



California State Board of Pharmacy

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DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

LEGISLATION AND REGULATION COMMITTEE

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The Legislation and Regulation Committee did not meet this quarter.

a. LEGISLATION REPORT

The Legislature is on Interim Recess and will reconvene on January 6. The last day for the Governor to sign or veto bills was October 13.

Legislative measures, related analyses and additional documents are provided for each bill in Attachment 1.

Attachment 1

1. Legislation Acted Upon in 2013

A. Board Sponsored Legislation

SB 294 (Emmerson) Compounded Sterile Drug Products, Chapter 565, Statutes of 2013

SB 294 is the board's sponsored legislation to strengthen the board's ability to regulate specialized pharmacies within and outside California that compound sterile drug products – that is, those that are compounded for injection, administration to the eye or for inhalation. The board maintained a Support position on this bill. The provisions provide for implementation of the requirements beginning July 1, 2014.

The Governor signed SB 294 on October 4, 2013, and the board is working on revisions to its compounding regulations through the Enforcement and Compounding Committee, and Licensing Unit staff are working on internal implementation processes.

**SB 821 (Senate Committee on Business Professions and Economic Development)
Omnibus Proposals, Chapter 473, Statutes of 2013**

Senate Bill 821 contained three board-sponsored provisions. Each will be effective on January 1, 2014. Due to the length of the bill, only those sections relevant to the board's proposals are provided in Attachment 1. The board had a Support position on this measure.

Add Business and Professions Code Section 4021.5 to define "Correctional Pharmacy"

SB 821 adds the definition of "correctional pharmacy" to Article 2 of Division 2 of Chapter 9 of the Business and Professions Code.

Amend Business and Professions Code Section 4053 related to Applicants for Licensure as a Designated Representative

Section 4053 was amended to specify the practice settings in which the requisite one year paid work experience shall be met for an applicant for a designated representative license. The board's proposal specifies that the one year of paid work experience shall be earned in a licensed facility.

Amend Business and Professions Code 4107 – One Site License per Premises; Exception

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Section 4107 was amended to also authorize the board to issue a centralized packaging pharmacy permit to a hospital that also holds a hospital pharmacy permit. This change was made following the (2012) passage of AB 377 (2012) which authorized a hospital to acquire a permit for the central packaging of prescriptions.

SB 305 (Lieu) Healing Arts Boards: Records, Chapter 516, Statutes of 2013

The Governor approved Senate Bill 305 on October 3 and the provisions will go into effect on January 1, 2014. SB 305 contains one board-sponsored provision that provides the board with the express authority to receive documents from local or state agencies for the purpose of completing an applicant or licensee investigation. To address the needs of the board and that of other healing arts boards, SB 305 placed this provision at Section 144.5 to all boards this authority. Because of the length of the bill, only the pages relevant to the proposal are provided in Attachment 1. The board maintained a Support position on this measure.

B. Chaptered Legislation

AB 512 (Rendon) Healing Arts Licensure Exemption, Chapter 111, Statutes of 2013

AB 512 extends the provisions of Section 901 of the Business and Professions Code to provide that until 1/1/18, an individual may be exempt from the licensure and regulation requirements for defined health care practitioners, to offer or provide health care services for which he or she is licensed or certified, through a sponsored event, as defined. The section was set to 'sunset' on January 1, 2014. The board had a "support" position on this bill.

AB 1045 (Quirk-Silva) Nonresident Sterile Compounding Pharmacies, Chapter 302, Statutes of 2013

The board had a support position on Assembly Bill 1045, which would do the following. The provisions of the bill go into effect on January 1, 2014.

- Amend Section 4303 of the Business and Professions Code to specify that if a nonresident pharmacy home state permit is canceled, revoked, or suspended for any reason, then the board's permit issued pursuant to Sections 4112 (nonresident pharmacies) or 4127.2 (nonresident sterile compounding) shall be immediately canceled, revoked, or suspended by operation of law; and
- Add Section 4127.9 to the Business and Professions Code to specify that a pharmacy licensed pursuant to Section 4127.1 (license to compound sterile drug products) or 4127.2 (nonresident sterile compounding) that issues a recall notice regarding a sterile compounded drug shall, in addition to other duties, contact the recipient pharmacy, prescriber, or patient as soon as possible within 12 hours of the recall notice, as specified.

