



California State Board of Pharmacy

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

Legislation and Regulation Committee

Greg Lippe, CPA, Chair, Public Member
Ramón Castellblanch, PhD, Public Member
Randy Kajioka, PharmD, Professional Member
Amy Gutierrez, PharmD, Professional Member
Tappan Zee, Esq., Public Member

LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee has not met since the beginning of the 2013-2014 Legislative Session. Information in this report is current as of April 7, 2013. All section references are to the Business and Professions Code, unless otherwise stated.

PART I LEGISLATION

1. Board-Sponsored Legislation for 2013

ATTACHMENT 1

a. SB 294 (Emmerson) Compounding Sterile Drug Products

Introduced: February 15, 2013
Location: Senate Appropriations
Status: Passed out of Sen Business, Professions and Economic Development
 (4/2/13)
Board Position: Support (3/25/13)

SB 294 contains board-sponsored provisions to strengthen board’s ability to regulate and monitor pharmacies that compound sterile drug products and distribute or ship into California sterile products for injection, for administration to the eye, or for inhalation.

A letter of support was provided to the author and to the Senate committee members in advance of the policy committee hearing on April 2. A copy of the letter of support, a staff analysis, and the bill text are provided in **Attachment 1**. Also attached is a letter of concern from the California Hospital Association, as well as a letter from the California Society of Health-System Pharmacists noting its position of Support if Amended. In addition to seeking clarification on the board’s proposal to amend Section 4127.1(a)(c), CSHP seeks to amend the bill to expand the bill to amend other Pharmacy Law sections, as specified in its letter. Finally, attached is testimony of Sarah Sellers, PharmD, that was submitted to the board by Fred S. Mayer, PPSI/Gray Panthers.

Staff Recommendation: Ratify the position of **Support** for SB 294 taken 3/25/13

b. Board-Approved Proposals for 2013-2014

The board approved the following proposals for the 2013-2014 Legislative year. Copies of the board-approved language are provided in **Attachment 1**.

Amendment to 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. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit. The board's proposal has been provided to the Senate Committee on Business, Professions and Economic Development and staff has been advised that the language will be amended into the Committee's Omnibus bill, SB 821.

Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents. At the October 2012 Board Meeting, draft language was approved to add Section 4008.5 to provide the board with the express authority to receive certified records for this purpose. In lieu of adding this provision to the Senate Committee on Business, Professions and Economic Development's omnibus measure, the committee has developed draft amendments to add a general BPC code that would be applicable to all DCA boards. Staff will continue to monitor legislation and advise the committee when this language has been amended into a bill.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. At the October 2012 Board Meeting, the board approved a draft amendment that would clearly specify that the one year of paid work experience shall be earned in a licensed facility, as specified. The board's proposal has been provided to the Senate Committee on Business, Professions and Economic Development and staff has been advised that the language will be amended into the Committee's Omnibus bill, SB 821.

c. Board Proposal to Define “Correctional Pharmacy”

A proposal to add Section 4066 BPC to define the term “Correctional Pharmacy” has been provided to the Senate Committee on Business, Professions and Economic Development, and staff has been advised that this will be amended into one of the committee’s omnibus measures, as follows:

4046. “Correctional Pharmacy” means a pharmacy, licensed by the board, located within any state correctional facility for the purpose of providing pharmaceutical care to inmates of the state correctional facility.

Staff Recommendation: Approve/Ratify the language provided to Senate BP&ED for inclusion in a committee omnibus measure.

d. Omnibus – SB 822, SB 821

The Senate Committee on Business, Professions and Economic Development sponsors omnibus measures each year. SB 821 is the committee’s bill related to health care board, and SB 822 is the committee’s bill related to Business and Professions. As noted above, three board-approved provisions are expected to be amended into SB 821. Staff will continue to monitor legislation and advise the committee when the board-approved provisions are amended in.

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

ATTACHMENT 2

Regulation of Dangerous Drugs and Devices

a. AB 396 (Fox) Prescription Label – Condition or Purpose

No analysis has been provided, as the author’s office has indicated they are not moving forward with this proposal.

b. AB 670 (Atkins) Pharmacy: Incentive Payments

The author’s office is addressing the issue where pharmacists or pharmacy employers receive incentives to substitute a patient’s medication therapy. AB 670 is intended to eliminate specific financial inducements that encourage pharmacists to change one drug product for another that does not have the same active ingredient. Attachment 2 contains a staff analysis, author’s Fact Sheet and a copy of the bill as amended April 2, 2013.

