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

Legislation and Regulation Committee

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LEGISLATION AND REGULATION COMMITTEE REPORT

PART II – LEGISLATION

1. Board Sponsored Legislation for 2012

ATTACHMENT 1

1575 (Senate Committee on Business, Professions and Economic Development, Price, Chair)

Last Amend: June 28, 2012
Location: Assembly Appropriations
Status: 6/28 - Heard in A-APPR.; Amended, and Re-Referred to A-APPR
Board Position: Support

Each year the Senate Committee on Business, Professions and Economic Development sponsors omnibus measures.

SB 1575 contains two omnibus proposals sponsored by the board:

- Section 4209 of the Business and Professions Code would 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. This language was approved by the board in October 2011. (SEC. 23)
- Section 4300.1 of the Business and Professions Code would ensure the board can put discipline on record even if the license is cancelled. This language was approved by the board in January 2012. (SEC. 24)

The bills attached are formatted to show the most recent version of the bill compared to current law (i.e., “amends the law” version).

As introduced, SB 1575 contained a provision sponsored by the Respiratory Care Board 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. This provision was removed (at the June 20 amendment) at the request of the Respiratory Care Board to address concerns by the American Council of Engineering Companies.

The latest version of the bill makes changes related to the Dental Board (see SEC 2). No provisions related to the Board of Pharmacy have been modified since they were amended into the bill on April 16.

The Board established a position of SUPPORT, which was affirmed at the May 1 Board Meeting. A copy of SB 1575 (pages relevant to Pharmacy provisions) and an analysis is provided in Attachment 1.

Committee Recommendation: *None (no changes needed)*

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

ATTACHMENT 2

Regulation of Dangerous Drugs and Devices

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

Board Position: Oppose (*Reaffirmed 5/1/12*)

Last Amend: January 17, 2012

Current Location: Enrolled and to the Governor (6/29/12)

Summary: AB 389 would 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 opposed this bill since introduction, 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 and again at the May 2012 Board Meeting. Since that time, the bill has passed both houses of the Legislature, and has been Enrolled and presented to the Governor. A copy of the bill and an analysis is provided in Attachment 2.

Committee Recommendation: *None*

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

Last Amend: June 14, 2012
Location: Senate Appropriations (referred on 7/2/12)
Board Position: Oppose Unless Amended (established 5/1)

COMMITTEE RECOMMENDATION: Change the Board's position from Oppose Unless Amended to Neutral

Summary: 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.

During the May 2012 board meeting, members discussed this measure and some of the concerns the bill posed in the current form. These concerns discussed the need for controls in the movement of the drugs that are picked up and shipped. After discussion the board established an Oppose Unless Amended position.

Staff has worked with the author's office requesting changes to the legislation that will provide for the security of the pharmaceutical waste. The bill in its current form incorporates many of the changes requested. In light of the changes incorporated at the request of the board and the author's office commitment to working with the board, staff recommended that the committee consider changing its position on this bill to a neutral position.

During the committee meeting, members discussed the measure as well as the amendments incorporated at the request of the board. After discussion the committee voted to recommend a change in the board's current position on this measure from an Oppose Unless Amended to a Neutral position.

At the request of the author's office, board staff recently testified before the Senate Committee on Environmental Quality expressing gratitude to the author's office and sponsor for working with the board to address its concerns and indicated that the board would be reconsidering its position during the July 2012 board meeting and could be moving to a Neutral position. A copy of the bill and the board's analysis is provided in Attachment 2.

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

Last Amend: June 27, 2012
Location: SEN Business, Professions & Economic Development
Status: Amended in committee 6/27 and re-referred back to SEN BP&ED

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. The bill would also authorize a registered nurse to dispense hormonal contraceptives pursuant to specified standardized procedures (without having to be in a specified clinic setting).

On May 1, 2012, the Board took a “Watch” position. Since that time, the bill has been amended to specify the standardized procedure / protocol under which a Registered Nurse may dispense self-administered hormonal contraceptives and also administer injections of hormonal contraceptives, and makes other changes specific to the Nursing Practice Act. The most recent version of the bill specifies that nothing shall be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed under Pharmacy Law. A copy of the bill and the board’s analysis is provided in Attachment 2.

Committee Recommendation: The committee did not recommend a position on this measure.

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

Introduced: February 16, 2011
Location: On the Assembly Inactive File
Status: According to the author’s staff, the bill is considered “inactive” and Senator Simitian may move the bill
Board Position: None

There has been no change in this measure since the May 1, 2012, Board Meeting.

Summary: 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. The measure is currently on the Inactive File. The board has not taken a position on this bill, and staff continues to monitor its activity. A copy of the bill and an analysis is provided in Attachment 2.

e. **SB 616 (DeSaulnier) CURES Program**

Last Amend: June 27, 2012
Location: Assembly Floor (3rd Reading)
Board Position:

The Legislation and Regulation Committee did not discuss this measure at its meeting held June 25.

This bill would establish the CURES Fund within the State Treasury to receive contributions to be allocated, upon appropriation by the Legislature, to the DOJ for the purpose of the CURES program. This bill was amended to affect CURES after the Legislation and Regulation Committee met in June. Staff recommends the board take a support position on this bill. A copy of the bill and an analysis is provided in Attachment 2.

STAFF RECOMMENDATION: Support

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

Last Amend: June 21, 2012
Location: Assembly Appropriations – As of 7/7 no hearing date has been set
Board Position: Support

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 established a position of Support on May 1. Since that time, the bill was amended to specify that a pharmacist shall not dispense a greater supply of a dangerous drug in accordance with the section, if the prescriber indicates “dispense as written” or words of similar meaning.

COMMITTEE RECOMMENDATION: The committee did not recommend a change in the board’s position.

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

Last Amend: June 26, 2012
Location: On the Assembly Floor – Third Reading File
Position: Support if Amended (A-3/29/12)

Summary: Under current law a county may establish a repository and distribution program under which a pharmacy may distribute donated/surplus medications, as defined, to persons in need of financial assistance. Currently, skilled nursing facilities, manufacturers, or pharmacy wholesalers may donate medications to a program. Under these programs, donated drugs must be either (1) dispensed to an eligible patient, (2) destroyed as pharmaceutical waste, or (3) returned to a reverse distributor. With

certain exceptions, those who donate medications to these programs are not subject to criminal or civil liability for injury caused when donating, accepting, or dispensing prescription drugs in compliance with the program. SB 1329 would expand repository and drug distribution programs by also allowing a county health officer to establish a program, and would expand the pool of defined entities that can donate drugs to the program. SB 1329 would also allow donated drugs to be transferred from one program to another. The bill would require certain information to be reported to the county, and would allow the board to request this information. The bill specifies entities, including the Board of Pharmacy, that may prohibit a pharmacy or clinic from participating in a program, as specified.

At the May 1, 2012 Board Meeting, the board established a position of Support if Amended. Since that time, staff has worked with the author's office to address the board's concerns. The current version of the bill contains some amendments that address the board's concerns, but there are a few areas that remain outstanding. Staff is continuing to work with Senator Simitian to address the board's concerns.

COMMITTEE RECOMMENDATION: The committee did not recommend a change in the board's position.

Sunset Review and Legislative Oversight

h. SB 1237 (Price) – Sunset Extension to 2017

Last Amend: June 15, 2012

Location: Assembly Business, Professions & Consumer Protection

Hearing: June 26, 2012

Position: Support (A-4/30/12)

Summary: 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 appeared before the Senate Committee on Business, Professions and Economic Development in March 2012.

The most recent version of the bill contains changes related to the Medical Board of California, the Physical Therapy Practice Act and the Naturopathic Doctors Act – no provisions related to the Board have changed.

The Legislation and Regulation Committee did not discuss this bill at its meeting on June 25. A copy the bill and an analysis is provided in Attachment 2.

Licensing and Pharmacy Operations

i. AB 377 (Solorio) Hospital Central Fill Pharmacies

Last Amend: April 14, 2011
Board Position: Support if Amended (Ver. A-4/14/11)
Location: Last Location was Senate Appropriations (6/14/11)

Summary: 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. The board's Executive Officer participated in a meeting with various stakeholders, and amendments to the bill are expected – basically, taking the bill back to a 2009 version that the board supported.

At the June 25 meeting of the Legislation and Regulation Committee, the chair reported that the measure has not changed since the board established its position in April 2011. Representatives from the California Society of Health System Pharmacists addressed committee and thanked the Executive Officer and the board for working with the sponsor and other stakeholders – adding that they expect amendments to be out any time. (As of July 7, the amendments were not yet in print.) The committee did not make a recommendation to change the board's position.

j. AB 1588 (Atkins) Reservist Licensees: Fees and Continuing Education

Last Amend: March 5, 2012
Board Position: None
Location: July 2, 2012 – Hearing in Senate Business, Professions & Economic Development
Board Position: The board has not previously discussed this measure

Summary: AB 1588 would require a licensing board to waive renewal fees and continuing education for a member of the California National Guard or member of the U.S. Armed Forces while they are on active duty.

At the June 25 meeting of the Legislation and Regulation Committee, the committee discussed the prior version of the bill (March 5, 2012). At that time, staff counsel advised that the bill did not specify what the 'status' of the license should be (while waived) nor did the bill define "good standing". The committee asked that staff clarify the intent of the bill and report back to the board.

Since that time, the bill was amended (June 25). The new version denotes a license is to be “current and valid” – not “in good standing.” However, the newly amended version does not specify what the status of the license is to be while “waived.” Because the bill authorizes a board to adopt regulations to implement the provisions, the board could specify what status the license is to be through regulations.

RECOMMENDATION: The committee did not recommend a position on this measure.

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

Enrolled: July 5, 2012

Board Position: None

Summary: 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.

Recently, it was brought to staff’s attention that under the Federal provisions of the Indian Health Care Improvement Act, non-Indian patients may be extended health care at all tribal facilities. According to the California Rural Indian Health Board, Tribal Health Programs (THPs) have the authority *and desire* to serve the non-Indian population. The CRIHB notes that other non-California licensed providers also serve California residents (University of California, Veterans Administration). The CRIHB states that in many rural parts of California, THPs are the only providers in these regions and they operate as part of an integrated rural health care delivery system. They state the purpose of AB 1896 is to assist in remedying the shortage of doctors, dentists, nurses, and other providers by conforming State law to Federal law.

The board did not take a position on AB 1896 at the May 1, 2012, Board Meeting.

The Legislation and Regulation Committee met on June 25 and discussed the March 27 version of the bill. Counsel noted it is unclear what legal standing the board may have to address concerns that Tribal Health Programs and populations they serve.

The committee recommended that the board establish a position of Oppose Unless Amended, and offer the author amendments that would require a Tribal Health Program to be licensed by the board if they wish to provide services to Californians off of tribal lands. Staff has been advised by the author’s office that the author has no intention to amend the language. Since that time, the bill has been enrolled and presented to the Governor.

COMMITTEE RECOMMENDATION: Oppose Unless Amended (*Note: The bill has been enrolled and sent to the Governor*)

I. **AB 1904 (Block) Military Spouses: Expedited Licensure**

Last Amend: June 12, 2012
Board Position: Support (Version: Introduced 2/22/12)
Location: Senate Appropriations – Set for hearing 8/6/12

Summary: As amended, this measure authorizes a board to expedite the licensure of an applicant that is a military spouse, and authorizes the board to adopt regulations to administer the provisions. Staff anticipates that this may impact two primary license types: Pharmacist, and Pharmacy Technician. The bill authorizes the board to promulgate regulations to implement the bill's provisions.

The former version of the bill provided for *temporary* licensure of applicants, as specified, and would have required the board to expedite the processing for the purpose of issuing the temporary license, specified the term of a temporary license, and authorized the board to promulgate regulations. The Board established a position of "Support" for the prior version.

The Legislation and Regulation Committee met on June 25, and discussed the term "current license" as reflected in subdivision (a). The committee asked staff to clarify the meaning of this term. The committee did not recommend that the board change its current position on the measure.

Staff note: Staff searched the Business and Professions Code as well as Title 16 of the California Code of Regulations and found that many boards use the term "current and valid" in describing an active license. Because the measure authorizes the board to adopt regulations to administer this provision, the board could further define the term "current license" through regulation.

