars (\$250,000) per
13 violation and shall also be subject to disgorgement of any proceeds
14 or other consideration obtained as a result of the violation. Nothing
15 in this subdivision shall be construed to limit the liability of a
16 health care service plan, a contractor, or a provider of health care
17 that is not a licensed health care professional for any violation of
18 this part.

19 (4) Nothing in this subdivision shall be construed as authorizing
20 an administrative fine or civil penalty under both paragraphs (2)
21 and (3) for the same violation.

22 (5) Any person or entity ~~who~~ *that* is not permitted to receive
23 medical information pursuant to this part and who knowingly and
24 willfully obtains, discloses, or uses medical information without
25 written authorization from the patient shall be liable for a civil
26 penalty not to exceed two hundred fifty thousand dollars (\$250,000)
27 per violation.

28 (d) In assessing the amount of an administrative fine or civil
29 penalty pursuant to subdivision (c), the Office of Health
30 Information Integrity, licensing agency, or certifying board or
31 court shall consider any one or more of the relevant circumstances
32 presented by any of the parties to the case including, but not limited
33 to, the following:

34 (1) Whether the defendant has made a reasonable, good faith
35 attempt to comply with this part.

36 (2) The nature and seriousness of the misconduct.

37 (3) The harm to the patient, enrollee, or subscriber.

38 (4) The number of violations.

39 (5) The persistence of the misconduct.

40 (6) The length of time over which the misconduct occurred.

- 1 (7) The willfulness of the defendant’s misconduct.
- 2 (8) The defendant’s assets, liabilities, and net worth.
- 3 (e) (1) The civil penalty pursuant to subdivision (c) shall be
- 4 assessed and recovered in a civil action brought in the name of the
- 5 people of the State of California in any court of competent
- 6 jurisdiction by any of the following:
- 7 (A) The Attorney General.
- 8 (B) Any district attorney.
- 9 (C) Any county counsel authorized by agreement with the
- 10 district attorney in actions involving violation of a county
- 11 ordinance.
- 12 (D) Any city attorney of a city.
- 13 (E) Any city attorney of a city and county having a population
- 14 in excess of 750,000, with the consent of the district attorney.
- 15 (F) A city prosecutor in any city having a full-time city
- 16 prosecutor or, with the consent of the district attorney, by a city
- 17 attorney in any city and county.
- 18 (G) The Director of the Office of Health Information Integrity
- 19 may recommend that any person described in subparagraphs (A)
- 20 to (F), inclusive, bring a civil action under this section.
- 21 (2) If the action is brought by the Attorney General, one-half
- 22 of the penalty collected shall be paid to the treasurer of the county
- 23 in which the judgment was entered, and one-half to the General
- 24 Fund. If the action is brought by a district attorney or county
- 25 counsel, the penalty collected shall be paid to the treasurer of the
- 26 county in which the judgment was entered. Except as provided in
- 27 paragraph (3), if the action is brought by a city attorney or city
- 28 prosecutor, one-half of the penalty collected shall be paid to the
- 29 treasurer of the city in which the judgment was entered and one-half
- 30 to the treasurer of the county in which the judgment was entered.
- 31 (3) If the action is brought by a city attorney of a city and
- 32 county, the entire amount of the penalty collected shall be paid to
- 33 the treasurer of the city and county in which the judgment was
- 34 entered.
- 35 (4) Nothing in this section shall be construed as authorizing
- 36 both an administrative fine and civil penalty for the same violation.
- 37 (5) Imposition of a fine or penalty provided for in this section
- 38 shall not preclude imposition of any other sanctions or remedies
- 39 authorized by law.

1 (6) Administrative fines or penalties issued pursuant to Section
2 1280.15 of the Health and Safety Code shall offset any other
3 administrative fine or civil penalty imposed under this section for
4 the same violation.

5 (f) For purposes of this section, “knowing” and “willful” shall
6 have the same meanings as in Section 7 of the Penal Code.

7 (g) No person who discloses protected medical information in
8 accordance with the provisions of this part shall be subject to the
9 penalty provisions of this part.

10 (h) Paragraph (6) of subdivision (e) shall only become operative
11 if Senate Bill 541 of the 2007–08 Regular Session is enacted and
12 becomes effective on or before January 1, 2009.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1250

VERSION: As Introduced February 23, 2012

AUTHOR: Alquist

SPONSOR: Author

BOARD POSITION:

SUBJECT: Medical Records: Confidentiality

AFFECTED SECTIONS: Act to amend Section 56.36 of the Civil Code

CURRENT STATUS: Referred to Senate Judiciary Committee

EXISTING LAW:

1. Establishes the Confidentiality of Medical Information Act that specifies the confidentiality of information maintained medical records by health care providers, health coverage plans, pharmaceutical companies and other contractors as specified.
2. Established monetary penalties for individuals and entities that violation this act.

THIS BILL WOULD:

Specify that in addition to other legal remedies, a defendant may be required to pay for credit monitoring and reporting services for one year from the unauthorized release of medical information.

COMMENTS:

Board staff was unable to speak with the author's office. Additional information will be provided during the committee meeting if available.

FISCAL IMPACT:

Board staff does not anticipate any significant fiscal impact. Any minor impact could be absorbed within existing resources.

SUPPORT/OPPOSITION:

Unknown

HISTORY:

Date Action

2012

Mar. 8 Referred to Com. on JUD.

Feb. 24 From printer. May be acted upon on or after March 25.

Feb. 23 Introduced. Read first time. To Com. on RLS. for assignment. To print.

ASSEMBLY BILL

No. 2342

Introduced by Assembly Member Torres

February 24, 2012

An act to amend Section 11165 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 2342, as introduced, Torres. Controlled substances.

Existing law classifies certain controlled substances into designated schedules, and prohibits, except as specified, a controlled substance classified in Schedule II, III, IV, or V from being dispensed without a prescription, as specified.

Existing law requires the Department of Justice, contingent upon the availability of adequate funds from various funds related to health care, to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

This bill would make a technical, nonsubstantive change to the provision requiring the Department of Justice to maintain CURES for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances, as described above.

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 11165 of the Health and Safety Code is
2 amended to read:

3 11165. (a) ~~To~~*In order to* assist law enforcement and
4 regulatory agencies in their efforts to control the diversion and
5 resultant abuse of Schedule II, Schedule III, and Schedule IV
6 controlled substances, and for statistical analysis, education, and
7 research, the Department of Justice shall, contingent upon the
8 availability of adequate funds from the Contingent Fund of the
9 Medical Board of California, the Pharmacy Board Contingent
10 Fund, the State Dentistry Fund, the Board of Registered Nursing
11 Fund, and the Osteopathic Medical Board of California Contingent
12 Fund, maintain the Controlled Substance Utilization Review and
13 Evaluation System (CURES) for the electronic monitoring of, and
14 Internet access to information regarding, the prescribing and
15 dispensing of Schedule II, Schedule III, and Schedule IV controlled
16 substances by all practitioners authorized to prescribe or dispense
17 these controlled substances.

18 (b) The reporting of Schedule III and Schedule IV controlled
19 substance prescriptions to CURES shall be contingent upon the
20 availability of adequate funds from the Department of Justice. The
21 department may seek and use grant funds to pay the costs incurred
22 from the reporting of controlled substance prescriptions to CURES.
23 Funds shall not be appropriated from the Contingent Fund of the
24 Medical Board of California, the Pharmacy Board Contingent
25 Fund, the State Dentistry Fund, the Board of Registered Nursing
26 Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical
27 Board of California Contingent Fund to pay the costs of reporting
28 Schedule III and Schedule IV controlled substance prescriptions
29 to CURES.

30 (c) CURES shall operate under existing provisions of law to
31 safeguard the privacy and confidentiality of patients. Data obtained
32 from CURES shall only be provided to appropriate state, local,
33 and federal persons or public agencies for disciplinary, civil, or
34 criminal purposes and to other agencies or entities, as determined
35 by the Department of Justice, for the purpose of educating
36 practitioners and others in lieu of disciplinary, civil, or criminal
37 actions. Data may be provided to public or private entities, as
38 approved by the Department of Justice, for educational, peer

1 review, statistical, or research purposes, provided that patient
2 information, including any information that may identify the
3 patient, is not compromised. Further, data disclosed to any
4 individual or agency as described in this subdivision shall not be
5 disclosed, sold, or transferred to any third party.

6 (d) For each prescription for a Schedule II, Schedule III, or
7 Schedule IV controlled substance, as defined in the controlled
8 substances schedules in federal law and regulations, specifically
9 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21
10 of the Code of Federal Regulations, the dispensing pharmacy or
11 clinic shall provide the following information to the Department
12 of Justice on a weekly basis and in a format specified by the
13 Department of Justice:

14 (1) Full name, address, and the telephone number of the ultimate
15 user or research subject, or contact information as determined by
16 the Secretary of the United States Department of Health and Human
17 Services, and the gender, and date of birth of the ultimate user.

18 (2) The prescriber's category of licensure and license number;
19 federal controlled substance registration number; and the state
20 medical license number of any prescriber using the federal
21 controlled substance registration number of a government-exempt
22 facility.

23 (3) Pharmacy prescription number, license number, and federal
24 controlled substance registration number.

25 (4) NDC (National Drug Code) number of the controlled
26 substance dispensed.

27 (5) Quantity of the controlled substance dispensed.

28 (6) ICD-9 (diagnosis code), if available.

29 (7) Number of refills ordered.

30 (8) Whether the drug was dispensed as a refill of a prescription
31 or as a first-time request.

32 (9) Date of origin of the prescription.

33 (10) Date of dispensing of the prescription.

34 (e) This section shall become operative on January 1, 2005.

AMENDED IN ASSEMBLY APRIL 16, 2012

CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1733

Introduced by Assembly Member Logue

February 16, 2012

An act to amend Section 1374.13 of the Health and Safety Code, *and to add Section 14594 to the Welfare and Institutions Code*, relating to ~~health care service plans~~ *telehealth*.

LEGISLATIVE COUNSEL'S DIGEST

AB 1733, as amended, Logue. ~~Health care service plans; telehealth.~~ *Telehealth.*

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of the act a crime. Existing law prohibits a health care service plan from requiring in-person contact between a health care provider and a patient before payment is made for covered services appropriately provided through telehealth, as specified. Existing law specifies that this requirement applies to certain Medi-Cal managed care plans, including county organized health systems and entities contracting with the department to provide services pursuant to 2-plan models and geographic managed care.

Existing law establishes the California Program of All-Inclusive Care for the Elderly (PACE) and provides that the State Department of Health Care Services may enter into contracts with public or private nonprofit organizations for implementation of the PACE program.

This bill would specify that the prohibition on requiring in-person contact also applies to other health care service plan contracts with the

State Department of Health Care Services for services under the Medi-Cal program, *and* publicly supported programs other than Medi-Cal, ~~and for services pursuant to the Program of All-Inclusive Care for the Elderly. as well as to the organizations implementing the PACE program.~~ By expanding the scope of a crime, the bill would impose a state-mandated local program.

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

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

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

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

1 SECTION 1. Section 1374.13 of the Health and Safety Code
2 is amended to read:

3 1374.13. (a) For the purposes of this section, the definitions
4 in subdivision (a) of Section 2290.5 of the Business and Professions
5 Code shall apply.

6 (b) It is the intent of the Legislature to recognize the practice
7 of telehealth as a legitimate means by which an individual may
8 receive health care services from a health care provider without
9 in-person contact with the health care provider.

10 (c) No health care service plan shall require that in-person
11 contact occur between a health care provider and a patient before
12 payment is made for the covered services appropriately provided
13 through telehealth, subject to the terms and conditions of the
14 contract entered into between the enrollee or subscriber and the
15 health care service plan, and between the health care service plan
16 and its participating providers or provider groups.

17 (d) No health care service plan shall limit the type of setting
18 where services are provided for the patient or by the health care
19 provider before payment is made for the covered services
20 appropriately provided through telehealth, subject to the terms and
21 conditions of the contract entered into between the enrollee or
22 subscriber and the health care service plan, and between the health
23 care service plan and its participating providers or provider groups.

1 (e) The requirements of this section shall also apply to health
2 care service plan contracts with the State Department of Health
3 Care Services pursuant to Chapter 7 (commencing with Section
4 ~~14000~~), *14000*) or Chapter 8 (commencing with Section 14200);
5 ~~or Chapter 8.75 (commencing with Section 14591) of, of~~ Part 3 of
6 Division 9 of the Welfare and Institutions Code.

7 (f) Notwithstanding any other provision, this section shall not
8 be interpreted to authorize a health care service plan to require the
9 use of telehealth when the health care provider has determined
10 that it is not appropriate.

11 *SEC. 2. Section 14594 is added to the Welfare and Institutions*
12 *Code, to read:*

13 *14594. (a) For the purposes of this section, the definitions in*
14 *subdivision (a) of Section 2290.5 of the Business and Professions*
15 *Code shall apply.*

16 *(b) It is the intent of the Legislature to recognize the practice*
17 *of telehealth as a legitimate means by which an individual may*
18 *receive health care services from a health care provider without*
19 *in-person contact with the health care provider.*

20 *(c) No PACE organization shall require that in-person contact*
21 *occur between a health care provider and a patient before payment*
22 *is made for the covered services appropriately provided through*
23 *telehealth, subject to the terms and conditions of the contract*
24 *entered into between the enrollee or subscriber and the PACE*
25 *organization, and between the PACE organization and its*
26 *participating providers or provider groups.*

27 *(d) No PACE organization shall limit the type of setting where*
28 *services are provided for the patient or by the health care provider*
29 *before payment is made for the covered services appropriately*
30 *provided through telehealth, subject to the terms and conditions*
31 *of the contract entered into between the enrollee or subscriber*
32 *and the PACE organization, and between the PACE organization*
33 *and its participating providers or provider groups.*

34 *(e) Notwithstanding any other provision, this section shall not*
35 *be interpreted to authorize a PACE organization to require the*
36 *use of telehealth when the health care provider has determined*
37 *that it is not appropriate.*

38 ~~SEC. 2.~~

39 *SEC. 3. No reimbursement is required by this act pursuant to*
40 *Section 6 of Article XIII B of the California Constitution because*

1 the only costs that may be incurred by a local agency or school
2 district will be incurred because this act creates a new crime or
3 infraction, eliminates a crime or infraction, or changes the penalty
4 for a crime or infraction, within the meaning of Section 17556 of
5 the Government Code, or changes the definition of a crime within
6 the meaning of Section 6 of Article XIII B of the California
7 Constitution.

O

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1733

VERSION: As Amended April 16, 2012

AUTHOR: Logue

SPONSOR: California State Rural Health Association

BOARD POSITION:

SUBJECT: Telehealth

AFFECTED SECTIONS: Amend Section 1374.13 of the Health and Safety Code and add Section 14594 to the Welfare and Institutions Code

CURRENT STATUS: Assembly Health Committee hearing scheduled for April 24, 2012

EXISTING LAW:

1. Establishes the provisions for telehealth.
2. Prohibits a health care service plan from requiring in-person contact between a health care professional and a patient for purposes of receiving payment.
3. Defines the health care plans affected by this prohibition.

THIS BILL WOULD:

1. Specify that the mandated in-person contact prohibition would also apply to health care service plan contracts with the Department of Health Care Services for services provided by the Medi-Cal program, other publicly support programs as well as to organizations implementing the California Program of All-Inclusive Care for the Elderly (PACE).

AUTHOR'S INTENT:

According to a fact sheet provided by the author's office, "This bill would remove barriers in current law and update to current practice the use of telehealth in the delivery of health care, by expanding the application of AB 415 (Logue, 2011) to all remaining contracts that health care service plans and other entities have with the Department of Health Care Services (DHCS). AB 415 effectively applied to all health care service plans in California, but failed to specifically reference two health care service plans that contract with DHCS – the SCAN Health Plan and the AIDS Healthcare Foundation. As well, AB 415 did not apply to entities contracting with DHCS under the Program of All-Inclusive Care for the Elderly (PACE)."

FISCAL IMPACT:

Board staff does not anticipate any significant impact. Any minor fiscal impact could be absorbed within existing resources.

PREVIOUS LEGISLATION:

AB 415 (Logue, Chapter 547, Statutes of 2011) amended the definitions used to implement existing telehealth provisions.

SUPPORT/OPPOSITION:

Support

California State Rural Health Association (sponsor)
California Communities United Institute
Aging Services of California
California Association of Marriage and Family Therapists
AIDS Healthcare Foundation

Opposition

None

HISTORY:

Date Action

2012

Apr. 17	Re-referred to Com. on HEALTH.
Apr. 16	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 27	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 1	Referred to Com. on HEALTH.
Feb. 17	From printer. May be heard in committee March 18.
Feb. 16	Read first time. To print.

Agenda Item A

Legislation Report

2. Board-Sponsored Legislation for 2012



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: April 18, 2012

To: Legislation and Regulation Committee

Subject: Agenda Item A2 – Board-Sponsored Legislation

SB 1575 (Senate Committee on Business, Professions and Economic Development)
Omnibus

Last Amend: April 16, 2012
Location: SEN Business, Professions and Economic Development

In October 2011 the Board approved language to amend Section 4209 of the Business and Professions Code to provide the board with the authority to accept intern hours earned in another state, as specified, and to specify requirements for certifications of intern hours earned for pharmacist applicants.

Additionally, in January 2012, the Board approved language to add Section 4300.1 to the Business and Professions Code to ensure the board can put discipline on record even if the license is cancelled.

SB 1575 was introduced on March 12, 2012, containing multiple omnibus provisions for various boards, bureaus and entities. On April 16, the bill was amended to include the board's sponsored provisions.

SB 1575 also contains a department-sponsored proposal to add Section 144.5 to the Business and Professions Code to authorize a board to request – and require a local or state agency to provide – certified records, such as arrests, convictions, and other documents required to complete an applicant or licensee investigation.

A copy of SB 1575 and a bill analysis is provided.

Status: 4/23/12 – Hearing in SEN BP&ED

Staff Recommendation: Support

Introduced by Committee on Business, Professions and Economic Development (Senators Price (Chair), Corbett, Correa, Emmerson, Hernandez, Negrete McLeod, Strickland, Vargas, and Wyland)

March 12, 2012

An act to amend Sections 1934, 1950.5, 2021, 2064, 2184, 2220, 2424, 2516, 2518, 2904.5, 3057.5, 3742, 3750, 3750.5, 4209, 4600, 4601, 4603.7, 4612, 4980.04, 4980.34, 4980.398, 4980.399, 4980.43, 4980.44, 4980.48, 4980.78, 4980.80, 4984.4, 4989.16, 4989.42, 4992.07, 4992.09, 4996.6, 4999.22, 4999.32, 4999.46, 4999.57, 4999.58, 4999.59, 4999.62, 4999.76, 4999.90, 4999.106, and 4999.120 of, to add ~~Section~~ Sections 144.5, 1902.2, 1942, 1958.1, and 4300.1 to repeal Section 1909.5 of, and to repeal and amend Section 4999.45 of, the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 1575, as amended, Committee on Business, Professions and Economic Development. Professions and vocations.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

(1) Under existing law, specified professions and vocations boards are required to require an applicant to furnish to the board a full set of fingerprints in order to conduct a criminal history record check.

This bill would authorize such a board to request, and would require a local or state agency to provide, certified records of, among other things, all arrests and convictions needed by a board to complete an

applicant or licensee investigation. *By imposing additional duties on local agencies, the bill would impose a state-mandated local program.*

(2) Existing law, the Dental Practice Act, provides for the licensure and regulation of the practice of dentistry by the Dental Board of California within the Department of Consumer Affairs. Existing law establishes the Dental Hygiene Committee of California under the jurisdiction of the board and provides for the licensure and regulation of the practice of dental hygienists by the committee.

This bill would require dental hygienists, upon initial licensure and renewal, to report their employment status to the committee and would require that information to be posted on the committee's Internet Web site. This bill would also require an approval dental hygiene education program to register extramural dental facilities, as defined, with the committee.

Existing law provides that a dental hygienist may have his or her license suspended or revoked by the board for committing acts of unprofessional conduct, as defined.

This bill would include within the definition of unprofessional conduct the aiding or abetting of the unlicensed or unlawful practice of dental hygiene and knowingly failing to follow infection control guidelines, as specified.

Existing law authorizes the committee to deny an application for licensure or to revoke or suspend a license for specified reasons.

This bill would require the committee to deny a license or renewal of a license to any person who is required by law to register as a sex offender.

(2)

(3) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California. Under existing law, the board issues a physician and surgeon's certificate to a licensed physician and surgeon. Existing law provides for the licensure and regulation of the practice of podiatric medicine by the California Board of Podiatric Medicine within the Medical Board of California.

Existing law requires the Medical Board of California and the California Board of Podiatric Medicine to provide written notification by certified mail to any physician and surgeon or podiatrist who does not renew his or her license within 60 days of expiration.

This bill would require the Medical Board of California and the California Board of Podiatric Medicine to provide that written

notification either by certified mail or by electronic mail if requested by the licensee. The bill would require the Medical Board of California to annually send an electronic notice to all licensees and applicants requesting confirmation that his or her electronic mail address is current.

Existing law authorizes the Medical Board of California to take action against all persons guilty of violating the Medical Practice Act. Existing law requires the Medical Board of California to enforce and administer various disciplinary provisions as to physician and surgeon certificate holders.

This bill would specify that those certificate holders include those who hold certificates that do not permit them to practice medicine, such as, but not limited to, retired, inactive, or disabled status certificate holders.

(3)

(4) Existing law, the Licensed Midwifery Practice Act of 1993, provides for the licensure and regulation of the practice of licensed midwifery by the Medical Board of California. A violation of the act is a crime. Under existing law, these licenses are subject to biennial renewal that includes the payment of a specified fee and the completion of specified continuing education.

This bill would exempt a licensee from those renewal requirements if the licensee has applied to the board and has been issued a retired status license. The bill would prohibit the holder of a retired status license from engaging in the practice of midwifery. Because a violation of that prohibition would constitute a crime, the bill would impose a state-mandated local program.

(4)

(5) Existing law, the Psychology Licensing Law, provides for the licensure and regulation of psychologists by the Board of Psychology. Existing law provides that a licensed psychologist is a health care practitioner for purposes of specified telehealth provisions that concern the delivery of health care via information and communication technologies.

This bill would instead provide that a licensed psychologist is a health care provider subject to those telehealth provisions.

(5)

(6) Existing law, the Respiratory Care Practice Act, provides for the licensure and regulation of the practice of respiratory care by the Respiratory Care Board of California.

Under existing law, during the period of any clinical training, a student respiratory care practitioner is required to be under the direct supervision, as defined, of a person holding a valid and current license.

This bill would require such a student to be under the direct supervision of a person with a valid, current, and unrestricted license.

Existing law authorizes the board to order the denial, suspension, or revocation of, or the imposition of probationary conditions upon, a license for specified causes including a pattern of substandard care.

This bill would expand that provision to also include negligence in the licensee's practice as a respiratory care practitioner, or in any capacity as a health care worker, consultant, supervisor, manager or health facility owner, or as a party responsible for the care of another.

Existing law authorizes the board to deny, suspend, place on probation, or revoke the license of any applicant or licenseholder who has obtained, possessed, used, or administered to himself or herself, or furnished or administered to another, any controlled substances or dangerous drug, except as directed by a specified health care provider.

This bill would also make illegally possessing any associated paraphernalia a ground for the denial, suspension, placing on probation, or revocation of a license.

(7) Existing law, the Pharmacy Law, provides for the California State Board of Pharmacy within the Department of Consumer Affairs, to license and regulate the practice of pharmacy.

Existing law authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct, as specified.

This bill would modify the practice requirements applicable to intern pharmacists. The bill would also provide that the board continues to have jurisdiction in a disciplinary action against a licensee, even if the license is expired, cancelled, forfeited, suspended, revoked, placed on retired status, or voluntarily surrendered.

(8) Existing law provides for the voluntary certification of massage practitioners and massage therapists by the California Massage Therapy Council. Existing law provides specified educational and other requirements for an applicant to obtain a massage therapy certificate.

This bill would set minimum educational hour and course requirements for an applicant to qualify to receive a massage therapy certificate. The bill would also define "operator of a massage business" for purposes of these provisions.

Existing law requires a certificate holder to display the certificate at his or her place of business.

This bill would require the certificate holder to display the original certificate at his or her place of business and to have the identification card, issued by the council, with him or her whenever providing massage therapy services. This bill would also require a massage therapist to surrender his or her identification card when his or her certificate is suspended or revoked.

Existing law authorizes a city, county, or city and county to require background checks of certain uncertified owners or operators of massage therapy establishments.

This bill would authorize that background check to include a criminal background check, including submission of fingerprints and employment history for the 10 preceding years.

Existing law authorizes a city, county, or city and county to charge certain massage businesses or establishments a business licensing fee, provided that the fee charged is no different than what is uniformly applied to other individuals and businesses providing professional services, as specified.

The bill would require that the licensing fee charged to massage businesses or establishments be no higher than those charged to other professions. The bill would also prohibit a city, county, or city and county from requesting information from those businesses or establishments that is different from that requested of others providing professional services.

~~(6)~~

(9) Under existing law, the Board of Behavioral Sciences is responsible for the licensure and regulation of marriage and family therapists, licensed educational psychologists, licensed clinical social workers, and licensed professional clinical counselors.

Under existing law, a license that is not renewed within 3 years after its expiration may not be renewed. However, the former licensee is authorized to apply for and obtain a new license if certain requirements are met, including, but not limited to, passing one or more current licensing examinations, as specified and submitting certain fees.

This bill would additionally require a former licensee to comply with the fingerprint requirements established by board regulation or as directed by the board. *The bill would make other technical and clarifying changes.*

~~(A)~~

(10) Existing law, the Marriage and Family Therapist Act, with respect to applicants for licensure or registration by reciprocity or for those applicants who obtained education or experience outside of California that apply on and after January 1, 2014, existing law provides that education is substantially equivalent if certain requirements are met, including the completion of a course in California law and professional ethics.

This bill would require that course to be 18 hours in length.