c. AB 1136 (Levine) Pharmacists: Drug Disclosures (Drug Warning Labels)

AB 1136 is intended to address drug warning labels related to dispensed prescriptions where the drug may impair a person's ability to operate a vehicle or vessel. Existing pharmacy law requires a pharmacist to inform a patient orally or in writing of the harmful effects of a dangerous drug if the drug poses substantial risk to the person when the drug is taken in combination with alcohol or if the drug may impair a person's ability to drive a motor vehicle. The board's regulation at 16 CCR 1744 requires a pharmacist to inform a patient of the harmful effects of certain drugs dispensed by prescription. A pharmacist utilizes professional judgment when adhering drug warning labels to a dispensed prescription. AB 1136 would remove such discretion when it involves a drug that may impair a person's ability to operate a vehicle or vessel.

Staff attended the Assembly Health Committee hearing and answered the committee's questions regarding current requirements. As noted in the staff analysis (Attachment 2) the board's regulation specifies substances for which a pharmacist shall orally or in writing provide such warnings. AB 1136 seeks to mandate a drug warning label for these types of substances.

d. AB 1139 (Lowenthal) Prescriptions: Biosimilar Products

AB 1139 seeks to amend Section 4073 to specify that a pharmacist filling a prescription order for a biological product, as specified, may select a biosimilar product, provided that the substituted biosimilar product is deemed by the FDA to be interchangeable with the prescribed product. The amendments would prohibit a pharmacist from making such a substitution if the prescriber indicates "Do not substitute" or words of similar meaning. As with current law, the pharmacist would be required to communicate to the patient the name of the drug dispensed, and ensure the drug container is appropriately labeled.

Additional legislation (SB 598, Hill) also seeks to amend Pharmacy Law as it relates to the substitution and dispensing of a biosimilar product, where a biological product is prescribed.

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

Existing Pharmacy Law requires that a prescription container dispensed to a patient include the directions for use of the drug (Section 4076). Board regulation at 16 CCR 1707.5 specifies standardized "directions for use" that shall be used, if they are applicable to the prescription. In addition, the board maintains on its website translations in five languages of the "directions for use" that are found at 16 CCR 1707.5(a)(D)(4).

SB 204 would add Section 4076.5 to require a pharmacist to use the translations for the "directions for use" available on the board's website, as applicable, when labeling a prescription. The section would also authorize a pharmacist to translate the directions for use into additional non-English languages if certified translation services are utilized to complete the translations.

Staff has requested a Fact Sheet from the author's office and has reached out to the author's staff to seek clarification on some of the components of the measure.

f. SB 205 (Corbett) Prescription Drugs: Labeling (12-point Font)

SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and is correctly labeled in at least a 12-point sans serif typeface. Existing regulation at 16 CCR 1707.5 requires that specified "patient-centered" information on a prescription drug label be printed in a minimum 10-point sans serif typeface, but that the pharmacy shall print the drug label in 12-point sans serif typeface if requested by the patient. Staff has requested a Fact Sheet from the author's office.

g. SB 506 (Hill) Ephedrine: Retail Sale

Hearing: April 9 in Senate Public Safety

Until January 1, 2019, SB 506 would restrict the furnishing of ephedrine products without a valid prescription. SB 506 would eliminate the current reporting of specified ephedrine products to the California Department of Justice (DOJ) and, instead, provide for the collection and reporting into a single web-based database operated by the National Precursor Log Exchange (NPLEx) specified proposed transactions of those products. The web-based single database would be available to a retailer at no charge, but would require a retailer to access this web-based system via the internet. Retailers would be required to submit specified information prior to completing a transaction, and the retailer would be prohibited from completing the transaction if an alert is generated by the system.

While the measure addresses the recordkeeping of these transactions during a mechanical or electronic failure of the system, the measure does not specify whether a retailer would be authorized to complete a transaction under those circumstances.

h. SB 598 (Hill) Biosimilars

SB 598 would add Section 4052.55 to the Business and Professions Code to specify conditions under which a pharmacist may exercise professional discretion to substitute a **biosimilar** for a prescribed **biological** product, if certain requirements are met.

Additional legislation (AB 1139, Lowenthal) also addresses the substitution of a biosimilar, where a prescription for a biologic was prescribed.

i. SB 669 (Huff) Emergency Medical Care: Epinephrine Auto-Injectors

Hearing: April 17 in Senate Health

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors (EpiPens), make them available to trained individuals (as specified) and allow those individuals to administer an EpiPen, without facing civil liability, in an emergency situation to a person suffering from a potentially fatal anaphylactic allergic reaction. Staff has sought clarification from the author's office on various components of the measure, as specified in the analysis.

j. SB 809 (DeSaulnier) CURES

Hearing: April 15 in Senate Business, Professions and Economic Development

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.