COMMITTEE RECOMMENDATION: The committee did not recommend a change in the board's position.

m. **AB 2570 (Hill) Licensees: Settlement Agreements**

Introduced: February 24, 2012
Location: Senate Judiciary (6/18/12)

There has been no change in this measure since the board established its position of "Oppose Unless Amended" at the May 1, 2012 Board Meeting.

Summary: This bill would prohibit a licensee who is regulated by the Department of Consumer Affairs or various boards, as specified, from including or permitting to be included a provision in an agreement to settle a civil dispute that prohibits the other party in that dispute from contacting, filing a complaint with, or cooperating with the department, board, bureau, or program, or that requires the other party to withdraw a complaint from the department, board, bureau, or program. A licensee in violation of these provisions would be subject to disciplinary action by the board. The board supported this provision.

The bill would also prohibit a board, bureau, or program from requiring its licensees in a disciplinary action that is based on a complaint or report that has been settled in a civil action to pay additional moneys to the benefit of any plaintiff in the civil action. The board opposed this provision.

Since the May Board Meeting, staff has had discussions with the author's staff, who do not share the board's perspective. Staff has been advised that amendments are forthcoming, but the board has not received language to specify what those amendments will be.

The Legislation and Regulation Committee met on June 25 where it discussed concerns with the restitution provision and why that provision was problematic.

COMMITTEE RECOMMENDATION: The committee did not recommend a change in the board's position.

n. **SB 1095 (Rubio) Surgical and Outpatient Clinics**

Introduced: February 16, 2012
Location: Senate Appropriations (Fiscal: yes)
Status: June 26 – Set for Hearing in Assembly Health

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 those clinics which are licensed by the board. A clinic licensed by the board would be able to commingle 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. As Introduced, the board established a position of Oppose Unless Amended (May 2012).

Since that time, staff has been working with the author's office and the sponsors to resolve concerns among the stakeholders.

At the June 25 meeting of the Legislation and Regulation Committee, the committee discussed the introduced version of the bill, and the amendments sought by the board. It was the consensus of the committee that given acceptance of the board's amendments, to change the board's position from Oppose Unless Amended to Support. The bill was amended that day (available in print the following day). The board then changed its position to Support (on July 2, 2012). Board policy has been that if the President of the Board and the Chair of the Legislation and Regulation Committee agree to change the board's position between board meetings, they can do so – and that the board may ratify the position taken at the next regularly scheduled board meeting.

As amended on June 25, SB 1095 would authorize the board to issue a clinic permit to a CDPH licensed surgical clinic, to an outpatient surgery center that is accredited by one of four accreditation agencies approved by the Medical Board, and to an ambulatory surgery center certified to participate in the Medicare Program. These clinics must notify the board of any change in a clinic address, and also that a clinic licensed pursuant to Section 4190 shall advise the board of any proposed changes in ownership or beneficial interest.

Recommendation: Ratify the position of “Support” taken on July 2, 2012

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

Introduced: June 13, 2012
Location: June 26 – Set for Hearing in Assembly Health
Board Position: Support (2/24/12 version)

Summary: This bill would exempt from clinical laboratory licensing requirements and regulations and would limit a community pharmacy to provide only blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA, and approved by the FDA for sale to the public without a prescription in the form of an over-the-counter test kit, as specified. The current version also requires a pharmacy that obtains a CLIA certificate of waiver, to notify the public health officer of the county in which the pharmacy is located, that the pharmacy is performing those tests.

The board established a SUPPORT position at the May 1st Board Meeting. The Legislation and Regulation Committee met on June 25 and discussed the status of the measure. A copy of the bill and an analysis are provided in Attachment 3.

Committee Recommendation: *(No change in position recommended)*

Other

p. AB 2369 (Valadao) Prisoners: Pharmacy Services

Introduced: June 14, 2012
Location: Re-referred to Assembly Health
Status: No hearing set as of 6/20/12

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 to use “less expensive” medications. AB 2369 does not seek to modify existing Pharmacy Law. The board considered the introduced version of the bill (2/24/12) which required that “generic” medications be specified; however, the amended version of the bill specifies that “less expensive” medications be specified.

The Legislation and Regulation Committee did not discuss this bill at its meeting held June 25. A copy of the bill and an analysis are provided in Attachment 3.

q. SB 1185 (Price) Centralized Intelligence Partnership Act

Last Amend: May 29, 2012

Status: July 2, 2012 – Hearing in ASM Revenue & Taxation

Summary: This bill would create a Centralized Intelligence Partnership (“partnership”) as a pilot program – until January 1, 2018 – for the purpose of combating the underground economy. This partnership would institutionalize collaboration among state agencies, with a key element being to authorize and facilitate data and intelligence sharing among the partnership and state agencies. The partnership shall consist of the Employment Development Department, the Franchise Tax Board and the State Board of Equalization. The Department of Consumer Affairs is one of six state agencies designated that may participate in the pilot program in an advisory capacity. Should the DCA wish to participate, the DCA may provide a representative to the advisory committee, which shall meet at least quarterly. The bill in its current form authorizes participating agencies to exchange intelligence, data, documents, information, complaints, leads, etc. SB 1185 specifies that the partnership shall report to the Legislature, and specifies the frequency and content of those reports.

The Legislation and Regulation Committee did not discuss this bill at its meeting held June 25. A copy of the bill and an analysis are provided in Attachment 3.

Attachment 1

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) 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) Existing law, the Occupational Therapy Practice Act, requires the California Board of Occupational Therapy to ensure proper supervision of occupational therapy assistants and aides. An aide is required to be supervised by an occupational therapist.

This bill would also provide for an aide to be supervised by an occupational therapy assistant.

(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.

(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, canceled, forfeited, suspended, revoked, placed on retired status, or voluntarily

surrendered.

(8) 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.

Existing law makes various changes to the licensing and associated examination requirements for marriage and family therapists, clinical social workers, and professional clinical counselors, effective January 1, 2013.

This bill would delay the implementation of these and other related changes until January 1, 2014.

(9) 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.

(10) 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.

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1640 of the Business and Professions Code is amended to read:
1640.

Any person meeting all the following eligibility requirements may apply for a special permit:

extent or in a manner dangerous or injurious to himself or herself, or to others, or that impaired his or her ability to conduct with safety the practice authorized by his or her license.

(c) Applied for employment or worked in any health care profession or environment while under the influence of alcohol.

(d) Been convicted of a criminal offense involving the consumption or self-administration of any of the substances described in subdivisions (a) and (b), or the possession of, or falsification of a record pertaining to, the substances described in subdivision (a), in which event the record of the conviction is conclusive evidence thereof.

(e) Been committed or confined by a court of competent jurisdiction for intemperate use of or addiction to the use of any of the substances described in subdivisions (a), (b), and (c), in which event the court order of commitment or confinement is prima facie evidence of that commitment or confinement.

(f) Falsified, or made grossly incorrect, grossly inconsistent, or unintelligible entries in any hospital, patient, or other record pertaining to the substances described in subdivision (a).

SEC. 22. Section 4209 of the Business and Professions Code is amended to read:
4209.

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. *Intern hours earned in another state may be certified by the licensing agency of that state to document proof of those hours.*

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience, *provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist.* Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

SEC. 23. Section 4300.1 is added to the Business and Professions Code, to read:
4300.1.

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

SEC. 24. Section 4980.04 of the Business and Professions Code is amended to read:
4980.04.

This chapter shall be known and may be cited as the *Licensed Marriage and Family Therapist Act*.

SEC. 25. Section 4980.34 of the Business and Professions Code is amended to read:
4980.34.

It is the intent of the Legislature that the board employ its resources for each and all of the following functions:

(a) The licensing of marriage and family therapists, clinical social workers, *professional clinical counselors*, and educational psychologists.

(b) The development and administration of licensing examinations and examination procedures, as specified, consistent with prevailing standards for the validation and use of licensing and certification tests. Examinations shall measure knowledge and abilities demonstrably important to the safe, effective practice of the profession.

(c) Enforcement of laws designed to protect the public from incompetent, unethical, or unprofessional practitioners.

(d) Consumer education.

SEC. 26. Section 4980.397 of the Business and Professions Code is amended to read:
4980.397.

(a) Effective January 1, ~~2013~~2014, an applicant for licensure as a marriage and family therapist shall pass the following two examinations as prescribed by the board:

(1) A California law and ethics examination.

(2) A clinical examination.

(b) Upon registration with the board, a marriage and family therapist intern shall, within the first year of registration, take an examination on California law and ethics.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: SB 1575 **VERSION:** June 28, 2012
AUTHOR: Senate Committee on Business, Professions and Economic Development
SUBJECT: Professions and Vocations (Omnibus)
Board Position: Support

Affected Sections: Amends / Adds various sections of the Business and Professions Code related to Healing Arts, including:
Section 4209 – Pharmacist Exam Applications; Certification of Intern Hours
Section 4300.1 – Board jurisdiction to proceed with discipline on a license

Current Status: In Assembly Appropriations – As of 7/7, no hearing date is set

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. Amends Section 4209 related to pharmacist exam applicants to [SEC. 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.

2. 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. 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

May 2012 – Board established a position of SUPPORT

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



		<u>Version</u>		<u>Position</u>
BILL NUMBER:	AB 389 (Mitchell)	I-2/14/11	8/18/11	Oppose
		A-1/17/12	5/1/12	Oppose Reaffirmed

Subject: Bleeding Disorders: Blood Clotting Products
Sponsor: Hemophilia Council of California

CURRENT STATUS: *Enrolled and to the Governor 6/29/12*

RECENT UPDATES:

At the June 25 meeting of the Legislation and Regulation Committee, the committee noted the Board's continuing opposition to the AB 389.

On June 21, the Senate passed the bill, and the measure was returned to the Assembly awaiting concurrence of amendments made in the Senate. On June 25th, the Senate amendments were concurred, and the bill was sent to Engrossing and Enrolling. The bill was Enrolled to the Governor on June 29th.

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

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:

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

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 (Pavelly, 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."

Attachment 2

BILL HISTORY (as of 7/6/12)

2012

- June 29 Enrolled and presented to the Governor at 2 p.m.
June 25 Senate amendments concurred in. To Engrossing and Enrolling. (Ayes 77. Noes 0. Page 5416.).
June 21 In Assembly. Concurrence in Senate amendments pending. May be considered on or after June 23 pursuant to Assembly Rule 77.
June 21 Read third time. Passed. Ordered to the Assembly. (Ayes 37. Noes 0. Page 4027.).
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.

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

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

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

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

(2) Promote access to a full range of essential, cost-effective, lifesaving, blood clotting products and related equipment, supplies, and high-quality services for home use for persons with hemophilia and other bleeding disorders.
125286.20.

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

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

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

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

(d) "Blood clotting product" means an intravenously administered medicine manufactured from human plasma or recombinant biotechnology techniques, approved for distribution by the federal Food and Drug Administration, that is used for the treatment and prevention of symptoms associated with bleeding disorders. Blood clotting products include, but are not limited to, factor VII, factor VIIa, factor VIII, and factor IX products, von Willebrand factor products, bypass products for patients with inhibitors, and activated prothrombin complex concentrates.

(e) "Emergency" means care as defined in Section 1317.1.

(f) "Hemophilia" means a human bleeding disorder caused by a hereditary deficiency of the factors I, II, V, VIII, IX, XI, XII, or XIII blood clotting protein in human blood.

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

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

(i) "Patient" means a person needing a blood clotting product for home use.

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

(A) Hospital pharmacies.

(B) Health system pharmacies.

(C) Pharmacies affiliated with hemophilia treatment centers.

(D) Specialty home care pharmacies.

(E) Retail pharmacies.

(2) The providers described in this subdivision 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.
125286.25.

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

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

(b) 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 clotting factor on hand and about proper storage and refrigeration of clotting factors.

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

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

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

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

(g) Upon receiving approved authorization for a nonemergency prescription, provided manufacturer supply exists, ship the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less for established and new patients.

(h) Upon receiving approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, deliver prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport.

(i) Provide patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery and respond to these calls within a reasonable time period.

(j) Provide patients with notification of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of the provider of blood clotting products for home use receiving notification and participate in the National Patient Notification System for blood clotting product recalls.