For persons who apply for licensure between January 1, 2010, and December 31, 2013, existing law authorizes the board to issue a license to a person who holds a valid license from another state if certain requirements are met, including the completion of specified coursework or training. Existing law provides that an applicant who completed a specified course in law and professional ethics is required to complete an 18-hour course in California law and professional ethics.

This bill would instead specify that an 18-hour course in California law and professional ethics is only required if the above specified course in law and professional ethics does not meet certain requirements. *The bill would make other technical changes to those provisions.*

The bill would rename the act as the Licensed Marriage and Family Therapist Act.

(B)

(11) Existing law, the Licensed Professional Clinical Counselor Act, provides for the licensure and regulation of the practice of professional clinical counseling by the Board of Behavioral Sciences.

Under existing law, to qualify for registration, an intern applicant is required to meet certain qualifications. With respect to applicants for registration who began graduate study before August 1, 2012, and complete study on or before December 31, 2018, an applicant is required to complete a minimum of 18 contact hours of instruction in California law and professional ethics prior to registration as an intern.

This bill would describe the content of that instruction for professional clinical counselors.

Existing law authorizes the board to refuse to issue any registration or license, or to suspend or revoke the registration or license of any intern or licensed professional clinical counselor, if the applicant, licensee, or registrant has been guilty of unprofessional conduct that includes, but is not limited to, the conviction of more than one misdemeanor or any felony involving the use, consumption, or

self-administration of any of specified substances, or any combination thereof.

This bill would delete the conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any of specified substances, or any combination thereof, from the list of what constitutes professional conduct. The bill would make it unprofessional conduct to willfully violate specified provisions governing patient access to health care records.

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

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

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

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.

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

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

1 SECTION 1. Section 144.5 is added to the Business and
2 Professions Code, to read:

3 144.5. Notwithstanding any other provision of law, a board
4 described in Section 144 may request a local or state agency to
5 provide certified records of all arrests and convictions, certified
6 records regarding probation, and any and all other related
7 documentation needed to complete an applicant or licensee
8 investigation. The local or state agency shall provide those records
9 to the board upon receipt of such a request.

10 SEC. 2. Section 1902.2 is added to the Business and Professions
11 Code, to read:

1 1902.2. (a) A licensee shall report, upon his or her initial
2 licensure and any subsequent application for renewal or inactive
3 license, the practice or employment status of the licensee,
4 designated as one of the following:

5 (1) Full-time practice or employment in a dental or dental
6 hygiene practice of 32 hours per week or more in California.

7 (2) Full-time practice or employment in a dental or dental
8 hygiene practice of 32 hours or more outside of California.

9 (3) Part-time practice or employment in a dental or dental
10 hygiene practice for less than 32 hours per week in California.

11 (4) Part-time practice or employment in a dental or dental
12 hygiene practice for less than 32 hours per week outside of
13 California.

14 (5) Dental hygiene administrative employment that does not
15 include direct patient care, as may be further defined by the
16 committee.

17 (6) Retired.

18 (7) Other practice or employment status, as may be further
19 defined by the committee.

20 (b) Information collected pursuant to subdivision (a) shall be
21 posted on the Internet Web site of the committee.

22 (c) (1) A licensee may report on his or her application for
23 renewal, and the committee, as appropriate, shall collect,
24 information regarding the licensee's cultural background and
25 foreign language proficiency.

26 (2) Information collected pursuant to this subdivision shall be
27 aggregated on an annual basis, based on categories utilized by
28 the committee in the collection of the data, into both statewide
29 totals and ZIP Code of primary practice or employment location
30 totals.

31 (3) Aggregated information under this subdivision shall be
32 compiled annually, and reported on the Internet Web site of the
33 committee as appropriate, on or before July 1 of each year.

34 (d) It is the intent of the Legislature to utilize moneys in the
35 State Dental Hygiene Fund to pay any cost incurred by the
36 committee in implementing this section.

37 SEC. 3. Section 1909.5 of the Business and Professions Code
38 is repealed.

39 ~~1909.5. Courses of instruction for direct supervision duties~~
40 ~~added to the scope of practice of dental hygiene on or after July~~

1 ~~1, 2009, shall be submitted by the committee for approval by the~~
2 ~~dental board.~~

3 *SEC. 4. Section 1934 of the Business and Professions Code is*
4 *amended to read:*

5 1934. A licensee who changes his or her *physical* address of
6 record *or e-mail address* shall notify the committee within 30 days
7 of the change. A licensee who changes his or her legal name shall
8 provide the committee with documentation of the change within
9 10 days.

10 *SEC. 5. Section 1942 is added to the Business and Professions*
11 *Code, to read:*

12 1942. (a) *As used in this section “extramural dental facility”*
13 *means any clinical facility employed by an approved dental hygiene*
14 *educational program for instruction in dental hygiene that exists*
15 *outside or beyond the walls, boundaries, or precincts of the primary*
16 *campus of the approved program and in which dental hygiene*
17 *services are rendered.*

18 (b) *An approved dental hygiene educational program shall*
19 *register extramural dental facilities with the committee. The*
20 *registration shall be accompanied by information supplied by the*
21 *dental hygiene program pertaining to faculty supervision, scope*
22 *of treatment to be rendered, name and location of the facility, date*
23 *operation will commence, discipline of which such instruction is*
24 *a part, and a brief description of the equipment and facilities*
25 *available. That information shall be supplemented by a copy of*
26 *the agreement between the approved dental hygiene educational*
27 *program or parent university and the affiliated institution*
28 *establishing the contractual relationship. Any change in the*
29 *information provided to the committee shall be communicated to*
30 *the committee.*

31 *SEC. 6. Section 1950.5 of the Business and Professions Code*
32 *is amended to read:*

33 1950.5. Unprofessional conduct by a person licensed under
34 this article is defined as, but is not limited to, any one of the
35 following:

36 (a) The obtaining of any fee by fraud or misrepresentation.

37 (b) The aiding or abetting of any unlicensed person to practice
38 dentistry *or dental hygiene*.

39 (c) The aiding or abetting of a licensed person to practice
40 dentistry *or dental hygiene* unlawfully.

- 1 (d) The committing of any act or acts of sexual abuse,
2 misconduct, or relations with a patient that are substantially related
3 to the practice of dental hygiene.
- 4 (e) The use of any false, assumed, or fictitious name, either as
5 an individual, firm, corporation, or otherwise, or any name other
6 than the name under which he or she is licensed to practice, in
7 advertising or in any other manner indicating that he or she is
8 practicing or will practice dentistry, except that name as is specified
9 in a valid permit issued pursuant to Section ~~1701.5~~ 1962.
- 10 (f) The practice of accepting or receiving any commission or
11 the rebating in any form or manner of fees for professional services,
12 ~~radiograms~~ *radiographs*, prescriptions, or other services or articles
13 supplied to patients.
- 14 (g) The making use by the licensee or any agent of the licensee
15 of any advertising statements of a character tending to deceive or
16 mislead the public.
- 17 (h) The advertising of either professional superiority or the
18 advertising of performance of professional services in a superior
19 manner. This subdivision shall not prohibit advertising permitted
20 by subdivision (h) of Section 651.
- 21 (i) The employing or the making use of solicitors.
- 22 (j) Advertising in violation of Section 651.
- 23 (k) Advertising to guarantee any dental hygiene service, or to
24 perform any dental hygiene procedure painlessly. This subdivision
25 shall not prohibit advertising permitted by Section 651.
- 26 (l) The violation of any of the provisions of this division.
- 27 (m) The permitting of any person to operate dental radiographic
28 equipment who has not met the requirements ~~of Section 1656~~ *to*
29 *do so, as determined by the committee.*
- 30 (n) The clearly excessive administering of drugs or treatment,
31 or the clearly excessive use of treatment procedures, or the clearly
32 excessive use of treatment facilities, as determined by the
33 customary practice and standards of the dental hygiene profession.
34 Any person who violates this subdivision is guilty of a
35 misdemeanor and shall be punished by a fine of not less than one
36 hundred dollars (\$100) or more than six hundred dollars (\$600),
37 or by imprisonment for a term of not less than 60 days or more
38 than 180 days, or by both a fine and imprisonment.
- 39 (o) The use of threats or harassment against any patient or
40 licensee for providing evidence in any possible or actual

1 disciplinary action, or other legal action; or the discharge of an
2 employee primarily based on the employee's attempt to comply
3 with the provisions of this chapter or to aid in the compliance.

4 (p) Suspension or revocation of a license issued, or discipline
5 imposed, by another state or territory on grounds that would be
6 the basis of discipline in this state.

7 (q) The alteration of a patient's record with intent to deceive.

8 (r) Unsanitary or unsafe office conditions, as determined by the
9 customary practice and standards of the dental hygiene profession.

10 (s) The abandonment of the patient by the licensee, without
11 written notice to the patient that treatment is to be discontinued
12 and before the patient has ample opportunity to secure the services
13 of another registered dental hygienist, registered dental hygienist
14 in alternative practice, or registered dental hygienist in extended
15 functions and provided the health of the patient is not jeopardized.

16 (t) The willful misrepresentation of facts relating to a
17 disciplinary action to the patients of a disciplined licensee.

18 (u) Use of fraud in the procurement of any license issued
19 pursuant to this article.

20 (v) Any action or conduct that would have warranted the denial
21 of the license.

22 (w) The aiding or abetting of a registered dental hygienist,
23 registered dental hygienist in alternative practice, or registered
24 dental hygienist in extended functions to practice dental hygiene
25 in a negligent or incompetent manner.

26 (x) The failure to report to the committee in writing within seven
27 days any of the following: (1) the death of his or her patient during
28 the performance of any dental hygiene procedure; (2) the discovery
29 of the death of a patient whose death is related to a dental hygiene
30 procedure performed by him or her; or (3) except for a scheduled
31 hospitalization, the removal to a hospital or emergency center for
32 medical treatment for a period exceeding 24 hours of any patient
33 as a result of dental or dental hygiene treatment. Upon receipt of
34 a report pursuant to this subdivision, the committee may conduct
35 an inspection of the dental hygiene practice office if the committee
36 finds that it is necessary.

37 (y) A registered dental hygienist, registered dental hygienist in
38 alternative practice, or registered dental hygienist in extended
39 functions shall report to the committee all deaths occurring in his
40 or her practice with a copy sent to the dental board if the death

1 occurred while working as an employee in a dental office. A dentist
2 shall report to the dental board all deaths occurring in his or her
3 practice with a copy sent to the committee if the death was the
4 result of treatment by a registered dental hygienist, registered dental
5 hygienist in alternative practice, or registered dental hygienist in
6 extended functions.

7 *(z) Except for good cause, the knowing failure to protect patients*
8 *by failing to follow infection control guidelines of the committee,*
9 *thereby risking transmission of infectious diseases from dental*
10 *assistant, registered dental assistant, registered dental hygienist,*
11 *registered dental hygienist in alternative practice, or registered*
12 *dental hygienist in extended functions to patient, from patient to*
13 *patient, and from patient to dental assistant, registered dental*
14 *assistant, registered dental hygienist, registered dental hygienist*
15 *in alternative practice, or registered dental hygienist in extended*
16 *functions. In administering this subdivision, the committee shall*
17 *consider referencing the standards, regulations, and guidelines*
18 *of the State Department of Public Health developed pursuant to*
19 *Section 1250.11 of the Health and Safety Code, and the standards,*
20 *guidelines, and regulations pursuant to the California*
21 *Occupational Safety and Health Act of 1973 (Part 1 (commencing*
22 *with Section 6300) of Division 5 of the Labor Code) for preventing*
23 *the transmission of HIV, hepatitis B, and other pathogens in health*
24 *care settings. The committee shall review infection control*
25 *guidelines, if necessary, on an annual basis and proposed changes*
26 *shall be reviewed by the dental board to establish a consensus.*
27 *The dental board shall submit any recommended changes to the*
28 *infection control guidelines for review to establish a consensus.*
29 *As necessary, the committee shall consult with the Medical Board*
30 *of California, the California Board of Podiatric Medicine, the*
31 *Board of Registered Nursing, and the Board of Vocational Nursing*
32 *and Psychiatric Technicians, to encourage appropriate consistency*
33 *in the implementation of this subdivision.*

34 *SEC. 7. Section 1958.1 is added to the Business and Professions*
35 *Code, to read:*

36 *1958.1. (a) Notwithstanding any other law, with regard to an*
37 *individual who is required to register as a sex offender pursuant*
38 *to Section 290 of the Penal Code, or the equivalent in another*
39 *state or territory, under military law, or under federal law, all of*
40 *the following shall apply:*

1 (1) *The committee shall deny an application by the individual*
2 *for licensure pursuant to this article.*

3 (2) *If the individual is licensed under this article, the committee*
4 *shall promptly revoke the license of the individual. The committee*
5 *shall not stay the revocation nor place the license on probation.*

6 (3) *The committee shall not reinstate or reissue the individual's*
7 *licensure under this article. The committee shall not issue a stay*
8 *of license denial and place the license on probation.*

9 (b) *This section shall not apply to any of the following:*

10 (1) *An individual who has been relieved under Section 290.5 of*
11 *the Penal Code of his or her duty to register as a sex offender, or*
12 *whose duty to register has otherwise been formally terminated*
13 *under California law or the law of the jurisdiction that requires*
14 *his or her registration as a sex offender.*

15 (2) *An individual who is required to register as a sex offender*
16 *pursuant to Section 290 of the Penal Code solely because of a*
17 *misdemeanor conviction under Section 314 of the Penal Code.*
18 *However, nothing in this paragraph shall prohibit the committee*
19 *from exercising its discretion to discipline a licensee under other*
20 *provisions of state law based upon the licensee's conviction under*
21 *Section 314 of the Penal Code.*

22 (3) *Any administrative adjudication proceeding under Chapter*
23 *5 (commencing with Section 11500) of Part 1 of Division 3 of Title*
24 *2 of the Government Code that is fully adjudicated prior to January*
25 *1, 2013. A petition for reinstatement of a revoked or surrendered*
26 *license shall be considered a new proceeding for purposes of this*
27 *paragraph, and the prohibition against reinstating a license to an*
28 *individual who is required to register as a sex offender shall be*
29 *applicable.*

30 ~~SEC. 2.~~

31 SEC. 8. Section 2021 of the Business and Professions Code is
32 amended to read:

33 2021. (a) If the board publishes a directory pursuant to Section
34 112, it may require persons licensed pursuant to this chapter to
35 furnish any information as it may deem necessary to enable it to
36 compile the directory.

37 (b) Each licensee shall report to the board each and every change
38 of address within 30 days after each change, giving both the old
39 and new address. If an address reported to the board at the time of
40 application for licensure or subsequently is a post office box, the

1 applicant shall also provide the board with a street address. If
2 another address is the licensee's address of record, he or she may
3 request that the second address not be disclosed to the public.

4 (c) Each licensee shall report to the board each and every change
5 of name within 30 days after each change, giving both the old and
6 new names.

7 (d) The board shall annually send an electronic notice to each
8 applicant and licensee who has chosen to receive correspondence
9 via electronic mail that requests confirmation from the applicant
10 or licensee that his or her electronic mail address is current. An
11 applicant or licensee that does not confirm his or her electronic
12 mail address shall receive correspondence at a mailing address
13 provided pursuant to subdivision (b).

14 ~~SEC. 3.~~

15 *SEC. 9.* Section 2064 of the Business and Professions Code is
16 amended to read:

17 2064. Nothing in this chapter shall be construed to prevent a
18 regularly matriculated student undertaking a course of professional
19 instruction in an approved medical school, or to prevent a foreign
20 medical student who is enrolled in an approved medical school or
21 clinical training program in this state, or to prevent students
22 enrolled in a program of supervised clinical training under the
23 direction of an approved medical school pursuant to Section 2104,
24 from engaging in the practice of medicine whenever and wherever
25 prescribed as a part of his or her course of study.

26 ~~SEC. 4.~~

27 *SEC. 10.* Section 2184 of the Business and Professions Code
28 is amended to read:

29 2184. (a) Each applicant shall obtain on the written
30 examination a passing score, established by the board pursuant to
31 Section 2177.

32 (b) (1) Passing scores on each step of the United States Medical
33 Licensing Examination shall be valid for a period of 10 years from
34 the month of the examination for purposes of qualification for
35 licensure in California.

36 (2) The period of validity provided for in paragraph (1) may be
37 extended by the board for any of the following:

38 (A) For good cause.

39 (B) For time spent in a postgraduate training program, including,
40 but not limited to, residency training, clinical training, fellowship

1 training, remedial or refresher training, or other training that is
2 intended to maintain or improve medical skills.

3 (C) For an applicant who is a physician and surgeon in another
4 state or a Canadian province who is currently and actively
5 practicing medicine in that state or province.

6 (3) Upon expiration of the 10-year period plus any extension
7 granted by the board under paragraph (2), the applicant shall pass
8 the Special Purpose Examination of the Federation of State Medical
9 Boards or a clinical competency written examination determined
10 by the board to be equivalent.

11 ~~SEC. 5.~~

12 *SEC. 11.* Section 2220 of the Business and Professions Code
13 is amended to read:

14 2220. Except as otherwise provided by law, the board may
15 take action against all persons guilty of violating this chapter. The
16 board shall enforce and administer this article as to physician and
17 surgeon certificate holders, including those who hold certificates
18 that do not permit them to practice medicine, such as, but not
19 limited to, retired, inactive, or disabled status certificate holders,
20 and the board shall have all the powers granted in this chapter for
21 these purposes including, but not limited to:

22 (a) Investigating complaints from the public, from other
23 licensees, from health care facilities, or from the board that a
24 physician and surgeon may be guilty of unprofessional conduct.
25 The board shall investigate the circumstances underlying a report
26 received pursuant to Section 805 or 805.01 within 30 days to
27 determine if an interim suspension order or temporary restraining
28 order should be issued. The board shall otherwise provide timely
29 disposition of the reports received pursuant to Section 805 and
30 Section 805.01.

31 (b) Investigating the circumstances of practice of any physician
32 and surgeon where there have been any judgments, settlements,
33 or arbitration awards requiring the physician and surgeon or his
34 or her professional liability insurer to pay an amount in damages
35 in excess of a cumulative total of thirty thousand dollars (\$30,000)
36 with respect to any claim that injury or damage was proximately
37 caused by the physician's and surgeon's error, negligence, or
38 omission.

1 (c) Investigating the nature and causes of injuries from cases
2 which shall be reported of a high number of judgments, settlements,
3 or arbitration awards against a physician and surgeon.

4 ~~SEC. 6.~~

5 *SEC. 12.* Section 2424 of the Business and Professions Code
6 is amended to read:

7 2424. (a) The board or the California Board of Podiatric
8 Medicine, as the case may be, shall notify in writing either by
9 certified mail, return receipt requested, or by electronic mail if
10 requested by the licensee, any physician and surgeon or any
11 podiatrist who does not renew his or her license within 60 days
12 from its date of expiration.

13 (b) Notwithstanding Section 163.5, any such licensee who does
14 not renew his or her expired license within 90 days of its date of
15 expiration shall pay all the following fees:

16 (1) The renewal fee in effect at the time of renewal.

17 (2) A penalty fee equal to 50 percent of the renewal fee.

18 (3) The delinquency fee required by Section 2435 or 2499.5, as
19 the case may be.

20 (c) Notwithstanding any other provision of law, the renewal of
21 any expired physician's and surgeon's or podiatrist's license within
22 six months from its date of expiration shall be retroactive to the
23 date of expiration of that license. The division or board, for good
24 cause, may waive the 50 percent penalty fee and may extend
25 retroactivity up to two years from the expiration date of any such
26 license.

27 ~~SEC. 7.~~

28 *SEC. 13.* Section 2516 of the Business and Professions Code
29 is amended to read:

30 2516. (a) Each licensed midwife who assists, or supervises a
31 student midwife in assisting, in childbirth that occurs in an
32 out-of-hospital setting shall annually report to the Office of
33 Statewide Health Planning and Development. The report shall be
34 submitted no later than March 30, with the first report due in March
35 2008, for the prior calendar year, in a form specified by the board
36 and shall contain all of the following:

37 (1) The midwife's name and license number.

38 (2) The calendar year being reported.

39 (3) The following information with regard to cases in California
40 in which the midwife, or the student midwife supervised by the

1 midwife, assisted during the previous year when the intended place
2 of birth at the onset of care was an out-of-hospital setting:

3 (A) The total number of clients served as primary caregiver at
4 the onset of care.

5 (B) The total number of clients served with collaborative care
6 available through, or given by, a licensed physician and surgeon.

7 (C) The total number of clients served under the supervision of
8 a licensed physician and surgeon.

9 (D) The number by county of live births attended as primary
10 caregiver.

11 (E) The number, by county, of cases of fetal demise, infant
12 deaths, and maternal deaths attended as primary caregiver at the
13 discovery of the demise or death.

14 (F) The number of women whose primary care was transferred
15 to another health care practitioner during the antepartum period,
16 and the reason for each transfer.

17 (G) The number, reason, and outcome for each elective hospital
18 transfer during the intrapartum or postpartum period.

19 (H) The number, reason, and outcome for each urgent or
20 emergency transport of an expectant mother in the antepartum
21 period.

22 (I) The number, reason, and outcome for each urgent or
23 emergency transport of an infant or mother during the intrapartum
24 or immediate postpartum period.

25 (J) The number of planned out-of-hospital births at the onset of
26 labor and the number of births completed in an out-of-hospital
27 setting.

28 (K) The number of planned out-of-hospital births completed in
29 an out-of-hospital setting that were any of the following:

30 (i) Twin births.

31 (ii) Multiple births other than twin births.

32 (iii) Breech births.

33 (iv) Vaginal births after the performance of a cesarean section.

34 (L) A brief description of any complications resulting in the
35 morbidity or mortality of a mother or a neonate.

36 (M) Any other information prescribed by the board in
37 regulations.

38 (b) The Office of Statewide Health Planning and Development
39 shall maintain the confidentiality of the information submitted
40 pursuant to this section, and shall not permit any law enforcement

1 or regulatory agency to inspect or have copies made of the contents
2 of any reports submitted pursuant to subdivision (a) for any
3 purpose, including, but not limited to, investigations for licensing,
4 certification, or regulatory purposes.

5 (c) The office shall report to the board, by April 30, those
6 licensees who have met the requirements of subdivision (a) for
7 that year.

8 (d) The board shall send a written notice of noncompliance to
9 each licensee who fails to meet the reporting requirement of
10 subdivision (a). Failure to comply with subdivision (a) will result
11 in the midwife being unable to renew his or her license without
12 first submitting the requisite data to the Office of Statewide Health
13 Planning and Development for the year for which that data was
14 missing or incomplete. The board shall not take any other action
15 against the licensee for failure to comply with subdivision (a).

16 (e) The board, in consultation with the office and the Midwifery
17 Advisory Council, shall devise a coding system related to data
18 elements that require coding in order to assist in both effective
19 reporting and the aggregation of data pursuant to subdivision (f).
20 The office shall utilize this coding system in its processing of
21 information collected for purposes of subdivision (f).

22 (f) The office shall report the aggregate information collected
23 pursuant to this section to the board by July 30 of each year. The
24 board shall include this information in its annual report to the
25 Legislature.

26 (g) Notwithstanding any other provision of law, a violation of
27 this section shall not be a crime.

28 ~~SEC. 8.~~

29 *SEC. 14.* Section 2518 of the Business and Professions Code
30 is amended to read:

31 2518. (a) Licenses issued pursuant to this article shall be
32 renewable every two years upon payment of the fee prescribed by
33 Section 2520 and submission of documentation that the
34 licenseholder has completed 36 hours of continuing education in
35 areas that fall within the scope of the practice of midwifery, as
36 specified by the board.

37 (b) Each license not renewed shall expire, but may be reinstated
38 within five years from the expiration upon payment of the
39 prescribed fee and upon submission of proof of the applicant's
40 qualifications as the board may require.

1 (c) A licensee is exempt from the payment of the renewal fee
2 required by Section 2520 and the requirement for continuing
3 education if the licensee has applied to the board for, and been
4 issued, a retired status license. The holder of a retired status license
5 may not engage in the practice of midwifery.

6 ~~SEC. 9.~~

7 *SEC. 15.* Section 2904.5 of the Business and Professions Code
8 is amended to read:

9 2904.5. A psychologist licensed under this chapter is a licentiate
10 for purposes of paragraph (2) of subdivision (a) of Section 805,
11 and thus is a health care provider subject to the provisions of
12 Section 2290.5.

13 ~~SEC. 10.~~

14 *SEC. 16.* Section 3057.5 of the Business and Professions Code
15 is amended to read:

16 3057.5. Notwithstanding any other provision of this chapter,
17 the board shall permit a graduate of a foreign university who meets
18 all of the following requirements to take the examinations for a
19 certificate of registration as an optometrist:

20 (a) Is over the age of 18 years.

21 (b) Is not subject to denial of a certificate under Section 480.

22 (c) Has a degree as a doctor of optometry issued by a university
23 located outside of the United States.

24 ~~SEC. 11.~~

25 *SEC. 17.* Section 3742 of the Business and Professions Code
26 is amended to read:

27 3742. During the period of any clinical training, a student
28 respiratory care practitioner shall be under the direct supervision
29 of a person holding a valid, current, and unrestricted license issued
30 under this chapter. "Under the direct supervision" means assigned
31 to a respiratory care practitioner who is on duty and immediately
32 available in the assigned patient care area.

33 ~~SEC. 12.~~

34 *SEC. 18.* Section 3750 of the Business and Professions Code
35 is amended to read:

36 3750. The board may order the denial, suspension, or revocation
37 of, or the imposition of probationary conditions upon, a license
38 issued under this chapter, for any of the following causes:

39 (a) Advertising in violation of Section 651 or Section 17500.

40 (b) Fraud in the procurement of any license under this chapter.

