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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

LEGISLATION AND REGULATION COMMITTEE

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The Legislation and Regulation Committee met on July 30, 2013. Any committee recommendations made on that date will be reported to the board on July 31, 2013.

a. LEGISLATION REPORT

The Senate and Assembly are on summer recess. The Assembly returns on August 5, and the Senate returns from recess on August 12.

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

Board-Sponsored Legislation for 2013

Attachment 1

1. SB 294 (Emmerson) Compounded Drug Products

Last Amend: July 3, 2013

Board Position: Support

Status: Set for Hearing: Assembly Health August 6, 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.

Under current law, a sterile compounding pharmacy is not required to possess a specialty permit to compound drug products if they are accredited, or otherwise exempted from the specialty permit. This measure will require all pharmacies – whether accredited or not – to possess a specialty permit from the board if they compound sterile drug products for distribution in California. SB 294 sets the license fee for a sterile compounding permit at \$780 annually, requires nonresident sterile compounding pharmacies to reimburse the board for actual and necessary expenses associated with the yearly inspection of a nonresident pharmacy.

As reflected in the attached analysis, staff has requested amendments to remove references to the Building Standards Commission, as the board does not anticipate the need

to implement (on an emergency basis for initial implementation) additional or different building standards.

SB 294 passed the Senate on May 29, 2013, was heard and passed out of the Assembly Committee on Business, Professions and Consumer Protection, and is scheduled for hearing in Assembly Health on August 6th.

2. SB 821 (Senate Comm. on Business Professions and Economic Development) Omnibus

Last Amend: June 27, 2013

Board Position: Support

Status: Re-referred to ASM Appropriations

SB 821 is a Senate Omnibus measure that contains three board-approved proposals, as summarized below. The bill passed the Senate (on consent) on May 28, 2013, and has passed the Assembly Committee on Business, Professions and Consumer Protection. The board's provisions were amended into SB 821 on June 14.

Due to the length of the bill, only the sections relevant to the board's proposals are provided in Attachment 1 (Sections 18-20 of the bill).

Add the Definition of "Correctional Pharmacy" – See SEC. 18 of SB 821

At the April 2013 Board Meeting, the board ratified the language provided to Senate Committee on Business, Professions and Economic Development to specify a definition of "Correctional Pharmacy." The board proposed the definition to be at Section 4066 of the Business and Professions Code. To keep board definitions in alphabetical order, however, Legislative Counsel placed the definition at Section 4021.5. Also, the board suggested that the word "state" be stricken from the definition, so as to broadly apply to any correctional pharmacy. That modification was not accepted as an omnibus provision.

Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative – See SEC. 19 of SB 821

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. The board's proposal specifies that the one year of paid work experience shall be earned in a licensed facility.

Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception – See SEC. 20 of SB 821

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.

3. SB 305 (Price) Healing Arts Boards

Last Amend: June 19, 2013

Board Position: (none)

Status: Referred to ASM Appropriations (6/25/13)

Committee Recommendation:

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; some of 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 the B&PC to provide the board with the express authority to receive certified records for this purpose. To address the board's request, and that of other healing arts boards, Senator Price introduced a provision to add Section 144.5 to the Business and Professions Code, applicable to all DCA boards that would authorize boards to request and receive such documents for the purpose of completing applicant and licensee investigations. The board's original proposal included a requirement that upon request, the courts and law enforcement jurisdictions would be required to provide the records being requested. This provision equated to a state mandate, which drew concerns from local jurisdictions. Thus, it was not included in the bill.

Section 144.5 was amended into SB 305 on April 15, 2013, and since that time has passed the Senate. The Assembly Committee on Business, Professions and Consumer Protection passed the measure on June 25th, and the bill was referred to Assembly Appropriations where it awaits hearing.

4. Other Board-Approved Proposals

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 is provided in Attachment 1.

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

5. AB 1045 (Quirk-Silva) Nonresident Sterile Compounding Pharmacies

Last Amend: June 19, 2013

Board Position: Support (5/10/13)

Status: 7/2/13 – Ordered to Senate Third Reading

AB 1045 will allow the board to immediately take action to cancel, revoke, or suspend a nonresident pharmacy license and a nonresident sterile compounding pharmacy permit if the home state license has been canceled, revoked or suspended.

In addition, AB 1045 specifies conditions under which prescribers, pharmacies, and patients shall be notified if a sterile compounding pharmacy issues a recall notice, and where the drug use of or exposure to the recalled drug may cause a serious adverse health consequence or death, and where the recalled drug was dispensed or is intended for use in California. The bill specifies that the board shall be notified within 12 hours of a recall notice.

6. AB 1136 (Levine) Pharmacists: Drug Disclosures (Auxiliary Label)

Last Amend: April 15, 2013

Board Position: Oppose

Status: 7/2/13 – Ordered to Senate Third Reading

Currently, board regulation specifies seven classes of drugs that may impair a person's ability to drive a motor vehicle or operate machinery when taken alone or in combination with alcohol. That section further defines examples of drugs that may have harmful effects when taken in combination with alcohol, but that may or may not affect a person's ability to operate a motor vehicle.

