



California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

LEGISLATION AND REGULATION COMMITTEE MINUTES

Date: Wednesday, January 29, 2014

Location: Department of Consumer Affairs Headquarters
1st Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

Committee Members Present: Greg Lippe, CPA, Chair, Public Member
Victor Law, R.Ph., Professional Member
Albert Wong, Pharm.D., Professional Member
Stan Weisser, R.Ph., President, Professional Member – Temporarily Appointed to the Committee

Committee Members Not Present: Ramon Castellblanch, Ph.D., Public Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Manager II
Laura Hendricks, Associate Analyst

Chairman Greg Lippe called the meeting to order at 8:14 a.m. and roll call was taken. All Section references are to the Business and Professions Code, unless specified otherwise.

I. LEGISLATION REPORT

Note: The California Legislature reconvened on January 6, 2014.

Chair Lippe reported the board voted to sponsor two statutory proposals.

a. Status of Board-Sponsored Provisions

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

Background: In May 2012, the board voted to sponsor 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.

Chair Lippe reported staff continues to work to secure an author to carry the proposal.

2. Designated Representatives – Minimum Age Requirement

Background: In 2012, the board voted to amend Business and Professions Code Section 4053 to amend requirements related to Designated Representatives, which were contained in the Senate Committee on Business, Professions and Consumer Protection’s 2013 omnibus measure, SB 821. Following introduction of Senate Bill 821, the board voted to also require that a designated representative meet a minimum age requirement of 18 years of age.

Chair Lippe reported staff has received feedback that this proposal should be carried in a Senate committee omnibus measure. This amendment has been provided to the committee for inclusion in the 2014 omnibus committee bill.

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

Chair Lippe reported the board has three pieces of legislation impacting the practice of pharmacy or the board’s jurisdiction.

1. AB 467 (Stone) Prescription Drug Collection and Distribution Program

Status:

Last Amend: January 7, 2014

Board Position: Support (1/10/14)

Status: On Senate Third Reading File (1/22/13)

Background: AB 467 would require board licensure of a “Surplus Medication Collection and Distribution Intermediary” and specifies the activities that can be conducted with such a license. The bill authorizes the board to issue and yearly renew a license, charge related fees and specifies license requirements; however, those that meet certain requirements (such as a 501(c)(e) nonprofit corporation) will be exempt from the payment of the license or renewal fee. In addition, the bill exempts these intermediaries from civil or criminal penalties associated with drugs distributed under an authorized Surplus Medication Collection and Distribution Program.

In October 2013 the board established a Support if Amended position, and instructed staff to work with the author’s office to specify the term of licensure and renewal for the license category. As a result, the author amended AB 467 on January 7 to specify that an Intermediary license shall be renewed annually.

Thereafter, on January 10, a Support position was taken by the board president and chair of the committee.

Chair Lippe reported at the January 2014 board meeting, the board will consider ratifying the Support position taken by the board president and chair of the committee on January 10, 2014.

2. SB 506 (Hill) Retail Sales of Ephedrine Products: Pilot Project

Status:

Introduced: February 21, 2013

Board Position: *None*

Status: In Senate Appropriations

Background: Under current law, pseudoephedrine and related products (PSE) are available without a prescription in limited quantities. These drugs must be kept behind the pharmacy counter, and pharmacies are required to maintain logs related to purchases. Retailers cannot sell in a single transaction more than three packages, or 9 grams of a product that he or she knows to contain PSE products. These limitations and requirements do not apply to the dispensing a PSE product pursuant to a valid prescription.

SB 506 would repeal existing statutory provisions for over-the-counter sales of PSE products and replace them with new sales limits consistent with federal law. The bill would impose restrictions on sales of PSE products, and require retailers to store them in a locked cabinet behind the counter.

SB 506 would authorize a pilot project (until 2019) to require the electronic recording of PSE sales (those not related to a prescription). The bill provides that retailers would be required to immediately transmit specified information regarding PSE purchases to the National Precursor Log Exchange (NPLEx), a privately funded out-of-state data base. This information would include the individual's name, date of birth, address and the product sold, the quantity of packages, and the total gram amount of PSE products involved in the sale. This system would also provide retailers with a real-time alert if an individual attempts to purchase PSE products in excess of the sale limits. This pilot project would sunset on January 1, 2019.