- 1 (c) Knowingly employing unlicensed persons who present
2 themselves as licensed respiratory care practitioners.
- 3 (d) Conviction of a crime that substantially relates to the
4 qualifications, functions, or duties of a respiratory care practitioner.
5 The record of conviction or a certified copy thereof shall be
6 conclusive evidence of the conviction.
- 7 (e) Impersonating or acting as a proxy for an applicant in any
8 examination given under this chapter.
- 9 (f) Negligence in his or her practice as a respiratory care
10 practitioner.
- 11 (g) Conviction of a violation of any of the provisions of this
12 chapter or of any provision of Division 2 (commencing with
13 Section 500), or violating, or attempting to violate, directly or
14 indirectly, or assisting in or abetting the violation of, or conspiring
15 to violate any provision or term of this chapter or of any provision
16 of Division 2 (commencing with Section 500).
- 17 (h) The aiding or abetting of any person to violate this chapter
18 or any regulations duly adopted under this chapter.
- 19 (i) The aiding or abetting of any person to engage in the unlawful
20 practice of respiratory care.
- 21 (j) The commission of any fraudulent, dishonest, or corrupt act
22 which is substantially related to the qualifications, functions, or
23 duties of a respiratory care practitioner.
- 24 (k) Falsifying, or making grossly incorrect, grossly inconsistent,
25 or unintelligible entries in any patient, hospital, or other record.
- 26 (l) Changing the prescription of a physician and surgeon, or
27 falsifying verbal or written orders for treatment or a diagnostic
28 regime received, whether or not that action resulted in actual patient
29 harm.
- 30 (m) Denial, suspension, or revocation of any license to practice
31 by another agency, state, or territory of the United States for any
32 act or omission that would constitute grounds for the denial,
33 suspension, or revocation of a license in this state.
- 34 (n) Except for good cause, the knowing failure to protect patients
35 by failing to follow infection control guidelines of the board,
36 thereby risking transmission of blood-borne infectious diseases
37 from licensee to patient, from patient to patient, and from patient
38 to licensee. In administering this subdivision, the board shall
39 consider referencing the standards, regulations, and guidelines of
40 the State Department of Health Services developed pursuant to

1 Section 1250.11 of the Health and Safety Code and the standards,
2 regulations, and guidelines pursuant to the California Occupational
3 Safety and Health Act of 1973 (Part 1 (commencing with Section
4 6300) of Division 5 of the Labor Code) for preventing the
5 transmission of HIV, hepatitis B, and other blood-borne pathogens
6 in health care settings. As necessary, the board shall consult with
7 the California Medical Board, the Board of Podiatric Medicine,
8 the Board of Dental Examiners, the Board of Registered Nursing,
9 and the Board of Vocational Nursing and Psychiatric Technicians,
10 to encourage appropriate consistency in the implementation of this
11 subdivision.

12 The board shall seek to ensure that licensees are informed of the
13 responsibility of licensees and others to follow infection control
14 guidelines, and of the most recent scientifically recognized
15 safeguards for minimizing the risk of transmission of blood-borne
16 infectious diseases.

17 (o) Incompetence in his or her practice as a respiratory care
18 practitioner.

19 (p) A pattern of substandard care or negligence in his or her
20 practice as a respiratory care practitioner, or in any capacity as a
21 health care worker, consultant, supervisor, manager or health
22 facility owner, or as a party responsible for the care of another.

23 ~~SEC. 13.~~

24 *SEC. 19.* Section 3750.5 of the Business and Professions Code
25 is amended to read:

26 3750.5. In addition to any other grounds specified in this
27 chapter, the board may deny, suspend, place on probation, or
28 revoke the license of any applicant or licenseholder who has done
29 any of the following:

30 (a) Obtained, possessed, used, or administered to himself or
31 herself in violation of law, or furnished or administered to another,
32 any controlled substances as defined in Division 10 (commencing
33 with Section 11000) of the Health and Safety Code, or any
34 dangerous drug as defined in Article 2 (commencing with Section
35 4015) of Chapter 9, except as directed by a licensed physician and
36 surgeon, dentist, podiatrist, or other authorized health care provider,
37 or illegally possessed any associated paraphernalia.

38 (b) Used any controlled substance as defined in Division 10
39 (commencing with Section 11000) of the Health and Safety Code,
40 or any dangerous drug as defined in Article 2 (commencing with

1 Section 4015) of Chapter 9 of this code, or alcoholic beverages,
2 to an extent or in a manner dangerous or injurious to himself or
3 herself, or to others, or that impaired his or her ability to conduct
4 with safety the practice authorized by his or her license.

5 (c) Applied for employment or worked in any health care
6 profession or environment while under the influence of alcohol.

7 (d) Been convicted of a criminal offense involving the
8 consumption or self-administration of any of the substances
9 described in subdivisions (a) and (b), or the possession of, or
10 falsification of a record pertaining to, the substances described in
11 subdivision (a), in which event the record of the conviction is
12 conclusive evidence thereof.

13 (e) Been committed or confined by a court of competent
14 jurisdiction for intemperate use of or addiction to the use of any
15 of the substances described in subdivisions (a), (b), and (c), in
16 which event the court order of commitment or confinement is
17 prima facie evidence of that commitment or confinement.

18 (f) Falsified, or made grossly incorrect, grossly inconsistent, or
19 unintelligible entries in any hospital, patient, or other record
20 pertaining to the substances described in subdivision (a).

21 *SEC. 20. Section 4209 of the Business and Professions Code*
22 *is amended to read:*

23 4209. (a) (1) An intern pharmacist shall complete 1,500 hours
24 of pharmacy practice before applying for the pharmacist licensure
25 examination.

26 (2) This pharmacy practice shall comply with the Standards of
27 Curriculum established by the Accreditation Council for Pharmacy
28 Education or with regulations adopted by the board.

29 (b) An intern pharmacist shall submit proof of his or her
30 experience on board-approved affidavits, or another form specified
31 by the board, which shall be certified under penalty of perjury by
32 a pharmacist under whose supervision such experience was
33 obtained or by the pharmacist-in-charge at the pharmacy while the
34 pharmacist intern obtained the experience. *Intern hours earned in*
35 *another state may be certified by the licensing agency of that state*
36 *to document proof of those hours.*

37 (c) An applicant for the examination who has been licensed as
38 a pharmacist in any state for at least one year, as certified by the
39 licensing agency of that state, may submit this certification to
40 satisfy the required 1,500 hours of intern experience, *provided that*

1 *the applicant has obtained a minimum of 900 hours of pharmacy*
2 *practice experience in a pharmacy as a pharmacist. Certification*
3 *of an applicant’s licensure in another state shall be submitted in*
4 *writing and signed, under oath, by a duly authorized official of the*
5 *state in which the license is held.*

6 *SEC. 21. Section 4300.1 is added to the Business and*
7 *Professions Code, to read:*

8 *4300.1. The expiration, cancellation, forfeiture, or suspension*
9 *of a board-issued license by operation of law or by order or*
10 *decision of the board or a court of law, the placement of a license*
11 *on a retired status, or the voluntary surrender of a license by a*
12 *licensee shall not deprive the board of jurisdiction to commence*
13 *or proceed with any investigation of, or action or disciplinary*
14 *proceeding against, the licensee or to render a decision suspending*
15 *or revoking the license.*

16 *SEC. 22. Section 4600 of the Business and Professions Code*
17 *is amended to read:*

18 4600. As used in this chapter, the following terms shall have
19 the following meanings:

20 (a) “Approved school” or “approved massage school” means a
21 school approved by the council that meets minimum standards for
22 training and curriculum in massage and related subjects and that
23 meets any of the following requirements:

24 (1) Is approved by the Bureau for Private Postsecondary
25 Education.

26 (2) Is approved by the Department of Consumer Affairs.

27 (3) Is an institution accredited by the Accrediting Commission
28 for Senior Colleges and Universities or the Accrediting
29 Commission for Community and Junior Colleges of the Western
30 Association of Schools and Colleges and that is one of the
31 following:

32 (A) A public institution.

33 (B) An institution incorporated and lawfully operating as a
34 nonprofit public benefit corporation pursuant to Part 2
35 (commencing with Section 5110) of Division 2 of Title 1 of the
36 Corporations Code, and that is not managed by any entity for profit.

37 (C) A for-profit institution.

38 (D) An institution that does not meet all of the criteria in
39 subparagraph (B) that is incorporated and lawfully operating as a
40 nonprofit public benefit corporation pursuant to Part 2

1 (commencing with Section 5110) of Division 2 of Title 1 of the
2 Corporations Code, that has been in continuous operation since
3 April 15, 1997, and that is not managed by any entity for profit.

4 (4) Is a college or university of the state higher education system,
5 as defined in Section 100850 of the Education Code.

6 (5) Is a school of equal or greater training that is recognized by
7 the corresponding agency in another state or accredited by an
8 agency recognized by the United States Department of Education.

9 (b) “Compensation” means the payment, loan, advance,
10 donation, contribution, deposit, or gift of money or anything of
11 value.

12 (c) “Massage therapist,” “bodyworker,” “bodywork therapist,”
13 or “massage and bodywork therapist” means a person who is
14 certified by the California Massage Therapy Council under
15 subdivision (c) of Section 4601 and who administers massage for
16 compensation.

17 (d) “Massage practitioner,” “bodywork practitioner,” or
18 “massage and bodywork practitioner” means a person who is
19 certified by the California Massage Therapy Council under
20 subdivision (b) of Section 4601 and who administers massage for
21 compensation.

22 (e) “Council” means the California Massage Therapy Council
23 created pursuant to this chapter, which shall be a nonprofit
24 organization exempt from taxation under Section 501(c)(3) of Title
25 26 of the United States Code. The council may commence activities
26 as authorized by this section once it has submitted a request to the
27 Internal Revenue Service seeking this exemption. Whenever the
28 term “organization” is used in this chapter, it shall mean the
29 council, except where the context indicates otherwise.

30 (f) “Registered school” means a school approved by the council
31 that meets minimum standards for training and curriculum in
32 massage and related subjects and that either is approved by the
33 Bureau for Private Postsecondary Education or the Department of
34 Consumer Affairs, or is an institution accredited by the senior
35 commission or the junior commission of the Western Association
36 of Schools and Colleges as defined in paragraph (3) of subdivision
37 (a), is a college or university of the state higher education system
38 as defined in Section 100850 of the Education Code, or is a school
39 of equal or greater training that is approved by the corresponding
40 agency in another state.

1 (g) For purposes of this chapter, the terms “massage” and
2 “bodywork” shall have the same meaning.

3 (h) “*Operator of a massage business*” means a person, whether
4 owner or nonowner, who manages or operates a massage business.

5 SEC. 23. Section 4601 of the Business and Professions Code
6 is amended to read:

7 4601. (a) The council shall issue a certificate under this chapter
8 to an applicant who satisfies the requirements of this chapter.

9 (b) (1) In order to obtain certification as a massage practitioner,
10 an applicant shall submit a written application and provide the
11 council with satisfactory evidence that he or she meets all of the
12 following requirements:

13 (A) The applicant is 18 years of age or older.

14 (B) The applicant has successfully completed, at a single
15 approved school, curricula in massage and related subjects totaling
16 a minimum of 250 hours, *or the credit unit equivalent*, that
17 incorporates appropriate school assessment of student knowledge
18 and skills. Included in the hours shall be instruction addressing
19 anatomy and physiology, contraindications, health and hygiene,
20 and business and ethics, with at least 100 hours of the required
21 minimum 250 hours devoted to these curriculum areas.

22 (C) All fees required by the council have been paid.

23 (2) New certificates shall not be issued pursuant to this
24 subdivision after December 31, 2015. Certificates issued pursuant
25 to this section or subdivision (a) or (c) of Section 4604 on or before
26 December 31, 2015, shall, after December 31, 2015, be renewed
27 without any additional educational requirements, provided that the
28 certificate holder continues to be qualified pursuant to this chapter.

29 (c) In order to obtain certification as a massage therapist, an
30 applicant shall submit a written application and provide the council
31 with satisfactory evidence that he or she meets all of the following
32 requirements:

33 (1) The applicant is 18 years of age or older.

34 (2) The applicant satisfies at least one of the following
35 requirements:

36 (A) He or she has successfully completed the curricula in
37 massage and related subjects totaling a minimum of 500 hours, *or*
38 *the credit unit equivalent*. Of this 500 hours, a minimum of 250
39 hours shall be from approved schools. The remaining 250 hours
40 required may be secured either from approved or registered schools,

1 or from continuing education providers approved by, or registered
2 with, the council or the Department of Consumer Affairs. After
3 December 31, 2015, applicants may only satisfy the curricula in
4 massage and related subjects from approved schools.

5 (B) The applicant has *successfully completed, at a single*
6 *approved school, a curricula in massage and related subjects*
7 *totaling a minimum of 250 hours that incorporates appropriate*
8 *school assessment of student knowledge and skills. Included in the*
9 *hours shall be instruction addressing anatomy and physiology,*
10 *contraindications, health and hygiene, and business and ethics,*
11 *with at least 100 hours of the required minimum 250 hours devoted*
12 *to these curriculum areas. The applicant has also passed a massage*
13 *and bodywork competency assessment examination that meets*
14 *generally recognized psychometric principles and standards, and*
15 *that is approved by the board. The successful completion of this*
16 *examination may have been accomplished before the date the*
17 *council is authorized by this chapter to begin issuing certificates.*

18 (3) All fees required by the council have been paid.

19 (d) The council shall issue a certificate to an applicant who
20 meets the other qualifications of this chapter and holds a current
21 and valid registration, certification, or license from any other state
22 whose licensure requirements meet or exceed those defined within
23 this chapter. The council shall have discretion to give credit for
24 comparable academic work completed by an applicant in a program
25 outside of California.

26 (e) An applicant applying for a massage therapist certificate
27 shall file with the council a written application provided by the
28 council, showing to the satisfaction of the council that he or she
29 meets all of the requirements of this chapter.

30 (f) Any certification issued under this chapter shall be subject
31 to renewal every two years in a manner prescribed by the council,
32 and shall expire unless renewed in that manner. The council may
33 provide for the late renewal of a license.

34 (g) (1) The council shall have the responsibility to determine
35 that the school or schools from which an applicant has obtained
36 the education required by this chapter meet the requirements of
37 this chapter. If the council has any reason to question whether or
38 not the applicant received the education that is required by this
39 chapter from the school or schools that the applicant is claiming,

1 the council shall investigate the facts to determine that the applicant
2 received the required education prior to issuing a certificate.

3 (2) For purposes of paragraph (1) and any other provision of
4 this chapter for which the council is authorized to receive factual
5 information as a condition of taking any action, the council shall
6 have the authority to conduct oral interviews of the applicant and
7 others or to make any investigation deemed necessary to establish
8 that the information received is accurate and satisfies any criteria
9 established by this chapter.

10 (h) *The certificate issued pursuant to this chapter, as well as*
11 *any identification card issued by the council, are the exclusive*
12 *property of the council and shall be surrendered to the council by*
13 *any certificate holder who is suspended or revoked.*

14 *SEC. 24. Section 4603.7 of the Business and Professions Code*
15 *is amended to read:*

16 4603.7. A certificate holder shall include the name under which
17 he or she is certified and his or her certificate number in any and
18 all advertising and shall display his or her *original* certificate at
19 his or her place of business. *A certificate holder shall have his or*
20 *her identification card in his or her possession while providing*
21 *massage services.*

22 *SEC. 25. Section 4612 of the Business and Professions Code*
23 *is amended to read:*

24 4612. (a) (1) The holder of a certificate issued pursuant to
25 this chapter shall have the right to practice massage, consistent
26 with this chapter and the qualifications established by his or her
27 certification, in any city, county, or city and county in this state
28 and shall not be required to obtain any other license, permit, or
29 other authorization, except as provided in this section, to engage
30 in that practice.

31 (2) Notwithstanding any other provision of law, a city, county,
32 or city and county shall not enact an ordinance that requires a
33 license, permit, or other authorization to provide massage for
34 compensation by an individual who is certified pursuant to this
35 chapter and who is practicing consistent with the qualifications
36 established by his or her certification, or by a massage business
37 or massage establishment that employs or uses only persons who
38 are certified pursuant to this chapter to provide massage for
39 compensation. No provision of any ordinance enacted by a city,
40 county, or city and county that is in effect before the effective date

1 of this chapter, and that requires a license, permit, or other
2 authorization to provide massage for compensation, may be
3 enforced against an individual who is certified pursuant to this
4 chapter or against a massage business or massage establishment
5 that employs or uses only persons who are certified pursuant to
6 this chapter to provide massage for compensation.

7 (3) Except as provided in subdivision (b), nothing in this section
8 shall be interpreted to prevent a city, county, or city and county
9 from adopting or enforcing any local ordinance that provides for
10 reasonable health and safety requirements for massage
11 establishments or businesses. Subdivision (b) shall not apply to
12 any massage establishment or business that employs or uses
13 persons to provide massage services who are not certified pursuant
14 to this chapter.

15 (b) (1) This subdivision shall apply only to massage
16 establishments or businesses that are sole proprietorships, where
17 the sole proprietor is certified pursuant to this chapter, and to
18 massage establishments or businesses that employ or use only
19 persons certified pursuant to this chapter to provide massage
20 services. For purposes of this subdivision, a sole proprietorship is
21 a business where the owner is the only person employed by that
22 business to provide massage services.

23 (2) (A) Any massage establishment or business described in
24 paragraph (1) shall maintain on its premises evidence for review
25 by local authorities that demonstrates that all persons providing
26 massage services are certified.

27 (B) Nothing in this section shall preclude a city, county, or city
28 and county from including in a local ordinance a provision that
29 requires a business described in paragraph (1) to file copies or
30 provide other evidence of the certificates held by the persons who
31 are providing massage services at the business.

32 (3) A city, county, or city and county may charge a massage
33 business or establishment a business licensing fee, provided that
34 the fee shall be no ~~different~~ *higher* than the fee that is uniformly
35 applied to all other individuals and businesses providing
36 professional services, as defined in subdivision (a) of Section
37 13401 of the Corporations Code.

38 (4) Nothing in this section shall prohibit a city, county, or city
39 and county from enacting ordinances, regulations, rules,
40 requirements, restrictions, land use regulations, moratoria,

1 conditional use permits, or zoning requirements applicable to an
2 individual certified pursuant to this chapter or to a massage
3 establishment or business that uses only individuals who are
4 certified pursuant to this chapter to provide massage for
5 compensation, provided that, unless otherwise exempted by this
6 chapter, these ordinances, regulations, rules, requirements,
7 restrictions, land use regulations, moratoria, conditional use
8 permits, and zoning requirements shall be no different than the
9 requirements that are uniformly applied to all other individuals
10 and businesses providing professional services, as defined in
11 subdivision (a) of Section 13401 of the Corporations Code. No
12 provision of any ordinance, regulation, rule, requirement,
13 restriction, land use regulation, moratoria, conditional use permit,
14 or zoning requirement enacted by a city, county, or city and county
15 that is in effect before the effective date of this chapter, and that
16 is inconsistent with this paragraph, may be enforced against an
17 individual who is certified pursuant to this chapter or against a
18 massage business or massage establishment that uses only
19 individuals who are certified pursuant to this chapter to provide
20 massage for compensation.

21 (5) Local building code or physical facility requirements
22 applicable to massage establishments or businesses shall not require
23 additional restroom, shower, or other facilities that are not
24 uniformly applicable to other professional or personal service
25 businesses, nor shall building or facility requirements be adopted
26 that (A) require unlocked doors when there is no staff available to
27 ensure security for clients and massage staff who are behind closed
28 doors, or (B) require windows that provide a view into massage
29 rooms that interfere with the privacy of clients of the massage
30 business.

31 (6) A city, county, or city and county may adopt reasonable
32 health and safety requirements with respect to massage
33 establishments or businesses, including, but not limited to,
34 requirements for cleanliness of massage rooms, towels and linens,
35 and reasonable attire and personal hygiene requirements for persons
36 providing massage services, provided that nothing in this paragraph
37 shall be interpreted to authorize adoption of local ordinances that
38 impose additional qualifications, such as medical examinations,
39 background checks, or other criteria, upon any person certified
40 pursuant to this chapter.

1 (7) Nothing in this section shall preclude a city, county, or city
2 and county from doing any of the following:

3 (A) Requiring an applicant for a business license to operate a
4 massage business or establishment to fill out an application that
5 requests the applicant to provide relevant information, *as long as*
6 *the information requested is the same as that required of other*
7 *individuals and professionals providing professional services as*
8 *defined in subdivision (a) of Section 13401 of the Corporations*
9 *Code.*

10 (B) Making reasonable investigations into the information so
11 provided.

12 (C) Denying or restricting a business license if the applicant
13 has provided materially false information.

14 (c) An owner or operator of a massage business or establishment
15 ~~subject to subdivision (b)~~ *who is certified pursuant to this chapter*
16 shall be responsible for the conduct of all employees or independent
17 contractors working on the premises of the business. Failure to
18 comply with this chapter may result in revocation of the owner's
19 or operator's certificate in accordance with Section 4603. Nothing
20 in this section shall preclude a local ordinance from authorizing
21 suspension, revocation, or other restriction of a license or permit
22 issued to a massage establishment or business if violations of this
23 chapter, or of the local ordinance, occur on the business premises.

24 (d) Nothing in this section shall preclude a city, county, or city
25 and county from adopting a local ordinance that is applicable to
26 massage businesses or establishments described in paragraph (1)
27 of subdivision (b) and that does either of the following:

28 (1) Provides that duly authorized officials of the city, county,
29 or city and county have the right to conduct reasonable inspections,
30 during regular business hours, to ensure compliance with this
31 chapter, the local ordinance, or other applicable fire and health
32 and safety requirements.

33 (2) Requires an owner or operator to notify the city, county, or
34 city and county of any intention to rename, change management,
35 or convey the business to another person.

36 (e) Nothing in this chapter shall be construed to preclude a city,
37 county, or city and county from requiring a background check of
38 an owner or operator of a massage establishment who owns 5
39 percent or more of a massage business or massage establishment
40 and who is not certified pursuant to this chapter. The background

1 check may consist of an application that requires the include, but
2 is not limited to, a criminal background check, including requiring
3 submission of fingerprints for a state and federal criminal
4 background check, submission of an application that requires the
5 applicant to state information, including, but not limited to, the
6 applicant's business, occupation, and employment history for the
7 five 10 years preceding the date of application, the inclusive dates
8 of same, and the name and address of any massage business or
9 other like establishment owned or operated by any person who is
10 subject to the background check requirement of this subdivision.
11 *If a noncertified owner's or operator's background check results*
12 *in a finding that the city, county, or city and county determines is*
13 *relevant to owning or operating a massage establishment, the*
14 *provisions of subdivisions (a) and (b) shall not apply to that*
15 *establishment and the city, county, or city and county may regulate*
16 *that establishment in any manner it deems proper that is in*
17 *accordance with the law.*

18 ~~SEC. 14.~~

19 SEC. 26. Section 4980.04 of the Business and Professions Code
20 is amended to read:

21 4980.04. This chapter shall be known and may be cited as the
22 Licensed Marriage and Family Therapist Act.

23 ~~SEC. 15.~~

24 SEC. 27. Section 4980.34 of the Business and Professions Code
25 is amended to read:

26 4980.34. It is the intent of the Legislature that the board employ
27 its resources for each and all of the following functions:

28 (a) The licensing of marriage and family therapists, clinical
29 social workers, professional clinical counselors, and educational
30 psychologists.

31 (b) The development and administration of licensing
32 examinations and examination procedures, as specified, consistent
33 with prevailing standards for the validation and use of licensing
34 and certification tests. Examinations shall measure knowledge and
35 abilities demonstrably important to the safe, effective practice of
36 the profession.

37 (c) Enforcement of laws designed to protect the public from
38 incompetent, unethical, or unprofessional practitioners.

39 (d) Consumer education.

1 ~~SEC. 16.~~

2 ~~SEC. 28.~~ Section 4980.398 of the Business and Professions
3 Code is amended to read:

4 4980.398. (a) Each applicant who had previously taken and
5 passed the standard written examination but had not passed the
6 clinical vignette examination shall also obtain a passing score on
7 the clinical examination in order to be eligible for licensure.

8 (b) An applicant who had previously failed to obtain a passing
9 score on the standard written examination shall obtain a passing
10 score on the California law and ethics examination and the clinical
11 examination.

12 (c) An applicant who had obtained eligibility for the standard
13 written examination shall take the California law and ethics
14 examination and the clinical examination.

15 (d) This section shall become operative on January 1, 2013.

16 ~~SEC. 17.~~

17 ~~SEC. 29.~~ Section 4980.399 of the Business and Professions
18 Code is amended to read:

19 4980.399. (a) Except as provided in *subdivision (a)* of Section
20 4980.398, each applicant and registrant shall obtain a passing score
21 on a board-administered California law and ethics examination in
22 order to qualify for licensure.

23 (b) A registrant shall participate in a board-administered
24 California law and ethics examination prior to his or her registration
25 renewal.

26 (c) If an applicant fails the California law and ethics
27 examination, he or she may retake the examination, upon payment
28 of the required fees, without further application except as provided
29 in subdivision (d).

30 (d) If a registrant fails to obtain a passing score on the California
31 law and ethics examination described in subdivision (a) within his
32 or her first renewal period on or after the operative date of this
33 section, he or she shall complete, at a minimum, a 12-hour course
34 in California law and ethics in order to be eligible to participate
35 in the California law and ethics examination. Registrants shall only
36 take the 12-hour California law and ethics course once during a
37 renewal period. The 12-hour law and ethics course required by the
38 section shall be taken through a board-approved continuing
39 education provider, a county, state or governmental entity, or a
40 college or university.

1 (e) The board shall not issue a subsequent registration number
2 unless the registrant has passed the California law and ethics
3 examination.

4 (f) This section shall become operative on January 1, 2013.

5 *SEC. 30. Section 4980.43 of the Business and Professions Code*
6 *is amended to read:*

7 4980.43. (a) Prior to applying for licensure examinations, each
8 applicant shall complete experience that shall comply with the
9 following:

10 (1) A minimum of 3,000 hours completed during a period of at
11 least 104 weeks.

12 (2) Not more than 40 hours in any seven consecutive days.

