



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES**

DATE: April 17, 2012

LOCATION: Department of Consumer Affairs
Headquarters Building II
1625 N. Market Boulevard, Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Greg Lippe, Chair
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

COMMITTEE MEMBERS

NOT PRESENT: Ryan Brooks, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Shellans, DCA Staff Counsel
Debbie Anderson, Licensing Manager
Debi Mitchell, Licensing Manager
Tessa Miller, Staff Analyst

Call to Order

Chair Greg Lippe called the meeting to order at 9:37 a.m.

Chair Lippe conducted a roll call. Board Members Rosalyn Hackworth and Deborah Veale were present.

Board President Stan Weisser was in attendance in the audience.

1. **Review and Discussion to Develop Regulation Requirements to Specify Standards for Agencies that Accredite Licensed Sterile Injectable Compounding Pharmacies (Proposed as 16 California Code of Regulations Section 1751.9)**

Relevant Statutes

California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are: 1. already licensed pharmacies, and 2. compound injectable sterile drug products. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

However, there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

- the pharmacy is licensed by the board or the Department of Public Health
AND
- the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Background

In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors. Provided below is the general criteria the board initially established in 2003.

1. Periodic inspection -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. Documented accreditation standards -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payers -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.

7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Over the past few years the board has reviewed and approved several new accreditation agencies. During the course of its discussion and evaluation, the board has expressed some hesitation in the approval of accreditation agencies that do not incorporate the following items:

1. A pharmacist as a member of the survey team
2. Perform annual inspections
3. Willingness to share information with the board on findings
4. Ensuring conformance with California's requirements for LSCs

As previously discussed by the committee, regulation language is necessary to facilitate implementation of this process. During the last committee meeting members discussed the proposal and suggested several changes to the proposed language.

Following this memo is revised language as well as the relevant portion of the December 2011 Licensing Committee Meeting.

Discussion

Chair Lippe referenced the revised language provided in the meeting materials and recommended approval by the committee.

DCA Staff Counsel Kristy Shellans requested additional time to review the revised language. She advised that she will bring comments for the board's consideration at the May 2012 Board Meeting.

It was the consensus of the committee to postpone further discussion on this issue until the May 2012 Board Meeting to allow for additional review of the revised language.

2. Recommendations for Regulation Changes

a. Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas, Amendment to 16 California Code of Regulations Section 1732.2

Background

For nearly only one year in meetings of this committee and of the board, there has been discussion about requiring continuing education in certain topics. At the February 2012 Board Meeting, the board determined to proceed with a rulemaking to require six of the 30 units required for pharmacist license renewal every two years to be in:

- Emergency/disaster Response

- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Drug Abuse

Discussion

Chair Lippe reviewed the following proposal to require continuing education in certain subject areas.

1732.5. Renewal Requirements for Pharmacists.

- a. Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
- b. Effective July 1, 2013, at least six of the 30 units required for pharmacist license renewal shall be completed in one or more of the following subject areas:
 1. Emergency/Disaster Response,
 2. Patient Consultation,
 3. Maintaining Control of a Pharmacy's Drug Inventory,
 4. Ethics,
 5. Drug Abuse.

Pharmacists renewing their licenses which expire on or after July 1, 2015 shall be subject to the requirements of this subdivision.
- c. All pharmacists shall retain their certificates of completion for four years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Ms. Shellans recommended an amendment to subdivision b(5) to replace "drug" with "substance."

The committee accepted this amendment.

No public comment was provided.

MOTION: Recommend to the board to direct staff to take all steps necessary to initiate a formal rulemaking process to amend 16 California Code of Regulations Section 1732.2 as amended.

M/S: Lippe/Veale

Support: 3 Oppose: 0 Abstain: 0

b. Proposal to Award CE for Attending Board and Committee Meetings, Amendment to 16 California Code of Regulations, Section 1732.2

Background

At the February 2012 Board Meeting, the board withdrew its proposed amendment to CCR 1732.2 to award continuing education (CE) for specific activities. The rulemaking was at that time undergoing review by the Office of Administrative Law, the final step in the regulation adoption process.

The reason the board withdrew the rulemaking was that it wished to reconsider and modify the CE that were to be awarded for attending board and committee meetings each renewal period.

At the February 2012 Board Meeting, the board instead voted to award six units of continuing education per renewal period to a pharmacist or pharmacy technician who attends a full day of a board meeting, and two units of CE per renewal period to a pharmacist or pharmacy technician who attends a committee meeting.

Discussion

Chair Lippe reviewed the following proposed text that adds the new CE amounts. The committee requested that the language be modified to replace use of “continuing education hours” and “continuing education credit” with “continuing education” to remain consistent with the statute. This modification is reflected below.