AB 1136 would require that where a drug is specified by the board to be a drug for which a warning shall be given (i.e., as specified in regulation), that in addition to the requirements of the regulation, on or after July 1, 2014, if the pharmacist exercises his or her professional judgment and determines that the drug may impair a person's ability to operate a vehicle or vessel, the pharmacist shall include a written warning on the drug container.

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

Last Amend: June 27, 2013

Board Position: (none)

Status: 6/27/13 – Referred to ASM Health

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.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year.

8. SB 205 (Corbett) Prescription Drugs: Labeling (12-Point Font)

Last Amend: July 1, 2013

Board Position: (none)

Status: 8/13/13 – Set for Hearing in Assembly Business, Professions and Consumer Protection

SB 205 would amend Section 4076 to require that any prescription dispensed meets the requirements of state and federal law, and that certain items on the label be printed in at least a 12-point font. 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. SB 205 also amends a reference to a facility *licensed* pursuant to Health & Safety Code 1250 to require that the facility be defined by that section.

At the April 2013 Board Meeting, the board did not take a position on the bill, as it is in the process of re-evaluating the requirements of patient-centered labels, a review that is to be completed by the end of the year.

9. SB 306 (Torres) Automated Dispensing Machines

Last Amend: July 1, 2013

Board Position: (none)

Status: 8/13/13 – Set for Hearing in Assembly Business, Professions and Consumer Protection

Committee Recommendation:

SB 306 would provide for board licensure of physician group practices, allow these groups to purchase drugs at wholesale; allow for the use of automated drug delivery systems in these settings for the purpose of providing point-of-care access to prescription medications, without having a pharmacist or consulting pharmacist. To accomplish this, 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 that inventory, including controlled substances. In addition, SB 306 will amend current provisions related to automated drug delivery systems to allow non-pharmacists to stock, re-stock and maintain these systems, and ‘designees’ of physicians to have access to the drug stock. SB 306 removes the existing requirement for a pharmacist that maintains an automated drug delivery system to be ‘located’ in California, rather that a pharmacist be *licensed* in California. Further, this bill would amend existing law to allow an automated drug dispensing system to not have 2-way video, if a prescriber provides a (drug) consultation to a patient.

10. SB 598 (Hill) Biosimilars

Last Amend: June 20, 2013
Board Position: Oppose
Status: In Assembly Appropriations
Passed out of ASM Health on 7/2/13

SB 598 would add Section 4073.5 to specify conditions under which a pharmacist can exercise professional discretion to substitute a biosimilar where a biologic has been prescribed. For prescriptions filled prior to January 1, 2017, SB 598 requires the pharmacy to notify the prescriber of any substitution made within five business days of the selection. The board opposed SB 598 at the April 2013 Board Meeting stating the board's concerns that the bill may be premature, the burden placed on the pharmacy to provide follow-up notification to a prescriber, as well as the role a pharmacist plays in substitutions. The board noted that once deemed "biosimilar" the board would support an approach similar to the authority that allows the substitution of generics. The board also has conveyed to the author that where there is an adverse event attributed to the use of a biosimilar that such an event be required to be reported to the FDA's "Medwatch."

During a recent policy hearing (ASM Health), the committee made comments in support of pharmacist notification to physicians each time a substitution would be made.

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

Last Amend: July 3, 2013
Board Position: Support if Amended
Status: 8/13/13 – Set for Hearing in ASM Judiciary

SB 669 would create a training program and standards for the safe and proper use of epinephrine auto-injectors, 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 at the April 2013 Board Meeting, with the suggested amendment to also authorize a pharmacist to approve the requisite training certification and issue the prescription for an epinephrine auto-injector, as specified. Staff has met with the author's staff and sponsor and conveyed the board's request to amend the bill.

12. SB 809 (DeSaulnier) CURES

Last Amend: June 26, 2013
Board Position: Support (4/24/13)
Status: 8/13/13 – Set for Hearing in ASM Business, Professions and Consumer Protection

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.

Enforcement

13. SB 62 (Price-Liu) Coroners: Reporting Requirements: Prescription Drug Use

Last Amend: June 27, 2013
Board Position: Support
Status: In ASM Appropriations (as of July 15, not yet scheduled for hearing)

Existing law requires a coroner to file a report with the Medical Board and others when findings indicate that a death may be the result of specified health care practitioners' gross negligence or incompetence. SB 62 will require a coroner to also file a report with the Medical Board when the findings of a pathologist indicate that a cause of death is due to a Schedule II, II or IV drug, and further specifies the information that is to be provided. SB 62 provides that following any initial report provided is followed by a final report of investigation, coroner's report, autopsy protocol and other relevant information within 90 days or as soon as possible.