(k) Provide language interpretive services over the telephone or in person, as needed by the patient.

(l) Have a detailed plan for meeting the requirements of this article in the event of a natural or manmade disaster or other disruption of normal business operations.

(m) Provide appropriate and necessary recordkeeping and documentation as required by state and federal law and retain copies of the patient's prescriptions.

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

125286.30.

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

125286.35.

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

Code.

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

(a) "Pharmaceutical waste" means any pharmaceutical, as defined in Section 117747, that for any reason may no longer be sold or dispensed for use as a drug.

(b) For purposes of this part, "pharmaceutical waste" does not include any pharmaceutical that is outdated or nonsalable and is being returned to a reverse distributor, as defined in Section 4040.5 of the Business and Professions Code, that is licensed both as a wholesaler of dangerous drugs by the California State Board of Pharmacy pursuant to Section 4160 of the Business and Professions Code and as a permitted transfer station pursuant to Section 117775, for possible manufacturer credit.

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

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

- (a) The name of the person-
- ~~(b) The business address of the person.~~
- ~~(c) The type of business.~~
- ~~(d) The types, and the estimated average monthly quantity, of medical waste generated.~~
- ~~(e) The type of treatment used onsite.~~
- ~~(f).~~
- (b) The business address of the person.
- (c) The type of business.
- (d) The types, and the estimated average monthly quantity, of medical waste generated.
- (e) The type of treatment used onsite.
- (f) The name and business address of the registered hazardous waste hauler used by the generator for backup treatment and disposal, for waste when the onsite treatment method is not appropriate due to the hazardous or radioactive characteristics of the waste, ~~or~~ the name of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment and disposal-
- ~~(g), and, if applicable, the name of the common carrier used by the generator to transport pharmaceutical waste offsite for treatment and disposal pursuant to Section 118032.~~
- (g) A statement indicating that the generator is hauling the medical waste generated in his or her business pursuant to Section 118030 and the name and any business address of the treatment and disposal facilities to which the waste is being hauled, if applicable-
- ~~(h).~~
- (h) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe and the name and business address of the treatment and disposal facilities used, if applicable-
- ~~(i).~~
- (i) A statement certifying that the information provided is complete and accurate--.

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

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

- (a) An information document stating how the generator contains, stores, treats, and disposes of any medical waste generated through any act or process of the generator.
- (b) Records of any medical waste transported offsite for treatment and disposal, including the quantity of waste transported, the date transported, ~~and~~ the name of the registered hazardous waste hauler or individual hauling the waste pursuant to Section 118030, ~~and, if applicable, the name of the common carrier transporting pharmaceutical waste pursuant to Section 118032.~~ The small quantity generator shall maintain these records for not less than two years.

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

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

- (a) The name of the person-
- ~~(b) The business address of the person.~~
- ~~(c) The type of business.~~

~~(d)~~.

~~(b) The business address of the person.~~

~~(c) The type of business.~~

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

~~(e)~~.

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

~~(f)~~.

~~(f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable.~~

~~(g), and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.~~

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

~~(h)~~.

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

~~(i)~~.

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

~~(j)~~.

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

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

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

~~(b)~~.

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

~~(c)~~.

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

~~(d)~~.

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

~~(e)~~.

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

~~(f)~~.

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

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

A pharmaceutical waste generator or parent organization that employs health care professionals who generate pharmaceutical waste is exempt from the requirements of subdivision (a) of Section 118000 if all of the following requirements are met:

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

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

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

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

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

(c) Except as provided in subdivision (d), all of the following requirements are met:

(1) Prior to shipment of the pharmaceutical waste, the generator notifies the intended destination facility that it is shipping pharmaceutical waste to it and provides a copy of the tracking document, as specified in Section 118040.

(2) The generator and the facility receiving the pharmaceutical waste maintain the tracking document, as specified in Section 118040.

(3) The facility receiving the pharmaceutical waste notifies the generator of the receipt of the pharmaceutical waste shipment and any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

(4) The generator notifies the enforcement agency of any discrepancies between the items received and the tracking document, as specified in Section 118040, evidencing diversion of the pharmaceutical waste.

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

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

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

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

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

(3) This subdivision does not prohibit the use of a single document to verify the return of more than one container to a parent organization or another health care facility, provided the form or log meets the requirements specified in paragraphs (1) and (2).

SEC. 8. Section 118033 is added to the Health and Safety Code, to read:
118033.

The pharmaceutical waste that is separated from medical waste by the generator shall be maintained in a manner to secure the pharmaceutical waste contents from access by unauthorized individuals. Any suspected or confirmed tampering of, unauthorized access to, or loss of this pharmaceutical waste shall be reported to the appropriate state licensing authority.

SEC. 9. Section 118040 of the Health and Safety Code is amended to read:
118040.

(a) Except with regard to sharps waste consolidated by a home-generated sharps consolidation point approved pursuant to Section 117904, a hazardous waste transporter or generator transporting medical waste shall maintain a completed tracking document of all medical waste removed for treatment or disposal. A hazardous waste transporter or generator who transports medical waste to a facility, other than the final medical waste treatment facility, shall also maintain tracking documents which show the name, address, and telephone number of the medical waste generator, for purposes of tracking the generator of medical waste when the waste is transported to the final medical waste treatment facility. At the time that the medical waste is received by a hazardous waste transporter, the transporter shall provide the medical waste generator with a copy of the tracking document for the generator's medical waste records. The transporter or generator transporting medical waste shall maintain its copy of the tracking document for three years.

~~(b)~~.

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

~~(1) information:~~

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

~~(2) The type and quantity of medical waste transported.~~

~~(3)~~.

(2) The type of pharmaceutical waste transported and the quantity or aggregate weight of pharmaceutical waste transported.

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

~~(4)~~.

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

~~(5)~~.

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

~~(e)~~.

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

~~(d)~~.

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

~~(e)~~.

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

~~(f)~~.

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

SEC. 10. Section 118165 of the Health and Safety Code is amended to read:
118165.

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

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

~~(b) All treatment facility operating records.~~

~~(e)~~.

(b) All treatment facility operating records.

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

SEC. 11.

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

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1442 **VERSION:** As Amended June 14, 2012
AUTHOR: Weickowski **SPONSOR:** EXP Pharmaceutical Services
BOARD POSITION: Oppose Unless Amended
SUBJECT: Common Carriers to Transport Pharmaceutical Waste

Affected Sections: Amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and add Sections 117637, 117748, 118032, and 118033 to, the Health and Safety Code, relating to pharmaceutical waste.

Current Status: Referred to Senate Appropriations Committee

Recommended Action: Change to a neutral position

Recent Updates:

Staff has worked with the author's office requesting changes to the legislation that will provide for the security of the pharmaceutical waste. The bill in its current form incorporates many of the changes requested. In light of the changes incorporated at the request of the board and the author's office commitment to working with the board, staff recommended that the committee board consider changing its position on this bill to a neutral position.

During the committee meeting, members discussed the measure as well as the amendments incorporated at the request of the board. After discussion the committee voted to recommend a change in the board's current position on this measure from an Oppose Unless Amended to a Neutral position.

At the request of the author's office, board staff recently testify during an Senate Environmental Quality expressing gratitude to the author's office and sponsor for working with the board to address its concerns and indicated that the board would be reconsidering its position during the July 2012 board meeting and could be moving to a Neutral position.

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."
 - 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).
 - c. Require generators of pharmaceutical waste to include in its medical waste management plan the name of the common carrier used to transport the pharmaceutical waste.
 - d. 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.
 - e. 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

- f. 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 as well as advanced notice of the shipment of pharmaceutical waste via a common carrier.
- g. Require that the records kept and maintained by Medical Waste Treatment Facilities also include tracking documents for generators of pharmaceutical waste.
- h. Specify that the pharmaceutical waste separated from the medical waste must be maintained in a secure manner and establishes a notice requirement for suspected or confirmed tampering of the pharmaceutical waste.

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:

Current law defines pharmacy waste as biohazardous waste, which in turn (in another code section) is designated as medical waste. The Medical Waste Management Act (MWMA) prescribes the methods for treating such waste because of the 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. Regulation of the MWMA is performed by the California Department of Public Health.

Under current law dangerous drugs being shipped through the traditional supply chain for dispensing are shipped to authorized entities in many instances by common carriers. In addition, drugs that are being returned to a reverse distributor for credit are also done so by common carrier.

In its current form, this proposal would make amendments to the MWMA to define pharmaceutical waste as a subset of medical waste and would allow for such waste to be transported by a common carrier. The proposal was amended to address many of the concerns identified by the board.

PRIOR BOARD DISCUSSION and ACTION:

During the May 2012 board meeting, members discussed this measure and some of the concerns the bill posed in the current form. These concerns discussed the need for controls in the movement of the drugs that are picked up and shipped. After discussion the board established an Oppose Unless Amended position.

PREVIOUS LEGISLATION

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

SUPPORT/OPPOSITION:Support

EXP Pharmaceutical Services Corp.
Fremont Chamber of Commerce

HISTORY:

Date	Action
June 14	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. On E.Q.
June 14	Referred to Com. on E.Q.
May 31	In Senate. Read first time. To Com. on RLS. for assignment.
May 30	Read third time. Passed. Ordered to the Senate. (Ayes 78. Noes 0. Page 5088.)
May 25	From committee: Do pass. (Ayes 17. Noes 0.) (May 25). Read second time. Ordered to third reading.

Apr. 18 In committee: Set, first hearing. Referred to APPR. Suspense file.
Mar. 28 Re-referred to Com. on APPR.
Mar. 27 Read second time and amended.
Mar. 26 From committee: Do pass as amended and re-refer to Com. on APPR. (Ayes 8. Noes 0.) (March 20).
Feb. 7 Re-referred to Com. on E.S. & T.M.
Feb. 6 From committee chair, with author's amendments: Amend, and re-refer to Com. on E.S. & T.M. Read second time and amended.
Jan. 26 Referred to Com. on E.S. & T.M.
Jan. 5 From printer. May be heard in committee February 4.
Jan. 4 Read first time. 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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Email: Ashley.Medina@asm.ca.gov

(d) Nothing in this section shall be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed pursuant to Chapter 9 (commencing with Section 4000).

SEC. 2. Section 2725.2 is added to the Business and Professions Code, to read:
2725.2.

(a) Notwithstanding any other provision of law, a registered nurse may dispense self-administered hormonal contraceptives approved by the Federal Food and Drug Administration (FDA) and may administer injections of hormonal contraceptives approved by the FDA in strict adherence to standardized procedures developed in compliance with subdivision (c) of Section 2725.

(b) The standardized procedure described in subdivision (a) shall include all of the following:

(1) Which nurse, based on successful completion of training and competency assessment, may dispense or administer the hormonal contraceptives.

(2) Minimum training requirements regarding educating patients on medical standards for ongoing women's preventive health, contraception options education and counseling, properly eliciting, documenting, and assessing patient and family health history, and utilization of the United States Medical Eligibility Criteria for Contraceptive Use.

(3) Demonstration of competency in providing the appropriate patient examination comprised of checking blood pressure, temperature, weight, and patient and family health history, including medications taken by the patient.

(4) Which hormonal contraceptives may be dispensed or administered under specified circumstances, utilizing the most recent version of the United States Medical Eligibility Criteria for Contraceptive Use.

(5) Criteria and procedure for identification, documentation, and referral of patients with contraindications for hormonal contraceptives and patients in need of a follow-up visit to a supervising physician and surgeon.

(6) The extent of physician and surgeon supervision required.

(7) The method of periodic review of the nurse's competence.

(8) The method of periodic review of the standardized procedure, including, but not limited to, the required frequency of review and the person conducting that review.

(c) For purposes of this section, in compliance with subdivision (a) of Section 2242, an "appropriate patient examination" shall be consistent with the evidence-based practice guidelines adopted by the federal Centers for Disease Control and Prevention in conjunction with the United States Medical Eligibility Criteria for Contraceptive Use.

(d) Nothing in this section shall be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed pursuant to Chapter 9 (commencing with Section 4000).