13 (3) Not less than 1,700 hours of supervised experience
14 completed subsequent to the granting of the qualifying master's
15 or doctoral degree.

16 (4) Not more than 1,300 hours of supervised experience obtained
17 prior to completing a master's or doctoral degree.

18 The applicant shall not be credited with more than 750 hours of
19 counseling and direct supervisor contact prior to completing the
20 master's or doctoral degree.

21 (5) No hours of experience may be gained prior to completing
22 either 12 semester units or 18 quarter units of graduate instruction
23 and becoming a trainee except for personal psychotherapy.

24 (6) No hours of experience may be gained more than six years
25 prior to the date the application for examination eligibility was
26 filed, except that up to 500 hours of clinical experience gained in
27 the supervised practicum required by subdivision (c) of Section
28 4980.37 and subparagraph (B) of paragraph (1) of subdivision (d)
29 of Section 4980.36 shall be exempt from this six-year requirement.

30 (7) Not more than a combined total of 1,000 hours of experience
31 in the following:

32 (A) Direct supervisor contact.

33 (B) Professional enrichment activities. For purposes of this
34 chapter, "professional enrichment activities" include the following:

35 (i) Workshops, seminars, training sessions, or conferences
36 directly related to marriage and family therapy attended by the
37 applicant that are approved by the applicant's supervisor. An
38 applicant shall have no more than 250 hours of verified attendance
39 at these workshops, seminars, training sessions, or conferences.

1 (ii) Participation by the applicant in personal psychotherapy,
2 which includes group, marital or conjoint, family, or individual
3 psychotherapy by an appropriately licensed professional. An
4 applicant shall have no more than 100 hours of participation in
5 personal psychotherapy. The applicant shall be credited with three
6 hours of experience for each hour of personal psychotherapy.

7 (8) Not more than 500 hours of experience providing group
8 therapy or group counseling.

9 (9) For all hours gained on or after January 1, 2012, not more
10 than 500 hours of experience in the following:

11 (A) Experience administering and evaluating psychological
12 tests, writing clinical reports, writing progress notes, or writing
13 process notes.

14 (B) Client centered advocacy.

15 (10) Not less than 500 total hours of experience in diagnosing
16 and treating couples, families, and children. For up to 150 hours
17 of treating couples and families in conjoint therapy, the applicant
18 shall be credited with two hours of experience for each hour of
19 therapy provided.

20 (11) Not more than 375 hours of experience providing personal
21 psychotherapy, crisis counseling, or other counseling services via
22 telehealth in accordance with Section 2290.5.

23 (12) It is anticipated and encouraged that hours of experience
24 will include working with elders and dependent adults who have
25 physical or mental limitations that restrict their ability to carry out
26 normal activities or protect their rights.

27 This subdivision shall only apply to hours gained on and after
28 January 1, 2010.

29 (b) All applicants, trainees, and registrants shall be at all times
30 under the supervision of a supervisor who shall be responsible for
31 ensuring that the extent, kind, and quality of counseling performed
32 is consistent with the training and experience of the person being
33 supervised, and who shall be responsible to the board for
34 compliance with all laws, rules, and regulations governing the
35 practice of marriage and family therapy. Supervised experience
36 shall be gained by interns and trainees either as an employee or as
37 a volunteer. The requirements of this chapter regarding gaining
38 hours of experience and supervision are applicable equally to
39 employees and volunteers. Experience shall not be gained by
40 interns or trainees as an independent contractor.

1 (1) If employed, an intern shall provide the board with copies
2 of the corresponding W-2 tax forms for each year of experience
3 claimed upon application for licensure.

4 (2) If volunteering, an intern shall provide the board with a letter
5 from his or her employer verifying the intern’s employment as a
6 volunteer upon application for licensure.

7 (c) ~~Supervision~~—*Except for experience gained pursuant to*
8 *subparagraph (B) of paragraph (7) of subdivision (a), supervision*
9 *shall include at least one hour of direct supervisor contact in each*
10 *week for which experience is credited in each work setting, as*
11 *specified:*

12 (1) A trainee shall receive an average of at least one hour of
13 direct supervisor contact for every five hours of client contact in
14 each setting.

15 (2) An individual supervised after being granted a qualifying
16 degree shall receive at least one additional hour of direct supervisor
17 contact for every week in which more than 10 hours of client
18 contact is gained in each setting. No more than five hours of
19 supervision, whether individual or group, shall be credited during
20 any single week.

21 (3) For purposes of this section, “one hour of direct supervisor
22 contact” means one hour per week of face-to-face contact on an
23 individual basis or two hours per week of face-to-face contact in
24 a group.

25 (4) Direct supervisor contact shall occur within the same week
26 as the hours claimed.

27 (5) Direct supervisor contact provided in a group shall be
28 provided in a group of not more than eight supervisees and in
29 segments lasting no less than one continuous hour.

30 (6) Notwithstanding paragraph (3), an intern working in a
31 governmental entity, a school, a college, or a university, or an
32 institution that is both nonprofit and charitable may obtain the
33 required weekly direct supervisor contact via two-way, real-time
34 videoconferencing. The supervisor shall be responsible for ensuring
35 that client confidentiality is upheld.

36 (7) All experience gained by a trainee shall be monitored by the
37 supervisor as specified by regulation.

38 (d) (1) A trainee may be credited with supervised experience
39 completed in any setting that meets all of the following:

- 1 (A) Lawfully and regularly provides mental health counseling
2 or psychotherapy.
- 3 (B) Provides oversight to ensure that the trainee’s work at the
4 setting meets the experience and supervision requirements set forth
5 in this chapter and is within the scope of practice for the profession
6 as defined in Section 4980.02.
- 7 (C) Is not a private practice owned by a licensed marriage and
8 family therapist, a licensed psychologist, a licensed clinical social
9 worker, a licensed physician and surgeon, or a professional
10 corporation of any of those licensed professions.
- 11 (2) Experience may be gained by the trainee solely as part of
12 the position for which the trainee volunteers or is employed.
- 13 (e) (1) An intern may be credited with supervised experience
14 completed in any setting that meets both of the following:
- 15 (A) Lawfully and regularly provides mental health counseling
16 or psychotherapy.
- 17 (B) Provides oversight to ensure that the intern’s work at the
18 setting meets the experience and supervision requirements set forth
19 in this chapter and is within the scope of practice for the profession
20 as defined in Section 4980.02.
- 21 (2) An applicant shall not be employed or volunteer in a private
22 practice, as defined in subparagraph (C) of paragraph (1) of
23 subdivision (d), until registered as an intern.
- 24 (3) While an intern may be either a paid employee or a
25 volunteer, employers are encouraged to provide fair remuneration
26 to interns.
- 27 (4) Except for periods of time during a supervisor’s vacation or
28 sick leave, an intern who is employed or volunteering in private
29 practice shall be under the direct supervision of a licensee that has
30 satisfied the requirements of subdivision (g) of Section 4980.03.
31 The supervising licensee shall either be employed by and practice
32 at the same site as the intern’s employer, or shall be an owner or
33 shareholder of the private practice. Alternative supervision may
34 be arranged during a supervisor’s vacation or sick leave if the
35 supervision meets the requirements of this section.
- 36 (5) Experience may be gained by the intern solely as part of the
37 position for which the intern volunteers or is employed.
- 38 (f) Except as provided in subdivision (g), all persons shall
39 register with the board as an intern in order to be credited for
40 postdegree hours of supervised experience gained toward licensure.

1 (g) Except when employed in a private practice setting, all
2 postdegree hours of experience shall be credited toward licensure
3 so long as the applicant applies for the intern registration within
4 90 days of the granting of the qualifying master's or doctoral
5 degree and is thereafter granted the intern registration by the board.

6 (h) Trainees, interns, and applicants shall not receive any
7 remuneration from patients or clients, and shall only be paid by
8 their employers.

9 (i) Trainees, interns, and applicants shall only perform services
10 at the place where their employers regularly conduct business,
11 which may include performing services at other locations, so long
12 as the services are performed under the direction and control of
13 their employer and supervisor, and in compliance with the laws
14 and regulations pertaining to supervision. Trainees and interns
15 shall have no proprietary interest in their employers' businesses
16 and shall not lease or rent space, pay for furnishings, equipment
17 or supplies, or in any other way pay for the obligations of their
18 employers.

19 (j) Trainees, interns, or applicants who provide volunteered
20 services or other services, and who receive no more than a total,
21 from all work settings, of five hundred dollars (\$500) per month
22 as reimbursement for expenses actually incurred by those trainees,
23 interns, or applicants for services rendered in any lawful work
24 setting other than a private practice shall be considered an
25 employee and not an independent contractor. The board may audit
26 applicants who receive reimbursement for expenses, and the
27 applicants shall have the burden of demonstrating that the payments
28 received were for reimbursement of expenses actually incurred.

29 (k) Each educational institution preparing applicants for
30 licensure pursuant to this chapter shall consider requiring, and
31 shall encourage, its students to undergo individual, marital or
32 conjoint, family, or group counseling or psychotherapy, as
33 appropriate. Each supervisor shall consider, advise, and encourage
34 his or her interns and trainees regarding the advisability of
35 undertaking individual, marital or conjoint, family, or group
36 counseling or psychotherapy, as appropriate. Insofar as it is deemed
37 appropriate and is desired by the applicant, the educational
38 institution and supervisors are encouraged to assist the applicant
39 in locating that counseling or psychotherapy at a reasonable cost.

1 *SEC. 31. Section 4980.44 of the Business and Professions Code*
2 *is amended to read:*

3 4980.44. An unlicensed marriage and family therapist intern
4 employed under this chapter shall comply with the following
5 requirements:

6 (a) Possess, at a minimum, a master's degree as specified in
7 Section 4980.36 or 4980.37, as applicable.

8 (b) Register with the board prior to performing any duties,
9 except as otherwise provided in subdivision (g) of Section 4980.43.

10 (c) Prior to performing any professional services, inform each
11 client or patient that he or she is an unlicensed marriage and family
12 therapist registered intern, provide his or her registration number
13 and the name of his or her employer, and indicate whether he or
14 she is under the supervision of a licensed marriage and family
15 therapist, licensed clinical social worker, *licensed professional*
16 *clinical counselor*, licensed psychologist, or a licensed physician
17 and surgeon certified in psychiatry by the American Board of
18 Psychiatry and Neurology.

19 (d) (1) Any advertisement by or on behalf of a marriage and
20 family therapist registered intern shall include, at a minimum, all
21 of the following information:

22 (A) That he or she is a marriage and family therapist registered
23 intern.

24 (B) The intern's registration number.

25 (C) The name of his or her employer.

26 (D) That he or she is supervised by a licensed person.

27 (2) The abbreviation "MFTI" shall not be used in an
28 advertisement unless the title "marriage and family therapist
29 registered intern" appears in the advertisement.

30 *SEC. 32. Section 4980.48 of the Business and Professions Code*
31 *is amended to read:*

32 4980.48. (a) A trainee shall, prior to performing any
33 professional services, inform each client or patient that he or she
34 is an unlicensed marriage and family therapist trainee, provide the
35 name of his or her employer, and indicate whether he or she is
36 under the supervision of a licensed marriage and family therapist,
37 a licensed clinical social worker, *a licensed professional clinical*
38 *counselor*, a licensed psychologist, or a licensed physician certified
39 in psychiatry by the American Board of Psychiatry and Neurology.

1 (b) Any person that advertises services performed by a trainee
2 shall include the trainee’s name, the supervisor’s license
3 designation or abbreviation, and the supervisor’s license number.

4 (c) Any advertisement by or on behalf of a marriage and family
5 therapist trainee shall include, at a minimum, all of the following
6 information:

- 7 (1) That he or she is a marriage and family therapist trainee.
- 8 (2) The name of his or her employer.
- 9 (3) That he or she is supervised by a licensed person.

10 ~~SEC. 18.~~

11 *SEC. 33.* Section 4980.78 of the Business and Professions Code
12 is amended to read:

13 4980.78. (a) This section applies to persons who apply for
14 licensure or registration on or after January 1, 2014.

15 (b) For purposes of Sections 4980.72 and 4980.74, education
16 is substantially equivalent if all of the following requirements are
17 met:

18 (1) The degree is obtained from a school, college, or university
19 accredited by an accrediting agency recognized by the United
20 States Department of Education and consists of, at a minimum, 48
21 semester or 72 quarter units, including, but not limited to, both of
22 the following:

23 (A) Six semester or nine quarter units of practicum, including,
24 but not limited to, a minimum of 150 hours of face-to-face
25 counseling.

26 (B) Twelve semester or 18 quarter units in the areas of marriage,
27 family, and child counseling and marital and family systems
28 approaches to treatment, as specified in subparagraph (A) of
29 paragraph (1) of subdivision (d) of Section 4980.36.

30 (2) The applicant completes any units and course content
31 requirements under subdivision (d) of Section 4980.36 not already
32 completed in his or her education.

33 (3) The applicant completes credit level coursework from a
34 degree-granting institution that provides all of the following:

35 (A) Instruction regarding the principles of mental health
36 recovery-oriented care and methods of service delivery in recovery
37 model practice environments.

38 (B) An understanding of various California cultures and the
39 social and psychological implications of socioeconomic position.

1 (C) Structured meeting with various consumers and family
2 members of consumers of mental health services to enhance
3 understanding of their experience of mental illness, treatment, and
4 recovery.

5 (D) Instruction in addiction and co-occurring substance abuse
6 and mental health disorders, as specified in subparagraph (I) of
7 paragraph (2) of subdivision (d) of Section 4980.36.

8 (4) The applicant completes an 18-hour course in California
9 law and professional ethics. The content of the course shall include,
10 but not be limited to, advertising, scope of practice, scope of
11 competence, treatment of minors, confidentiality, dangerous
12 patients, psychotherapist-patient privilege, recordkeeping, patient
13 access to records, ~~the Health Insurance Portability and~~
14 ~~Accountability Act~~ *state and federal laws relating to confidentiality*
15 *of patient health information*, dual relationships, child abuse, elder
16 and dependent adult abuse, online therapy, insurance
17 reimbursement, civil liability, disciplinary actions and
18 unprofessional conduct, ethics complaints and ethical standards,
19 termination of therapy, standards of care, relevant family law,
20 therapist disclosures to patients, differences in legal and ethical
21 standards in different types of work settings, and licensing law
22 and licensing process.

23 (5) The applicant's degree title need not be identical to that
24 required by subdivision (b) of Section 4980.36.

25 ~~SEC. 19.~~

26 *SEC. 34.* Section 4980.80 of the Business and Professions Code
27 is amended to read:

28 4980.80. (a) This section applies to persons who apply for
29 licensure between January 1, 2010, and December 31, 2013,
30 inclusive.

31 (b) The board may issue a license to a person who, at the time
32 of application, holds a valid license issued by a board of marriage
33 counselor examiners, marriage therapist examiners, or
34 corresponding authority of any state, if all of the following
35 requirements are satisfied:

36 (1) The person has held that license for at least two years
37 immediately preceding the date of application.

38 (2) The education and supervised experience requirements are
39 substantially the equivalent of this chapter.

40 (3) The person complies with Section 4980.76, if applicable.

1 (4) The person successfully completes the board administered
2 licensing examinations as specified by subdivision (d) of Section
3 4980.40 and pays the fees specified.

4 (5) The person completes all of the following coursework or
5 training:

6 (A) (i) An applicant who completed a two semester or three
7 quarter unit course in law and professional ethics for marriage and
8 family therapists that does not meet the requirements of Section
9 4980.41 as part of his or her qualifying degree shall complete an
10 18-hour course in California law and professional ethics that
11 includes, but is not limited to, the following subjects: advertising,
12 scope of practice, scope of competence, treatment of minors,
13 confidentiality, dangerous patients, psychotherapist-patient
14 privilege, recordkeeping, patient access to records, ~~requirements~~
15 ~~of the Health Insurance Portability and Accountability Act of 1996,~~
16 *state and federal laws relating to the confidentiality of patient*
17 *health information*, dual relationships, child abuse, elder and
18 dependent adult abuse, online therapy, insurance reimbursement,
19 civil liability, disciplinary actions and unprofessional conduct,
20 ethics complaints and ethical standards, termination of therapy,
21 standards of care, relevant family law, and therapist disclosures
22 to patients.

23 (ii) An applicant who has not completed a two semester or three
24 quarter unit course in law and professional ethics for marriage and
25 family therapists that included areas of study as specified in Section
26 4980.41 as part of his or her qualifying degree, shall complete a
27 two semester or three quarter unit course in California law and
28 professional ethics that includes, at minimum, the areas of study
29 specified in Section 4980.41.

30 (B) A minimum of seven contact hours of training or coursework
31 in child abuse assessment and reporting as specified in Section 28
32 and any regulations promulgated thereunder.

33 (C) A minimum of 10 contact hours of training or coursework
34 in human sexuality as specified in Section 25 and any regulations
35 promulgated thereunder.

36 (D) A minimum of 15 contact hours of training or coursework
37 in alcoholism and other chemical substance dependency as
38 specified by regulation.

39 (E) (i) Instruction in spousal or partner abuse assessment,
40 detection, and intervention. This instruction may be taken either

1 in fulfillment of other requirements for licensure or in a separate
2 course.

3 (ii) A minimum of 15 contact hours of coursework or training
4 in spousal or partner abuse assessment, detection, and intervention
5 strategies.

6 (F) A minimum of a two semester or three quarter unit survey
7 course in psychological testing. This course may be taken either
8 in fulfillment of other requirements for licensure or in a separate
9 course.

10 (G) A minimum of a two semester or three quarter unit survey
11 course in psychopharmacology. This course may be taken either
12 in fulfillment of other requirements for licensure or in a separate
13 course.

14 (H) With respect to human sexuality, alcoholism and other
15 chemical substance dependency, spousal or partner abuse
16 assessment, detection, and intervention, psychological testing, and
17 psychopharmacology, the board may accept training or coursework
18 acquired out of state.

19 (c) This section shall remain in effect only until January 1, 2014,
20 and as of that date is repealed, unless a later enacted statute, that
21 is enacted before January 1, 2014, deletes or extends that date.

22 ~~SEC. 20.~~

23 *SEC. 35.* Section 4984.4 of the Business and Professions Code
24 is amended to read:

25 4984.4. A license that is not renewed within three years after
26 its expiration may not be renewed, restored, reinstated, or reissued;
27 however, the former licensee may apply for and obtain a new
28 license if the following criteria are satisfied:

29 (a) No fact, circumstance, or condition exists that, if the license
30 were issued, would constitute grounds for its revocation or
31 suspension.

32 (b) He or she submits an application for examination eligibility
33 and the fee for that application.

34 (c) He or she takes and passes the current licensing
35 examinations.

36 (d) He or she submits the fee for initial license issuance.

37 (e) He or she complies with the fingerprint requirements
38 established by board regulation.

1 ~~SEC. 21.~~

2 *SEC. 36.* Section 4989.16 of the Business and Professions Code
3 is amended to read:

4 4989.16. (a) A person appropriately credentialed by the
5 Commission on Teacher Credentialing may perform the functions
6 authorized by that credential in a public school without a license
7 issued under this chapter by the board.

8 (b) Nothing in this chapter shall be construed to constrict, limit,
9 or withdraw the Medical Practice Act (Chapter 5 (commencing
10 with Section 2000)), the Nursing Practice Act (Chapter 6
11 (commencing with Section 2700)), the Psychology Licensing Law
12 (Chapter 6.6 (commencing with Section 2900)), the Licensed
13 Marriage and Family Therapist Practice Act (Chapter 13
14 (commencing with Section 4980)), or the Clinical Social Worker
15 Practice Act (Chapter 14 (commencing with Section 4991)).

16 ~~SEC. 22.~~

17 *SEC. 37.* Section 4989.42 of the Business and Professions Code
18 is amended to read:

19 4989.42. A license that is not renewed within three years after
20 its expiration may not be renewed, restored, reinstated, or reissued
21 thereafter. A former licensee may apply for a new license if he or
22 she satisfies all of the following requirements:

23 (a) No fact, circumstance, or condition exists that, if the license
24 were issued, would constitute grounds for its revocation or
25 suspension.

26 (b) Payment of the fees that would be required if he or she were
27 applying for a license for the first time.

28 (c) Passage of the current licensure examination.

29 (d) He or she complies with the fingerprint requirements
30 established by board regulation.

31 ~~SEC. 23.~~

32 *SEC. 38.* Section 4992.07 of the Business and Professions Code
33 is amended to read:

34 4992.07. (a) An applicant who had previously taken and passed
35 the standard written examination but had not passed the clinical
36 vignette examination shall also obtain a passing score on the
37 clinical examination in order to be eligible for licensure.

38 (b) An applicant who had previously failed to obtain a passing
39 score on the standard written examination shall obtain a passing

1 score on the California law and ethics examination and the clinical
2 examination.

3 (c) An applicant who had obtained eligibility for the standard
4 written examination shall take the California law and ethics
5 examination and the clinical examination.

6 (d) This section shall become operative on January 1, 2013.

7 ~~SEC. 24.~~

8 *SEC. 39.* Section 4992.09 of the Business and Professions Code
9 is amended to read:

10 4992.09. (a) Except as provided in *subdivision (a)* of Section
11 4992.07, an applicant and registrant shall obtain a passing score
12 on a board-administered California law and ethics examination in
13 order to qualify for licensure.

14 (b) A registrant shall participate in a board-administered
15 California law and ethics examination prior to his or her registration
16 renewal.

17 (c) If an applicant fails the California law and ethics
18 examination, he or she may retake the examination, upon payment
19 of the required fees, without further application except for as
20 provided in subdivision (d).

21 (d) If a registrant fails to obtain a passing score on the California
22 law and ethics examination described in subdivision (a) within his
23 or her first renewal period on or after the operative date of this
24 section, he or she shall complete, at a minimum, a 12-hour course
25 in California law and ethics in order to be eligible to participate
26 in the California law and ethics examination. Registrants shall only
27 take the 12-hour California law and ethics course once during a
28 renewal period. The 12-hour law and ethics course required by the
29 section shall be taken through a board-approved continuing
30 education provider, a county, state or governmental entity, or a
31 college or university.

32 (e) The board shall not issue a subsequent registration number
33 unless the registrant has passed the California law and ethics
34 examination.

35 (f) This section shall become operative on January 1, 2013.

36 ~~SEC. 25.~~

37 *SEC. 40.* Section 4996.6 of the Business and Professions Code
38 is amended to read:

1 4996.6. (a) Licenses issued under this chapter shall expire no
2 more than 24 months after the issue date. The expiration date of
3 the original license shall be set by the board.

4 (b) To renew an unexpired license, the licensee shall, on or
5 before the expiration date of the license, complete the following
6 actions:

7 (1) Apply for a renewal on a form prescribed by the board.

8 (2) Pay a two-year renewal fee prescribed by the board.

9 (3) Certify compliance with the continuing education
10 requirements set forth in Section 4996.22.

11 (4) Notify the board whether he or she has been convicted, as
12 defined in Section 490, of a misdemeanor or felony, or whether
13 any disciplinary action has been taken by any regulatory or
14 licensing board in this or any other state, subsequent to the
15 licensee's last renewal.

16 (c) To renew an expired license within three years of its
17 expiration, the licensee shall, as a condition precedent to renewal,
18 complete all of the actions described in subdivision (b) and pay a
19 delinquency fee.

20 (d) A license that is not renewed within three years after its
21 expiration may not be renewed, restored, reinstated, or reissued
22 thereafter; however, the former licensee may apply for and obtain
23 a new license if he or she satisfies all of the following requirements:

24 (1) No fact, circumstance, or condition exists that, if the license
25 were issued, would justify its revocation or suspension.

26 (2) He or she submits an application for examination eligibility.

27 (3) He or she takes and passes the current licensing
28 examinations.

29 (4) He or she submits the fees for examination eligibility and
30 for initial license issuance.

31 (5) He or she complies with the fingerprint requirements
32 established by board regulation.

33 ~~SEC. 26.~~

34 *SEC. 41.* Section 4999.22 of the Business and Professions Code
35 is amended to read:

36 4999.22. (a) Nothing in this chapter shall prevent qualified
37 persons from doing work of a psychosocial nature consistent with
38 the standards and ethics of their respective professions. However,
39 these qualified persons shall not hold themselves out to the public
40 by any title or description of services incorporating the words

1 “licensed professional clinical counselor” and shall not state that
2 they are licensed to practice professional clinical counseling, unless
3 they are otherwise licensed to provide professional clinical
4 counseling services.

5 (b) Nothing in this chapter shall be construed to constrict, limit,
6 or withdraw provisions of the Medical Practice Act, the Clinical
7 Social Worker Practice Act, the Nursing Practice Act, the
8 Psychology Licensing Law, or the Licensed Marriage and Family
9 Therapist Act.

10 (c) This chapter shall not apply to any priest, rabbi, or minister
11 of the gospel of any religious denomination who performs
12 counseling services as part of his or her pastoral or professional
13 duties, or to any person who is admitted to practice law in this
14 state, or who is licensed to practice medicine, who provides
15 counseling services as part of his or her professional practice.

16 (d) This chapter shall not apply to an employee of a
17 governmental entity or a school, college, or university, or of an
18 institution both nonprofit and charitable, if his or her practice is
19 performed solely under the supervision of the entity, school,
20 college, university, or institution by which he or she is employed,
21 and if he or she performs those functions as part of the position
22 for which he or she is employed.

23 (e) All persons registered as interns or licensed under this
24 chapter shall not be exempt from this chapter or the jurisdiction
25 of the board.

26 ~~SEC. 27.~~

27 *SEC. 42.* Section 4999.32 of the Business and Professions Code
28 is amended to read:

29 4999.32. (a) This section shall apply to applicants for
30 examination eligibility or registration who begin graduate study
31 before August 1, 2012, and complete that study on or before
32 December 31, 2018. Those applicants may alternatively qualify
33 under paragraph (2) of subdivision (a) of Section 4999.33.