1732.2. Board Accredited Continuing Education

- (a) Individuals may petition the board to allow continuing education ~~credit hours~~ for specific coursework which is not offered by a provider but meets the standards of Section 1732.3.
- (b) Notwithstanding subdivision (a) of this section, coursework which meets the standard of relevance to pharmacy practice and has been approved for continuing education by the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California shall, upon satisfactory completion, be considered approved continuing education for pharmacists.
- (c) A pharmacist serving on a designated subcommittee of the board for the purpose of developing the California Practice Standards and Jurisprudence Examination for pharmacists pursuant to section 4200.2 of the Business and Professions Code may annually be awarded up to six hours of continuing education ~~hours~~ for conducting a review of exam test questions. A subcommittee member shall not receive continuing education ~~hours~~ pursuant to this subdivision if that subcommittee member requests reimbursement from the board for time spent conducting a review of exam test questions.
- (d) A pharmacist or pharmacy technician who attends a full day board meeting may be awarded ~~up to~~ six hours of continuing education per

~~renewal period on an annual basis.~~ The board shall designate on its public agenda which day shall be eligible for continuing education ~~credit.~~ A pharmacist or pharmacy technician requesting continuing education ~~hours~~ pursuant to this subdivision must sign in and out on an attendance sheet at the board meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.

- (e) A pharmacist or pharmacy technician who attends a full committee meeting of the board may be awarded ~~up to two hours of continuing education per renewal period on an annual basis. A maximum of four continuing education hours may be earned each year by attending the full meetings of two different board committees.~~ A pharmacist or pharmacy technician requesting continuing education ~~hours~~ pursuant to this subdivision must sign in and out on an attendance sheet at the committee meeting that requires the individual to provide his or her first and last name, license number, time of arrival and time of departure from the meeting.
- (f) An individual may be awarded three hours of continuing education for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Ms. Shellans advised that subdivision (d) includes a provision to award CE to pharmacy technicians. She stated that although there is no requirement that pharmacy technicians earn CE, this provision is an opportunity for the board to offer CE for technicians to satisfy the Pharmacy Technician Certification Board's requirement.

Public Comment

Philip Swanger, representing the California Society of Health-System Pharmacists (CSHP), spoke in support of the board offering CE to pharmacy technicians. He stated that CSHP also offers pharmacy technician CE accredited by the Accreditation Council for Pharmacy Education (ACPE).

MOTION: Recommend to the board to direct staff to take all steps necessary to initiate a formal rulemaking process to add to and amend 16 California Code of Regulations, Section 1732.2 as amended.

M/S: Lippe/Veale

Support: 3 Oppose: 0 Abstain: 0

c. Proposal to Update Reference to Accreditation Agencies for Continuing Education, Amendment to 16 California Code of Regulations Section 1732.05

Discussion

Executive Officer Virginia Herold provided that the board recently received a request from the California Pharmacists Association requesting a modification to CCR section 1732.05 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.

Mr. Lippe reviewed the following proposal:

1732.05. Accreditation Agencies for Continuing Education.

- (a) The following organizations are approved as accreditation agencies:
- (1) The Accreditation Council for Pharmacy Education.
 - (2) ~~The Pharmacy Foundation of California.~~ The California Pharmacists Association.
- (b) Accreditation agencies shall:
- (1) Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of section 1732.1 of this Division.
 - (2) Maintain a list of the name and address of person responsible for the provider's continuing education program. The accreditation agency shall require that any change in the responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of the change.
 - (3) Provide the board with the names, addresses and responsible party of each provider, upon request.
 - (4) Respond to complaints from the board, providers or from pharmacists concerning activities of any of its accredited providers or their coursework.
 - (5) Review at least one course per year offered by each provider accredited by the agency for compliance with the agency's requirements and requirements of the board and, on request, report the findings of such reviews to the board.
 - (6) Take such action as is necessary to assure that the continuing education coursework offered by its providers meets the continuing education requirements of the board; and
 - (7) Verify the completion of a specific continuing education course by an individual pharmacist upon request of the board.
- (c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b) shall constitute cause for revocation of its approval as an accreditation agency by the board.

Authority cited: section 4005, Business and Professions Code. Reference:
section 4232, Business and Professions Code.

No public comment was provided.

MOTION: Recommend to the board to direct staff to take all steps necessary to initiate a formal rulemaking process to amend 16 California Code of Regulations Section 1732.05 as amended.