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 2348 **VERSION:** A-6/27/12
A-6/20/12 (No position)

AUTHOR: Mitchell **SPONSORS:** Planned Parenthood Affiliates of Ca.
California Family Health Council

BOARD POSITION: The Board has not taken a position on this bill

SUBJECT: Registered nurses: dispensation of drugs

Affected Sections: An act to amend Section 2725.1 of the Business and Professions Code, and add section 2725.2 to the Business and Professions Code, relating to healing arts.

Current Status: 6/27 – Heard and Amended in SEN Committee on Business, Professions and Economic Development. Re-referred back to SEN BP&ED

Recent Update:

On May 1, 2012, the Board took a “Watch” position. The bill was amended on June 20 to specify the standardized procedure / protocol under which a Registered Nurse may dispense self-administered hormonal contraceptives and also administer injections of hormonal contraceptives, and makes other changes specific to the Nursing Practice Act.

The Legislation and Regulation Committee met on June 25 and made no recommendation to establish a position.

On June 27, the bill was amended to remove the requirement that a nurse dispensing hormonal contraceptives be in a specified clinic setting. This version also specifies in each section that nothing shall be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed pursuant to Pharmacy Law.

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. Specifies various clinic settings in the Health and Safety Code.

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.
3. Specify that nothing in the sections shall be construed to affect the sites or types of health care facilities at which drugs or devices are authorized to be dispensed pursuant to Pharmacy Law (Chapter 9, commencing with Section 4000).
4. Define “appropriate patient examination.”
5. Specify requirements for the standardized procedure by which a nurse may dispense self-administered hormonal contraceptives.

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:

Information obtained from the Board of Registered indicates that a registered nurse would be able to perform these duties if deemed clinically competent to do so by the supervising physician, nurse practitioner, certified nurse-midwife or physician assistant.

The bill is not keyed as “fiscal” so the Senate will return the bill to the Assembly for concurrence of amendments made while in the Senate.

BILL HISTORY (as of 7/7/12)

2012

- June 27 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
- June 21 In committee: Set, first hearing. Hearing canceled at the request of author.
- June 20 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
- June 14 Referred to Com. on B., P. & E.D.
- June 4 In Senate. Read first time. To Com. on RLS. for assignment.
- May 31 Read third time. Passed. Ordered to the Senate. (Ayes 44. Noes 28. Page 5173.)
- May 29 Read third time and amended. Ordered to third reading. (Ayes 49. Noes 27. Page 5031.)
- May 14 Read second time. Ordered to third reading.
- May 10 From committee: Assembly Rules committee granted permission for the bill to be returned to the Assembly floor pursuant to Assembly Rule 96(b). Motion to withdraw the bill from committee pursuant to Assembly Rule 96(a) carries. (Ayes 50. Noes 24. Page 4765.) Ordered to second reading.
- Apr. 25 From committee: Do pass and re-refer to Com. on RLS. (Ayes 5. Noes 3.) (April 24). Re-referred to Com. on RLS.
- 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.

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



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

AUTHOR: Simitian **SPONSOR:**

SUBJECT: Solid Waste: Home-Generated Sharps

BOARD POSITION: None

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

Current Status: On the Assembly Inactive File (6/20/12)

COMMENTS:

As recently as June 20, 2012, staff has been in touch with the author's office. According to the Senator's staff, the Senator considers the bill active – though on the Inactive File. Amendments are likely towards the end of the session, but no amendments have been shared with the board.

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.

FISCAL/ECONOMIC IMPACT:

No fiscal impact, as introduced.

HISTORY:

Date	Action
2012	
Jan. 9	Ordered to inactive file on request of Assembly Member Allen

has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

SEC. 2. Section 11165 of the Health and Safety Code is amended to read:
11165.

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, ~~and the Osteopathic Medical Board of California Contingent Fund,~~ *and the CURES Fund*, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, 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.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

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

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, and federal controlled substance registration number.

(4) NDC (National Drug Code) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) ~~This section shall become operative on January 1, 2005. The CURES Fund is hereby established within the State Treasury. The Cures Fund shall consist of all funds contributed by organizations for the purposes of funding the CURES program. Money in the CURES Fund shall, upon appropriation by the Legislature, be available for allocation to the Department of Justice for the purposes of funding the CURES program.~~

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 616

VERSION: As Amended June 27, 2012

AUTHOR: DeSaulnier

SUBJECT: Controlled Substance Utilization Review and Evaluation System (CURES)

Affected Sections: Amend Section 11165 of the Health and Safety Code

CURRENT STATUS: On the Floor of the Assembly (Third Reading)

THIS BILL:

This bill would establish the CURES Fund within the State Treasury to receive contributions to be allocated, upon appropriation by the Legislature, to the DOJ for the purpose of the CURES program.

EXISTING LAW:

The Uniform Controlled Substances Act places controlled substances into four schedules, found in Health and Safety Code sections 11054 through 11057.

Health and Safety Code sections 11165 – 11165.1 provides for the Controlled Substances Utilization Review and Evaluation System (CURES), administered by the DOJ, to provide for monitoring of the prescribing and dispensing of Schedule II, III and IV controlled substances. Upon dispensing of a controlled substance in Schedules II – IV, the dispensing pharmacy or clinic must provide dispensing information to the DOJ within a specified time frame. CURES data is utilized by those approved to have access through the DOJ. This data can assist a prescriber or pharmacist to make informed decisions and detect those patients who may be attempting to abuse controlled substances by obtaining multiple prescriptions through various practitioners. The board pays approximately \$92,000 annually to help fund the CURES system.

Part of the Governor's 2011-12 Budget included substantial reduction to the Department of Justice's Bureau of Narcotic Enforcement (BNE) – the unit that houses California's CURES program, a prescription monitoring program for controlled substances in schedules II-IV. This resulted in the dissolution of the BNE, and in some services that have lapsed. As of January 2012, DOJ was temporarily operating the CURES program in its information unit.

The CURES program is an important program to this board and is used in drug diversion enforcement actions. Since the latter part of 2011, the board has received inquiries about the status of the program and licensees have reported problems in reaching the program.

AUTHOR'S STATEMENT (From the Assembly Public Safety Committee Analysis)

According to the author, "SB 616 establishes a dedicated fund to assist law enforcement and regulatory agencies in their efforts to control the diversion and abuse of prescription drugs and increase the frequency that a pharmacy or clinic reports filled controlled substance prescriptions. The fund will support the Controlled Substance Utilization Review and Evaluation System (CURES) Program administered by the California Department of Justice (DOJ).

In 2009, the DOJ launched its automated Prescription Drug Monitoring Program (PDMP) within the CURES program. The program allows licensed health care practitioners eligible to prescribe controlled substances access to patient controlled substance prescription information in real-time, 24 hours a day at the point of care. Prescribers and pharmacists used the PDMP to make informed decisions about patient care and detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners. While the automated PDMP within the CURES program is a valuable investigative, preventative, and educational tool for law enforcement, regulatory boards, and health care providers, recent funding reductions have resulted in insufficient funds to support the CURES. Without dedicated resources, the CURES program will be suspended."

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

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

(b) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

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

(d) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

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

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.
 - Preclude a pharmacist from dispensing an amount greater than the prescription is written for if the prescription indicates “dispense as written” or words of similar meaning.

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.

division:

(a) "Eligible entity" means all of the following:

(1) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is county owned or that contracts with the county pursuant to this division and is not on probation with the California State Board of Pharmacy.

(2) A licensed pharmacy, as defined in subdivision (a) of Section 4037 of the Business and Professions Code, that is owned and operated by a licensed primary care clinic, as defined in Section 1204, and is not on probation with the California State Board of Pharmacy.

(3) A licensed primary care clinic, as defined in Section 1204, that is licensed to administer and dispense drugs pursuant to subparagraph (A) of paragraph (1) of subdivision (a) of Section 4180 of the Business and Professions Code and is not on probation with the California State Board of Pharmacy.

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

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

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

Notwithstanding any other provision of law, ~~a licensed skilled nursing facility, as defined in Section 1250, including a skilled nursing facility designated as an institution for mental disease, may donate unused medications under a program established pursuant to this division-~~

the following health and care facilities may donate unused medications under a program established pursuant to this division:

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) (1) A county may establish, by ~~ordinance, a repository and distribution program for purposes of this division. Only pharmacies that are county-owned or that contract with the county pursuant to this division-~~ an action of the county board of supervisors or by an action of the public health officer of the county, as directed by the county board of supervisors, a repository and distribution program for purposes of this division. The county shall advise the California State Board of Pharmacy within 30 days from the date it establishes a repository and distribution program.

(2) Only an eligible entity, pursuant to subdivision (a) of Section 150201, may participate in this program to dispense medication donated to the drug repository and distribution program.

(3) An eligible entity that seeks to participate in the program shall inform the county health department, and the California State Board of Pharmacy, in writing of its intent to participate in the program. An eligible entity may not participate in the program until it has received written or electronic documentation from the county health department confirming that the department has received its notice of intent.

(4) (A) A participating entity shall disclose to the county health department the name and location of the source of all donated medication it receives.

(B) A participating primary care clinic, as described in paragraph (3) of subdivision (a) of Section 150201 shall disclose to the county health department the name of the licensed physician who shall be accountable to the California State Board of Pharmacy for the clinic's program operations pursuant to this division. This

physician shall be the professional director, as defined in subdivision (c) of Section 4182 of the Business and Professions Code.

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

(5) The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy may prohibit an eligible or participating entity from participating in the program if the entity does not comply with the provisions of the program, pursuant to this division. If the county board of supervisors, the public health officer of the county, or the California State Board of Pharmacy prohibits an eligible or participating entity from participating in the program, it shall provide written notice to the prohibited entity within 15 days of making this determination. The county board of supervisors, the public health officer of the county, and the California State Board of Pharmacy shall ensure that this notice also is provided to one another.

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

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

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

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

(4) Ensuring proper safety and management of any medications collected by and maintained under the authority of a ~~county-owned or county-contracted, licensed pharmacy~~ participating entity.

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

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

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

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

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

(d) Only medication that is donated in unopened, tamper-evident packaging or modified unit dose containers that meet USP standards is eligible for donation to the repository and distribution program, provided lot numbers and expiration dates are affixed. Medication donated in opened containers shall not be dispensed by the repository and distribution program.

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

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

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

(1) Dispensed to an eligible patient.

(2) Destroyed.

(3) Returned to a reverse distributor.

(4) ~~Transferred to another participating entity to be dispensed to eligible patients pursuant to this division.~~

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

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

(j) Medication donated to the repository and distribution program shall be segregated from the ~~pharmacy's participating entity's~~ other drug stock by physical means, for purposes including, but not limited to, inventory, accounting, and inspection.

(k) ~~The pharmacy~~ A participating entity shall keep complete records of the acquisition and disposition of medication donated to, and transferred and dispensed under, the repository and distribution program. These records shall be kept separate from the

~~pharmacy's participating entity's~~ other acquisition and disposition records and shall conform to the Pharmacy Law (Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code), including being readily retrievable.

~~(1)-(1)~~ Local and county protocols established pursuant to this division shall conform to the Pharmacy Law regarding packaging, transporting, storing, and dispensing all medications.

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

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

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

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

(a) A prescription drug manufacturer, wholesaler, governmental entity, ~~county-owned or county-contracted licensed pharmacy, or skilled nursing facility~~ *or participating entity*.

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

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

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.

FOR DISCUSSION:

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

Donating Facilities [SEC. 2, H&SC 150202] – Staff are addressing the bill’s provisions that allow Residential Care Facilities for the Elderly to donate unused Medications.

Board Authority – The author has agreed to amendments that would require eligible entities to notify the board of their intent to participate in the program (in addition to notifying the county of that intent), notify the board of the entity’s participating, and to submit records on a quarterly basis.

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. Staff continue to address the “transfer” of donated drugs.

Physician Oversight – The author has agreed to amendments that would specify that the physician responsible at a clinic, would be the professional director that is on file with the Board for the clinic license.

Drug Disposal – Staff continue to address with the author provisions regarding the destruction or transportation of donated medications that are not eligible for redistribution.

² Licensed by the Department of Social Services

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

January 1, 2017, and would specify that the board is subject to review by the appropriate policy committees of the Legislature.

(5) 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.