AB 1057 (Medina) Licenses: Military Service, Chapter 693, Statutes of 2013

The board did not have a position on this bill. Assembly Bill 1057 is one of the many DCA bills the board was tracking – the board did not have a position on the bill. As chaptered, AB 1057 will require that commencing January 2015, every application for licensure shall inquire as to the applicant's current service in, or previous service in the military.

AB 1136 (Levine) Pharmacists: Drug Disclosures (warning labels) Chapter 304, Statutes of 2013

Assembly Bill 1136 will require that on or after July 1, 2014, if a pharmacist exercises his or her professional judgment and determines that a drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written warning on the drug container. The board opposed this measure, and felt the bill was unnecessary. A copy of the chaptered bill is in Attachment 1.

SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors, Chapter 725, Statutes of 2013

Senate Bill 669 creates a training program and standards for the safe and proper use of epinephrine auto-injectors, and make them available to trained individuals (as specified) and allow those individuals, in good faith and not for compensation, to administer an epinephrine auto-injector without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction.

The board established a position of Support if Amended, however, the author did not accept the board's suggested amendment to also authorize a pharmacist to approve the requisite training certification and issue the prescription for an epinephrine auto-injector. A copy of the chaptered legislation is provided in Attachment 1.

SB 809 (De Saulnier) CURES, Chapter 400, Statutes of 2013

Health and Safety Code Sections 11165 – 11165.3 establishes and defines the parameters and use of the CURES Program within the California Department of Justice. Under current law, prescribers and pharmacies are required to report each week to DOJ every Schedule II, III and IV prescription dispensed. The board maintained a Support position on this measure.

As enacted, Senate Bill 809 provides for the continued funding of the CURES program by requiring, effective April 1, 2014, an annual fee of \$6 be assessed on specified health care practitioners, including pharmacists, and also to wholesalers, nonresident wholesalers and veterinary food-animal drug retailers. There are provisions that allow DCA, by regulation, to reduce that fee if the regulatory cost to operate and maintain CURES is less than \$6 per licensee.

SB 809 requires the Medical Board of California to periodically develop and disseminate to physicians and surgeons and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information related to CURES. Finally, SB 809 will require, by January 1, 2016, every health care practitioner authorized to prescribe, order, administer, furnish or dispense controlled substances to apply for access to CURES.

C. Vetoed Legislation

SB 205 (Corbett) Prescription Drugs: Labeling (Font Size)

The board opposed Senate Bill 205 would have required that the “patient-centered” elements of a prescription label be printed in 12-point typeface. The board opposed this bill, largely in part because the board is concluding its review of the patient-centered prescription label requirements, of which font size is a component. In his Veto Message, the Governor cited his preference to wait for the board’s findings of its review of patient-centered labels. A copy of the bill as Enrolled, along with the Governor’s Veto Message is provided in Attachment 1.

SB 598 (Hill) Biosimilars

The board opposed Senate Bill 598, which would have authorized ‘biosimilar’ substitution, as defined, but also require pharmacists to notify a prescriber after dispensing a biologic or biosimilar. The board expressed concerns that the bill may be premature, as well as concerns over the burden placed on the pharmacy to provide follow-up notification to a prescriber. The Governor vetoed the bill on October 12 citing similar concerns in the Veto Message. A copy of the bill and the Veto Message are provided in Attachment 1.

2. Legislation for 2014

A. Status of Board-Sponsored Provisions

Issuance of a Public Reprimand for Violations That Would Not Warrant License Denial or Issuance of a Probationary License

In May 2012, the board voted to sponsor the addition of a statutory provision to authorize the board to issue a public reprimand for violations that may not warrant license denial or issuance of a probationary license. Any such reprimand issued with a license would constitute discipline, and would be reported to the National Practitioner Data Bank. Staff has not yet secured an author to carry this proposal. A copy of the board-approved language (to add Business and Professions Code Section 119) is provided in Attachment 1.

Other Board-Approved Proposals for 2013-2014

Applicants for Licensure as a Designated Representative Must Be At Least 18 Years of Age

Through the board’s omnibus proposal, the board amended Section 4053 to specify the practice settings in which the requisite one year paid work experience shall be met for an applicant for a designated representative license. In April 2013, the board approved a proposal to ensure applicants for licensure as a Designated

Representative is at least 18 years of age. Staff will be pursuing this as an Omnibus proposal. A copy of the proposal is provided in Attachment 1.