The board does not have a position on SB 506.

Chair Lippe reported that the bill was amended Monday, January 27, 2014. Staff Manager Carolyn Klein commented the difference between the versions included amendments for the California Department of Justice (CA DOJ) to be reimbursed for developing the Memorandum of Understanding (MOU) and overseeing the program.

Chair Lippe continued to report in California pharmacies, sales of PSE products are limited to 3 packages / 9 grams. Logs must be kept of the transactions and the information must be transmitted to the CA Department of Justice.

Under SB 506, a pilot project would be implemented from July 2015 to January 1, 2019, where sales would conform to federal limits: 3.6 grams in a single calendar day. The logs would be electronically reported to a vendor database, and transmitted to the CA DOJ.

Chair Lippe inquired if the Controlled Substance Utilization, Review and Evaluation System (CURES) would be used for this reporting. Executive Officer Virginia Herold stated regrettably not and indicated a prior version of the board's amendments included using the CURES system.

Chair Lippe continued to report this electronic system would "alert" the pharmacy if an individual has exceeded purchase limits or if the transaction is not authorized. The database would be funded by the National Association of Drug Diversion Investigators (NADDI). Chair Lippe stated he recalled the requirement for PSE products to be stored in a locked cabinet and requested staff research to clarify this requirement. Assistant Executive Officer Anne Sodergren clarified the requirement is a locked cabinet behind the counter in the pharmacy.

The most recent version of the bill requires NADDI to fund the CA DOJ to execute an MOU, and to reimburse the CA DOJ for all costs associated with the oversight of the program.

As of January 28, 2014, Chair Lippe reported the bill had passed the Senate and was sent to the Assembly. Chair Lippe reiterated the board does not have a position on this bill.

3. SB 727 (Jackson) Medical Waste: pharmaceutical product stewardship

Status:

Last Amend: April 3, 2013

Board Position: *None*

Status: 2-Year Bill

Chair Lippe reported the board does not have a position on the bill and the author's office recently advised staff that they are no longer moving the bill.

Chair Lippe concluded the legislation portion of the committee report and asked for public comment. In the absence of public comment, Chair Lippe continued with the regulation portion of the committee report.

II. REGULATION REPORT

a. Discussion and Possible Initiation of a Rulemaking to Amend Title 16 California Code of Regulations Section 1707.5 Related to Patient-Centered Prescription Labels

Chair Lippe reported at the October 2013 Board Meeting, the board voted to modify the board's patient-centered prescription label requirements at Section 1707.5 (a) (1) to read as follows:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only those four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed ~~in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point sans serif typeface~~ and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the name of the manufacturer.

(C) The directions for the use of the drug.

(D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

The language reflects the board's discussion and vote to require that only the four items listed in section 1707.5 (a) (1) be clustered into one area of the label that comprises at least 50 percent of the label and to require these items to be printed in 12-point sans serif typeface.

The committee may wish to discuss whether or not it wishes to recommend that the board initiate a rulemaking to modify the text of 16 CCR Section 1707.5 as directed at the October 2013 board meeting; authorize the executive officer to make any non-substantive changes to the rulemaking package, and provide the proposed language for a 45-day public comment period.

Ms. Herold stated that the President suggested these two items move forward in a separate regulation as the other items required further discussion. Ms. Herold stated that "at least" needs to be included in the text of the language. Additionally, text in (a)(1) should read "and only these four items" rather than stated as "and only those four items."

Ms. Herold suggested that the committee readopt the language as previously approved. Chair Lippe stated he recalled a potential of going back to the Public Education and Communication Committee. Ms. Herold stated that it did go back to the Public Education and Communication Committee earlier in the month. Ms. Herold did not recall agreement on any of the other items.

Ms. Herold recommended the language approved by the Legislation and Regulation Committee is forwarded to the board for formal approval to ensure the language is accurate.