(6) Existing law, the Electronic and Appliance Repair Dealer Registration Law, provides for the registration and regulation of electronic and appliance service dealers and service contractors by the Bureau of Electronic and Appliance Repair, Home Furnishings, and Thermal Insulation within the Department of Consumer Affairs and makes a failure to comply with its provisions a crime. Existing law, until January 1, 2013, requires a service contractor to pay specified fees to the bureau, including a registration fee and a registration renewal fee. Existing law, until January 1, 2013, requires the Director of Consumer Affairs to gather evidence of violations of the Electronic and Appliance Repair Dealer Registration Law, and any of its regulations, by a service contractor or by any employee, partner, officer, or member of any service contractor. Existing law, until January 1, 2013, requires a service contractor to maintain specified records to be open for inspection by the director and other law enforcement officials. Existing law, until January 1, 2013, also provides for the revocation of the registration of a service contractor by the director and for the superior court to issue a restraining order or injunction against a service contractor who violates these provisions.

This bill would extend the operation of these provisions to January 1, 2015. By extending the operation of certain of these provisions, the violation of which is a crime, this bill would impose a state-mandated local program.

(7) Existing law, until January 1, 2013, establishes the Health Quality Enforcement Section within the Department of Justice for the purpose of investigating and prosecuting proceedings against licensees and applicants within the jurisdiction of the Medical Board of California, the California Board of Podiatric Medicine, the Board of Psychology, or any committee under the jurisdiction of the Medical Board of California. Existing law, until January 1, 2013, requires all complaints against licensees of these boards to be made available to the Health Quality Enforcement Section.

This bill would extend the operation of these provisions until January 1, 2014.

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

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

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

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 2006 of the Business and Professions Code is amended to read:
2006.

(a) Any reference in this chapter to an investigation by the board shall be deemed to refer to a joint investigation conducted by employees of the Department of Justice and the board under the vertical enforcement and prosecution model, as specified in Section 12529.6 of the Government Code.

(b) This section shall remain in effect only until January 1, ~~2013~~2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~2014, deletes or extends that date.

SEC. 2. Section 2450.3 of the Business and Professions Code is amended to read:
2450.3.

There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, ~~2013~~2014, and, as of that date is repealed, unless a later enacted statute that is enacted before January 1, ~~2013~~2014, deletes or extends that date. ~~The Notwithstanding any other provision of law, the repeal of this section renders the Naturopathic Medicine Committee subject to the review required by Division 1.2 (commencing with Section 473) by the appropriate policy committees of the Legislature.~~

SEC. 3. Section 2602 of the Business and Professions Code is amended to read:
2602.

The Physical Therapy Board of California, hereafter referred to as the board, shall enforce and administer this chapter—.

This section shall ~~become inoperative on July 1, 2013, and, as of January 1, 2014, remain in effect only until January 1, 2014, and as of that date~~ is repealed, unless a later enacted statute, ~~which becomes effective on or that is enacted~~ before January 1, 2014, deletes or extends ~~the dates on which it becomes inoperative and is repealed-~~

~~The that date.~~

~~Notwithstanding any other provision of law, the repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473) by the appropriate policy committees of the Legislature.~~

SEC. 4. Section 2607.5 of the Business and Professions Code is amended to read:
2607.5.

The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in him or her by this chapter.

This section shall ~~become inoperative on July 1, 2013, and, as of January 1, 2014, remain in effect only until January 1, 2014, and as of that date~~ is repealed, unless a later enacted statute, ~~which becomes effective on or that is enacted~~ before January 1, 2014, deletes or extends ~~the dates on which it becomes inoperative and is repealed-~~

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

SEC. 5. Section 4001 of the Business and Professions Code is amended to read:
4001.

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

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

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

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

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

(f) ~~In accordance with Sections 101.1 and 473.1, this This~~ section shall remain in effect only until January 1, ~~2013~~2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~2017, deletes or extends that date. ~~The Notwithstanding any other provision of law, the repeal of this section renders the board subject to the review required by Division 1.2 (commencing with Section 473) by the appropriate policy committees of the Legislature.~~

SEC. 6. Section 4003 of the Business and Professions Code is amended to read:

4003.

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

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

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

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

(e) ~~In accordance with Sections 101.1 and 473.1, this This~~ section shall remain in effect only until January 1, ~~2013~~2017, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, ~~2013~~2017, deletes or extends that date.

SEC. 7. Section 8000 of the Business and Professions Code is amended to read:

8000.

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

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

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

SEC. 8. Section 8005 of the Business and Professions Code is amended to read:

8005.

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

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

SEC. 9. Section 8027 of the Business and Professions Code is amended to read:

8027.

(a) As used in this section, "school" means a court reporter training program or an institution that provides a course of instruction approved by the board and the Bureau for Private Postsecondary ~~and Vocational~~ Education, is a public school in this state, or is accredited by the Western Association of Schools and Colleges.

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

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

(d) The board may grant provisional recognition to a new court reporting school upon satisfactory evidence that it has met all of

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NO.: SB 1237
Version: A – July 5, 2012
Author: Price
Subject: Sunset Review
Board Position: Support

Affected Sections: Amend Sections 4001 and 4003 of the Business and Professions Code (B&PC) related to the Board of Pharmacy. The measure also amends various sections of the Business and Professions Code related to other boards and bureaus.

CURRENT STATUS:

7/5/2012 In Assembly Appropriations. Amended in committee 7/5 and re-referred back to ASM Appropriations.

EXISTING LAW:

1. Business and Professions Code Section 4001 sets forth the structure composition of the Board of Pharmacy, specifies terms of appointment, provides for board member per diem, etc. Existing law “sunsets” the Board of Pharmacy and its authority on January 1, 2013.
2. Business and Professions Code Section 4003 sets forth provisions related to the appointment of an Executive Officer (EO) of the board to include compensation and reimbursement of necessary expenses. This section further specifies duties of the EO related to records and revenue. Existing law “sunsets” these provisions on January 1, 2013.

AS AMENDED THIS BILL WOULD:

1. Amend B&PC Sections 4001 and 4003 to extend the operation of the 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. Amend various code sections related to various boards and bureaus. The most recent amendment contains changes relative to the Medical Board of California, the Physical Therapy Practice Act, and the Naturopathic Doctors Act.
3. Amend other sections not related to the Board of Pharmacy.

Pharmacy provisions remain unchanged since they were introduced.

COMMENTS:

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.

http://www.pharmacy.ca.gov/publications/sunset_2011.pdf

On February 23, 2012, Senator Current Price, Chair of the Senate Committee on Business, Professions and Economic Development introduced SB 1237 to extend the board's authority to 2017. The bill would also extend the sunset of the Court Reporters Board. On April 16, 2012, the bill was amended to include additional amendments related to the Court Reporters Board Transcript Reimbursement Fund.

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

BOARD POSITION:

The board established a SUPPORT position at the May 2012 Board Meeting.

COMMITTEE RECOMMENDATION:

The committee did not make a recommendation to change the board's position.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1588
VERSION: As Amended June 25, 2012
AUTHOR: Atkins
SUBJECT: Professions and Vocations: Reservist licensees: fees and continuing education

Affected Sections: Add Section 114.3 to the Business and Professions Code

CURRENT STATUS: August 6 – Scheduled for hearing in Senate Appropriations

RECENT UPDATE:

At the June 25 meeting of the Legislation and Regulation Committee, the committee discussed the prior version of the bill (March 5, 2012). At that time, staff counsel advised that the bill did not specify what the ‘status’ of the license should be (while waived) nor did the bill define “good standing”. The committee asked that staff clarify the intent of the bill and report back to the board.

Since that time, the bill was amended (June 25). The new version denotes a license is to be “current and valid” – not “in good standing.” However, the newly amended version does not specify what the status of the license is to be while “waived.” Because the bill authorizes a board to adopt regulations to implement the provisions, the board could specify what status the license is to be through regulations.

RECOMMENDATION: The committee did not recommend a position on this measure.

EXISTING LAW:

1. Pharmacy Law provides that a license, if not renewed, will be cancelled. A cancelled license cannot be renewed.
2. Business and Professions Code Section 114 allows members of the California National Guard or the U.S. Armed Forces to reinstate his or her professional license or registration without examination or penalty if their license expired while the licensee or registrant was on active duty.

AS AMENDED, THIS BILL WOULD:

Applies to military reservists called to active duty.

Requires the board to waive a licensee’s renewal fee and continuing education requirements, if applicable, for any licensee who is a reservist called to active duty as a member of the U.S. Military Reserve or the California National Guard, provided

- The licensee was in good standing at the time the reservist was called to active duty;
- The renewal fee or C.E. requirements are waived only for the period during which the reservist is on active duty; and

Prohibit a licensee – during the period that waivers are provided – from engaging in any activity related to the license; specifying that in order to engage in any activity for which he or she is licensed, the licensee shall meet all necessary renewal requirements as determined by the board, as specified.

Require that when reactivating a waived license, a licensee shall meet all conditions for licensure renewal, including payment of fees and continuing education, if applicable.

Authorize the board to adopt regulations to carry out the provisions of the bill.

AUTHOR'S INTENT:

The author's intent is to establish a provision that would allow a licensee to waive licensure renewal for the period of time when the reservist is called to active duty, and to ensure that military professionals will not be penalized by having his or her license fall into delinquency while called to active duty.

FISCAL IMPACT:

No fiscal impact is anticipated. Any such impact to the processing of renewal licenses would be absorbed with the board's existing staff resources.

COMMENTS:

Board staff anticipates that the two primary license types would be impacted - - pharmacist and pharmacy technician.

RELATED LEGISLATION:

AB 1940 would add Section 115.5 to the Business and Professions Code to require a board to expedite the license application of a spouse of an active military, and would authorize the board the promulgate regulations to implement the provisions of the bill. The board established a Support position on the introduced version of AB 1904.

(c) A board may adopt regulations to carry out the provisions of this section.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 1896 **VERSION:** *Enrolled – July 5, 2012*

AUTHOR: Chesbro **SPONSORS:**

SUBJECT: Healing Arts: Tribal Health Programs: Healthcare Practitioners

Affected Sections: Amends the heading of Article 10, and Adds Section 719 to Division 2 of the Business and Professions Code

Current Status: *Enrolled and to the Governor – July 5, 2012*

Recent Updates:

Recently, it was brought to staff's attention that under the Federal provisions of the Indian Health Care Improvement Act, non-Indian patients may be extended health care at all tribal facilities. According to the California Rural Indian Health Board, Tribal Health Programs (THPs) have the authority *and desire* to serve the non-Indian population. The CRIHB notes that other non-California licensed providers also serve California residents (University of California, Veterans Administration). The CRIHB states that in many rural parts of California, THPs are the only providers in these regions and they operate as part of an integrated rural health care delivery system. They state the purpose of AB 1896 is to assist in remedying the shortage of doctors, dentists, nurses, and other providers by conforming State law to Federal law.



The Legislation and Regulation Committee met on June 25, where counsel noted it is unclear what legal standing the board may have to address concerns that Tribal Health Programs and populations they serve.

The committee recommended that the board establish a position of Oppose Unless Amended, and offer the author amendments that would require a Tribal Health Program to be licensed by the board if they wish to provide services to Californians off of tribal lands. Staff has been advised by the author's office that the author has no intention to amend the language. Since that time, the bill has been enrolled and presented to the Governor.

Committee Recommendation: Oppose Unless Amended

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.

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.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 1904

VERSION: Amended June 12, 2012

AUTHOR: Block, Butler and Cook

SUBJECT: Military Spouses: Expedited Licensure

BOARD POSITION: Support (Ver. 2/22/12)

Affected Sections: Add Section 115.5 to the Business and Professions Code

CURRENT STATUS: August 6 – Set for Hearing in Senate Appropriations

➤ Recent Updates:

The Legislation and Regulation Committee met on June 25, and discussed the term “current license” as reflected in subdivision (a). The committee asked staff to clarify the meaning of this term. The committee did not recommend that the board change its current position on the measure.

Staff note: Staff searched the Business and Professions Code as well as Title 16 of the California Code of Regulations and found that many boards use the term “current and valid” in describing an active license. Because the measure authorizes the board to adopt regulations to administer this provision, the board could further define the term “current license” through regulation.

EXISTING LAW:

1. Allows for the regulation of various business and professions within the Department of Consumer Affairs
2. Defines the licensing requirements for the board to issue a license.