34 (b) To qualify for examination eligibility or registration,
35 applicants shall possess a master’s or doctoral degree that is
36 counseling or psychotherapy in content and that meets the
37 requirements of this section, obtained from an accredited or
38 approved institution, as defined in Section 4999.12. For purposes
39 of this subdivision, a degree is “counseling or psychotherapy in
40 content” if it contains the supervised practicum or field study

1 experience described in paragraph (3) of subdivision (c) and, except
2 as provided in subdivision (d), the coursework in the core content
3 areas listed in subparagraphs (A) to (I), inclusive, of paragraph (1)
4 of subdivision (c).

5 (c) The degree described in subdivision (b) shall contain not
6 less than 48 graduate semester or 72 graduate quarter units of
7 instruction, which shall, except as provided in subdivision (d),
8 include all of the following:

9 (1) The equivalent of at least three semester units or four and
10 one-half quarter units of graduate study in each of following core
11 content areas:

12 (A) Counseling and psychotherapeutic theories and techniques,
13 including the counseling process in a multicultural society, an
14 orientation to wellness and prevention, counseling theories to assist
15 in selection of appropriate counseling interventions, models of
16 counseling consistent with current professional research and
17 practice, development of a personal model of counseling, and
18 multidisciplinary responses to crises, emergencies, and disasters.

19 (B) Human growth and development across the lifespan,
20 including normal and abnormal behavior and an understanding of
21 developmental crises, disability, psychopathology, and situational
22 and environmental factors that affect both normal and abnormal
23 behavior.

24 (C) Career development theories and techniques, including
25 career development decisionmaking models and interrelationships
26 among and between work, family, and other life roles and factors,
27 including the role of multicultural issues in career development.

28 (D) Group counseling theories and techniques, including
29 principles of group dynamics, group process components,
30 developmental stage theories, therapeutic factors of group work,
31 group leadership styles and approaches, pertinent research and
32 literature, group counseling methods, and evaluation of
33 effectiveness.

34 (E) Assessment, appraisal, and testing of individuals, including
35 basic concepts of standardized and nonstandardized testing and
36 other assessment techniques, norm-referenced and
37 criterion-referenced assessment, statistical concepts, social and
38 cultural factors related to assessment and evaluation of individuals
39 and groups, and ethical strategies for selecting, administering, and
40 interpreting assessment instruments and techniques in counseling.

1 (F) Multicultural counseling theories and techniques, including
2 counselors' roles in developing cultural self-awareness, identity
3 development, promoting cultural social justice, individual and
4 community strategies for working with and advocating for diverse
5 populations, and counselors' roles in eliminating biases and
6 prejudices, and processes of intentional and unintentional
7 oppression and discrimination.

8 (G) Principles of the diagnostic process, including differential
9 diagnosis, and the use of current diagnostic tools, such as the
10 current edition of the Diagnostic and Statistical Manual, the impact
11 of co-occurring substance use disorders or medical psychological
12 disorders, established diagnostic criteria for mental or emotional
13 disorders, and the treatment modalities and placement criteria
14 within the continuum of care.

15 (H) Research and evaluation, including studies that provide an
16 understanding of research methods, statistical analysis, the use of
17 research to inform evidence-based practice, the importance of
18 research in advancing the profession of counseling, and statistical
19 methods used in conducting research, needs assessment, and
20 program evaluation.

21 (I) Professional orientation, ethics, and law in counseling,
22 including professional ethical standards and legal considerations,
23 licensing law and process, regulatory laws that delineate the
24 profession's scope of practice, counselor-client privilege,
25 confidentiality, the client dangerous to self or others, treatment of
26 minors with or without parental consent, relationship between
27 practitioner's sense of self and human values, functions and
28 relationships with other human service providers, strategies for
29 collaboration, and advocacy processes needed to address
30 institutional and social barriers that impede access, equity, and
31 success for clients.

32 (2) In addition to the course requirements described in paragraph
33 (1), a minimum of 12 semester units or 18 quarter units of advanced
34 coursework to develop knowledge of specific treatment issues,
35 special populations, application of counseling constructs,
36 assessment and treatment planning, clinical interventions,
37 therapeutic relationships, psychopathology, or other clinical topics.

38 (3) Not less than six semester units or nine quarter units of
39 supervised practicum or field study experience, or the equivalent,

- 1 in a clinical setting that provides a range of professional clinical
2 counseling experience, including the following:
- 3 (A) Applied psychotherapeutic techniques.
 - 4 (B) Assessment.
 - 5 (C) Diagnosis.
 - 6 (D) Prognosis.
 - 7 (E) Treatment.
 - 8 (F) Issues of development, adjustment, and maladjustment.
 - 9 (G) Health and wellness promotion.
 - 10 (H) Other recognized counseling interventions.
 - 11 (I) A minimum of 150 hours of face-to-face supervised clinical
12 experience counseling individuals, families, or groups.
- 13 (d) (1) An applicant whose degree is deficient in no more than
14 two of the required areas of study listed in subparagraphs (A) to
15 (I), inclusive, of paragraph (1) of subdivision (c) may satisfy those
16 deficiencies by successfully completing post-master's or
17 postdoctoral degree coursework at an accredited or approved
18 institution, as defined in Section 4999.12.
- 19 (2) Coursework taken to meet deficiencies in the required areas
20 of study listed in subparagraphs (A) to (I), inclusive, of paragraph
21 (1) of subdivision (c) shall be the equivalent of three semester units
22 or four and one-half quarter units of study.
- 23 (3) The board shall make the final determination as to whether
24 a degree meets all requirements, including, but not limited to,
25 course requirements, regardless of accreditation.
- 26 (e) In addition to the degree described in this section, or as part
27 of that degree, an applicant shall complete the following
28 coursework or training prior to registration as an intern:
- 29 (1) A minimum of 15 contact hours of instruction in alcoholism
30 and other chemical substance abuse dependency, as specified by
31 regulation.
 - 32 (2) A minimum of 10 contact hours of training or coursework
33 in human sexuality as specified in Section 25, and any regulations
34 promulgated thereunder.
 - 35 (3) A two semester unit or three quarter unit survey course in
36 psychopharmacology.
 - 37 (4) A minimum of 15 contact hours of instruction in spousal or
38 partner abuse assessment, detection, and intervention strategies,
39 including knowledge of community resources, cultural factors,
40 and same gender abuse dynamics.

1 (5) A minimum of seven contact hours of training or coursework
2 in child abuse assessment and reporting as specified in Section 28
3 and any regulations adopted thereunder.

4 (6) A minimum of 18 contact hours of instruction in California
5 law and professional ethics for professional clinical counselors
6 that includes, but is not limited to, instruction in advertising, scope
7 of practice, scope of competence, treatment of minors,
8 confidentiality, dangerous clients, psychotherapist-client privilege,
9 recordkeeping, client access to records, dual relationships, child
10 abuse, elder and dependent adult abuse, online therapy, insurance
11 reimbursement, civil liability, disciplinary actions and
12 unprofessional conduct, ethics complaints and ethical standards,
13 termination of therapy, standards of care, relevant family law,
14 therapist disclosures to clients, and state and federal laws related
15 to confidentiality of patient health information. When coursework
16 in a master's or doctoral degree program is acquired to satisfy this
17 requirement, it shall be considered as part of the 48 semester unit
18 or 72 quarter unit requirement in subdivision (c).

19 (7) A minimum of 10 contact hours of instruction in aging and
20 long-term care, which may include, but is not limited to, the
21 biological, social, and psychological aspects of aging. On and after
22 January 1, 2012, this coursework shall include instruction on the
23 assessment and reporting of, as well as treatment related to, elder
24 and dependent adult abuse and neglect.

25 (8) A minimum of 15 contact hours of instruction in crisis or
26 trauma counseling, including multidisciplinary responses to crises,
27 emergencies, or disasters, and brief, intermediate, and long-term
28 approaches.

29 (f) This section shall remain in effect only until January 1, 2019,
30 and as of that date is repealed, unless a later enacted statute that
31 is enacted before January 1, 2019, deletes or extends that date.

32 ~~SEC. 28.~~

33 *SEC. 43.* Section 4999.45 of the Business and Professions
34 Code, as amended by Section 32 of Chapter 387 of the Statutes of
35 2011, is repealed.

36 ~~SEC. 29.~~

37 *SEC. 44.* Section 4999.45 of the Business and Professions
38 Code, as added by Section 33 of Chapter 387 of the Statutes of
39 2011, is amended to read:

40 4999.45. (a) An intern employed under this chapter shall:

1 (1) Not perform any duties, except for those services provided
2 as a clinical counselor trainee, until registered as an intern.

3 (2) Not be employed or volunteer in a private practice until
4 registered as an intern.

5 (3) Inform each client prior to performing any professional
6 services that he or she is unlicensed and under supervision.

7 (4) Renew annually for a maximum of five years after initial
8 registration with the board.

9 (b) When no further renewals are possible, an applicant may
10 apply for and obtain a new intern registration if the applicant meets
11 the educational requirements for registration in effect at the time
12 of the application for a new intern registration and has passed the
13 California law and ethics examination described in Section
14 4999.53. An applicant issued a subsequent intern registration
15 pursuant to this subdivision may be employed or volunteer in any
16 allowable work setting except private practice.

17 *SEC. 45. Section 4999.46 of the Business and Professions*
18 *Code, as added by Section 35 of Chapter 387 of the Statutes of*
19 *2011, is amended to read:*

20 4999.46. (a) To qualify for the licensure examination specified
21 by paragraph (2) of subdivision (a) of Section 4999.53, applicants
22 shall complete clinical mental health experience under the general
23 supervision of an approved supervisor as defined in Section
24 4999.12.

25 (b) The experience shall include a minimum of 3,000 postdegree
26 hours of supervised clinical mental health experience related to
27 the practice of professional clinical counseling, performed over a
28 period of not less than two years (104 weeks), which shall include:

29 (1) Not more than 40 hours in any seven consecutive days.

30 (2) Not less than 1,750 hours of direct counseling with
31 individuals or groups in a setting described in Section 4999.44
32 using a variety of psychotherapeutic techniques and recognized
33 counseling interventions within the scope of practice of licensed
34 professional clinical counselors.

35 (3) Not more than 500 hours of experience providing group
36 therapy or group counseling.

37 (4) Not more than 250 hours of experience providing counseling
38 or crisis counseling on the telephone.

1 (5) Not less than 150 hours of clinical experience in a hospital
2 or community mental health setting, *as defined in Section 1820 of*
3 *Title 16 of the California Code of Regulations.*

4 (6) Not more than a combined total of 1,250 hours of experience
5 in the following related activities:

6 (A) Direct supervisor contact.

7 (B) Client centered advocacy.

8 (C) Not more than 250 hours of experience administering tests
9 and evaluating psychological tests of clients, writing clinical
10 reports, writing progress notes, or writing process notes.

11 (D) Not more than 250 hours of verified attendance at
12 workshops, training sessions, or conferences directly related to
13 professional clinical counseling that are approved by the applicant's
14 supervisor.

15 (c) No hours of clinical mental health experience may be gained
16 more than six years prior to the date the application for examination
17 eligibility was filed.

18 (d) An applicant shall register with the board as an intern in
19 order to be credited for postdegree hours of experience toward
20 licensure. Postdegree hours of experience shall be credited toward
21 licensure, provided that the applicant applies for intern registration
22 within 90 days of the granting of the qualifying degree and is
23 registered as an intern by the board.

24 (e) All applicants and interns shall be at all times under the
25 supervision of a supervisor who shall be responsible for ensuring
26 that the extent, kind, and quality of counseling performed is
27 consistent with the training and experience of the person being
28 supervised, and who shall be responsible to the board for
29 compliance with all laws, rules, and regulations governing the
30 practice of professional clinical counseling.

31 (f) Experience obtained under the supervision of a spouse or
32 relative by blood or marriage shall not be credited toward the
33 required hours of supervised experience. Experience obtained
34 under the supervision of a supervisor with whom the applicant has
35 had or currently has a personal, professional, or business
36 relationship that undermines the authority or effectiveness of the
37 supervision shall not be credited toward the required hours of
38 supervised experience.

1 (g) Supervision shall include at least one hour of direct
2 supervisor contact in each week for which experience is credited
3 in each work setting.

4 (1) No more than five hours of supervision, whether individual
5 or group, shall be credited during any single week.

6 (2) An intern shall receive at least one additional hour of direct
7 supervisor contact for every week in which more than 10 hours of
8 face-to-face psychotherapy is performed in each setting in which
9 experience is gained.

10 (3) For purposes of this section, “one hour of direct supervisor
11 contact” means one hour of face-to-face contact on an individual
12 basis or two hours of face-to-face contact in a group of not more
13 than eight persons in segments lasting no less than one continuous
14 hour.

15 (4) Notwithstanding paragraph (3), an intern working in a
16 governmental entity, a school, a college, or a university, or an
17 institution that is both nonprofit and charitable, may obtain the
18 required weekly direct supervisor contact via two-way, real-time
19 videoconferencing. The supervisor shall be responsible for ensuring
20 that client confidentiality is upheld.

21 (h) This section shall become operative on January 1, 2013.

22 ~~SEC. 30.~~

23 *SEC. 46.* Section 4999.57 of the Business and Professions Code
24 is amended to read:

25 4999.57. (a) This section applies to a person who applies for
26 examination eligibility or registration between January 1, 2011,
27 and December 31, 2013, inclusive, who does not hold a license
28 described in subdivision (a) of Section 4999.58.

29 (b) Experience gained outside of California shall be accepted
30 toward the licensure requirements if it is substantially equivalent
31 to that required by this chapter, if the applicant complies with
32 Section 4999.40, if applicable, and if the applicant has gained a
33 minimum of 250 hours of supervised experience in direct
34 counseling within California while registered as an intern with the
35 board.

36 (c) Education gained while residing outside of California shall
37 be accepted toward the licensure requirements if it is substantially
38 equivalent to the education requirements of this chapter, *and* if the
39 applicant has completed the training or coursework required under
40 subdivision (e) of Section 4999.32, which includes, in addition to

1 the course described in subparagraph (I) of paragraph (1) of
2 subdivision (c) of Section 4999.32, an 18-hour course in California
3 law and professional ethics for professional clinical counselors.

4 (d) For purposes of this section, the board may, in its discretion,
5 accept education as substantially equivalent if the applicant's
6 education meets the requirements of Section 4999.32. If the
7 applicant's degree does not contain the content or the overall units
8 required by Section 4999.32, the board may, in its discretion, accept
9 the applicant's education as substantially equivalent if the following
10 criteria are satisfied:

11 (1) The applicant's degree contains the required number of
12 practicum units under paragraph (3) of subdivision (c) of Section
13 4999.32.

14 (2) The applicant remediates his or her specific deficiency by
15 completing the course content and units required by Section
16 4999.32.

17 (3) The applicant's degree otherwise complies with this section.

18 (e) This section shall become inoperative on January 1, 2014,
19 and as of that date is repealed, unless a later enacted statute, which
20 is enacted before January 1, 2014, deletes or extends that date.

21 ~~SEC. 31.~~

22 *SEC. 47.* Section 4999.58 of the Business and Professions Code
23 is amended to read:

24 4999.58. (a) This section applies to a person who applies for
25 examination eligibility between January 1, 2011, and December
26 31, 2013, inclusive, and who meets both of the following
27 requirements:

28 (1) At the time of application, holds a valid license as a
29 professional clinical counselor, or other counseling license that
30 allows the applicant to independently provide clinical mental health
31 services, in another jurisdiction of the United States.

32 (2) Has held the license described in paragraph (1) for at least
33 two years immediately preceding the date of application.

34 (b) The board may issue a license to a person described in
35 subdivision (a) if all of the following requirements are satisfied:

36 (1) The education and supervised experience requirements of
37 the other jurisdiction are substantially the equivalent of this chapter,
38 as described in subdivision (e) and in Section 4999.46.

39 (2) The person complies with subdivision (b) of Section 4999.40,
40 if applicable.

1 (3) The person successfully completes the examinations required
2 by the board pursuant to paragraph (3) of subdivision (a) of Section
3 4999.50.

4 (4) The person pays the required fees.

5 (c) Experience gained outside of California shall be accepted
6 toward the licensure requirements if it is substantially equivalent
7 to that required by this chapter. The board shall consider hours of
8 experience obtained in another state during the six-year period
9 immediately preceding the applicant's initial licensure by that state
10 as a licensed professional clinical counselor.

11 (d) Education gained while residing outside of California shall
12 be accepted toward the licensure requirements if it is substantially
13 equivalent to the education requirements of this chapter, *and* if the
14 applicant has completed the training or coursework required under
15 subdivision (e) of Section 4999.32, which includes, in addition to
16 the course described in subparagraph (I) of paragraph (1) of
17 subdivision (c) of Section 4999.32, an 18-hour course in California
18 law and professional ethics for professional clinical counselors.

19 (e) For purposes of this section, the board may, in its discretion,
20 accept education as substantially equivalent if the applicant's
21 education meets the requirements of Section 4999.32. If the
22 applicant's degree does not contain the content or the overall units
23 required by Section 4999.32, the board may, in its discretion, accept
24 the applicant's education as substantially equivalent if the following
25 criteria are satisfied:

26 (1) The applicant's degree contains the required number of
27 practicum units under paragraph (3) of subdivision (c) of Section
28 4999.32.

29 (2) The applicant remediates his or her specific deficiency by
30 completing the course content and units required by Section
31 4999.32.

32 (3) The applicant's degree otherwise complies with this section.

33 (f) This section shall become inoperative on January 1, 2014,
34 and as of that date is repealed, unless a later enacted statute, which
35 is enacted before January 1, 2014, deletes or extends that date.

36 ~~SEC. 32.~~

37 *SEC. 48.* Section 4999.59 of the Business and Professions Code
38 is amended to read:

39 4999.59. (a) This section applies to a person who applies for
40 examination eligibility or registration between January 1, 2011,

1 and December 31, 2013, inclusive, who meets both of the following
2 requirements:

3 (1) At the time of application, holds a valid license described
4 in paragraph (1) of subdivision (a) of Section 4999.58.

5 (2) Has held the license described in paragraph (1) for less than
6 two years immediately preceding the date of application.

7 (b) Experience gained outside of California shall be accepted
8 toward the licensure requirements if it is substantially equivalent
9 to that required by this chapter, if the applicant complies with
10 Section 4999.40, if applicable, and if the applicant has gained a
11 minimum of 250 hours of supervised experience in direct
12 counseling within California while registered as an intern with the
13 board. The board shall consider hours of experience obtained in
14 another state during the six-year period immediately preceding the
15 applicant's initial licensure in that state as a professional clinical
16 counselor.

17 (c) Education gained while residing outside of California shall
18 be accepted toward the licensure requirements if it is substantially
19 equivalent to the education requirements of this chapter, *and* if the
20 applicant has completed the training or coursework required under
21 subdivision (e) of Section 4999.32, which includes, in addition to
22 the course described in subparagraph (I) of paragraph (1) of
23 subdivision (c) of Section 4999.32, an 18-hour course in California
24 law and professional ethics for professional clinical counselors.

25 (d) For purposes of this section, the board may, in its discretion,
26 accept education as substantially equivalent if the applicant's
27 education meets the requirements of Section 4999.32. If the
28 applicant's degree does not contain the content or the overall units
29 required by Section 4999.32, the board may, in its discretion, accept
30 the applicant's education as substantially equivalent if the following
31 criteria are satisfied:

32 (1) The applicant's degree contains the required number of
33 practicum units under paragraph (3) of subdivision (c) of Section
34 4999.32.

35 (2) The applicant remediates his or her specific deficiency by
36 completing the course content and units required by Section
37 4999.32.

38 (3) The applicant's degree otherwise complies with this section.

1 (e) This section shall become inoperative on January 1, 2014,
2 and as of that date is repealed, unless a later enacted statute, which
3 is enacted before January 1, 2014, deletes or extends that date.

4 *SEC. 49. Section 4999.62 of the Business and Professions Code*
5 *is amended to read:*

6 4999.62. (a) This section applies to persons who apply for
7 examination eligibility or registration on or after January 1, 2014.

8 (b) For purposes of Sections 4999.60 and 4999.61, education
9 is substantially equivalent if all of the following requirements are
10 met:

11 (1) The degree is obtained from an accredited or approved
12 institution, as defined in Section 4999.12, and consists of, at a
13 minimum, 48 semester or 72 quarter units, including, but not
14 limited to, both of the following:

15 (A) Six semester or nine quarter units of practicum, including,
16 but not limited to, a minimum of 280 hours of face-to-face
17 counseling.

18 (B) The required areas of study listed in subparagraphs (A) to
19 (M), inclusive, of paragraph (1) of subdivision (c) of Section
20 4999.33.

21 (2) The applicant completes any units and course content
22 requirements under Section 4999.33 not already completed in his
23 or her education.

24 (3) The applicant completes credit level coursework from a
25 degree-granting institution that provides all of the following:

26 (A) Instruction regarding the principles of mental health
27 recovery-oriented care and methods of service delivery in recovery
28 model practice environments.

29 (B) An understanding of various California cultures and the
30 social and psychological implications of socioeconomic position.

31 (C) Structured meeting with various consumers and family
32 members of consumers of mental health services to enhance
33 understanding of their experience of mental illness, treatment, and
34 recovery.

35 (D) Instruction in behavioral addiction and co-occurring
36 substance abuse and mental health disorders, as specified in
37 subparagraph (K) of paragraph (1) of subdivision (c) of Section
38 4999.33.

39 (4) The applicant completes, in addition to the course described
40 in subparagraph (I) of paragraph (1) of subdivision (c) of Section

1 4999.33, an 18-hour course in California law and professional
2 ethics that includes, but is not limited to, instruction in advertising,
3 scope of practice, scope of competence, treatment of minors,
4 confidentiality, dangerous clients, psychotherapist-client privilege,
5 recordkeeping, client access to records, ~~the Health Insurance~~
6 ~~Portability and Accountability Act state and federal laws relating~~
7 ~~to confidentiality of patient health information~~, dual relationships,
8 child abuse, elder and dependent adult abuse, online therapy,
9 insurance reimbursement, civil liability, disciplinary actions and
10 unprofessional conduct, ethics complaints and ethical standards,
11 termination of therapy, standards of care, relevant family law, and
12 therapist disclosures to clients.

13 *SEC. 50. Section 4999.76 of the Business and Professions Code*
14 *is amended to read:*

15 4999.76. (a) ~~(1) Except as provided in paragraph (2) and~~
16 ~~subdivision (c), the board shall not renew any license pursuant to~~
17 ~~this chapter unless the applicant certifies to the board, on a form~~
18 ~~prescribed by the board, that he or she has completed not less than~~
19 ~~36 hours of approved continuing education in or relevant to the~~
20 ~~field of professional clinical counseling in the preceding two years,~~
21 ~~as determined by the board.~~

22 ~~(2) Except as provided in subdivision (c), the board shall not~~
23 ~~renew a license issued pursuant to paragraph (1) of subdivision~~
24 ~~(a) of Section 4999.54 unless the applicant certifies to the board,~~
25 ~~on a form prescribed by the board, that he or she has completed~~
26 ~~not less than 18 hours of approved continuing education in or~~
27 ~~relevant to the field of professional clinical counseling in the~~
28 ~~preceding year, as determined by the board. This paragraph shall~~
29 ~~become inoperative on January 1, 2018.~~

30 (b) The board shall have the right to audit the records of any
31 applicant to verify the completion of the continuing education
32 requirement. Applicants shall maintain records of completed
33 continuing education coursework for a minimum of two years and
34 shall make these records available to the board for auditing
35 purposes upon request.

36 (c) The board may establish exceptions from the continuing
37 education requirement of this section for good cause, as defined
38 by the board.

39 (d) The continuing education shall be obtained from one of the
40 following sources:

1 (1) A school, college, or university that is accredited or
2 approved, as defined in Section 4999.12. Nothing in this paragraph
3 shall be construed as requiring coursework to be offered as part
4 of a regular degree program.

5 (2) Other continuing education providers, including, but not
6 limited to, a professional clinical counseling association, a licensed
7 health facility, a governmental entity, a continuing education unit
8 of a four-year institution of higher learning that is accredited or
9 approved, or a mental health professional association, approved
10 by the board.

11 (e) The board shall establish, by regulation, a procedure for
12 approving providers of continuing education courses, and all
13 providers of continuing education, as described in paragraphs (1)
14 and (2) of subdivision (d), shall adhere to procedures established
15 by the board. The board may revoke or deny the right of a provider
16 to offer continuing education coursework pursuant to this section
17 for failure to comply with the requirements of this section or any
18 regulation adopted pursuant to this section.

19 (f) Training, education, and coursework by approved providers
20 shall incorporate one or more of the following:

21 (1) Aspects of the discipline that are fundamental to the
22 understanding or the practice of professional clinical counseling.

23 (2) Significant recent developments in the discipline of
24 professional clinical counseling.

25 (3) Aspects of other disciplines that enhance the understanding
26 or the practice of professional clinical counseling.

27 (g) A system of continuing education for licensed professional
28 clinical counselors shall include courses directly related to the
29 diagnosis, assessment, and treatment of the client population being
30 served.

31 (h) The board shall, by regulation, fund the administration of
32 this section through continuing education provider fees to be
33 deposited in the Behavioral Sciences Fund. The fees related to the
34 administration of this section shall be sufficient to meet, but shall
35 not exceed, the costs of administering the corresponding provisions
36 of this section. For the purposes of this subdivision, a provider of
37 continuing education as described in paragraph (1) of subdivision
38 (d) shall be deemed to be an approved provider.

39 (i) The continuing education requirements of this section shall
40 fully comply with the guidelines for mandatory continuing

1 education established by the Department of Consumer Affairs
2 pursuant to Section 166.