Motion: Approve the revised language for Section 1707.5 Related to Patient-Centered Prescription Labels

M/S: Law/Wong

Support: 4 Oppose: 0 Abstain: 0

Committee Member Victor Law and was seconded by President Weisser.

Chair Lippe called for public comment. In the absence of public comment, Mr. Lippe called for the vote. All present voted for the motion.

President Weisser asked for clarification as to whether or not “at least” would be included. Ms. Herold clarified that the language would read:

§ 1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements.

(a) Labels on drug containers dispensed to patients in California shall conform to the following format:

(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a ~~10-point sans serif typeface~~ or, if requested by the consumer, at least a 12-point sans serif typeface, and listed in the following order:

- (A) Name of the patient
- (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.
- (C) The directions for the use of the drug.
- (D) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.

Ms. Herold indicated this would be forwarded to the board as a committee recommendation.

b. Board-Approved – Undergoing Administrative Review (Information Only)

Chair Lippe provided the board has two board-adopted regulations that are currently being reviewed.

1. Fee Schedule – Proposal to Amend Title 16 California Code of Regulations Section 1749

Background: 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 a regulation hearing was held on July 30, 2013.

At the July 2013 Board Meeting, the board voted to adopt the regulation text that was noticed on June 14, 2013 and directed staff to complete all steps necessary to complete the rulemaking process. In accordance with the board’s directive, staff compiled the rulemaking file. The rulemaking is currently undergoing administrative at the Business, Consumer Services and Housing Agency.

2. Combined Rulemaking – Proposal to Amend Sections 1745 and 1769, and to add Section 1761 to Title 16 California Code of Regulations Related to Partial Filling of a Schedule II Prescription, Criteria for Rehabilitation, and to Define Unprofessional Conduct

Background: At the February 2013 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.

The rulemaking was completed, the text adopted, and 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. On January 10, 2014, the rulemaking file was delivered to the Office of Administrative Law for review.

c. Board-Approved – Discussion and Possible Action

1. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Section 1732.2, 1732.5, and 1732.05 Related to Continuing Education

Chair Lippe provided to the committee the previously board-approved awaiting notice and public comment regulatory proposals related to continuing education.

Mr. Lippe stated given recent significant changes in pharmacy law as a result of SB 294 (Emmerson, Chapter 565, Statutes of 2013), SB 493 (Hernandez, Chapter 469, Statutes of 2013) and with regard to the changes to compounding and the addition of the advanced practice pharmacist, the committee may want to consider returning the draft language to the Licensing Committee to determine if additional updates should be made before the language is noticed for public comment.

Chair Lippe provided the committee with a summary of the pending regulation.

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.

The committee agreed the regulation was sufficient as currently written. Chair Lippe asked for public comments. There were no public comments.

d. Board-Approved – Awaiting Notice

Chair Lippe referenced the committee packet for board-approved regulation notices pending public notice.

1. Combined Rulemaking – Proposal to Amend Title 16 California Code of Regulations Sections 1702, 1702.1, 1702.2 and 1702.6 Related to Renewal Requirements

At the July 2013 Board Meeting, the board voted to modify Sections 1702, 1702.1, 1702.2, and 1702.5 of 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.

2. Proposal to Amend Title 16 California Code of Regulations Section 1703 Related to "Section 100" Regulatory Actions

During the October 2012 Board Meeting, the board voted to delegate to the Executive Officer the authority to adopt regulation changes that are deemed to be "without regulatory effect" in accordance with Section 100 of Title 1 of the California Code of Regulations. This delegation expired December 31, 2013.

At the October 2013 Board Meeting, the board voted to amend Title 16 California Code of Regulations Section 1703 to deplete to the Executive Officer the authority to initiate a rulemaking to adopt "changes without regulatory effect" and to initiate the formal rulemaking process.

Staff is preparing the required notice documents to initiate this rulemaking. A copy of the approved proposed text is provided in Attachment 3.

III. Public Comment on Items Not on the Agenda / Agenda Items for Future Meetings

Chair Lippe asked the committee members and members of the public for any items to be added to a future agenda. With no response from the committee members or members of the public, Mr. Lippe concluded the meeting at 8:36 a.m.