THIS BILL, AS AMENDED, WOULD:

1. Require the board to expedite the licensure process for an applicant that is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces who is assigned to a duty station in California under active duty military orders, so long as the applicant holds a current license in another state for the profession for which he or she is seeking licensure.
2. Authorize the board to adopt regulations to administer the section.

The prior version of the bill would have authorize the board to issue a “temporary license” to an applicant, as specified, to the spouse or domestic partner of an active

duty member of the Armed Forces. At the May 2012 Board Meeting, the board established a "Support" position on this measure.

AUTHOR'S INTENT:

The author's office states, "State licensing and certification requirements are intended to ensure that practitioners meet a minimum level of competency. Because each state has its own licensing requirements, these requirements often vary greatly across state lines. Consequently, the lack of license portability...can impose significant administrative and financial burdens on licensed professionals when they move across state lines."

FISCAL IMPACT:

It is anticipated that any fiscal impact associated with this version of the bill would be absorbed within the board's existing resources.

COMMENTS:

Board staff anticipates that the two primary license types would be impacted - - pharmacist and pharmacy technician.

RELATED LEGISLATION:

AB 1588 (Atkins) would provide for a waiver of licensing renewal and continuing education requirements for a reservist called to active duty.

Attachment 3

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: AB 377

VERSION: As Amended April 14, 2011

AUTHOR: Solorio

SPONSOR: California Hospital Association

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 was Assembly Appropriations (6/14/11) – We are waiting for amendments to be in print.

RECENT UPDATES: In recent months, board staff has been working with the author's office on amendments to address the board's concerns. Though not yet in print, amendments are expected which would closely mirror the provisions found in AB 1370 (2009/2010 Session). The board had a position of "Support" for AB 1370.

At the June 25 meeting of the Legislation and Regulation Committee, the chair reported that the measure has not changed since the board established its position in April 2011. Representatives from the California Society of Health System Pharmacists addressed committee and thanked the Executive Officer and the board for working with the sponsor and other stakeholders – adding that they expect amendments to be out any time. (As of July 7, the amendments were not yet in print.) The committee did not make a recommendation to change the board's position.

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 barcoded 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:

Any minor fiscal impact could be absorbed within existing resources.

COMMENTS:

Recent 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 barcoding technology that must be readable at the patient's bedside.

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. Barcoding 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 barcoding, the board may want to consider offering an amendment to clarify what information should be contained within barcode. The board may want to consider the FDA requirement elements established in 21 CFR Parts 201, 606, et al.

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.”



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Assembly Bill 377 (Solorio) Reducing Medication Errors in Hospitals

Background:

Medication errors in hospitals have been a public policy concern for years, and despite on-going efforts, the incidence of these errors remains unacceptably high. Studies show that the ability of hospitals to deliver bar-coded unit doses to patients' bedsides can effectively reduce the incidence of medication errors. Unfortunately, the cost of this technology is prohibitively expensive, because current law mandates that only an on-site hospital pharmacy can prepare drugs for inpatients.

Hospitals wanting to implement a bar-coded unit dose system face both technological and legal impediments. In most circumstances, it is simply too expensive to invest in this technology on a per-hospital basis, even for large hospitals. Clearly, patient-safety modernization is beyond the practical reality for virtually all hospitals.

Problem:

Current law requires medications for inpatients to be prepared by a licensed pharmacy located on the hospital's premise. This limits the opportunity to invest in expensive technology that would improve efficiency and enhance patient safety. In addition, certain medications, notably injectable compounds that are prepared within the hospital pharmacy, would come under federal "manufacturing" regulations if prepared off-site unless there is a state regulatory law to govern this activity.

Legislative Solution:

Assembly Bill 377 would establish a licensing category for a "centralized hospital pharmacy" and set parameters governing these pharmacies. Specifically, the bill would authorize a centralized pharmacy to deliver bar-coded unit dose medications to hospitals that are under common ownership or control and within a 100 mile geographic radius. It also would allow these pharmacies to prepare pill/capsule, as well as injectable and intravenous medications for inpatients at an offsite location.

This bill would amend the current definition of "manufacturer" to exclude pharmacies packaging drugs for distribution or administration in a hospital. In addition, this bill would amend the definition of "hospital pharmacy" to allow an off-site pharmacy operating under a hospital's license to support the pharmacy needs of all its hospitals. The pharmacy activities authorized under this bill are the same activities that are currently performed in individual pharmacies on hospital premises.

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SECTION 1. Section 4029 of the Business and Professions Code is amended to read:
4029.

(a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a ~~pharmacy-pharmacy, licensed by the board,~~ that may be located outside of the hospital, in either another physical plant ~~that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the 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. A centralized hospital pharmacy may only provide pharmaceutical services to its own patients who are either admitted or registered patients of a hospital within the same health care system. Nothing in this ~~paragraph~~ subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

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

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

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

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

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

(2) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy compounding ~~or repackaging~~ a drug for parenteral ~~therapy, pursuant to a prescription, for delivery to another pharmacy therapy or oral therapy in a hospital for delivery to another pharmacy or hospital under common ownership~~ for the purpose of ~~delivering dispensing or administering the drug to the patient or patients named in the prescription, provided that neither the components for the drug nor the drug are compounded, fabricated, packaged, or otherwise prepared prior to receipt of the prescription~~ drug, pursuant to a prescription or order, to the patient or patients named in the prescription or order. A pharmacy compounding or repackaging a drug as described in this paragraph shall notify the board in writing of the location where the compounding or repackaging is being performed within 30 days of initiating the compounding or repackaging. The pharmacy shall report any change in that information to the board in writing within 30 days of the change.

(3) Notwithstanding paragraph (1), "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

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

SEC. 3.

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

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 2570 **VERSION:** Introduced February 24, 2012

AUTHOR: Hill

SUBJECT: Licensees: Settlement Agreements

BOARD POSITION: Oppose Unless Amended

Affected Sections: Add Section 143.5 to the Business and Professions Code relating to professions and vocations

Current Status: August 6 – Hearing Set for Senate Appropriations

➡ **Recent Updates:** The Legislation and Regulation Committee met on June 25, where it discussed concerns with the restitution provision and why that provision was problematic. The committee did not make a recommendation to change the board's position.

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.

THIS BILL:

1. Would prohibit a licensee from including in a settlement to a civil suit a provision that would prohibit the other party in the dispute from contacting, filing a complaint with, or cooperating with the board or require the other party to withdraw a complaint from the board.
2. Prohibit the board from including in a disciplinary action a requirement that the licensee pay additional sums, if the civil action has been settled for monetary damages.

COMMENTS:

In 2011, the board approved language for a proposed rulemaking to add Title 16 Section 1762 to specify actions that would constitute “unprofessional conduct.” Item 1 (above) is consistent with the board’s regulatory proposal.

The provision that would prohibit the board from including in a disciplinary action a requirement that the licensee pay additional sums, if the civil action has been settled for monetary damages, could limit the board’s discretion in its disciplinary actions.

The Board established a position of “Oppose Unless Amended” at the May 1, 2012 Board Meeting. Staff discussed the board’s concerns with the author’s staff – who indicated they viewed the bill differently and were not open to amending the bill to address the board’s concerns.

**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



		<u>Version</u>		<u>Position</u>
BILL NUMBER:	SB 1095 (Rubio)	I-2/16/12	5/24/12	Opp. Unless Amended
		A-6/25/12		
			6/29/12	Removal of Opposition
			7/2/12	Support

Subject: Licensing: Surgical / Outpatient Clinics
Sponsor: California Ambulatory Surgery Association

Affected Sections: Amend Sections 4190 and 4195 of the Business and Professions Code

CURRENT STATUS: In Assembly Appropriations

ACTION REQUESTED: Ratify the Position of Support (established on July 2, 2012)

RECENT UPDATES:

At the June 25 meeting of the Legislation and Regulation Committee, the committee discussed amendments sought by staff. It was the consensus of the committee that given acceptance of the board's amendments, to change the board's position from Oppose Unless Amended to Support.

The bill was amended on June 25 (available in print the following day), and the board's position was changed to Support on July 2, 2012. Board policy has been that if the President and Chair of the Legislation and Regulation Committee agree to change the board's position between board meetings, they can do so – and that the board may ratify the position taken at the next regularly scheduled board meeting.

As introduced, the board took a position of Oppose Unless Amended. Since the May 2012 Board Meeting, staff has worked with the author's office, the sponsors and other parties to address the board's concerns.

As amended on June 25, SB 1095 would authorize the board to issue a clinic permit to a CDPH licensed surgical clinic, to an outpatient surgery center that is accredited by one of four accreditation agencies approved by the Medical Board, and to an ambulatory surgery center certified to participate in the Medicare Program. These clinics must notify the board of any change in a clinic address, and also that a clinic licensed pursuant to Section 4190 shall advise the board of any proposed changes in ownership or beneficial interest.

The board anticipates an increase in compliance inspections of clinics licensed pursuant to Section 4190, requiring one additional Board of Pharmacy Inspector position, which would be offset by the licensing fees of these clinics.

On July 5, the bill (as amended 6/25) passed out of ASM Health and was referred to ASM Appropriations.

EXISTING LAW:

1. Defines a surgical clinic as a clinic that is not part of a hospital and that provides ambulatory surgical care for patients who remain less than 24 hours. Provides that no surgical clinic licensed pursuant to Section 1204 of the Health and Safety Code may purchase drugs at wholesale or maintain a commingled drug stock unless licensed by the California State Board of Pharmacy.
2. Defines the licensing requirements for the board to issue a clinic license to surgical clinic.

THIS BILL WOULD:

1. Change the heading of Article 14 from “Surgical Clinic” to “Clinic”
2. Expand the definition of a “clinic” in Section 4190 to include:
 - Licensure by the Department of Public Health (DPH) under H&SC Section § 1204
 - An outpatient setting accredited by an approved agency as defined in H&SC § 1248 (Note: The MBC has four accreditation agencies: AAAHC, JCAHO, AAAASF, and CMA IMQ)
 - An ambulatory surgical center certified by CDPH to participate in the Medicare Program
3. Authorize any of the clinics referenced above to purchase drugs at wholesale as specified.
4. Make licensure with the board optional.
5. Require notification to the board of any changes in ownership for any clinic licensed by the board.
6. Specify that nothing in the section will limit the ability of a physician and surgeon or a group medical practice to prescribe, dispense, administer or furnish drugs at a clinic.
7. Specify that the board has authority to inspect any clinic that is licensed by the board.

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.

Under the provisions of the bill, some accredited surgical clinics – that are not licensed by Public Health – could seek board licensure, making the Board the only regulator of the clinic’s comingled drug stock. 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, which would be offset by initial licensure and renewal fees.

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

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SENATOR, SIXTEENTH DISTRICT

SB 1095 – Fact Sheet
Ambulatory Surgical Centers

What does SB 1095 do?

SB 1095 would expand the term “clinic” to include accredited or Medicare certified Ambulatory Surgical Centers (ASCs) in statute. This change would allow ASCs to obtain a license from the California Board of Pharmacy in order to purchase drugs at wholesale and safely store them within the facilities.

Background

ASCs are specialty clinics that perform same-day surgical care, including diagnostic and preventive procedures in an outpatient setting. As of 2007, there were more than twice as many outpatient surgeries performed as inpatient procedures in hospitals. The number of Medicare accredited ASCs have grown 8.3% annually due to the cost effective, high quality care that they provide. For example, studies show that Medicare would pay \$464 million dollars more per year if the procedures performed in ASCs were instead provided at hospitals.

In 2007, the California Court of Appeal ruled in *Capen v. Shewry* to prohibit the Department of Public Health from licensing ASCs that are either partially or fully owned by a physician, even if the physician-owned ASC is properly accredited and Medicare certified. This is problematic because approximately 90% of ASCs have some form of physician ownership. Furthermore, without licensure from the Department of Public Health, an ASC cannot obtain a pharmacy license.

Why is SB 1095 needed?

As a result of the *Capen v. Shewry* decision, physicians that own ASCs incur a significant liability by having to purchase drugs at retail prices. This bill provides physician-owned ASCs the proper licensing necessary to administer high quality care by allowing them to purchase certain drugs wholesale and storing them on site.

Support

California Ambulatory Surgery Association (Sponsor)

subject to this chapter.