Following substantial funding reductions that were part of the 2011-2012 Governor's Budget, the Department of Justice has been maintaining the program with limited resources. In 2009 DOJ launched an automated Prescription Drug Monitoring Program (PDMP) within CURES. This program allows authorized users, including pharmacists, prescribers, and others, to access at the point of care patient controlled substance prescription information. This information allows prescribers and pharmacists to make informed decisions about patient care and to detect patients who may be abusing controlled substances by obtaining multiple prescriptions from various practitioners.

SB 809 would establish permanent funding for CURES by increasing fees for specified health care practitioners and also to wholesalers, nonresident wholesalers and veterinary food-animal drug retailers.

Staff Recommendation: Support SB 809

k. SB 62 (Price) Coroners: Reporting Requirements: Prescription Drug Use

Under existing law, Section 802.5 of the Business and Professions Code, when a coroner receives information that a death may be the result of gross negligence or incompetence, as specified, the coroner shall file a report with the Medical Board of California and other entities. This bill would amend Section 802.5 to require that when a coroner receives

information indicating that a death may be the result of prescription drug use, the coroner shall file a report with the Medical Board of California and other specified entities, **and the California State Board of Pharmacy**. The bill specifies what information that must be reported, and further specifies that within 90 days of the initial report, the coroner's report, autopsy protocol, and other relevant information shall follow.

Staff estimates that the receipt, review, analysis and inspection of these reports will require an additional three (3) associate analysts, and an additional six (6) inspectors to determine if there are any violations of Pharmacy Law related to the prescription drugs. The board voted to SUPPORT SB 62 at the February 2012 Board Meeting.

I. AB 186 (Maienschein) Professions and Vocations: Military Spouses: Temporary Licenses

AB 186 would amend Section 115.5 to require a board to issue a provisional license to an applicant who meets specified requirements, provided the application

- Includes an affidavit that the information submitted in the application is accurate and
- Where verification from the other jurisdiction has been *requested*.

Further amendments provide that the applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under the BPC at the time the act was committed, as specified. Of concern is the requirement that the board issue a provisional license based on limited information. For example, for a Pharmacist applicant, the board requires that in addition to passing the NAPLEX, an applicant must also pass the CPJE as a condition of licensure. ***The board may wish to consider if – through the provisional licensing of an individual – placing such an individual in a pharmacy setting before it is able to ensure the individual meets the requirements for licensure in California is in the best interest of the public safety.***

The board faces challenges in implementing such provisional licenses because the board is unable to modify its current applicant tracking system to accommodate the new license types. The board will be migrating to the new DCA BreEZe system in 2013 and possibly into 2014. The attached staff analysis contains current application processing times (as of December 2012).

m. AB 213 (Logue) Healing Arts: Licensure and Certification Requirements: Military Experience

Existing Pharmacy provides for the licensure of Pharmacists, Pharmacist Interns, Pharmacy Technicians and other individuals and representatives related to its site licenses, and specifies the minimum requirements for licensure of these individuals. For Pharmacy Technicians, board regulation (16 CCR 1793.6(b)) specifies that a course of training provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, shall meet the requirements of Section 4202(a) for a Pharmacy Technician applicant.

AB 213 would specify that not later than 7/1/14, if a board accredits or otherwise approves schools offering educational course credit for meeting licensure qualification, the board shall require a school seeking accreditation or approval to submit to the board proof that the school has procedures in place to evaluate, upon presentation of satisfactory evidence by the applicant, the applicant's military education, training, and practical experience toward the completion of a program that would qualify a person for licensure, as specified.

Staff Recommendation: Watch

n. AB 258 (Chavez) State Agencies: Veterans

SB 258 would standardize the way any state government organization would ask an individual as to their veteran status. The author states that individuals who may not identify themselves as a veteran because the way a question is asked may lose out on many Federal benefits to which they are entitled.

Staff Recommendation: Watch

o. AB 512 (Rendon) Healing Arts: Licensure Exemption

Existing law provides that until 1/1/14, 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. This section also requires an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other requirements, including the payment of a fee as determined by a board. The board does not have regulations to specify requirements for pharmacists from other states to serve at sponsored healthcare events, as allowed by Section 901 BPC.

AB 512 would extend the sunset provisions of Section 901 BPC from 2014 to 2018.