3 ~~SEC. 33.~~

4 *SEC. 51.* Section 4999.90 of the Business and Professions Code
5 is amended to read:

6 4999.90. The board may refuse to issue any registration or
7 license, or may suspend or revoke the registration or license of
8 any intern or licensed professional clinical counselor, if the
9 applicant, licensee, or registrant has been guilty of unprofessional
10 conduct. Unprofessional conduct includes, but is not limited to,
11 the following:

12 (a) The conviction of a crime substantially related to the
13 qualifications, functions, or duties of a licensee or registrant under
14 this chapter. The record of conviction shall be conclusive evidence
15 only of the fact that the conviction occurred. The board may inquire
16 into the circumstances surrounding the commission of the crime
17 in order to fix the degree of discipline or to determine if the
18 conviction is substantially related to the qualifications, functions,
19 or duties of a licensee or registrant under this chapter. A plea or
20 verdict of guilty or a conviction following a plea of nolo contendere
21 made to a charge substantially related to the qualifications,
22 functions, or duties of a licensee or registrant under this chapter
23 shall be deemed to be a conviction within the meaning of this
24 section. The board may order any license or registration suspended
25 or revoked, or may decline to issue a license or registration when
26 the time for appeal has elapsed, or the judgment of conviction has
27 been affirmed on appeal, or, when an order granting probation is
28 made suspending the imposition of sentence, irrespective of a
29 subsequent order under Section 1203.4 of the Penal Code allowing
30 the person to withdraw a plea of guilty and enter a plea of not
31 guilty, or setting aside the verdict of guilty, or dismissing the
32 accusation, information, or indictment.

33 (b) Securing a license or registration by fraud, deceit, or
34 misrepresentation on any application for licensure or registration
35 submitted to the board, whether engaged in by an applicant for a
36 license or registration, or by a licensee in support of any application
37 for licensure or registration.

38 (c) Administering to himself or herself any controlled substance
39 or using any of the dangerous drugs specified in Section 4022, or
40 any alcoholic beverage to the extent, or in a manner, as to be

1 dangerous or injurious to the person applying for a registration or
2 license or holding a registration or license under this chapter, or
3 to any other person, or to the public, or, to the extent that the use
4 impairs the ability of the person applying for or holding a
5 registration or license to conduct with safety to the public the
6 practice authorized by the registration or license. The board shall
7 deny an application for a registration or license or revoke the
8 license or registration of any person, other than one who is licensed
9 as a physician and surgeon, who uses or offers to use drugs in the
10 course of performing licensed professional clinical counseling
11 services.

12 (d) Gross negligence or incompetence in the performance of
13 licensed professional clinical counseling services.

14 (e) Violating, attempting to violate, or conspiring to violate any
15 of the provisions of this chapter or any regulation adopted by the
16 board.

17 (f) Misrepresentation as to the type or status of a license or
18 registration held by the person, or otherwise misrepresenting or
19 permitting misrepresentation of his or her education, professional
20 qualifications, or professional affiliations to any person or entity.

21 (g) Impersonation of another by any licensee, registrant, or
22 applicant for a license or registration, or, in the case of a licensee
23 or registrant, allowing any other person to use his or her license
24 or registration.

25 (h) Aiding or abetting, or employing, directly or indirectly, any
26 unlicensed or unregistered person to engage in conduct for which
27 a license or registration is required under this chapter.

28 (i) Intentionally or recklessly causing physical or emotional
29 harm to any client.

30 (j) The commission of any dishonest, corrupt, or fraudulent act
31 substantially related to the qualifications, functions, or duties of a
32 licensee or registrant.

33 (k) Engaging in sexual relations with a client, or a former client
34 within two years following termination of therapy, soliciting sexual
35 relations with a client, or committing an act of sexual abuse, or
36 sexual misconduct with a client, or committing an act punishable
37 as a sexually related crime, if that act or solicitation is substantially
38 related to the qualifications, functions, or duties of a licensed
39 professional clinical counselor.

- 1 (l) Performing, or holding oneself out as being able to perform,
2 or offering to perform, or permitting any trainee, applicant, or
3 registrant under supervision to perform, any professional services
4 beyond the scope of the license authorized by this chapter.
- 5 (m) Failure to maintain confidentiality, except as otherwise
6 required or permitted by law, of all information that has been
7 received from a client in confidence during the course of treatment
8 and all information about the client which is obtained from tests
9 or other means.
- 10 (n) Prior to the commencement of treatment, failing to disclose
11 to the client or prospective client the fee to be charged for the
12 professional services, or the basis upon which that fee will be
13 computed.
- 14 (o) Paying, accepting, or soliciting any consideration,
15 compensation, or remuneration, whether monetary or otherwise,
16 for the referral of professional clients. All consideration,
17 compensation, or remuneration shall be in relation to professional
18 clinical counseling services actually provided by the licensee.
19 Nothing in this subdivision shall prevent collaboration among two
20 or more licensees in a case or cases. However, no fee shall be
21 charged for that collaboration, except when disclosure of the fee
22 has been made in compliance with subdivision (n).
- 23 (p) Advertising in a manner that is false, fraudulent, misleading,
24 or deceptive, as defined in Section 651.
- 25 (q) Reproduction or description in public, or in any publication
26 subject to general public distribution, of any psychological test or
27 other assessment device, the value of which depends in whole or
28 in part on the naivete of the subject, in ways that might invalidate
29 the test or device.
- 30 (r) Any conduct in the supervision of a registered intern,
31 associate clinical social worker, or clinical counselor trainee by
32 any licensee that violates this chapter or any rules or regulations
33 adopted by the board.
- 34 (s) Performing or holding oneself out as being able to perform
35 professional services beyond the scope of one's competence, as
36 established by one's education, training, or experience. This
37 subdivision shall not be construed to expand the scope of the
38 license authorized by this chapter.
- 39 (t) Permitting a clinical counselor trainee or intern under one's
40 supervision or control to perform, or permitting the clinical

1 counselor trainee or intern to hold himself or herself out as
2 competent to perform, professional services beyond the clinical
3 counselor trainee's or intern's level of education, training, or
4 experience.

5 (u) The violation of any statute or regulation of the standards
6 of the profession, and the nature of the services being rendered,
7 governing the gaining and supervision of experience required by
8 this chapter.

9 (v) Failure to keep records consistent with sound clinical
10 judgment, the standards of the profession, and the nature of the
11 services being rendered.

12 (w) Failure to comply with the child abuse reporting
13 requirements of Section 11166 of the Penal Code.

14 (x) Failing to comply with the elder and dependent adult abuse
15 reporting requirements of Section 15630 of the Welfare and
16 Institutions Code.

17 (y) Repeated acts of negligence.

18 (z) (1) Engaging in an act described in Section 261, 286, 288a,
19 or 289 of the Penal Code with a minor or an act described in
20 Section 288 or 288.5 of the Penal Code regardless of whether the
21 act occurred prior to or after the time the registration or license
22 was issued by the board. An act described in this subdivision
23 occurring prior to the effective date of this subdivision shall
24 constitute unprofessional conduct and shall subject the licensee to
25 refusal, suspension, or revocation of a license under this section.

26 (2) The Legislature hereby finds and declares that protection of
27 the public, and in particular minors, from sexual misconduct by a
28 licensee is a compelling governmental interest, and that the ability
29 to suspend or revoke a license for sexual conduct with a minor
30 occurring prior to the effective date of this section is equally
31 important to protecting the public as is the ability to refuse a license
32 for sexual conduct with a minor occurring prior to the effective
33 date of this section.

34 (aa) Engaging in any conduct that subverts or attempts to subvert
35 any licensing examination or the administration of an examination
36 as described in Section 123.

37 (ab) Revocation, suspension, or restriction by the board of a
38 license, certificate, or registration to practice as a professional
39 clinical counselor, clinical social worker, educational psychologist,
40 professional clinical counselor, or marriage and family therapist.

1 (ac) Failing to comply with the procedures set forth in Section
2 2290.5 when delivering health care via telemedicine.

3 (ad) Willful violation of Chapter 1 (commencing with Section
4 123100) of Part 1 of Division 106 of the Health and Safety Code.
5 ~~SEC. 34.~~

6 *SEC. 52.* Section 4999.106 of the Business and Professions
7 Code is amended to read:
8 4999.106. A license that is not renewed within three years after
9 its expiration may not be renewed, restored, reinstated, or reissued,
10 except that a former licensee may apply for and obtain a new
11 license if he or she complies with all of the following:

12 (a) No fact, circumstance, or condition exists that, if the license
13 were issued, would justify its revocation or suspension.

14 (b) He or she takes and passes the current examinations required
15 for licensing.

16 (c) He or she submits an application for initial licensure.

17 (d) He or she meets the requirements pursuant to Section
18 4999.51.

19 ~~SEC. 35.~~

20 *SEC. 53.* Section 4999.120 of the Business and Professions
21 Code is amended to read:
22 4999.120. The board shall assess fees for the application for
23 and the issuance and renewal of licenses and for the registration
24 of interns to cover administrative and operating expenses of the
25 board related to this chapter. Fees assessed pursuant to this section
26 shall not exceed the following:

27 (a) The fee for the application for examination eligibility shall
28 be up to two hundred fifty dollars (\$250).

29 (b) The fee for the application for intern registration shall be up
30 to one hundred fifty dollars (\$150).

31 (c) The fee for the application for licensure shall be up to one
32 hundred eighty dollars (\$180).

33 (d) The fee for the board-administered clinical examination, if
34 the board chooses to adopt this examination in regulations, shall
35 be up to two hundred fifty dollars (\$250).

36 (e) The fee for the law and ethics examination shall be up to
37 one hundred fifty dollars (\$150).

38 (f) The fee for the examination described in subdivision (b) of
39 Section 4999.54 shall be up to one hundred dollars (\$100).

1 (g) The fee for the issuance of a license shall be up to two
2 hundred fifty dollars (\$250).

3 (h) The fee for annual renewal of an intern registration shall be
4 up to one hundred fifty dollars (\$150).

5 (i) The fee for two-year renewal of licenses shall be up to two
6 hundred fifty dollars (\$250).

7 (j) The fee for issuance of a retired license shall be forty dollars
8 (\$40).

9 (k) The fee for rescoring an examination shall be twenty dollars
10 (\$20).

11 (l) The fee for issuance of a replacement license or registration
12 shall be twenty dollars (\$20).

13 (m) The fee for issuance of a certificate or letter of good standing
14 shall be twenty-five dollars (\$25).

15 ~~SEC. 36. No reimbursement is required by this act pursuant to~~
16 ~~Section 6 of Article XIII B of the California Constitution because~~
17 ~~the only costs that may be incurred by a local agency or school~~
18 ~~district will be incurred because this act creates a new crime or~~
19 ~~infraction, eliminates a crime or infraction, or changes the penalty~~
20 ~~for a crime or infraction, within the meaning of Section 17556 of~~
21 ~~the Government Code, or changes the definition of a crime within~~
22 ~~the meaning of Section 6 of Article XIII B of the California~~
23 ~~Constitution.~~

24 *SEC. 54. No reimbursement is required by this act pursuant*
25 *to Section 6 of Article XIII B of the California Constitution for*
26 *certain costs that may be incurred by a local agency or school*
27 *district because, in that regard, this act creates a new crime or*
28 *infraction, eliminates a crime or infraction, or changes the penalty*
29 *for a crime or infraction, within the meaning of Section 17556 of*
30 *the Government Code, or changes the definition of a crime within*
31 *the meaning of Section 6 of Article XIII B of the California*
32 *Constitution.*

33 *However, if the Commission on State Mandates determines that*
34 *this act contains other costs mandated by the state, reimbursement*
35 *to local agencies and school districts for those costs shall be made*
36 *pursuant to Part 7 (commencing with Section 17500) of Division*
37 *4 of Title 2 of the Government Code.*

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 1575 **VERSION:** Amended April 16, 2012

AUTHOR: Senate Committee on Business, Professions and Economic Development

BOARD POSITION:

SUBJECT: Professions and Vocations (Omnibus)

Affected Sections: Amends / Adds various sections of the Business and Professions Code related to Healing Arts, including:
Section 144.5 - Records
Section 4209 – Pharmacist Exam Applications; Certification of Intern Hours
Section 4300.1 – Board jurisdiction to proceed with discipline on a license

Current Status: 4/23/12 – Hearing in SEN Business, Professions and Economic Development

EXISTING LAW:

1. Provides for the licensure and regulation of a variety of healing arts professionals under various boards within the Department of Consumer Affairs, including the Board of Pharmacy.
2. Provides for the licensing, oversight and regulation of the practice of pharmacy by the Board of Pharmacy (Business and Professions Code Section 4000 et seq.)
 - a. Authorizes the board to suspend or revoke a license if the holder has been convicted of certain crimes or has engaged in unprofessional conduct.
 - b. Requires a pharmacist exam applicant who has been licensed as a pharmacist in another state for at least one year, as specified, to submit certification of licensure from the other state to satisfy the required 1,500 hours of intern experience required to sit for the exam.

THIS BILL:

1. Adds Section 144.5 to the Business and Professions Code to allow the board to request – and require a local or state agency to provide – certified records of arrests, convictions and other related documentation needed to complete an applicant or licensee investigation. [SECTION 1., p. 7]

2. Amends Section 4209 related to pharmacist exam applicants to [SEC. 20, p. 22]
 - a. Specify that an intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours; and,
 - b. For the pharmacist exam applicant that has been licensed as a pharmacist in another state for at least one year, that he or she may submit certification of licensure from the other state to satisfy the 1,500 hours of intern experience required, so long as the applicant has obtained *a minimum of 900 hours* of pharmacy practice experience in a pharmacy as a pharmacist.
3. Adds Section 4300.1 to the Business and Professions Code to ensure the board's jurisdiction to commence or proceed with an investigation of, or action or disciplinary action against, a license or render a decision to suspend or revoke a license even if that license has been cancelled, forfeited, suspended, surrendered, placed on retired status, etc. [SEC. 21, p. 23]

COMMENTS:

October 2011 – The board approved the omnibus provisions to amend Section 4209

January 2012 – The board approved omnibus provisions to add Section 4300.1

STAFF RECOMMENDATION: SUPPORT

HISTORY:

Date Action
2012

Apr. 16 From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.

Apr. 11 Set for hearing April 23.

Mar. 26 Referred to Com. on B., P. & E.D.

Mar. 13 From printer. May be acted upon on or after April 12.

Mar. 12 Introduced. Read first time. To Com. on RLS. for assignment. To print.

Agenda Item A

Legislation Report

3. Additional Legislation Impacting the Board or its Regulatory Jurisdiction



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Date: April 18, 2012

To: Legislation and Regulation Committee

**Subject: Agenda Item A3 – Additional Legislation Impacting the Board or Its
Regulatory Jurisdiction**

Staff will bring to the Committee Meeting additional legislation identified that may impact the Board or its regulatory jurisdiction.



Legislation and Regulation Committee

Shirley Wheat, Chair, Public Member
Ramón Castellblanch, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

LEGISLATION AND REGULATION COMMITTEE

The Legislation and Regulation Committee did not meet during the last quarter.

AGENDA ITEM B: REGULATION REPORT

1. Board Approved Regulations – Undergoing Review by the Administration (*Update Only*)

- a. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
- b. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination – Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)

On May 6, 2011, the board initiated a rulemaking to add Title 16 CCR § 1727.2 and to amend Title 16 CCR § 1728. The proposal would require a Pharmacist Intern applicant to submit with his or her application a Self-Query Report from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDBHIPPDB). This proposal would also require an applicant seeking board authority to take the pharmacist licensure examination to submit with his or her application a Self-Query Report from the NPDB-HIPDB. The board determined that the requirement(s) to submit a Self-Query Report, as specified in the proposal, is necessary and pertinent to the board's investigation of an applicant and will allow the board to determine if an applicant has been the subject of discipline in another state prior to making a decision on an application. This is the same type of Self-Query Report that was recently approved for Pharmacy Technician applicants.

The board did not receive any comments during the 45-day comment period and in July 2011 the board directed staff to complete the rulemaking process. The Executive Officer adopted the text as proposed in the Notice for the 45-day public

comment period. Staff compiled the final rulemaking file and submitted it to the Department of Consumer Affairs for administrative review on November 10, 2011.

Board staff has been advised that the DCA and the State and Consumer Services Agency have completed their review. The file has been at the Department of Finance awaiting review / approval since January 9, 2012, and staff checks weekly with the Department on the status of this rulemaking. Once all administrative approvals are received, the board will make available on its web site additional documents associated with the rulemaking and file the completed file with the Office of Administrative Law for final review.

The one-year notice period for this rulemaking will expire on May 5, 2012, unless extended by the Director of the Department of Consumer Affairs. A copy of the Adopted Text is **attached**.

2. Possible Action: Board-Approved Regulations Recently Noticed

Proposed Amendments to § 1746 – Emergency Contraception Protocol

On January 6, 2012, the board noticed for a 45-day public comment period, proposed amendments to 16 CCR § 1746 related to update the board's Emergency Contraception protocol. The proposed amendments were approved by the Medical Board of California at its July 2011 board meeting.

The 45-day public comment period concluded on February 20, 2012. **Attached** is a copy of the proposed text, as well as comments received during the 45-day comment period.

3. Information Only: Regulations Undergoing Initial 45-Day Comment Period

Proposed Amendments to § 1735.1, 1735.2, 1735.3 and 1751.2 Related to Compounding

On March 9, 2012, the board noticed for a 45-day public comment period, proposed amendments to Title 16 California Code of Regulations beginning at Section 1735.1 related to compounding drug products. The 45-day comment period will conclude on Monday, April 23, 2012.

Staff will provide the committee with comments received to the proposed rulemaking after the close of the comment period. A copy of the proposed text is attached.

4. Board Approved – Awaiting Notice (Information Only)

The following board-approved regulation proposals are awaiting notice. Attached are copies of the language approved by the board.

a. Proposed Addition of Section 1762 – Unprofessional Conduct

In October 2010, the board began discussions to add 16 CCR § 1762 to implement components of the DCA's Consumer Protection Enforcement Initiative relative to unprofessional conduct. In February 2011 the board addressed draft language and moved to initiate the rulemaking process to amend Section 1762 to specify that certain acts would constitute unprofessional conduct including: gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender.

Staff is working to prepare a rulemaking package for a 45-day public comment period.

b. Proposed Addition of Section 1769 – Application Review and Criteria for Rehabilitation

Protection Enforcement Initiative with regarding to 16 CCR § 1769 – a proposal that would authorize the board to request that an applicant for licensure undergo an examination, as specified, to determine if the applicant is safe to practice. The board directed that staff initiate the rulemaking process to amend 16 CCR § 1769, specifying that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board. A copy of the language as provided in the minutes of the Board Meeting is attached.

Staff is working to prepare a rulemaking package for a 45-day public comment period.

c. Proposed Amendment of Title 16 Section 1745 – Partial Fill of Schedule II Controlled Substance

At the October 2010 Board Meeting the board voted to initiate a rulemaking to amend Section 1745(c)(2) to allow pharmacies to maintain electronic records or document on the original prescription when partially filling a Schedule II controlled substance. The language approved by the board is below. Staff is working to prepare a rulemaking package for a 45-day public comment period.

1745(c)(2) The pharmacist records the date and amount of each partial filling in a readily retrievable form ~~and~~ or on the original prescription, also recording the initials of the pharmacist dispensing the prescription;

5. Board Proposed Regulations Being Discussed by Committees (Update Only)

The following regulatory topics are currently being discussed by various committees of the board. This is provided as information only.

a. Licensing Committee

- Updates to the USP Standards Reference Manual
- Standards for Agencies that Accredit Licensed Sterile Injectable Compounding Pharmacies
- Continuing Education
- Accreditation Agencies for Continuing Education
- Self-Assessment of a Veterinary Food-Animal Drug Retailer

b. Enforcement Committee

- Requirements for Unique ID Numbers for Rx / E-Pedigree
- Development of “Grandfathering” Provisions for Non-Pedigree Dangerous Drugs

c. Communication and Public Education Committee

- Notice to Consumers Posters / Video Display Format Option / Interpreter Availability

Agenda Item B

Regulation Report

1. Board Approved –
Undergoing Review by the
Administration

Order of Adoption
Board of Pharmacy
California Code of Regulations

Add Section 1727.2. to Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1727.2. Requirements for Pharmacist Intern.

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4207 and 4208, Business and Professions Code.

Amend Section 1728. in Article 3 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

(2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.

(3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.

(4) A signed copy of the examination security acknowledgment.

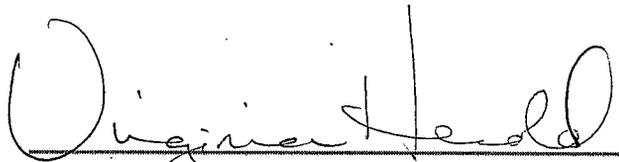
(5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the board to take the examinations.

(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Note: Authority cited: Sections 851 and 4005, Business and Professions Code.

Reference: Sections 144, 851 and 4200, Business and Professions Code.

A handwritten signature in cursive script, appearing to read "Virginia Herold", written over a horizontal line.

Virginia Herold
Executive Officer
Board of Pharmacy

Agenda Item B

Regulation Report

2. Possible Action - Board-Approved Regulations Recently Noticed

Title 16. Board of Pharmacy Proposed Language

To Amend § 1746 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1746. Emergency Contraception

(a) A pharmacist furnishing emergency contraception pursuant to Section ~~4052(a)(8)~~ 4052.3.(a)(2) of the Business and Professions Code shall follow the protocol specified in subdivision (b) of this section.

(b) Protocol for Pharmacists Furnishing Emergency Contraception (EC).

~~(1) Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to the protocols specified in Business and Professions Code section 4052.3. Use of the following protocol satisfies that requirement.~~

(1) Authority: Section 4052.3(a)(2) of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the California State Board of Pharmacy and the Medical Board of California. Use of the protocol specified in this section satisfies that requirement.

(2) Purpose: To provide timely access to emergency contraceptive medication ~~within required limits~~ and ensure that the patient receives adequate information to successfully complete therapy.

(3) Procedure: When a patient requests emergency contraception, the pharmacist will ask and ~~state~~ communicate the following:

Are you allergic to any medications?

Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) ~~of~~ after unprotected intercourse. ~~EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.~~

EC use will not interfere with an established or implanted pregnancy.

If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD.

(4) The pharmacist shall provide ~~the~~ a fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a

patient medication record required by Section 1707.1 of Title 16 of the California Code of Regulations.

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy as required by Business and Professions Code Section ~~4052(b)(3)~~ 4052.3(e).

(5) Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

(6) The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

(7) Advanced provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

(8) EC Product Selection: The pharmacist will provide emergency contraception medication ~~compatible with product information~~ from the list of products specified in this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC containing estrogen. Patients will be provided information concerning dosing and potential adverse effects.

(9) Documentation: Each prescription authorized by a pharmacist will be documented in a patient medication record as required by law.

(10) Training: Prior to furnishing emergency contraception, pharmacists who participate in ~~the~~ this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

~~(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.~~

(11) Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Dedicated Emergency Contraception

Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One-Dose Regimen				
Plan-B	Women's Capital Corporation	2 tablets	0	1.5
Two-Dose Regimens				
Plan-B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynetics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart*)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60
Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

(11) Medications Used for Emergency Contraception

<u>Dedicated Approved Products for Emergency Contraception</u>			
<u>Brand</u>	<u>Dose</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	
<u>One Dose Regimen</u>			
<u>Plan B™ One-Step</u>	<u>1 tablet</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>ella™</u>	<u>1 tablet</u>	<u>0</u>	<u>30mg ulipristal</u>
<u>Two Dose Regimen</u>			
<u>Next Choice™</u>	<u>1 tablet per dose</u>	<u>0</u>	<u>1.5mg levonorgestrel</u>
<u>Oral Contraceptive Pills</u>			
<u>Brand</u>	<u>Tablets per Dose (two doses 12 hours apart*)</u>	<u>Ethinyl Estradiol per dose (mcg)</u>	<u>Levonorgestrel per dose (mg)*</u>
<u>Allesse</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Aviane</u>	<u>5 orange tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levlen</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Levlite</u>	<u>5 pink tablets</u>	<u>100</u>	<u>0.50</u>
<u>Levora</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Lo/Ovral</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.50</u>
<u>Low-Ogestrel</u>	<u>4 white tablets</u>	<u>120</u>	<u>0.60</u>
<u>Nordette</u>	<u>4 light-orange tablets</u>	<u>120</u>	<u>0.60</u>
<u>Ogestrel</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Ovral</u>	<u>2 white tablets</u>	<u>100</u>	<u>0.50</u>
<u>Tri-Levlen</u>	<u>4 yellow tablets</u>	<u>100</u>	<u>0.50</u>
<u>Triphasil</u>	<u>4 yellow tablets</u>	<u>120</u>	<u>0.50</u>
<u>Trivora</u>	<u>4 pink tablets</u>	<u>120</u>	<u>0.50</u>
<u>Ovrette</u>	<u>20 yellow tablets</u>	<u>0</u>	<u>0.75</u>

*The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel.

In addition to the products specified in this paragraph, generic equivalent products may be furnished. Estrogen containing regimens are not preferred and should be used only when the other options are not available.

(12) Anti-nausea Treatment Options for use with Emergency Contraception

<u>Anti-Nausea Treatment Options For Use With Emergency Contraception</u>		
Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; Repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP <u>EC</u> dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code. Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4052 and 4052.3, Business and Professions Code.

Amanda Davis, Pharm.D.
10972 Campus Street
Loma Linda, CA 92354

February 16, 2012

California Board of Pharmacy
1625 North Market Boulevard, N219
Sacramento, CA 95834

To Carolyn Klein and the Board of Pharmacy:

I am writing in regards to the proposed amendment to § 1746 of Article 5 of Division 17 of Title 16 of the California Code of Regulations regarding emergency contraception, specifically, subdivision (b)(3). There are several erroneous, unclear, and problematic statements that I believe must be addressed before this amendment is to take effect.