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

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

(B) The person has been provided written instructions by the child's health care provider or an agent of the child's health care provider in accordance with the manufacturer's instructions on the proper use of the monitoring instrument and the handling of any lancets, test strips, cotton balls, or other items used during the process of conducting a blood glucose test.

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

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

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

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

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

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

(9) A community pharmacy that is providing only blood glucose, hemoglobin A1c, or cholesterol tests classified as waived under CLIA and approved by the federal Food and Drug Administration for sale to the public without a prescription in the form of an over-the-counter test kit, provided that all of the following requirements are satisfied:

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

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

(C) The pharmacy notifies the public health officer of the county in which the pharmacy is located that the pharmacy is performing one or more of the tests identified in this paragraph.

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

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

Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 *or paragraph (9) of subdivision (b) of Section 1241*. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for himself or herself, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 *or paragraph (9) of subdivision (b) of Section 1241*. A pharmacist performing these functions shall report the results obtained from a

test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

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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.

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."

~~(6)~~ Use of an enterprise-based pharmacy operating system that provides management with information on prescription workloads, medication utilization, prescribing data, and other key pharmacy information.

(b) *The comprehensive pharmacy services program shall require the use of less expensive medications as achieved by the statewide pharmaceutical program pursuant to Chapter 12 (commencing with Section 14977) of Part 5.5 of Division 3 of Title 2 of the Government Code, when those medications are available, unless an exception is reviewed and approved in accordance with an established nonformulary approval process, or unless the prescriber has indicated on the face of the prescription or on any other appropriate form for electronic prescriptions "dispense as written".*

(c) The department is authorized to operate and maintain a centralized pharmacy distribution center to provide advantages of scale and efficiencies related to medication purchasing, inventory control, volume production, drug distribution, workforce utilization, and increased patient safety. It is the intent of the Legislature that the centralized pharmacy distribution center and institutional pharmacies be licensed as pharmacies by the California State Board of Pharmacy meeting all applicable regulations applying to a pharmacy.

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

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

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

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

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

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

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

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

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

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

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

~~(d)-(e)~~ The department should ensure that there is a program providing for the regular inspection of all department pharmacies in the state to verify compliance with applicable law, rules, regulations, and other standards as may be appropriate to ensure the health, safety, and welfare of the department's inmate patients.

~~(e)-(f)~~ On March 1, 2012, and each March 1 thereafter, the department shall report all of the following to the Joint Legislative Budget Committee, the Senate Committee on Appropriations, the Senate Committee on Budget and Fiscal Review, the Senate Committee on Health, the Senate Committee on Public Safety, the Assembly Committee on Appropriations, the Assembly Committee on Budget, the Assembly Committee on Health, and the Assembly Committee on Public Safety:

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

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

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

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

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

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

CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS



BILL NUMBER: AB 2369 **VERSION:** A – June 14, 2012
AUTHOR: Valadao **SPONSOR:** Author
SUBJECT: Prisoners: Pharmacy Services

Affected Sections: Amend Section 5024.2 of the Penal Code

Current Status: On the Senate Floor – Third Reading (as of 7/6)

Recent Updates:

AB 2369 does not seek to modify existing Pharmacy Law. The board considered the introduced version of the bill (2/24/12) which required that “generic” medications be specified; however, the amended version of the bill specifies that “less expensive” medications be specified. The board has not taken a position on this measure.

- The Legislation and Regulation Committee discussed the status of the measure at its meeting on June 25 – the committee did not make a recommendation to establish a position on this bill.
-

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 that “less expensive” medications be utilized.

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 amended, no impact to Pharmacy Law. The board does not have a position on this measure.

(c) For purposes of this section, "underground economy" means the activities of individuals, businesses, or other entities that knowingly and intentionally use practices designed to conceal illegal or fraudulent activities that negatively impact legitimate businesses, workers, and consumers, as well as deprive the state and local governments of vital resources.

(d) The underground economy hurts all Californians. Revenues to support government services are lost, workers are forced to go without basic employment protections, and legitimate businesses are confronted with unfair competition.

(e) Since the activities of many operating in the underground economy span across multiple jurisdictions, various joint agency enforcement efforts have been undertaken to combat the underground economy, including, but not limited to, the creation of the Joint Enforcement Strike Force on the Underground Economy in 1993, and the creation of the Economic and Employment Enforcement Coalition in 2005. Furthermore, various individual agency efforts have been created, including, but not limited to, the State Board of Equalization's Statewide Compliance and Outreach Program and the Contractors' State License Board's Statewide Investigative Fraud Team. Thus, investigative collaboration among state agencies is not a new concept in California. Many collaborative efforts are already under way, pursuant to which investigators periodically meet to discuss current investigations, collaborate to conduct sting operations, and develop best practices policies.

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

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

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

SEC. 2. Part 12.2 (commencing with Section 15910) is added to 15910.

This part shall be known, and may be cited, as the Centralized Intelligence Partnership Act.
15912.

(a) The Centralized Intelligence Partnership is hereby established in state government as a pilot program.

(b) For purposes of this part, the term "partnership" shall refer to the Centralized Intelligence Partnership.
15914.

(a) The partnership shall include all of the following state entities:

- (1) Employment Development Department.*
- (2) Franchise Tax Board.*
- (3) State Board of Equalization.*

(b) In addition to the agencies listed in subdivision (a), the following agencies may participate in the pilot program in an advisory capacity to the partnership:

- (1) California Health and Human Services Agency.*
- (2) Department of Consumer Affairs.*
- (3) Department of Industrial Relations.*
- (4) Department of Insurance.*
- (5) Department of Justice.*
- (6) Department of Motor Vehicles.*

(c) If, in its normal course of investigation, an agency listed in subdivision (b) discovers a violation of law that would result in increased tax revenues to the state, that agency shall notify the appropriate tax agency listed in subdivision (a).
15916.

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

(b) The advisory committee shall be comprised of one representative from each of the entities in the partnership listed under subdivision (a) of Section 15914. Each representative shall be

appointed by the head of the entity in the partnership and serve at the pleasure of the appointing authority. An agency participating in an advisory capacity may provide a representative to the advisory committee to offer guidance and advice to the partnership.

(c) The advisory committee shall meet as needed, but at least quarterly, to conduct its business.
15918.

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

- (1) Provide a central intake process and organizational structure to document, review, and evaluate data and complaints.
- (2) Establish a processing center to receive and analyze data, share complaints, and research leads from the input of each impacted agency.
- (3) Provide participating and nonparticipating agencies with value-added investigative leads where collaboration opportunities exist for felony-level criminal investigations, including, but not limited to, referring leads to agencies with appropriate enforcement jurisdiction.
- (4) Provide that each participating and nonparticipating agency retain jurisdictional authority over whether to pursue partnership strategies or collaborative investigative leads based upon the direction of their respective governing structures or available resources.
- (5) Document and provide intake data analysis, analytic data findings, referrals, collaborative opportunities, outcomes, emerging evasion trends, lessons learned, as well as additional enforcement, administrative, and legislative opportunities.

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

(c) The advisory committee to the partnership shall determine the appropriate agency to house the processing center for the partnership.

(d) The partnership may hire an administrator and staff.
15920.

Duly authorized representatives of members of the partnership, and agencies participating in an advisory capacity, may exchange intelligence, data, documents, information, complaints, or lead referrals for the purpose of investigating illegal underground operations. Any member or ex-member of the partnership, any agent employed by any member of the partnership, or any person who has at any time obtained such knowledge from any of the foregoing partners or persons, shall not divulge, or make known in any manner not provided by law, any of the confidential information received by, or reported to, the partnership. Information exchanged pursuant to this section shall retain its confidential status and shall remain subject to the confidentiality provisions contained in the following provisions:

(a) California Health and Human Services Agency: Subdivision (c) of Section 6254 of this code and Section 14100.2 of the Welfare and Institutions Code.

(b) Department of Consumer Affairs: Section 30 of the Business and Professions Code and Section 56.29 of the Civil Code.

(c) Department of Industrial Relations: Sections 11181, 11183, and 15553 of this code, Section 1877 of the Insurance Code, and Sections 92, 138.7, 1026, 3762, 6309, 6322, 6396, and 6412 of the Labor Code.

(d) Department of Insurance: Section 11180 of this code and Sections 1872.6, 1873, 1874.2, 1875.1, 1877.1, 1877.3, 1877.4, and 1877.5 of the Insurance Code.

(e) Department of Justice: Section 11183.

(f) Department of Motor Vehicles: Sections 1808.2, 1808.4, 1808.5, 1808.6, 1808.21, 1808.24, and 12800.5 of the Vehicle Code.

(g) Employment Development Department: Sections 1094 and 1095 of the Unemployment Insurance Code.

(h) Franchise Tax Board: Sections 19542, 19542.1, and 19542.3 of the Revenue and Taxation Code.

(i) State Board of Equalization: Section 15619 of this code, Section 42464.8 of the Public Resources Code, and Sections 7056, 7056.5, 8255, 9255, 9255.1, 30455, 38705, 38706, 43651, 45981, 45982, 45983, 45984, 46751, 50159, 50160, 50161, 55381, 60608, and 60609 of the Revenue and Taxation Code.
15922.

On or before July 1, 2014, and annually thereafter, the partnership shall report on its activities and accomplishments to the Legislature and each entity in the partnership.
15923.

The partnership shall submit to the Legislature on or before December 1, 2016, a report of the pilot program that includes, but is not limited to, the following information:

(a) The number of leads or complaints received by the partnership.

(b) The number of cases investigated or prosecuted through civil action or criminal prosecution.

(c) Recommendations for modifying, eliminating, or continuing the operation of any or all of the provisions of this part.
15924.

This part shall remain in effect only until January 1, 2018, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2018, deletes or extends that date.

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**CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS**



BILL NUMBER: SB 1185

VERSION: As Amended May 29, 2012

AUTHOR: Price

SPONSOR: State Board of Equalization

SUBJECT: Centralized Intelligence Partnership Act: Pilot Program

Board Position: None

AFFECTED SECTIONS: An act to Add and Repeal Part 12.2 (commencing with Section 15910) to Division 3 of Title 2 of the Government Code

CURRENT STATUS: July 2, 2012 – Set for Hearing in Assembly Revenue & Taxation

RECENT UPDATES: The Legislation and Regulation Committee did not discuss this bill at its meeting held June 25.

SUMMARY:

This bill would create a Centralized Intelligence Partnership (“partnership”) as a pilot program – until January 1, 2018 – for the purpose of combating the underground economy. This partnership would institutionalize collaboration among state agencies, with a key element being to authorize and facilitate data and intelligence sharing among the partnership and state agencies. The partnership shall consist of the Employment Development Department, the Franchise Tax Board and the State Board of Equalization. The Department of Consumer Affairs is one of six state agencies designated that *may* participate in the pilot program in an advisory capacity. Should the DCA wish to participate, the DCA may provide a representative to the advisory committee, which shall meet at least quarterly. The bill in its current form authorizes participating agencies to exchange intelligence, data, documents, information, complaints, leads, etc. SB 1185 specifies that the partnership shall report to the Legislature, and specifies the frequency and content of those reports.

Agenda Item VII

- Part III -



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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

PART III – LEGISLATION AND REGULATION COMMITTEE

The Legislation and Regulation Committee met on June 25, 2012.

a. Second Quarterly Report on the Committee’s Goals for 2011/2012

Attachment 1

The fourth quarterly report on the Legislation and Regulation Committee’s goals is attached.