Staff Recommendation: Watch

p. AB 555 (Salas) Professions and Vocations: Military and Veterans

Existing law provides for the licensure and regulation of various professions and vocations by DCA boards, and that boards may adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the profession to which they are applying.

For Pharmacy Technicians, board regulation (16 CCR 1793.6(b)) specifies that a course of training provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, shall meet the requirements of Section 4202(a) for a Pharmacy Technician applicant.

AB 555 would require a board to consider, and that a board may accept, any relevant training received while serving in the armed services of the United States for purposes of satisfying the requirements for a license, as specified. The measure authorizes a board to consult with the Department of Veterans Affairs and the Military Department when evaluating whether training acquired during military service is applicable to the requirements for the license being sought.

Staff Recommendation: Watch

q. AB 1057 (Medina) Professions and Vocations: License: Military Experience

Existing law provides for the licensure and regulation of various professions and vocations by DCA boards, and that boards may adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the profession to which they are applying.

AB 1057 would require every board to inquire on every application for licensure if the applicant is serving in, or has previously served in the military.

The board will be migrating to the new DCA BreZE system in 2013 and possibly into 2014. Board staff will communicate with the DCA on how the department may plan to implement the provisions of the measure, if enacted. Staff will continue to monitor this legislation and will communicate with DCA on how the department may plan to implement the provisions of the measure, if enacted.

Staff Recommendation: Watch

r. AB 1003 (Maienschein) Professional Corporations: Healing Arts Practitioners

This measure is specific to physical therapists and the Physical Therapy Board. No staff analysis is provided. If the measure is amended to include provisions related to Pharmacy, staff will bring it back to the committee's attention.

s. AB 299 (Holden) Health Care Service Plans / Insurer: Mail Order

SB 299 is a bill sponsored by the California Pharmacists Association, which would amend Section 4112 BPC to prohibit a resident or nonresident pharmacy that delivers prescriptions via mail from entering into, or being a party to, an agreement with a health care service plan or disability insurer that requires a plan enrollee to utilize mail order services, or that requires a plan enrollee or insured to opt out of a mail order process.

t. AB 804 (Lowenthal) Medi-Cal Pharmacy Providers: Invoices

To safeguard the confidentiality of proprietary information that retail pharmacies are required to submit to the Department of Health Care Services as part of establishing a new Medi-Cal Fee-For-Service reimbursement methodology, AB 804 would provide that pharmacy invoice information provided for this purpose be confidential and exempt from disclosure under the California Public Records Act.

u. SB 146 (Lara) Workers' Compensation: Medical Treatment: Billing

Existing law provides that any provider of services, as defined, shall submit with a request for payment an itemization of services to include a copy of the prescription. As introduced 1/31/13, the measure struck the requirement for a copy of a prescription to be submitted with such a request for payment. As amended, the bill does allow specified entities to request a copy of the prescription document during a review of records of prescription drugs dispensed by a pharmacy.

v. SB 445 (Price) Pharmacies: Advertising: Controlled Substances

Existing Pharmacy Law requires that an advertisement of the retail price of a drug shall be limited to quantities of the drug that are consistent with good medical practice, and specifies information required for such an advertisement. There is no section that restricts the advertising of controlled substances. Additionally, existing law requires every pharmacy to post a notice concerning the availability of prescription price information; the notice may be provided to consumers via a written receipt with the required information, and allows an individual to receive price information, as specified.

SB 445 would specify that under no circumstances may an advertisement from a pharmacy specifically promote the sale or dispensing of controlled substances.

w. SB 727 (Jackson) Medical Waste: Pharmaceutical Product Stewardship Program

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.

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.

Security and handling of returned dangerous drugs are not specifically described, and could result in diversion of these drugs.

x. Other Legislation Impacting the Practice of Pharmacy

- SB 493 (Hernandez) Pharmacy Practice

Article 3 of the Business and Professions Code provides for the scope of practice, and exemptions, for a pharmacist licensed by the board.

SB 493 would create a board designation of “Advanced Practice Pharmacist” to be recognized by the Board of Pharmacy; would declare that pharmacists are health care providers who have the authority to provide health care services. Additionally, SB 493 would specify expand the types of services that may be provided by a pharmacist to include immunizations and other functions, as specified; and make conforming changes to Sections 4052 and 4060 to effect the provisions of the bill.



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LEGISLATION AND REGULATION COMMITTEE REPORT

The Legislation and Regulation Committee has not met since the beginning of the 2013-2014 Legislative Session. Information in this report is current as of April 7, 2013. All section references are to the Business and Professions Code, unless otherwise stated.