M/S: Lippe/Veale

Support: 3 Oppose: 0 Abstain: 0

3. Proposed Statutory Amendment to Authorize the Board to Issue a Public Reprimand for Violations That Would not Warrant License Denial or Issuance of a Probationary License

Background

Chair Lippe provided that before issuing a license, the board does a background review of all applicants for licensure. He stated that this review is also done on the owners and officers of applicants for site licenses. Chair Lippe explained that there are several components to this review.

Chair Lippe provided that the background review includes mandatory submission of fingerprints, which are reviewed at state and federal levels to determine prior arrests and convictions within and outside California. He stated that the board reviews the reports of arrests and convictions it obtains from the courts and law enforcement agencies before making any licensing decision. Chair Lippe added that the board also asks questions about prior convictions on every application, and collects information from the applicant about these events.

Chair Lippe provided that the board also requires information about prior administrative actions taken by any regulatory agency against an applicant. He stated that it collects this information in several ways, one by requiring responses to specific questions on the applications -- signed under penalty of perjury about the truth of the responses -- that there has been no prior discipline. Increasingly the board also relies upon national HIPDP data base searches to ensure the accuracy of the self reported information collected on the application. Pharmacy technician applications must now submit a "self query report" from the HIPDB to ensure the accuracy of their responses. Chair Lippe advised that a similar requirement for interns and pharmacists technicians has been approved by the board as a regulation and the regulation requirements are undergoing review by the Administration.

Chair Lippe discussed that sometimes the information gained from these background reviews shows serious violations in an applicant's past. He stated that in such cases, when the matters are substantially related to the duties of the license, the board denies the license or may issue a probationary license. Chair Lippe advised that currently, these are the only two options open to the board when making a licensing decision about an application.

Chair Lippe provided that some violations while serious, are not sufficient or are so old that the board would have difficulty in denying the license today based on the violation.

Chair Lippe provided that this issue is faced by all boards when making a licensing decision about an applicant. He reviewed the following Medical Board provision that provides another alternative – issuance of the license, but with a public reproof.

- 2221.05.** (a) Notwithstanding subdivision (a) of Section **2221**, the board may issue a physician's and surgeon's certificate to an applicant who has committed minor violations that the board deems, in its discretion, do not merit the denial of a certificate or require probationary status under Section **2221**, and may concurrently issue a public letter of reprimand.
- (b) A public letter of reprimand issued concurrently with a physician's and surgeon's certificate shall be purged three years from the date of issuance.
- (c) A public letter of reprimand issued pursuant to this section shall be disclosed to an inquiring member of the public and shall be posted on the board's Internet Web site.
- (d) Nothing in this section shall be construed to affect the board's authority to issue an unrestricted license.

Discussion

Chair Lippe reviewed the following staff proposal to seek addition of such a provision to the board's statutory provisions to address this issue:

- 4310.5 (a) Notwithstanding subdivision (c) Section 4300, the board may issue a license to an applicant who has committed minor violations that the board deems, in its discretion, do not merit the denial of a certificate or require probationary status under Section 4300, and may concurrently issue a public letter of reprimand.
- (b) A public letter of reprimand issued concurrently with a board license shall be purged three years from the date of issuance.
- (c) A public letter of reprimand issued pursuant to this section shall be disclosed to an inquiring member of the public and shall be posted on the board's Internet Web site.
- (d) Nothing in this section shall be construed to affect the board's authority to issue an unrestricted license.

Ms. Shellans advised that the letter or reprimand constitutes discipline; and as such, must be approved by the board prior to issuance.

Ms. Veale clarified that the letter of reprimand is an additional option that can be applied to document a violation that does not warrant denial or probation.

Mr. Lippe spoke in opposition to the proposal and questioned the necessity of this option. He discussed that the letter of reprimand would negatively impact the ability of licensees to find employment.

Assistant Executive Officer Anne Sodergren provided that this option will allow the board to acknowledge the significance of the violation and document it for consideration in the event the licensee receives any subsequent discipline.

No public comment was provided.

MOTION: Recommend addition of the provision to authorize the board to issue a public reprimand for violations that would not warrant license denial or issuance of a probationary license to the board's statutory provisions.

M/S: Veale/Hackworth

Support: 2 Oppose: 1 Abstain: 0

4. **Proposed Statutory Amendment to Specify Conditions Under Which Wholesalers May Purchase Drugs from Pharmacies**

Chair Lippe provided that this item will be rescheduled for a future meeting.

5. **Evaluation of the Impact of Changes Incorporated on the Pharmacy Technician Application Form**

Background

Chair Lippe provided that historically a significant majority of pharmacy technician applications were received with deficiencies. He stated that this resulted in delays in processing applications and issuing licenses. Chair Lippe discussed that to remedy this, in October 2011, the board began using a revised pharmacy technician application. He explained that the revised application more clearly specifies the requirements for licensure as well as the information necessary to confirm compliance. Chair Lippe stated that additional changes were made to reduce the likelihood of applicants providing false information to the board.