Attachment 1

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: Governor signs SB 1476 which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.</i></p> <p><i>4th Qtr 06/07: SB 963 (Ridley-Thomas) is amended to alter the sunset review process.</i></p> <p><i>1st Qtr 08/09: SB 963 (Ridley-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.</i></p> <p><i>Governor signs SB 963 (Chapter 385, Statutes of 2008)</i></p> <p><i>1st Qtr 09/10: Sunset extension amended into AB 1071. Bill enrolled and sent to Governor.</i></p> <p><i>2nd Qtr 09/10: Governor signs AB 1071 (Chapter 270, Statutes of 2009) to extend the board's sunset date to 2013.</i></p> <p><i>3rd Qtr 09/10: Sunset bills introduced</i></p> <p><i>AB 1659 (Huber) – State Government, Agency Repeals</i></p> <p><i>AB 2130 (Huber) – Joint Committee on Boards, Commissions and Consumer Protection</i></p> <p><i>SB 954 (Harmon) – Legislative Procedure, Committee Referrals</i></p> <p><i>SB 1171 (Negrete McLeod) – Regulatory Boards, Operations</i></p> <p><i>4th Qtr 09/10: SB 954 (Harmon) – Bill is dead (Failed deadline)</i></p> <p><i>SB 1171 (Negrete McLeod) – Bill is dead (Failed deadline)</i></p> <p><i>1st Qtr 10/11: Governor signs AB 1659 (Chapter 666, Statutes of 2010)</i></p> <p><i>Governor signs AB 2130 (Chapter 670, Statutes of 2010)</i></p> <p><i>Nov. 2011: Board submits Sunset Report to Senate Committee on Business, Professions and Economic Development</i></p> <p><i>Mar. 2011: Oversight Hearing of the Senate Committee on Business, Professions and Economic Development</i></p> <p><i>3rd Qtr 11/12: SB 1237 amended to extend the board's sunset to 2017.</i></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

Jan. 2008:	<i>Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill SB 1779.</i>
	<i>Board approved language for omnibus bill.</i>
April 2008:	<i>Some provisions of omnibus bill removed:</i>
	<ul style="list-style-type: none"> • <i>Section 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty to Notify the Board.</i> • <i>Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications</i> • <i>Section 4160 – Wholesaler Licenses</i> • <i>Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked</i> • <i>Section 4362 – Entry Into Pharmacists Recovery Program.</i>
Oct. 2008:	<i>Governor vetoes SB 1779</i>
1st Qtr 08/09:	<i>Board seeks to pursue omnibus provisions (formerly contained in SB 1779).</i>
	<i>Four areas of change: (Included in SB 819)</i>
	<i>(1) Changes specific to the PIC and DRC requirements</i>
	<ul style="list-style-type: none"> • <i>Section 4022.5 – Designated Representative; Designated Representative-in-Charge</i> • <i>Section 4036.5 – Pharmacist-in-Charge</i> • <i>Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action</i> • <i>Section 4329 – Nonpharmacists; Prohibited Acts</i> • <i>Section 4330 – Proprietors; Prohibited Acts</i>
	<i>(2) Changes to allow for the use of mobile pharmacies</i>
	<ul style="list-style-type: none"> • <i>Section 4062 – Furnishing Dangerous Drugs During an Emergency.</i> • <i>Section 4110 – License Required, Temporary Permit Upon Transfer of Ownership.</i>
	<i>(3) General changes</i>
	<ul style="list-style-type: none"> • <i>Section 4059.5 – Who May order Dangerous Drugs or Devices, Exceptions.</i> • <i>Section 4081 – Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory</i> • <i>Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.</i> • <i>Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.</i> <p><i>H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.</i></p>

(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.

- 4th Qtr 09/10:** 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.
- 1st Qtr 10/11:** Governor signs SB 1489 (Chapter 653, Statutes of 2010).
- 2nd Qtr 10/11:** 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.
- 3rd Qtr 10/11:** Staff provides language to Senate Business Professions and Economic Development for inclusion in Omnibus Bill.
 SB 943 is introduced. Contains amendments to section 4200.
- 1st Qtr 11/12:** Governor signs SB 943 (Chapter 350, Statutes of 2011).
- 2nd Qtr 11/12:** 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
- 3rd Qtr 11/12:** 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
- 3. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).**
Sep. 30, 2006: 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.
- 4. Secure statutory standards for pharmacies that compound medications (AB 595).**
Aug. 2006: 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.
Aug. 2008: Regulatory effort initiated. (See Objective 3.2, Task 12)
Oct. 2009: Board approves regulatory language for Initial Notice.
Jan. 2010: Office of Administrative Law approves regulation.
July 2010: Regulation effective.
- 5. Secure implementation of e-pedigrees on prescription drugs dispensed in California.**
Sep. 2006: 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.
Sep. 2008: Governor signs SB 1307 which delays implementation of e-pedigree.

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.
- Oct. 2007:** **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.
- Oct. 2008:** **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
AB1574 (Plescia) Surgical Clinics: Licensure
- Jan. 2009:** *Legislation introduced affecting Pharmacy law:*
(New Session) *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.

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
 AB 877 (Emmerson) Healing Arts; DCA Committee Analysis; Scope of Healing 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
 SB 341 (DeSaulnier) California Department of Public Health to Contract with UC to Evaluate the Safety and Effectiveness of Prescription Drugs
 SB 389 (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)
 SB 389 (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

1st Qtr 09/10: Governor signs SB 762 (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 AB 830 (Cook) Drugs and Devices; 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>4th Qtr 09/10: Board considers additional legislation AB 1939 (Fletcher) Sharps Waste SB1111 (Negrete McLeod) DCA Enforcement Model</p> <p>Apr. 2010: 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>May 2010: AB 1869 (Anderson) Bill is dead (failed deadline) AB 1939 (Fletcher) Bill is dead (failed deadline)</p> <p>June 2010: 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>Apr./May 2010: AB 2104 (Hayashi) Amended twice</p> <p>June 2010: AB 2104 (Hayashi) Amended to authorize Board appointment of Executive Officer with approval of DCA Director.</p> <p>July 2010: 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
 - AB 399 (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
 - SB 360 (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
 - SB 227 (Wyland) Business and professions: licensure (corrected)
 - SB 538 (Price) Healing arts
 - SB 544 (Price) Healing arts
 - SB 667 (Wyland) Healing arts
 - e. Other
 - AB 389 (Mitchell) Bleeding disorders: blood clotting products
 - AB 604 (Skinner) Needle exchange programs
 - SB 41 (Yee) Hypodermic Needles and Syringes
 - SB 514 (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
- SB 1575 (Price) Omnibus - Support

4th Qtr 11/12: Board takes positions on legislation

- AB 389 (Mitchell) Bleeding Disorders, Blood Clotting Products - Oppose reaffirmed
- AB 1442 (Weickowski) Pharmaceutical Waste - Oppose unless amended
- AB 1896 (Chesbro) Tribal Health Programs: Health care practitioners - Oppose unless amended
- AB 1904 (Block) Military Spouses: Expedited licensure - Support
- AB 2570 (Hill) Licensees: Settlement agreements - Oppose unless amended
- SB 1095 (Rubio) Pharmacy: Clinics - Oppose unless amended
- SB 1237 (Price) Board of Pharmacy: Sunset - Support
- SB 1301 (Hernandez) Prescription Drugs: 90 day supply - Support
- SB 1329 (Simitian) Prescription Drugs: Collection and Distribution Program - Support if amended
- SB 1481 (Negrete McLeod) Clinical Laboratories: Community Pharmacies - Support

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 boards 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 Emmerson 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

SB 1575 (Price) is amended to include the board's omnibus provisions to amend B&PC 4209 and to add section 4300.1.

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 1485 363">1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (§ 1793.7-1793.8). <i>Jan. 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 373 1485 510">2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (§ 1713 and 1717(e)). <i>Jan. 2007: Regulation takes effect following approval by the Office of Administrative Law.</i> <li data-bbox="370 520 1485 730">3. Make technical changes in pharmacy regulations to keep the code updated. <i>April 2007: 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> <i>June 2007: Section 1706.2 – Criteria for abandonment of files, changes take effect following approval by the Office of Administrative Law.</i> <li data-bbox="370 741 1485 804">4. Repeal the requirement to post a notice regarding electronic files (§ 1717.2). <i>March 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <li data-bbox="370 814 1485 1182">5. Revise and update Disciplinary Guidelines (§ 1760). <i>Oct. 2007: Board approves regulation for 45-day comment period.</i> <i>May 2009: Regulation and revised Disciplinary Guidelines approved and takes effect.</i> <i>July 2011: Discussion to update Disciplinary Guidelines to also incorporate recommendations of the Substance Abuse Coordination Committee.</i> <i>Sep. 2011: Board approves draft regulation text and Disciplinary Guidelines for 45-day public comment.</i> <i>Oct. 2011: 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> <i>Jan. 2012: Regulation Hearing</i> <li data-bbox="370 1224 1485 1360">6. Self-assessment of a wholesaler by the designated representative (§ 1784). <i>April 2007: Office of Administrative Law approves rulemaking. Regulation takes effect.</i> <i>March 2011: Board releases language for 45-day comment to update regulation text and update Self-Assessment Form 17M-26 (See Objective 3.2, Task 25)</i> <li data-bbox="370 1371 1485 1507">7. Exempt the address of records of interns from display on the board's Website (§ 1727.1). <i>Sep. 2006: Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.</i> <li data-bbox="370 1518 1485 1736">8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission. <i>July 2006: Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.</i> <i>June 2007: Board staff submit rulemaking file to the California Building Standards Commission.</i>

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
3rd Qtr 11/12: Board releases language to amend sections 1735.1, 1735.2, 1735.3 and 1751.2 for 45-day comment period.
4th Qtr 11/12: Board modifies text for 15-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.
4th Qtr 11/12: Board rejects 45-day comments.

- 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.
4th Qtr 11/12: Board approves draft language to modify 1732.1 and votes to initiate rulemaking.
- 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.
4th Qtr 11/12: Board approves regulation text to add section 1751.9 and votes to initiate a rulemaking.
- 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 17A 5) 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)
4th Qtr 11/12: Rulemaking submitted to the Office of Administrative Law.
- 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.

26. Partial Filling of Schedule II Prescriptions

2nd Qtr 10/11: Board approves language to initiate rulemaking to amend 16 CCR 1745 regarding record keeping requirements for partial fill of a Schedule II prescription.

27. Activities that Constitute Unprofessional Conduct [CPEI] (Add § 1762)

2nd Qtr 10/11: Board considers language and refers back to the Enforcement Committee
Enforcement Committee discusses draft language and makes recommendation to the Board.

3rd Qtr 10/11: Board approves language to add 16 CCR § 1762 and directs staff to initiate rulemaking.

28. Application Review and Criteria for Rehabilitation [CPEI] (Amend § 1769)

2nd Qtr 10/11: Board approves amendments to § 1769 and directs staff to initiate a rulemaking

Objective 3.3	Review five areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011.
Measure:	Number of areas of pharmacy law reviewed.
Tasks:	<p>1. Initiate review of the pharmacist-in-charge requirement.</p> <p><i>Aug. 2007:</i> Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.</p> <p><i>Oct. 2007:</i> Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.</p> <p><i>Jan. 2008:</i> Board approves omnibus language recommended by Legislation and Regulation Committee.</p> <ul style="list-style-type: none"> • Section 4022.5 – Designated Representative; Designated Representative-in-Charge • Section 4036.5 – Pharmacist-in-Charge • Section 4101 – Pharmacist-in-Charge; Designation 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 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action • Section 4329 – Nonpharmacists; Prohibited Acts • Section 4330 – Proprietors; Prohibited Acts <p><i>April 2008:</i> The following provisions are not incorporated into omnibus bill.</p> <ul style="list-style-type: none"> • Section 4101 – Pharmacist-in-Charge; Designation 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 <p><i>Sept. 2008:</i> Governor vetoes SB 1779.</p> <p><i>Jan. 2009:</i> Board seeks to reintroduce provisions contained in SB 1779 via omnibus bill. Provisions contained in SB 819 and SB 821. Senate BP & ED introduce Omnibus bills containing previously-approved / Pharmacist-in-Charge provisions.</p> <p><i>Sept. 2009:</i> SB 819 and SB 821 enrolled and sent to the Governor.</p> <p><i>Oct. 2009:</i> Governor signs SB 819 and SB 821. Provisions go into effect January 2010.</p>

	<p>2. Update Protocol for Pharmacists Furnishing Emergency Contraception (EC) (\$1746) <i>July 2010: Board begins working with the Medical Board to update the EC Protocol.</i> <i>4th Qtr 11/12: See Objective 3.2, Task 17.</i></p> <p>3. Initiate review of Pharmacist-in-Charge Requirements.</p> <p>4. Review of Continuing Education for Pharmacists in Specific Areas. <i>1st Qtr 10/11: Board moves to pursue implementation of CE for specific content areas.</i></p>
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