PART II REGULATION

1. Regulations Approved by the Office of Administrative Law

ATTACHMENT 1

On March 13, 2013, the Office of Administrative Law approved the board's rulemaking to amend Section 1746 of Title 16 of the California Code of Regulations related to the Emergency Contraception Protocol. The regulation goes into effect on July 1, 2013. The Fact Sheet utilized by pharmacists when dispensing emergency contraceptives pursuant to this protocol is being updated and should be available when the regulation goes into effect. A copy of the approved regulation (no mark-up) is provided in **Attachment 1**.

2. Regulations Approved – Recently Noticed

ATTACHMENT 2

The Board initiated a rulemaking to Amend Sections 1745 and 1769, and to Add Section 1762 to Title 16 of the California Code of Regulations. A summary of each proposal is provided below. The rulemaking was noticed on October 19, 2012, and the 45-day public comment period concluded on December 10. The board did not receive any comments related to this rulemaking during the public comment period. At the February 5, 2013 Board Meeting the board discussed the proposal and voted to modify proposed Section 1762 to strike subdivision (b). **Staff is preparing modified text for a 15-day comment period.**

Proposal to add Section 1762 – Unprofessional Conduct: Defined

In February 2011, the board moved to initiate a rulemaking to add Section 1762 to Title 16 California Code of Regulations to implement components of the Department of Consumer Affairs' Consumer Protection Enforcement Initiative (CPEI) relative to unprofessional conduct. The provisions would specify that unprofessional conduct include acts such as gag clauses in a civil suit settlement; failure to provide information as requested by the board; failure to comply with a court order or subpoena for records; and authorize the board to revoke a license or deny an application for an act requiring an individual to register as a sex offender. At the February 2012 Board Meeting, the board voted to strike subdivision (b) and issue modified text for a 15-day comment period.

Proposal to amend Section 1745 – Partial Fill of Schedule II Controlled Substance

Current regulation requires that when a pharmacist partially fills a prescription for a Schedule II controlled substance that specified information be recorded in a readily retrievable form and also on the original prescription document. The board approved draft language to allow a pharmacist to record specified information in a readily retrievable form **or** on the original prescription document.

Proposal to amend Section 1769 – Criteria for Rehabilitation

To implement components of the DCA's CPEI, the board directed that staff initiate a rulemaking that would authorize the board to request an applicant for licensure to undergo an examination, as specified, to determine if the applicant is safe to practice. The board further specified that once it has been determined that an applicant is to be evaluated, the evaluation shall be completed within 60 days, and that within 60 days of the evaluation, the report be received by the board.

3. Board Approved – Undergoing Administrative Review

ATTACHMENT 3

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.

A copy of the Adopted Text is provided in **Attachment 3**. The board will be updating its website with its Final Statement of Reasons and other rulemaking documents.

4. Board Approved – Awaiting Notice

ATTACHMENT 4

Below are four 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 4**, and a summary of each is provided below.

Staff is seeking the committee's guidance as to whether or not the board should move forward with its proposal to amend Section 1751.9 as it relates to standards for agencies that accredit sterile injectable compounding pharmacies. This regulation is no longer needed given the board's legislation (SB 294) to strengthen board's ability to regulate and monitor pharmacies that compound sterile drug products, which would eliminate existing requirements that authorize accreditation in lieu of licensure for sterile compounding pharmacies that do business in California.

Background

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education

In January 2012, the board withdrew a pending regulation to Section 1732.2 which, at that time, was pending final review at the Office of Administrative Law. Thereafter, the Licensing Committee vetted revised language which, in May 2012, was approved by the board for public notice.

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

In May 2012, the board approved a draft regulatory proposal for public comment to require continuing education in specific content areas. 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

In May 2012, the board approved a draft regulatory proposal to modify Section 1732.05(a)(2) and to initiate a rulemaking. This proposal was at the request of the California Pharmacists Association, 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.

Proposal to Add Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies

In May 2012, the board approved for public notice a draft regulatory proposal from the Licensing Committee to add Section 1751.9 to Title 16 of the CCR for the purpose of specifying standards for agencies that accredit licensed sterile injectable compounding pharmacies.



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LEGISLATION AND REGULATION COMMITTEE REPORT

PART III THIRD QUARTERLY REPORT – COMMITTEE GOALS FOR 2012/2013

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. At this meeting, the committee will discuss what items shall be reported in support of the Board's Strategic Plan. Staff will provide the committee with recommendations at the meeting.