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

AB 467 (Stone) Prescription Drug Collection and Distribution Program

Last Amend: September 6, 2013

Board Position: Oppose Unless Amended (prior version, est 8/23/13)

Status: 9/6/13 – Re-referred to SEN BP&ED

Assembly Bill 467 would provide for the licensure of a “Surplus Medication Collection and Distribution Intermediary” to allow such an entity to perform duties related to the movement of drugs donated through a Surplus Medication Collection and Distribution program.

The previous version of AB 467 (as amended 8/19/13) was a “gut & amend” where the bill would have exempted an entity (now referred to as an ‘intermediary’) from oversight by the board with regard to the movement of drugs through a Surplus Medication Collection and Distribution program and would have declared that such an entity’s activities would not be deemed wholesaling activities. The board thereafter (on 8/23/13) established a position of *Oppose Unless Amended* and provided the author with suggested amendments.

The current version of the bill amends Pharmacy Law to define these intermediaries and provide for the board’s licensing of these entities. However, the bill does not specify the term of the license (annual, biannual) or address any renewal requirements for the license. AB 467 also amends the Health & Safety Code (Division 16. Surplus Medication Collection & Distribution) to exempt these intermediaries from civil or criminal liability with regard to the distribution of donated drugs for these programs.

Staff has engaged in discussions with the author, sponsor and other interested parties; the next stakeholders meeting may be scheduled for some time in November. A bill analysis, current version of the bill, and the board’s (8/23/13) position letter are provided in Attachment 1.

Staff Recommendation: Change the board’s position to Support if Amended, and amend AB 467 to specify the term and renewal requirements of the license.

SB 204 (Corbett) Prescription Drugs: Labeling (Translations)

Last Amend: June 27, 2013

Board Position: (none)

Status: 2-Year bill. Last location was ASM Health on 7/23/13.

SB 204 would require that non-English translations of the “directions for use” as published on the board’s web site be printed on prescription container labels. SB 204 would permit a pharmacy to use its own translations of the “directions for use” if a trained and qualified translator or translation service is utilized. In addition, SB 204 provides that a pharmacist has not breached his or her legal duty if the pharmacist uses a translation on the board’s web site, where the directions contained an error, and where the pharmacist did not know, or have reason to know of the error. SB 204 provides that where a non-English translation is used on a prescription container label, the English directions for use also be provided.

Staff will continue to work with the author’s office, sponsors and other interested parties. A copy of the board’s bill analysis (for the 6/27 version) is provided in Attachment 1, as well as a copy of Senator Corbett’s July 30 letter, which indicates her office is working on amendments to clarify how both directions for use (English and translated) should be on the prescription container. Likewise, by the time the Legislature reconvenes in January, the board will have concluded its review of the patient-centered prescription label requirements.

SB 306 (Torres) Automated Dispensing Machines

Last Amend: June 20, 2013

Board Position: Oppose Unless Amended (7/30/13)

Status: 2-year Bill. Last location was ASM Business, Professions and Consumer Protection (8/8/13).

SB 306 proposes to amend Pharmacy Law to allow physician group practices the ability to acquire a board license, own comingled inventories of drugs, and allow all physicians in the group practice, or in a contract with the group practice, to be able to dispense patient medications from an inventory of drugs held in an automated drug delivery system, including controlled substances. SB 306 would amend current provisions related to automated drug delivery systems to delete the current requirement for 2-way video, allow non-pharmacists to stock, re-stock and maintain these systems, and ‘designees’ of physicians to have access to the drug stock.

As reflected in the board’s letter of opposition, SB 306 would create a system that lacks appropriate oversight for the widespread distribution of dangerous drugs to patients. It would allow “designees” to receive drugs from wholesalers and stock automated dispensing machines, and allow these individuals to label and dispense dangerous drugs to patients, without direction professional medical or pharmacist intervention. As currently written, the board believes SB 306 fosters the use of automated dispensing systems, and eliminates existing patient protections that

provide for visual pharmacist review of patient records and interaction with patients to provide counseling. Staff will continue to work with the author's office, sponsor and other interested parties to address the board's concerns and to ensure that California patients have appropriate safeguards. A copy of the bill, a staff analysis and the board's position letter are provided in Attachment 1.

SB 727 (Jackson) Medical Waste: pharmaceutical product stewardship program

Last Amend: April 3, 2013

Board Position: None

Status: 2-year Bill. Last location was SEN Environmental Quality.

Current law defines pharmacy waste as bio hazardous 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. Existing Pharmacy Law defines the ways in which a pharmacy may take possession of and return drugs.