First, with the advent of ulipristal acetate on the market as an alternative emergency contraceptive, it is important to differentiate between the two types of emergency contraception when counseling patients. Although they are used for the same purpose, they have very different properties. Because of this, I suggest that you strike the phrase "EC use will not interfere with an established or implanted pregnancy." and replace it with, "Progesterone-based emergency contraception will not interfere with an established pregnancy," or any similar phrase that would exclude ulipristal. Considering the current scientific evidence regarding ulipristal, it would be incorrect tell a patient, implicitly or explicitly, that this medication cannot disrupt an established pregnancy. Such evidences can be found in animal studies on guinea pigs (1), rats (2), and macaque monkeys (3) where ulipristal acetate was found to be capable of inducing abortion. Human studies have found that the corpus luteum, which is necessary for maintaining pregnancy in early gestation, can undergo luteolysis after doses as low as 1 mg of ulipristal acetate are taken (4). Additionally, the official assessment report published by the European Medicines Agency for ellaOne (the trade name for ella in Europe) states that, "Ulipristal acetate prevents progesterone from occupying its receptor, thus the gene transcription normally turned on by progesterone is blocked, and the proteins necessary to begin **and maintain** pregnancy are not synthesized" (5). It is for these reasons that I recommend that the statement be changed from a blanket statement concerning all emergency contraception to a more directed statement concerning only progesterone-based emergency contraceptives. This is something that might also be applied to the EC fact sheet for patients.

Second, I would like to suggest that you strike the point, "If more than 72 hours have elapsed since unprotected intercourse, the use of ella™ (ulipristal) may be more effective than levonorgestrel. Other options for EC include consultation with your physician regarding insertion of an IUD." and replacing it with the phrase, "If more than 72 hours have elapsed since unprotected intercourse, consult with your physician to discuss other options for EC." There are three reasons why the current phrasing is problematic:

1. Ulipristal is only approved for EC up to 120 hours post unprotected intercourse; therefore, recommending the use of ulipristal “more than 72 hours” after intercourse would only be accurate if less than 120 hours has elapsed since the event. The proposed phrasing does not specify this and may provide confusing or inaccurate information to the patient.
2. If more than 72 hours have elapsed since unprotected intercourse, whether it be 5 days or 10 days, the ONLY other option a patient has is to consult with their doctor. We cannot provide ella at the pharmacy without a prescription, so it would be more beneficial to recommend that they see their physician immediately.
3. Since ulipristal has abortifacient properties and is likely able to cause a drug-induced abortion in the early stages of gestation, the recommendation of this particular product to patients is morally problematic. Like levonorgestrel, ulipristal is capable of preventing pregnancy, and if this was its only mechanism of action, then it might be appropriate to recommend this product in the pharmacy; however, given the abortifacient nature of this drug, we should be weary to casually recommend this medication to patients without even counseling them on its mechanism of action or even ascertaining their views on abortion. The pharmacy is no place to impose such a grave and life-altering decision on women. The California medical board and board of pharmacy should reconsider standing behind this drug when many of the pharmacists in this state do not stand behind it at all.

Thank you for taking the time to read through and consider my comments on this amendment. My hope and goal is for women to receive informed and accurate information from their pharmacists on emergency contraception and for pharmacists to feel confident in the medications that they are recommending to their patients.

Sincerely,

Amanda Davis, Pharm.D.

References

1. Poyser NL, Forcelledo ML. A comparison of the pregnancy-terminating potencies of three anti-progestins in guinea-pigs, and the effects of sulprostone. *Prostaglandins Leukotrienes and Essential Fatty Acids* (1994) 50; 245-247.
2. Teutsch G, Philibert D. History and perspectives of antiprogestins from the chemist's point of view. *Hum Reprod.* 1994 Jun;9 Suppl 1:12-31.
3. Tarantal AF, Hendrickx AG, Matlin SA, et al. Effects of two anti-progestins on Early Pregnancy in the long-tailed macaque. *Contraception.* 1996;54:107-115.
4. Passaro MD, *et al.* Luteal phase dose-response relationships of the antiprogestin CDB-2914 in normally cycling women. *Human Reproduction.* 2003; 18(9): 1820-1827.
5. CHP Assessment Report for ellaOne. European Medicines Agency: *Evaluation of Medicines for Human Use.* Doc.Ref.: EMEA/261787/2009.

Follow up
 You replied on 1/23/2012 7:33 AM.
 This message was sent with High importance.

From: Kathy Besinque [kbesin@pharmacy.usc.edu] Sent: Fri 1/13/2012 3:27 PM
 To: Klein, Carolyn@DCA
 Cc:
 Subject: EC Language

There is one error in the posting of the EC language and one addition (see below)-

Dedicated Approved Products for Emergency Contraception

Brand	Dose	Ethinyl Estradiol per dose (mcg)	
<u>One Dose Regimen</u>			
Plan B™ One-Step	1 tablet	0	1.5mg levonorgestrel
ella™	1 tablet	0	30mg ulipristal
<u>Two Dose Regimen</u>			
Next Choice™	1 tablet per dose	0	Each tablet is 0.75mg

Note- Levonorgestrel tablets are new – it is a generic that uses
 Thank you

Kathleen Hill-Besinque, Pharm.D.,MSEd., FASHP, FCSHP
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 Director, Professional Experience Programs
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Dedicated Approved Products for Emergency Contraception

Brand

Dose Ethinyl Estradiol per dose (mcg)

One Dose Regimen

Plan B™ One-Step
 1 tablet
 0 1.5mg
 levonorgestrel

ella™ 1 tablet 0 30mg ulipristal

Two Dose Regimen

Next Choice™
 Levonorgestrel Tablets
 1 tablet per dose
 0 Each tablet is 0.75mg levonorgestrel

Agenda Item B

Regulation Report

3. Board-Approved -
Undergoing Initial 45-Day
Comment Period
(Information Only)

Board of Pharmacy Proposed Language

To Amend Section 1735.1 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.1. Compounding Definitions.

(a) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(a)~~ (b) "Integrity" means retention of potency until the expiration date noted on the label.

~~(b)~~ (c) "Potency" means active ingredient strength within +/- 10% of the labeled amount.

~~(c)~~ (d) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, and absence of active ingredients other than those noted on the label.

~~(d)~~ (e) "Strength" means amount of active ingredient per unit of a compounded drug product.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1735.2 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug product shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug product either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug product in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of

patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A “reasonable quantity” as used in Business and Professions Code section 4052(a)(1) means that amount of compounded drug product that:

(1) is sufficient for administration or application to patients in the prescriber's office, or for distribution of not more than a 72-hour supply to the prescriber's patients, as estimated by the prescriber; and

(2) is reasonable considering the intended use of the compounded medication and the nature of the prescriber's practice; and

(3) for any individual prescriber and for all prescribers taken as a whole, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug product.

(d) A drug product shall not be compounded until the pharmacy has first prepared a written master formula record that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) Expiration dating requirements.

~~(2)~~ (4) Inactive ingredients to be used.

~~(3)~~ (5) Process and/or procedure used to prepare the drug.

~~(4)~~ (6) Quality reviews required at each step in preparation of the drug.

~~(5)~~ (7) Post-compounding process or procedures required, if any.

~~(6)~~ Expiration dating requirements.

(e) Where a pharmacy does not routinely compound a particular drug product, the master formula record for that product may be recorded on the prescription document itself.

(f) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug product until it is dispensed.

(g) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendial and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

(h) Every compounded drug product shall be given an expiration date representing the date beyond which, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used. This “beyond use date” of the compounded drug product shall not exceed 180 days from preparation or the shortest expiration date of any component in the compounded drug product, unless a longer date is supported by stability studies of finished drugs or compounded drug products using the same components and packaging. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug product.

(j) Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board. (Incorporated by reference is “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” Form 17M-39 Rev. ~~01/11~~ 02/12.) That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile injectable compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start of a new pharmacist-in-charge, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1735.3 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1735.3. Records of Compounded Drug Products.

(a) For each compounded drug product, the pharmacy records shall include:

- (1) The master formula record.
- (2) The date the drug product was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug product.
- (4) The identity of the pharmacist reviewing the final drug product.
- (5) The quantity of each component used in compounding the drug product.
- (6) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are sterile products compounded on a one-time basis for administration within ~~twenty-four~~ seventy-two (72) hours and stored in accordance with United States Pharmacopeia Standards to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code.

~~(7) The equipment used in compounding the drug product.~~

~~(8)~~ (7) A pharmacy assigned reference or lot number for the compounded drug product.

~~(9)~~ (8) The expiration date of the final compounded drug product.

~~(10)~~ (9) The quantity or amount of drug product compounded.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Chemicals, bulk drug substances, drug products, and components used to compound drug products shall be obtained from reliable suppliers. The pharmacy shall acquire and retain any available certificates of purity or analysis for chemicals, bulk drug substances, drug products, and components used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the Food and Drug Administration.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created.

Note: Authority cited: Sections 4005, 4127 and 4169, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend Section 1751.2 of Article 7 of Division 17 of Title 16 to read as follows:

§ 1751.2. Sterile Injectable Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and section 1735.4, a pharmacy which compounds sterile injectable products shall include the following information on the labels for those products:

- (a) Telephone number of the pharmacy, except for sterile injectable products dispensed for inpatients of a hospital pharmacy.
- (b) Name and concentrations of ingredients contained in the sterile injectable product.
- (c) Instructions for storage and handling.
- (d) All cytotoxic agents shall bear a special label which states “Chemotherapy - Dispose of Properly.” or “Cytotoxic Product – Dispose of Properly.”

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

Agenda Item B

Regulation Report

4. Board-Approved -
Awaiting Notice
(Information Only)

Title 16. Board of Pharmacy Proposed Language

To Add Section 1762 to Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1762. Unprofessional Conduct Defined.

In addition to those acts detailed in Business and Professions Code Section 4301, the following shall also constitute unprofessional conduct:

(a) Including or permitting to be included any of the following provisions in an agreement to settle a civil dispute arising from the licensee's practice, whether the agreement is made before or after the filing of an action:

(1) A provision that prohibits another party to the dispute from contacting, cooperating, or filing a complaint with the board; or,

(2) A provision that requires another party to the dispute to attempt to withdraw a complaint the party has filed with the board.

(b) Failure without lawful excuse to provide records requested by the board within 15 days of the date of receipt of the request or within the time specified in the request, whichever is later.

(c) Failure or refusal to comply with any court order issued in the enforcement of a subpoena, mandating the release of records to the board.

(d) Commission of any act resulting in the requirement that a licensee or applicant registers as a sex offender. The board may revoke the license of any licensee and deny the application of any applicant who is required to register as a sex offender pursuant to Section 290 of the Penal Code or any other equivalent federal, state or territory's law that requires registration as a sex offender.

Authority: Section 4005, Business and Professions Code. Reference: Sections 726, 4300 and 4301, Business and Professions Code.

Dr. Ratcliff discussed that section 4332 requires that a licensee must produce a record. He explained that this amendment requires that they must provide the record within a specific timeframe. He stated that the board will resort to an administrative subpoena if the board is not entitled to the record.

Dr. Schell spoke in support to adding clarifying language to specify records that the board is entitled to.

There was no additional board discussion or public comment.

MOTION: Direct staff to modify amendments to section 1762 to specify records within the board's purview and to bring revisions back to the Enforcement Committee for possible recommendation to the board.

M/S: Kajioaka/Schell

Support: 8 Oppose: 0 Abstain: 0

3. Amendment to section 1769 – Application Review and Criteria for Rehabilitation. The proposed amendment would allow the board to request that an applicant for licensure undergo an examination as specified to determine if the applicant is safe to practice. The board voted to require that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days. Within 60 days of the evaluation, the report must be received from the evaluator.

§1769. Application Review and Criteria for Rehabilitation

Proposed Amendments

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date of the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

~~(a)~~ (b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code, the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:

- (1) The nature and severity of the act(s) or offense(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.
- (5) Evidence, if any, of rehabilitation submitted by the applicant.

~~(b)~~ (c) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

- (1) Nature and severity of the act(s) or offense(s).
- (2) Total criminal record.
- (3) The time that has elapsed since commission of the act(s) or offense(s).
- (4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.
- (5) Evidence, if any, of rehabilitation submitted by the licensee.

Dr. Kajioka provided an overview of the amendment.

Ms. Schiedge Shellans suggested that that the language be changed to require that the evaluation and report be completed within 60 days rather than received within 60 days. She advised that the board cannot require that the report be received within 60 days and added that this standard would be difficult to implement and enforce.

Mr. Room provided that as drafted, the requirement that the report be received within 60 days is actually a requirement on the board.

No public comment was provided.

MOTION: Amend the proposed language for section 1769 to require that once it has been determined that an applicant is to be evaluated, the evaluation and report shall be completed within 60 days.

M/S: Castellblanch/Veale

Support: 8 Oppose: 0 Abstain: 0

Ms. Schiedge Shellans asked whether the board would like this proposal to be moved forward as part of a rulemaking process.

Ms. Herold provided that this proposal could be moved into another regulation package.

Mr. Room recommended that this proposal not be linked with the proposals for sections 1760 and 1762.

MOTION: Direct staff to take all steps necessary to initiate the formal rulemaking process to amend section 1769.

M/S: Lippe/Schell

Support: 8 Oppose: 0 Abstain: 0

4. Review and act on the performance standards developed by staff to conform to the department's online reporting of major enforcement milestones.

Ms. Herold provided an overview of the eight performance standards established by the department. She reviewed the board's timeframes and target dates for meeting these standards.

Ms. Herold reviewed current challenges impacting the board's ability to meet these standards as a result of the budget situation including a hiring freeze preventing the filling of the positions allocated by the CPEI, overtime prohibitions,

Agenda Item B

Regulation Report

5. Proposed Regulations Being Discussed By Committees
(Not for Action - Information Only)

Agenda Item C

Legislation and Regulation Committee

Third Quarterly Report on the
Committee's Goals for 2011/12

LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

Objective 3.1	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes.
Tasks:	<p>1. Secure extension of board's sunset date.</p> <p><i>1st Qtr 06/07:</i> Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</p> <p><i>4th Qtr 06/07:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</p> <p><i>1st Qtr 08/09:</i> SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</p> <p>Governor signs SB 963 (Chapter 385, Statutes of 2008)</p> <p><i>1st Qtr 09/10:</i> Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.</p> <p><i>2nd Qtr 09/10:</i> Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.</p> <p><i>3rd Qtr 09/10:</i> Sunset bills introduced</p> <p>AB 1659 (Huber) – State Government, Agency Repeals</p> <p>AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection</p> <p>SB 954 (Harmon) – Legislative Procedure, Committee Referrals</p> <p>SB 1171 (Negrete McLeod) – Regulatory Boards, Operations</p> <p><i>4th Qtr 09/10:</i> SB 954 (Harmon) – Bill is dead (Failed deadline)</p> <p>SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)</p> <p><i>1st Qtr 10/11:</i> Governor signs AB 1659 (Chapter 666, Statutes of 2010)</p> <p>Governor signs AB 2130 (Chapter 670, Statutes of 2010)</p> <p><i>Nov. 2011:</i> Board submits Sunset Report to Senate Committee on Business, Professions and Economic Development</p> <p><i>Mar. 2011:</i> Oversight Hearing of the Senate Committee on Business, Professions and Economic Development</p>

2. Sponsor legislation to update pharmacy law.
Enacted - 1st Qtr. 08/09: SB 1048 (Chapter 588, Statutes 2007) containing board omnibus provisions
- Oct. 2007:* Board sponsors omnibus provisions for 2008. Four types of changes are discussed.
- (1) Changes specific to the PIC and DRC requirements
 - Section 4022.5 – Designated Representative; Designated Representative-in-Charge
 - Section 4036.5 – Pharmacist-in-Charge
 - Section 4161 – Nonresident wholesaler
 - Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
 - Section 4329 – Nonpharmacists; Prohibited Acts
 - Section 4330 – Proprietors; Prohibited Acts
 - (2) Changes to allow for the use of mobile pharmacies
 - Section 4062 – Furnishing Dangerous Drugs During an Emergency.
 - Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.
 - (3) General changes
 - Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.
 - Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
 - Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.
 - Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.
 - H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.
 - (4) Changes based on recodification of Business and Professions Code section 4052
 - Section 733 – Dispensing Prescription Drugs and Devices
 - Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
 - Section 4040 – Prescription; Content Requirements
 - Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
 - Section 4060 – Controlled Substance – Prescription Required, Exceptions
 - Section 4076 – Prescription Container – Requirements for Labeling
 - Section 4111 – Restrictions on Prescriber Ownership
 - Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
 - H&SC 11150 – Persons Authorized to Write or Issue a Prescription

	<p><i>Jan. 2008:</i> Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779. Board approved language for omnibus bill.</p> <p><i>April 2008:</i> Some provisions of omnibus bill removed:</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board. • Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications • Section 4160 – Wholesaler Licenses • Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked • Section 4362 – Entry Into Pharmacists Recovery Program. <p><i>Oct. 2008:</i> Governor vetoes SB 1779</p> <p><i>1st Qtr 08/09:</i> Board seeks to pursue omnibus provisions (formerly contained in SB 1779). Four areas of change: (Included in SB 819)</p> <p>(1) Changes specific to the PIC and DRC requirements</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p>(2) Changes to allow for the use of mobile pharmacies</p> <ul style="list-style-type: none"> • Section 4062 – Furnishing Dangerous Drugs During an Emergency. • Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership. <p>(3) General changes</p> <ul style="list-style-type: none"> • Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions. • Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory • Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy. • Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee. <p>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</p>
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(4) Changes based on recodification of Business and Professions Code section 4052

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription

1st Qtr 08/09: Board seeks to introduce additional changes: (Included in SB 821)

- Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the board.
- Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
- Section 4160 – Wholesaler Licenses
- Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
- Section 4362 – Entry Into Pharmacists Recovery Program.

New Provisions

- 4200.1 – Pharmacist Examination; Remedial Education
- 4112 – Non-resident Pharmacy: Registration Required
- 4146 – Return and Disposal of Sharps
- 4013 – Subscriber Alert

3rd Qtr 08/09: SB 821 introduced

2nd Qtr 09/10: Governor signs SB 819 and SB 821, which contains all omnibus provisions with the exception of 4200.1 - Pharmacists Examination.

3rd Qtr 09/10: Staff provides language to Senate Business Professions and Economic Development Committee for inclusion in two omnibus bills.

Omnibus Proposal #1:

(1) Amendments to update references to the California Department of Public Health (formerly known as Department of Health Services)

- §4017 – Authorized Officers of the Law
- §4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- §4028 – Definition of Licensed Hospital
- §4037 – Definition of Pharmacy
- §4052.3 – Emergency Contraception Drug Therapy; Requirements and Limitations
- §4072 – Oral or Electronic Transmission of Prescription – Health Care Facility
- §4101 – Pharmacist-in-Charge, Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board Prescription: Exceptions.
- §4119 – Furnish Prescription Drug to Licensed Health Care Facility – Secured Emergency Supplies
- §4127.1 – License to Compound Injectable Sterile Drug Products Required
- §4169 – Prohibited Acts (also, strike operative date of 2008)
- §4181 – License Requirements; Policies and Procedures; Who May Dispense
- §4191 – Compliance with California Department of Public Health Requirements; Who May dispense Drugs

(2) Amendment to update a reference to the Physical Therapy Board of California (formerly known as the Physical Therapy Examining Committee of California)

- §4059 – Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Exceptions

(3) Amendments to update references to the State Department of Health Care Services (formerly known as the Department of Health Services)

- §4425 – Pharmacy Participation in Medi-Cal Program; Conditions; Department of Health Care Services Utilization Review and Monitoring
- §4426 – Department of Health Care Services to Study Reimbursement Rates

Omnibus Proposal #2

(1) Amend §4196(e) – Veterinary Food-Animal Drug Retailer; Designated Representative-in-Charge

(2) Amend §4200.1 – Retaking Examinations; Limits; Requirements (NAPLEX and CPJE 4x Failure)

(3) Add §4362 – Pharmacists Recovery Program

3rd Qtr 09/10: SB 1489 introduced (Senate Business, Professions, and Economic Development Committee). Includes proposals #1 and #2, with the exception of §4362.

	<p><i>4th Qtr 09/10:</i> Board establishes support position of SB 1489. SB 1489 is amended to modify §4013 – Subscriber Alert provisions for an owner of two or more pharmacies. SB 1489 is amended to modify §4076.5 – Patient-Centered Prescription Labels to authorize the board to exempt long-term health care facilities from regulations.</p> <p><i>1st Qtr 10/11:</i> Governor signs SB 1489 (Chapter 653, Statutes of 2010).</p> <p><i>2nd Qtr 10/11:</i> Board seeks to pursue omnibus provisions Section 4200 – Remove obsolete reference to prior pharmacist examination Staff provides language to Senate Committee on Business, Professions and Economic Development for inclusion in an omnibus bill.</p> <p><i>3rd Qtr 10/11:</i> Staff provides language to Senate Business Professions and Economic Development for inclusion in Omnibus Bill. SB 943 is introduced. Contains amendments to section 4200.</p> <p><i>1st Qtr 11/12:</i> Governor signs SB 943 (Chapter 350, Statutes of 2011).</p> <p><i>2nd Qtr 11/12:</i> Board seeks to pursue omnibus provision Section 4209 – To allow for the reporting of intern hours to the Board of Pharmacy by other state boards of pharmacy</p> <p><i>3rd Qtr 11/12:</i> SB 1575 introduced which includes the board’s omnibus provisions Section 4209 – Reporting of Intern Hours Section 4300.1 – Board jurisdiction to take action on a license</p> <p>3. Advocate the board’s role and its positions regarding pharmacists’ care and dispensing of dangerous drugs and devices (AB 2408). <i>Sep. 30, 2006:</i> Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists’ care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.</p> <p>4. Secure statutory standards for pharmacies that compound medications (AB 595). <i>Aug. 2006:</i> Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future. <i>Aug. 2008:</i> Regulatory effort initiated. (See Objective 3.2, Task 12) <i>Oct. 2009:</i> Board approves regulatory language for Initial Notice. <i>Jan. 2010:</i> Office of Administrative Law approves regulation. <i>July 2010:</i> Regulation effective.</p> <p>5. Secure implementation of e-pedigrees on prescription drugs dispensed in California. <i>Sep. 2006:</i> Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations. <i>Sep. 2008:</i> Governor signs SB 1307 which delays implementation of e-pedigree.</p>
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	<p>6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.</p> <p><i>Oct. 2007:</i> Governor signs the following: AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects. SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements. SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal. Governor vetoes the following: AB 249 (Eng) Healing Arts: Settlement Agreements. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure. AB 1025 (Bass) Professions and Vocations: Denial of Licensure. SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.</p> <p><i>Oct. 2008:</i> Governor signs the following: AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review Governor vetoes the following: AB 501 (Swanson) Pharmaceutical Devices AB 865 (Davis) State Agencies AB 1574 (Plescia) Surgical Clinics: Licensure</p> <p><i>Jan. 2009:</i> Legislation introduced affecting Pharmacy law: <i>(New Session)</i> AB 67 (Nava) Pharmacy Patient Protection Act of 2008. Dispensing of prescriptions, irrespective of a pharmacist's ethical, moral, or religious objections. SB 26 (Simitian) Home-generated pharmaceutical wastes and the disposal of devices.</p>
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4th Qtr 08/09: AB 418 (Emmerson) Pharmacy Technicians – Education and CE Requirements
 AB 484 (Eng) Licensees Not in Compliance with Judgment or Order; Enforcement; Action on a License
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB877(Emmerson)HealingArts;DCACommitteeAnalysis;ScopeofHealing Arts Practice
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
 AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)
 AB 1370 (Solorio) “Best Before” Date on a Prescription Label
 AB 1458 (Davis) Drugs: Adverse Effects Reporting
 SB 26 (Simitian) Home-Generated Pharmaceutical Waste
 SB 43 (Alquist) Cultural and Linguistic Competency
 SB 238 (Calderon) Medical Information
 SB341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
 SB389 (McLeod) – FBI and State Fingerprinting Requirements for DCA Boards and Bureaus
 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts
 AB 718 (Emmerson) Prescription Drugs: Electronic Transmissions – Requirement to Electronically Transmit Data by January 2012
 AB 830 (Cook) Drugs and Devices. References to US Pharmacopoeia; Compendia Recognized by the Centers of Medicare and Medicaid
 AB 931 (Fletcher) Emergency Supplies – Doses Stored in an Emergency Supplies Container
 AB 1310 (Hernandez) Specifies Mandatory Fields for Initial and Renewal Application Forms (Various Healing Arts Boards). Annual Transmission of Data to Health Care Workforce Clearinghouse (OSHPD)
 SB389(McLeod)–FBIandStateFingerprintingRequirementsforDCABoards and Bureaus
 SB 484 (Wright) Ephedrine Products to Schedule V
 SB 638 (Negrete McLeod) DCA Regulatory Boards -- Sunset Reviews
 SB 762 (Aanestad) Professions and Vocations; Healing Arts
1st Qtr 09/10: Governor signs SB762 (Aanestad) Professions and Vocations; Healing Arts
2nd Qtr 09/10: Governor signs SB 819 (Omnibus)
 Governor vetoes SB 820 (Omnibus)
 Governor signs SB 821 (Omnibus)
 Governor signs SB 470 (Corbett) - “Purpose”
 Governor signs AB 1071 (Emmerson) Pharmacy Fees; Sunset
 Governor signs AB 931 (Fletcher) - Emergency Supplies Container
 Governor signs AB830(Cook)DrugsandDevices;references to Compendia

3rd Qtr 09/10: Board considers new legislation

1. Board of Pharmacy
 - AB 2104 (Hayashi) – California State Board of Pharmacy
 - SB 1390 (Corbett) – Prescription Container Labels
2. Pharmacy Practice
 - AB 1869 (Anderson) – Pharmacy (spot bill)
 - AB 1916 (Davis) – Pharmacies: Mandatory Reporting of Med Errors
3. Sunset Review and Legislative Oversight Proposals
 - AB 1659 (Huber) – State Government, Agency Repeals
 - AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection
 - SB 954 (Harmon) – Legislative Procedure, Committee Referrals
 - SB 1171 (Negrete McLeod) – Regulatory Boards, Operations
 - SB 1172 (Negrete McLeod) – Sunset of Diversion Program
4. Regulation of Dangerous Drugs and Devices
 - AB 1455 (Hill) -- Pseudoephedrine
 - AB 2548 (Block) – CURES – Prescription Drug Monitoring Program
 - SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products
 - SB 1071 (DeSaulnier) – CURES
 - SB 1106 (Yee) – Prescribers – Dispensing of Samples
5. Pharmacy Licensing Issues
 - AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies
 - AB 2292 (Lowenthal) – Pharmacy: Clinics
 - AB 2551 (Hernandez) – Pharmacy Technician: Scholarship and Loan Repayment Program
6. Distribution of Needles and Syringes
 - AB 1701 (Chesbro) – Hypodermic Needles and Syringes
 - AB 1858 (Blumenfield) – Hypodermic Needles and Syringes: Exchange Services
 - AB 2139 (Chesbro) – Solid Waste: Product Stewardship
 - SB 1029 (Yee) -- Hypodermic Needles and Syringes
7. General / Other
 - AB 2112 (Monning) – Prescription Record Privacy Act