The introduced version of the bill included the Board of Pharmacy as one of the recipients of the reports, but was amended out in April 2013 based on concerns from coroners over having to file reports with multiple agencies. The board has requested amendments to SB 62 to expressly state that the MBC and other boards that receive the reports are authorized to share the information with the Board of Pharmacy.

Licensing

14. AB 258 (Chavez) State Agencies: Veterans

Last Amend: April 23, 2013
Status: As of 7/2/13, on the Senate Floor

SB 258 would standardize the way any state government organization would ask an individual about their veteran status. As amended on April 23, every agency that requests on any written form or written publication, or through its Internet Web site, whether a person is a veteran, that the information be requested in the following format:

"Have you ever served in the United States military?"

This item is provided for information only; the board does not have a position on this measure. Please see AB 1057 for related legislation.

15. AB 512 (Rendon) Healing Arts Licensure Exemption

Introduced: February 20, 2013
Status: As of 7/8/13, Passed to the Senate
Position: Support

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 current provisions 'sunset' on 1/1/14. 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.

This item is provided for information only.

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

Last Amend: June 3, 2013
Status: As of 6/25/13, on the Senate Floor

AB 1057 would require every board on or after January 1, 2015, to inquire on every application for licensure if the applicant is serving in, or has previously served in, the military.

This item is provided for information only; the board does not have a position on this measure. Please see AB 258 for related legislation.

Pharmacy / Other

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

Last Amend: June 13, 2013

Status: Ordered to Engrossing and Enrolling (7/3/13)

SB 146 is an urgency measure that specifies a copy of a prescription shall not be required with a request for payment for pharmacy services, unless the provider of services has entered into a written agreement that requires a copy of a prescription for a pharmacy service.

The bill specifies that any request for payment as established by the Division of Workers' Compensation that was denied for not providing a copy of the prescription, may resubmit the bill for payment, until March 31, 2014.

SB 146 also provides that nothing shall preclude an employer, insurer, pharmacy benefits manager, or third-party claims administrator from requesting a copy of the prescription during a review of any records of prescription drugs that were dispensed by a pharmacy.

This item is for information only; the board does not have a position on this measure.

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

Last Amend: June 13, 2013

Status: Ordered to Engrossing and Enrolling (7/3/13)

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.

This item is for information only; the board does not have a position on this measure and staff will continue to monitor its movement.

19. Other Legislation Impacting the Practice of Pharmacy

b. REGULATION REPORT

Attachment 2

Recently Noticed Regulations

1. Fee Schedule – Proposal to Amend Title 16 Section 1746

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 will conclude on Monday, July 29. A Regulation Hearing is scheduled for 1:00 p.m. on July 30, 2013. (Note: this item is listed on the Board Agenda as Item VIII.) A copy of the Proposed Text to amend Section 1746 is provided in Attachment 2.

2. 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 is preparing a notice of modified text that will be issued for a 15-day public comment period. The modified language approved by the board is provided in Attachment 2.

Board Approved - Undergoing Administrative Review (Information Only)

3. 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. Staff recently learned that on July 9, the Business, Consumer Services and Housing Agency approved the regulation and transmitted the file to the Department of Finance for review and sign-off. Upon receipt of the approved file, staff will deliver the rulemaking to the Office of Administrative Law for final review.

A copy of the Adopted Text is provided in Attachment 2. Once the approvals are received by the board, staff will update the board's website with final rulemaking documents prior to transmitting the file to OAL.

Board Approved – Awaiting Notice

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

The board has approved for 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. The board-approved proposals are provided in Attachment 2.

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 (CPJE) for pharmacists 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.

4. Update on Self-Assessments

On May 15, the board submitted a Section 100 regulatory update to the Office of Administrative Law to revise the board's self-assessment forms. The modifications made to the self-assessment forms reflect changes in Pharmacy Law in the prior legislative session.

Self-Assessment forms are required to be completed by pharmacies by July 1 of every odd-numbered year. The board anticipated having these forms available in advance of the July 1 deadline. However, the Office of Administrative Law indicated to staff that while the new information on the forms may reflect changes to pharmacy Law, the requirement that a pharmacist-in-charge or designated representative-in-charge certify under penalty of perjury as to those items was discretionary, and equated to a new requirement; thus, the proposal would not qualify as a Section 100 update. As a result staff withdrew the request for review.

At the October 2013 meeting, staff will bring to the board for consideration and discussion a formal rulemaking proposal to amend the board's self-assessment forms.

Until that time, however, board staff will make available on the board's website the self-assessment forms prepared for the Section 100 review. Pharmacies may utilize the self-assessment forms last approved by the Office of Administrative Law (Rev. 05/11). The board would also accept the completion of the newly revised self-assessment forms (showing draft revision dates of 07/13) which reflect recent changes in Pharmacy Law. A copy of the newly drafted self-assessment forms are provided in Attachment 2.

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.