SB 727 would add the "Drug Abuse Prevention and Safe Disposal Program" to the Public Resources Code. This article would set forth definitions, requirements for stewardship plans, to include the minimum number of collection sites for each plan submitted. The program would require that a stewardship plan include the number of collection services, and that there shall be on and after January 1, 2016 one collection service within 10 miles per person in the state, with a 20 percent increase in the number of collection services one year thereafter, and other information. The plan shall also include a description of the methods to be used to collect, transport and process home-generated pharmaceuticals in this state.

The sponsors of SB 727 are interesting in establishing a statewide solution to handle the disposal of home-generated prescription drug waste and in April conveyed to the board their willingness to work with the board and other stakeholders to find solutions. At that time, the board encouraged staff to work with the author's office to ensure the board's concerns related to the safety of the drugs is addressed. Recently, the Senate Committee on Environmental Quality has convened meetings where interested parties provide presentations, and where participants discuss what is currently available, and what programs are currently in place. Staff attended a meeting on October 17 and another stakeholder meeting is scheduled for mid-November. A copy of SB 727 and a staff analysis is provided in Attachment 1.

3. Updates to Pharmacy Law

Attachment 1 contains updates to Pharmacy Law as a result of legislation passed in 2013. In the document, added text is underlined, while deleted text is shown in strikeout. Following the board's review, staff will load the document to the board's website. This document is not inclusive of all legislation passed in 2013 (such as a variety of legislation that affects all of DCA and/or rulemaking, etc.) but does show changes based on the bills that the board has taken positions on.

b. REGULATION REPORT

Attachment 2

1. Recently Noticed Regulations (Information Only)

A. Drop Shipment –Proposal to add Title 16 California Code of Regulations Section 1747.2

At the July 2013 Board Meeting, the board approved a proposal to amend Title 16 California Code of Regulations Section 1749 to outline pedigree requirements when manufactures use the drop shipment method of sale when selling dangerous drugs to a pharmacy or other person authorized by law to dispense or administer dangerous drugs.

The rulemaking was initiated on September 13, 2013, and the 45-day public comment period will conclude on October 28, 2013. A regulation hearing is scheduled for October 29, 2013, at 4:00 p.m. (Note: This item is listed on the Board Agenda as Item XII.) As of October 24, 2013, the board has received one written comment during the comment period. If additional comments are received, the comments will be brought to the board meeting. A copy of the Proposed Text to add Section 1747.2 and received written comment is provided in Attachment 2.

2. Board Approved – Undergoing Administrative Review (Information Only)

B. Fee Schedule – Proposal to Amend Title 16 Section 1749

On April 24, 2013, the board approved a proposal to amend Title 16 California Code of Regulations Section 1746 to increase the board's fees to the statutory maximum. The rulemaking was initiated on June 14, 2013, and the 45-day public comment period concluded Monday, July 29. A regulation hearing was held at 1:00 p.m. on July 30, 2013.

At the July 2013 Board Meeting, the Board approved the motion to direct staff to take all steps necessary to complete the rulemaking process, including the filing of

the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1749 as noticed on June 14, 2013.

The final rulemaking file was submitted to the Department of Consumer Affairs for review on October 21, 2013. A copy of the Proposed Text to amend Section 1749 is provided in Attachment 2.

C. Proposed Addition of a new Article 5.5, and new Sections 1747 and 1747.1 Related to Pedigree Requirements

The board noticed its proposal to add a new Article 5.5 to Title 16 of the California Code of Regulations related to Pedigree Requirement. The board's proposal to add a new Section 1747 would establish requirements for the "unique identification number" required by Section 4034 of the Business and Professions Code, and the board's proposal to add a new Section 1747.1 would establish requirements for declarations that must be filed with the board, as required by Sections 4163.2 and 4163.5 of the Business and Professions Code.

The board's proposal was initially noticed on September 21, 2012. The board conducted a regulation hearing in conjunction with the December 2012 Board Meeting and subsequently issued two Notices of modified text. Thereafter, the board adopted the final regulation language at the Board Meeting held February 5, 2013, and staff completed the rulemaking file. The rulemaking file was submitted to the department for administrative review in March. On July 9, the Business, Consumer Services and Housing Agency approved the regulation and transmitted the file to the Department of Finance who also approved the regulation.

The rulemaking file was delivered to the Office of Administrative Law for final review on September 24, 2013. OAL has 30 business days in which to complete its review. Board staff anticipates learning of the status of OAL's review the week of October 21, 2013.

A copy of the Adopted Text is provided in Attachment 2.