	<p><i>4th Qtr 09/10:</i> Board considers additional legislation AB 1939 (Fletcher) Sharps Waste SB1111 (Negrete McLeod) DCA Enforcement Model</p> <p><i>Apr. 2010:</i> Board takes positions on legislative measures: AB 1701 (Chesbro) Support AB 2104 (Hayashi) Oppose AB 2292 (Lowenthal) Support SB 1106 (Yee) Support if Amended AB 1916 (Davis) Bill is dead (failed deadline) AB 2112 (Monning) Bill is dead (failed deadline) SB 1111 (Negrete McLeod) Bill is dead (failed deadline)</p> <p><i>May 2010:</i> AB 1869 (Anderson) Bill is dead (failed deadline) AB 1939 (Fletcher) Bill is dead (failed deadline)</p> <p><i>June 2010:</i> SB 1390 (Corbett) Fails passage in policy committee SB 954 (Harman) Bill is dead (failed deadline) SB 1171 (Negrete McLeod) Bill is dead (failed deadline) AB 2139 (Chesbro) Bill is dead (failed deadline) AB 2292 (Lowenthal) Bill is dead (failed deadline) AB 2548 (Block) Bill is dead (Failed deadline)</p> <p><i>Apr./May 2010:</i> AB 2104 (Hayashi) Amended twice</p> <p><i>June 2010:</i> AB2104(Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.</p> <p><i>July 2010:</i> AB 2077 (Solorio – Centralized Hospital Packaging Pharmacies. Board establishes Support position.</p>
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1st Qtr 10/11: Governor signs the following legislation:

AB 2104 (Hayashi) – Requires DCA Director approval of the Board's appointment of Executive Officer (Chapter 374, Statutes of 2010)
AB 1659 (Huber) – State Government, Agency Repeals (Chapter 666, Statutes of 2010)
AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection (Chapter 670, Statutes of 2010)
SB 1172 (Negrete McLeod) – Diversion Programs (Chapter 517, Statutes of 2010)
AB 1071 (Chesbro) – Hypodermic Needles and Syringes (Chapter 667, Statutes of 2010)
SB 1414 (Hill) – Apomorphine: Unscheduled (Chapter 76, Statutes of 2010)
AB 2699 (Bass) – Licensure Exemption: State of Emergency (Chapter 270, Statutes of 2010)

Governor vetoes the following legislation:

AB 1858 (Blumenfield) – Hypodermic Needles and Syringes
SB 1029 (Yee) – Hypodermic Needles and Syringes
AB 2077 (Solorio) – Centralized Hospital Packaging Pharmacies
SB 971 (Pavley) – Bleeding Disorders: Blood Clotting Products
AB 2747 (Lowenthal) – Prisons: Pharmacy Services

The following legislation fails passage:

AB 1455 (Hill) – Pseudoephedrine
SB 1071 (DeSaulnier) – CURES
SB 1106 (Yee) – Prescribers Dispensing of Samples
AB 2551 (Hernandez) – Pharmacy Technician Scholarship & Loan Repayment Program
AB 1310 (Hernandez) – Healing Arts Database

2nd Qtr 10/11: SB 41 (Yee) Introduced – Hypodermic Needles and Syringes

AB 36 (Hill) Introduced – Ephedrine: Retail Sale

Board approves provisions for sponsorship in 2011/2012 Session:

(1) Pharmacists Recovery Program

- Section 4362 – Amend to require that a participant in the pharmacists recovery program be responsible to pay an administrative co-pay each month to cover a portion of the administrative costs borne by the board; provision to allow the board to waive or defer the requirement based on a demonstrated financial hardship.

3rd Qtr 10/11: Board advised changes to 4362 will not be sought this year.

1. Board-Sponsored Legislation
 - SB 431 (Emmerson) Pharmacies: regulation
 - Sections 4040.5, 4081 and 4126.5 – Proposal Regarding Return of Medicine to Reverse Distributors
 - Sections 4104, 4105 and 4112 – Enforcement Enhancements
2. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction
 - a. Board of Pharmacy/Licensing
 - AB 377 (Solorio) Pharmacy: Centralized hospital packaging
 - AB399(Lowenthal, Bonnie) Corrections: offender pharmacies
 - AB 847 (Lowenthal, Bonnie) Pharmacy: clinics
 - SB 100 (Price) Healing arts
 - SB 632 (Emmerson) Pharmacy
 - b. Controlled Substances/Marijuana
 - AB 507 (Hayashi) Pain management
 - SB 847 (Correa) Medical Cannabis Licensing Act
 - SB 786 (Dutton) Controlled substances
 - c. Reporting Requirements/Records
 - SB 260 (Cannella) Controlled substances
 - SB 315 (Wright) Ephedrine and pseudoephedrine
 - SB360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System
 - d. Healing Arts/DCA
 - AB 675 (Hagman) Continuing education
 - AB 958 (Berryhill) Regulatory boards: limitation periods
 - AB 1003 (Smyth) Professional and vocational licenses
 - AB 1328 (Pan) Professions and vocations
 - SB 231 (Emmerson) Regulatory boards: healing arts
 - SB227(Wyland) Business and professions: licensure (corrected)
 - SB 538 (Price) Healing arts
 - SB 544 (Price) Healing arts
 - SB 667 (Wyland) Healing arts
 - e. Other
 - AB389(Mitchell) Bleeding disorders: blood clotting products
 - AB 604 (Skinner) Needle exchange programs
 - SB 41 (Yee) Hypodermic Needles and Syringes
 - SB514(Simitian) Dextromethorphan: sale to minors prohibited
 - SB 850 (Leno) Medical records: confidential information

- 4th Qtr 10/11:* Board considers and establishes positions on the following legislation
- a. Board of Pharmacy/Licensing
 - AB 377 (Solorio) Pharmacy: Centralized hospital packaging - Support if amended
 - AB 399 (Lowenthal, Bonnie) Corrections: offender pharmacies -Support
 - b. Controlled Substances/Marijuana
 - AB 507 (Hayashi) Pain management - Oppose
 - c. Reporting Requirements/Records
 - SB 315 (Wright) Ephedrine and pseudoephedrine - Support
 - SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System - Watch
 - AB 1280 (Hill) Ephedrine Sales - Watch
 - d. Healing Arts/DCA
 - SB 541 (Price) Expert Consultants - Support
 - e. Other
 - AB 389 (Mitchell) Bleeding disorders: blood clotting products - Watch
 - AB 604 (Skinner) Needle exchange programs - Support
 - SB 41 (Yee) Hypodermic Needles and Syringes - Support if amended
 - SB 514 (Simitian) Dextromethorphan: sale to minors prohibited - Support
- 1st Qtr 11/12:* Board considers and changes positions in the following legislation
- a. Controlled Substances/Marijuana
 - AB 507 (Hayashi) Pain management - Watch
 - AB 389 (Mitchell) Bleeding disorders: blood clotting products - Oppose
- Governor signs the following legislation
- SB 541 (Price) Expert Consultants (Chapter 339, Statutes of 2011)
- 2nd Qtr 11/12:* Governor signs the following legislation
- AB 507 (Hayashi) Pain management (Chapter 396, Statutes of 2011)
 - SB 360 (DeSaulnier) Controlled Substance Utilization Review and Evaluation System (Chapter 418, Statutes of 2011)
 - SB 514 (Simitian) Dextromethorphan: sale to minors prohibited (Chapter 199, Statutes of 2011)
 - SB 431 (Emmerson) Pharmacies (Chapter 646, Statutes of 2011)
 - SB 850 (Leno) Medical records: confidential information (Chapter 714, Statutes of 2011)
- Governor signs the following legislation
- AB 604 (Skinner) Needle exchange programs (Chapter 744, Statutes of 2011)
 - SB 41 (Yee) Hypodermic Needles and Syringes (Chapter 738, Statutes of 2011)
- 3rd Qtr 11/12:* AB 1442 (Wieckowski) introduced. Pharmaceutical Waste Board takes positions on legislation
- AB 389 (Mitchell) Bleeding Disorders, Blood Clotting Products - Oppose

7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.
- March 2007:* Licensing Committee considers and approves concept. More work is required.
- June 2007:* Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.
- Sept. 2007:* Licensing Committee forwards to full board legislative proposal.
- Oct. 2007:* Board approved draft legislation.
- Nov. 2007:* Staff meeting with stakeholders to elicit support for the proposal.
- Dec. 2007:* Staff develop fact sheets and work with experts in immunizations.
- Feb. 2009:* Assembly Member Skinner authors AB 977, to allow pharmacists to initiate and administer immunizations pursuant to the Centers for Disease Control's guidelines for the adult and adolescent immunizations schedules.
- April 2009:* Bill amended to allow pharmacists to initiate and administer pneumococcal and influenza vaccines.
- May 2009:* Bill amended to intent language requesting the California Pharmacists Association to provide information to legislative Committees on the status of immunization protocols. (2-year bill)
- Jan. 2010:* Bill amended (removing opposition) to allow pharmacists to administer influenza vaccinations pursuant to protocol and to require specified documentation and reporting.
- Jan. 2010:* AB 977 passes out of Assembly Health Committee
Board reaffirms "support" position.
- April 2010:* Board changes position from "sponsor" to "support".
- June 2010:* AB 977 amended to apply only to a pharmacist associated with an independent community pharmacy. Bill died in committee.

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.
- Oct. 2007:* Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.
- Apr. 2008:* First public forum held in Fremont.
- May 2008:* Staff develop survey form to distribute to consumers to solicit input
Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.
- June 2008:* Staff attends community events, interview attendees about prescription label and distribute surveys.
- July 2008:* Staff attends community events, interview attendees about prescription label and distribute surveys.
- Oct. 2008:* Staff continues to attend community events, interview attendees about prescription label and distribute surveys.
Public Education Committee updated on the status of survey results.
- Feb. 2009:* Senator Corbett authors SB 470, to allow the purpose for which a medicine is prescribed to be included in the prescription and prescription label.
- May 2009:* Bill passes out of the Senate
- Oct. 2009:* Governor signs SB 470 (Chapter 590, Statutes of 2009).
- Oct. 2009:* Board approves regulatory language for notice.
- Nov. 2009:* Regulatory effort initiated.
- June 2010:* Board adopts final text (See Objective 3.2, Task 16).
- Nov. 2010:* Office of Administrative Law approves regulation.
- Jan. 2011:* Regulation takes effect.
9. Secure statutory fee increase to ensure sufficient funding to fulfill all of the board's statutory obligations as a consumer protection agency.
- Dec. 2008:* Board receives findings of independent fee audit.
- Jan. 2009:* Board votes to pursue fee increase.
- Feb. 2009:* Assembly Member Emerson authors AB 1071 which establishes new application and renewal fees.
- June 2009:* Bill passes out of the Assembly.
- Sept. 2009:* Bill is enrolled and sent to the Governor.
- Sept. 2009:* Bill enrolled, then pulled back and amended to include sunset provisions for the board. Amendments pass Senate and Assembly concurs. The bill is re-enrolled.
- Oct. 2009:* Governor signs AB 1071 (Chapter 270, Statutes of 2009)
- Jan. 2010:* Statutory fee schedule implemented (supersedes 16 CCR 1749)

10. Advocate legislation to enhance the board's enforcement activities.

- Jan. 2010:* Staff working to include in department-wide enforcement legislation the following enhancements to the board's enforcement activities (board approved Oct 2009):
- Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory.
 - Section 4104 - Licensed Employee, Theft or Impairment, Pharmacy Procedures.
 - Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation
- 2nd Qtr 10/11:* Board approves provisions for sponsorship in 2011/2012 Session.
- (1) Enforcement Enhancements
- Section 4104 – Amend to clarify that a pharmacy shall provide to the board, within 14 days, evidence of a licensee's theft or impairment. Require the pharmacy to conduct an audit to determine the scope of loss, and to provide the board with a certified copy of the audit results.
 - Section 4105 – Amend to specify a time period in which records shall be provided to the board when requested by an inspector or authorized representative of the board.
 - Section 4112 - Nonresident Pharmacy; Registration; Provision of information to Board; Maintaining Records; Patient Consultation.
- (2) Pharmaceutical Waste – Reverse Distributors
- Section 4040.5 – Amend to specify that a reverse distributor may not accept previously dispensed medicine and specify that previously dispensed medicine returned to a pharmacy can only be handled by a licensed integrated waste hauler.
 - Section 4081 – Amend to specify what records must be maintained of drugs being returned to a wholesaler or reverse distributor; and specify information that is to be maintained for drugs that are returned via a licensed integrated waste hauler.
 - Section 4126.5 – Amend to authorize a pharmacy to furnish drugs to a licensed integrated waste hauler for the sole purpose of disposing of pharmaceutical waste returned to a pharmacy.
- 3rd Qtr 10/11:* SB 431 is introduced containing – amendments to 4104, 4105, and 4112.
- 4th Qtr 10/11:* SB 431 amended to also contain changes to 4081, 4126.5, and 4126.7.
- 2nd Qtr 11/12:* Governor signs SB 431 (Chapter 646, Statutes of 2011).
- 3rd Qtr 11/12:* Board approves omnibus provisions to add section 4300.1 related to discipline of licenses

Objective 3.2	Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.
Measure:	Percentage successful enactment of promoted regulatory changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 268 1528 359">1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (§ 1793.7-1793.8). <i>Jan. 2007:</i> Office of Administrative Law approves rulemaking. Regulation takes effect. <li data-bbox="370 369 1528 506">2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (§ 1713 and 1717(e)). <i>Jan. 2007:</i> Regulation takes effect following approval by the Office of Administrative Law. <li data-bbox="370 516 1528 726">3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007:</i> Section 1775.4 – contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn. <i>June 2007:</i> Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law. <li data-bbox="370 737 1528 806">4. Repeal the requirement to post a notice regarding electronic files (§ 1717.2). <i>March 2007:</i> Office of Administrative Law approves rulemaking. Regulation takes effect. <li data-bbox="370 816 1528 1209">5. Revise and update Disciplinary Guidelines (§ 1760). <i>Oct. 2007:</i> Board approves regulation for 45-day comment period. <i>May 2009:</i> Regulation and revised Disciplinary Guidelines approved and takes effect. <i>July 2011:</i> Discussion to update Disciplinary Guidelines to also incorporate recommendations of the Substance Abuse Coordination Committee. <i>Sep. 2011:</i> Board approves draft regulation text and Disciplinary Guidelines for 45-day public comment. <i>Oct. 2011:</i> Board releases regulation text for 45-day comment to update the regulation and the Disciplinary Guidelines incorporated by reference. Regulation Hearing scheduled for January 31, 2012. <i>Jan. 2012:</i> Regulation Hearing <li data-bbox="370 1220 1528 1356">6. Self-assessment of a wholesaler by the designated representative (§ 1784). <i>April 2007:</i> Office of Administrative Law approves rulemaking. Regulation takes effect. <i>March 2011:</i> Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-26 (See Objective 3.2, Task 25) <li data-bbox="370 1367 1528 1503">7. Exempt the address of records of interns from display on the board's Website (§ 1727.1). <i>Sep. 2006:</i> Office of Administrative Law approves rulemaking. Regulation takes effect October 2006. <li data-bbox="370 1514 1528 1736">8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006:</i> Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007. <i>June 2007:</i> Board staff submit rulemaking file to the California Building Standards Commission.

9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(§ 1707.2).
Feb. 2007: Board notices regulation for 45 days comment period.
Nov. 2007: Regulation changes takes effect.
Jul. 2008: Board mails updated Notice to Consumers to all pharmacies in California.
1st Qtr 10/11: Board discusses updates to Notices to Consumers (See Objective 3.2, Task 19)
10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.
Dec. 2007: Office of Administrative Law approves Section 100 Changes. Amend the following:
1707 – Waiver of requirements for off-site storage of records
1709.1 – Designation of pharmacist-in-charge
1715 – Self-assessment of a pharmacy by the pharmacist-in-charge
1717 – Pharmacy practice
1746 – Emergency contraception
1780.1 – Minimum standards for veterinary food-animal drug retailers
1781 – Exemption certificate
1787 – Authorization to distribute dialysis drugs and devices
1790 – Assembling and packaging
1793.8 – Technician check technician
Repeal section 1786 – Exemptions
March 2009: Office of Administrative Law approves Section 100 Changes to update the self-assessment forms required in California Code of Regulations 1715 and 1784.
11. Increase fees to keep the board's contingency fund solvent and maintain operations.
Nov. 2007: Office of Administrative Law approves rulemaking.
Nov. 2007: Staff complete necessary programming changes and begin advising licensees of the change.
Jan. 1, 2008: New fees take effect.
Oct. 2009: Governor signs AB 1071, new fee schedule.
Jan. 2010: Statutory fee schedule becomes effective (supersedes 16 CCR §1749)
12. Secure regulatory standards for pharmacies that compound. (§1735 et al)
Nov. 2007: Board releases language for the 45-day comment period.
Sep. 2008: Board releases (withdrawn) language for 45-day comment period.
Oct. 2008: Regulation hearing
Jan. 2010: Office of Administrative Law approves regulation.
July 2010: Regulation and Self-Assessment Form 17M-39 is effective.
Board staff developing fact sheet for pharmacies.
March 2011: Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-39 (See Objective 3.2, Task 24)
Board notices regulation for 45-day comment period to update § 1735.2 and § 1751 and to revise/update the Compounding Self-Assessment form (17M-39).
4th Qtr 10/11: Board motions to adopt regulation.
Rulemaking submitted to the Department for review.
1st Qtr 11/12: Office of Administrative Law approves Rulemaking
Regulation takes effect October 19, 2011
March 2012: Board releases language to amend sections 1735.1, 1735.2, 1735.3 and 1751.2 for 45-day comment period.

13. Establish an ethics course (§1773 and §1773.5).
Sep. 2008: Board notices regulation for 45-day comment period.
Sep. 2009: Regulation takes effect.
14. Pharmacist Renewal Requirements (§1702).
Dec. 2009: Board notices regulation for 45-day comment period.
Feb. 2010: Board adopts regulation.
June 2010: Office of Administrative Law approves regulation.
Dec. 2011: Regulation takes effect.
15. Dishonest Conduct During Pharmacist Examination; Confidentiality of Exam Questions (§1721 and §1723.1).
Oct. 2009: Board notices regulation for 45-day comment period.
Jan. 2010: Board adoption of regulation as noticed.
July 2010: Rulemaking submitted to the Office of Administrative Law for review.
Aug. 2010: Office of Administrative Law approves regulation.
Sep. 2010: Regulation takes effect.
16. Standardized, Patient-Centered Prescription Labels (§1707.5)
Nov. 2009: Board notices regulation for 45-day comment period.
Jan. 2010: Regulation hearing.
Feb. 2010: Board modifies text of regulation.
Board notices modified text for 1st 15-day comment period.
Apr. 2010: Board modifies text of regulation.
Board notices modified text for 2nd 15-day comment period.
June 2010: Board adopts regulation language noticed on April 28.
July 2010: Rulemaking submitted to Department for review.
Oct. 2010: Rulemaking submitted to the Office of Administrative Law for review.
Nov. 2010: Office of Administrative Law approves rulemaking.
Jan. 2011: Regulation takes effect.
1st Qtr 11/12: Communication and Public Ed Comm. discusses existing requirements
3rd Qtr 11/12: Communication and Public Ed Comm. discusses existing requirements
17. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (§1746)
Jan. 2010: Board approves language to initiate rulemaking to correct a typographical error in the Emergency Contraception Protocol regulation.
July 2010: Board begins working with Medical Board to update the EC Protocol.
May-June 2011: Executive Officer works with Medical Board (MBC) and others to revise the protocol. The MBC will discuss at its July 2011 meeting. Pharmacy will discuss update of board regulation after MBC approval. The board will also need to update the Patient Information Fact Sheet on EC Protocol.
2nd Qtr 11/12: Medical Board of California approves draft regulation text
3rd Qtr 11/12: Board Notices regulation for 45-day comment period.
18. Board Issued Continuing Education (CE) Credit (§1732.2)
Feb. 2010: Board votes to amend section 1732.2 defining board-issued CE and notice regulation for 45-day comment period.
Oct. 2010: Board notices regulation for 45-day comment period.
Feb. 2011: Board issues modified text for 15-day comment period.
2nd Qtr 11/12: Board adopts and completes rulemaking and submits the file for administrative review.
Director of DCA extends one-year filing period per B&PC 313.1(e)(1)
Final Regulation to Office of Administrative Law for review (12/28/11)
3rd Qtr 11/12: Board withdraws rulemaking from the Office of Administrative Law

19. Notice to Consumers re: Patient-Centered Prescription Labels
- Apr. 2010:* Board directs staff to bring regulatory language to the July 2010 meeting re: increased font size, and language services.
- July 2010:* Board discusses possible language for Notice to Consumers.
- Oct. 2010:* Board discusses possible language for Notices to Consumers. Votes to modify and move existing Consumer Notices from §1707.2 to a new section at 16 CCR §1707.6, to include language for increased font size and oral interpretive services, and other changes.
- 1st - 3rd Qtr 10/11:* Board discusses updates to the Notices to Consumers to incorporate Patient-Centered Requirements.
- 3rd Qtr 10/11:* Board approves language to amend 16 CCR 1707.2 and to add 16 CCR §1707.6; for 45-day comment period and schedules regulation hearing for July 2011.
- 4th Qtr 10/11:* Board notices regulation for 45-day comment period and notices regulation hearing for July 27, 2011.
- 1st Qtr 11/12:* Board conducts Regulation Hearing
Board revises text and releases modified text for 15-day public comment. Absent negative comments, directs Executive Officer to adopt and complete rulemaking.
- 2nd Qtr 11/12:* Executive Officer adopts regulation and submits rulemaking for Administrative Review.
Rulemaking filed with Office of Administrative Law for review.
Rulemaking withdrawn from OAL to secure Department of Finance approval of Std. 399.
- 3rd Qtr 11/12:* Rulemaking resubmitted to OAL for review. OAL approves rulemaking. Regulation takes effect February 16, 2012.
Office of Administrative Law approves Rulemaking
Regulation effective 2/16/2012
20. Update references to USP Standards (§1780)
- 1st Qtr 07/08:* Board considers review of USP references.
- 2nd Qtr 07/08:* Subcommittee established to conduct full review of USP updates needed.
21. Veterinarian Food-Animal Drug Retailer Self-Assessment (§1785)
- 1st Qtr 07/08:* Board approves regulation for notice.
- 2nd Qtr 07/08:* Work on rulemaking stopped to allow for comprehensive review of Veterinary Food-Animal Drug Retailer Program.
22. Accreditation Agencies for Pharmacies that Compound (§1751.x)
- 1st Qtr 07/08:* Board approves regulation text for notice (upon additional review by counsel, modification of language is necessary prior to notice of proposed text)
- 3rd Qtr 11/12:* Board discusses draft language

23. Pharmacist and Intern Pharmacist Applicants to submit a Self-Query from the National Practitioner Data Bank-Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) (§ 1727.2, 1728)
- 1st Qtr 10/11:* Board approves additional modifications to the Pharmacy Technician Application (Form 17A5) and directs that the language approved in October 2010 and the application approved February 2011 be issued for a 45-day public comment period.
- 2nd Qtr 10/11:* Board votes to require applicants to submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB), and to amend/update the Pharmacy Technician application:
- Section 1728 – Amend to require an applicant for the pharmacist examination to submit a Self-Query Report from NPDB-HIPDB.
 - Section 1727.2. – Add new section to require an applicant for an Intern Pharmacist license to submit a Self-Query Report from NPDB-HIPDB.
 - Section 1793.5. – Amend to require a Pharmacy Technician applicant to submit a Self-Query Report from NPDB-HIPDB; and to modify the Pharmacist Technician Application (17A-5), incorporated by reference.
- April 2011:* Proposed Text to Amend §1793.5 and modify Form 17A-5 issued for 45 day public comment.
- Oct. 2011:* Board votes to require applicants to submit a Self-Query from the NPDB HIPDB.
- May 2011:* Board notices regulation for 45-day comment period.
- 2nd Qtr 11/12:* Rulemaking submitted to Department for administration review.
- 3rd Qtr 11/12:* Rulemaking pending review at the Department of Finance (1/9/12)
24. Pharmacy Technician Applicants to submit a Self-Query from the National Practitioner Data Bank-Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) and Revise Pharmacy Technician Application (§ 1793.5)
- Oct. 2011:* Board votes to require applicants to submit a Self-Query from the NPDB HIPDB and to amend/update the Pharmacy Technician Application (17A-5)
- Feb. 2011:* Board approves additional modifications to TCH application.
- April 2011:* Board notices regulation for 45-day comment period.
- June 2011:* Regulation adopted.
Rulemaking submitted to the Department for review.
- 2nd Qtr 11/12:* Rulemaking submitted to the Office of Administrative Law
Office of Administrative Law approves rulemaking (9/1/2011)
Regulation effective 10/1/2011
25. Update of Self-Assessment Forms
- March 2011:* Board notices regulation for 45-day public comment period to update 16 CCR §1715, §1735.2, §1751 and §1784 and the self assessment forms incorporated by reference:
17M-13 Community Pharmacy & Hospital Outpatient Pharmacy Self-Assessment
17M-14 Hospital Pharmacy Self-Assessment
17M-26 Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment
17M-39 Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment
- May 2011:* Board approves rulemaking.
- June 2011:* Rulemaking submitted to the Department for review.