Chair Lippe provided that Business and Professions Code section 4202(a) specifies an individual is a high school graduate or possesses a general education development

(GED) certificate. He stated that the revised application now requires the applicant to submit an official high school transcript or GED test scores as a result of applicants providing fraudulent documents indicating they had graduated high school.

Chair Lippe provided that California Codes of Regulations section 1793.5(a)(4) now specifies the applicant must provide a sealed original Self-Query Report from the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB). He stated that this query validates the information provided by the applicant about their background.

Chair Lippe provided that to ensure more complete applications are received, staff has been reaching out to the pharmacy technician programs notifying them of the revised application and what is required to make an application complete.

Chair Lippe provided that the number of deficient applications the board receives is reducing each month. He stated that in October 2011 79% of applications received were deficient compared to February 2012 where 49% of the applications were deficient. Chair Lippe advised that receiving completed applications allows the board to process applications and issue licenses to qualified applicants more quickly.

Discussion

Ms. Sodergren discussed that board staff will continue to provide outreach to pharmacy technician schools and implement improvements in this area. She stated that it is expected that the application deficiencies will continue to decrease.

No public comment was provided.

6. Review of the Education and Experience Requirements for Pharmacist Licensure in California and other US States

Background

Chair Lippe provided that Business and Professions Code section 4200 establishes the requirements for an applicant to be deemed eligible for the pharmacist licensure examination. He stated that the requirements include the following:

1. At least 18 years of age.
2. Graduation from a school of pharmacy recognized by the board or certification by the Foreign Pharmacy Graduate Examination Committee if the applicant is a graduate from a foreign country.
3. A minimum of 150 semester units, no less than 90 of those must be completed at a school of pharmacy.
4. At least a baccalaureate degree in a course of study devoted to the practice of pharmacy.
5. Completion of 1500 hours of pharmacy practice experience.
6. Pass the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists.

Chair Lippe provided that over the past several years the committee and board have discussed the requirements for pharmacist licensure, especially in the area of intern hour experience. He reviewed the following comparison of California requirements with several other states in three general areas: examination; education; and experience. Chair Lippe also referenced information collected by the National Association of Boards of Pharmacy that details specific requirements for each state provided in the meeting materials.

Examination

All states require pharmacist examination applicants to pass the North American Pharmacist Licensure Examination (NAPLEX) and all but seven states required the Multistate Pharmacy Jurisprudence Examination (MPJE). California is one of the seven that does not require the MPJE as it has its own California Jurisprudence Pharmacist Examination (CPJE).

Education

Although states vary in the method by which they confirm education, all states require similar education requirements for domestic graduates including graduation from a school of pharmacy by the Accreditation Council for Pharmacy Education (ACPE).

Experience

One area where states vary is in the number of intern hours experience as well as the method by which such experience is verified. The majority of the states require a minimum of 1,500 hours of practice experience. Some state accept hours in conjunction with academic credit and some states accept hours earned and verified by another state board of pharmacy.

Discussion

Ms. Veale discussed that at previous meetings the committee has discussed modifying the intern hours requirement that specifies that an intern pharmacist shall complete 1,500 hours of pharmacy practice before an applicant can apply for the pharmacist licensure examination. She stated that this requirement must be satisfied with a minimum of 900 hours of pharmacy practice experience obtained in a pharmacy and a maximum of 600 hours of pharmacy practice experience substantially related to the practice of pharmacy. Ms. Veale indicated that the board has received proposals from pharmacy students to increase the number of hours that can be earned outside of a pharmacy.

Ms. Herold discussed that the board has discussed this issue for a number of years. She stated that there is no consensus among pharmacy schools as to whether this change should be pursued.

7. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chair Lippe provided that the board instituted a quality assurance review of the CPJE effective April 2, 2012. He explained that this process is done periodically to ensure the reliability of the examination. Chair Lippe stated that as of the date of this report, the quality assurance review is still under review. He advised that based on historical patterns, the board anticipates results being released approximately August 2012.

Examination Development

Chair Lippe provided that the Competency Committee workgroups will continue to conduct examination development meetings during the spring of 2012.

No public comment was provided.

8. Licensing Statistics

Chair Lippe referenced the licensing statistics provided in the meeting materials.

Ms. Herold provided an overview of the statistics and advised that processing times have been significantly impacted by furloughs, hiring freezes, and vacancies.

Ms. Sodergren stated that staff will be redirected to process applications for the surge of pharmacist applications expected for pending graduates.

No public comment was provided.

9. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 10:24 a.m.