D. Combined Rulemaking - Proposal to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 California Code of Regulations Related to Partial Fill of Schedule II Prescriptions, Criteria for Rehabilitation, and to Define Unprofessional Conduct

At the February Board Meeting, the board voted to modify the text of its proposal at Section 1762. This is the board's combined rulemaking to Amend Sections 1745 and 1769, and to add Section 1762 to Title 16 of the California Code of Regulations. Staff

prepared a notice of modified text that was issued for a 15-day public comment period.

The final rulemaking file was submitted to the Department of Consumer Affairs for review on October 10, 2013. In accordance with Business and Professions Code section 313.1, the Director of the Department of Consumer Affairs may request an extension for the one-year notice period review in the event that the one-year notice period lapses during the Director's 30-day review period. Board staff was advised on October 17, 2013, that the Director of the Department of Consumer Affairs signed an extension letter for the review of rulemaking file as the one-year notice lapsed October 18, 2013, during the Director's 30-day review period.

The modified language approved by the board is provided in Attachment 2.

3. Board Approved – Awaiting Notice (Information Only)

Below are two board-approved regulatory proposals that have not yet been noticed for public comment. A copy of the language approved for public notice is provided in **Attachment 2**, and a summary of each is provided below. Staff is preparing the required notice documents and will be noticing these proposals.

E. Combined Rulemaking – Proposal to Amend Title 16 Sections 1732.2, 1732.5, 1732.05 Related to Continuing Education

The board has approved a 45-day public comment period four proposals: three related to continuing education. At the April 2013 Board Meeting, staff requested and the board approved to not notice with the combined rulemaking a previously approved proposal to amend Section 1751.9 related to Standards for Agencies that Accredited Sterile Injectable Compounding Pharmacies. Staff is preparing a notice package for the following three provisions.

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education

Proposed amendments to Section 1732.2 would specify additional methods of obtaining board-accredited continuing education. Pharmacists are required to complete 30 hours of continuing education per renewal period. Specifically, the board's proposal would specify that a pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) may annually be awarded up to six (6) hours of CE hours for conducting a review of exam test questions; would specify that a pharmacist or pharmacy technician may be awarded up to six (6) hours of CE for attending a full-day board meeting and up to two (2) hours of CE for attending a full committee meeting of the board; and would specify that an individual may be awarded three (3) hours of CE for successfully

passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas

The board's proposal would require continuing education in specific content areas for pharmacists. Specifically, the proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education

The board's proposal would amend Section 1732.05(a)(2) to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

F. Combined Rulemaking – Proposal to Amend Title 16 Sections 1702, 1702.1, 1702.2 and 1702.5 Related to Renewal Requirements

At the July 2013 Board Meeting, the board voted to approve the text to amend Sections 1702, 1702.1, 1702.2, and 1702.5 to Title 16 of the California Code of Regulations. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking

Proposal to Amend Section 1702 – Update Pharmacist Renewal Requirements

The board's proposal would amend Section 1702 to add as a condition of renewal, the requirement for a pharmacist licensee to disclose on the renewal form any disciplinary action against any license issued to the individual by a government agency as well as defines disciplinary action.

Proposal to Amend Section 1702.1 – Update Pharmacy Technician Renewal Requirements

The board's proposal would amend Section 1702.1 to add as a condition of renewal a fingerprint requirement for those who have not previously submitted fingerprints as a condition of renewal of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identifier. Additionally, this proposal adds as a condition of renewal the requirement for a licensee to disclose specified convictions and disciplinary actions.

Proposal to Amend Section 1702.2 – Update Designated Representative Renewal Requirements

The board's proposal would amend Section 1702.2 to add as a condition of renewal a fingerprint requirement for those who have not previously submitted fingerprints as a condition of renewal of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identifier. Additionally, this proposal adds as a condition of renewal the requirement for a licensee to disclose specified convictions and disciplinary actions.

Proposal to Amend Section 1702.5 – Update Nonresident Wholesaler or Nonresident Pharmacy Requirements

The board's proposal would amend Section 1702.5 to add as a condition of renewal, a requirement for a nonresident wholesaler or nonresident pharmacy to disclose on the renewal form any disciplinary action against any license issued to the licensee by a government agency as well as defines disciplinary action.

c. LEGISLATION AND REGULATION COMMITTEE

Third Quarterly Report - Committee Goals for 2012/13

Since the adoption of the board's new Strategic Plan, the committee has not met to review and determine what committee goals shall be reported.