



California State Board of Pharmacy
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STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE: December 2, 2010

LOCATION: Department of Consumer Affairs
El Dorado Room, 2nd Floor, N-220
1625 N. Market Boulevard
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Greg Lippe, Public Member, Chair
Deborah Veale, RPh
Ryan Brooks, Public Member
Kenneth Schell, PharmD

STAFF

PRESENT: Virginia Herold, Executive Officer
Janice Dang, Supervising Inspector
Kristy Schieldge Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Debbie Anderson, Licensing Manager
Debi Mitchell, Licensing Manager
Tessa Miller, Staff Analyst

Call to Order

Chair Lippe called the meeting to order at 1:37 p.m.

1. Review of Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies

Background

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.

Currently the board has over 240 such licensed facilities in California, and approximately 90 nonresident pharmacies with such permits.

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.

There are three accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc (ACHC), 2. Community Health Accreditation Program (CHAP), and Det Norske Veritas (DNV). At the April 2010 Board Meeting, the board extended the accreditation of the first two agencies for one year while the board prepares a detailed review. At the July 2010 Board Meeting, the board added DNV as an accreditation agency, and approved it for three years.

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. At the beginning of 2010, the board modified its regulations for pharmacies that compound medication. Included in these requirements are modified requirements for pharmacies that compound sterile injectable medication. These regulations were approved and filed with the Secretary of State on January 6, 2010, and pursuant to the board's directive, took effect July 6, 2010. The board also directed an additional six months of "educational" enforcement for the new requirements to facilitate compliance.

Since 2003 when both ACHC and CHAP were initially approved by the board, board inspectors have not identified a problem with the accreditation standards used to accredit any pharmacy in California. 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.

- 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.

Discussion

Supervising Inspector Janice Dang provided an overview of her assessment of the Accreditation Commission for Health Care, Inc. (ACHC) and the Community Health Accreditation Program (CHAP). She provided a comparison of both agencies and reviewed site inspection results from 2 pharmacies for each agency. Dr. Dang indicated that the two pharmacies inspected from ACHC passed inspection. She discussed that the two pharmacies accredited by CHAP appeared to “ramp up” their standards for accreditation purposes and indicated that many corrections were issued based on the prior regulations.

The committee discussed these results. Tim Safley (ACHC) and Terry Duncome (CHAP) responded to questions from the committee.

Executive Officer Virginia Herold discussed that the board conducts random and unscheduled inspections.

Ms. Duncome provided that CHAP does conduct unannounced visits for facilities seeking exemption to licensure.

Debbie Veale asked how CHAP plans to address the results from the board's assessment.

Ms. Duncome provided that the results are a concern. She requested information regarding the two pharmacies that were inspected by the board in order to appropriately address their deficiencies. Ms. Duncome discussed that pharmacies that have identified deficiencies must complete a plan of correction and are subject to a subsequent visit. She indicated that the minimum number of visits for a facility is once every three years; but, annual inspections may be necessary based on a facility's performance.

Mr. Safley provided that all ACHC visits are unannounced.

Dr. Dang indicated that one pharmacy assessed by the board indicated that it was overdue for an accreditation review.

Ken Schell asked how many organizations CHAP accredits annually.

Ms. Duncome provided that CHAP accredits several hundred entities a year for all of the 10 services accredited. She indicated that CHAP accredits 13 pharmacies in California.

Dr. Schell asked if CHAP has identified critical findings in the past that have jeopardized licensure.

Ms. Duncome provided that these findings are not typical of the pharmacy program. She indicated that CHAP accredits 467 pharmacies in the US.

Ms. Herold asked for statistics regarding the amount of provisional statuses issued as well as decline rates within the past five years.

Ms. Duncome discussed that a deferred status indicates that a facility has deficiencies that must be corrected prior to accreditation. She stated that accreditation can be denied or withdrawn. Ms. Duncome indicated that denial rates for CHAP accreditation are increasing.

Ms. Herold requested that CHAP and ACHC provide information to the board by January 10, 2011 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn, and denied within the last five years. She asked that the numbers reflect both national and California statistics and include nonresident pharmacies that are shipping into California.

Mr. Lippe asked if these findings will initiate a review of other California pharmacies accredited by CHAP.

Ms. Duncome provided that she will be requiring that all California pharmacies be reviewed.

Mr. Lippe asked how often similar findings occur.

Ms. Duncome provided that this is the first occurrence during her nine years as president of CHAP. She advised that CHAP has no deficiencies upon validation visits by the Centers for Medicare and Medicaid Services (CMS).

Dr. Schell requested that validation information be provided to the board.

Mr. Safley provided that ACHC is certified by the International Organization for Standardization (ISO). He agreed to provide this information to the board.

Ms. Veale asked how ACHC would respond if it received similar findings to that of CHAP.

Mr. Safley provided that ACHC would conduct an investigation to validate whether the accreditation should be revoked. He stated that the pharmacy would be required to complete a plan of correction and the accreditation would be contingent on a follow-up inspection known as a “dependant survey.”

Ms. Veale asked whether the board has the ability to provide investigation information to accreditation agencies.

Ms. Shellans advised that providing this information would make it public.

Ms. Herold indicated that both CHAP and ACHC have been approved accreditation agencies in California since 2003. She asked why neither agency has reported a substandard report to the board.

Mr. Safley provided that pharmacies are given 30 days to come into compliance. He stated that pharmacies that are found to be deficient with a state regulation will be reported to the board immediately.

Ms. Herold provided that the pharmacies accredited by ACHC were found to have some minor violations. She asked how ACHC will ensure compliance in these areas.

Mr. Safley provided that a plan of correction is required for minor violations. He stated that pharmacies will be placed on a “dependant status” for more significant violations and will be subject to a focus visit. He stated that any pharmacy requiring a second or third visit for a compliance issue will most likely be placed on revocation status.

Dr. Schell requested statistics regarding revocation statuses from both agencies.

Ms. Duncome provided that pharmacies will be placed on a warning status if deficiencies are not corrected by the second visit. She stated that accreditation will be revoked if the correction is not made by the third visit. Ms. Duncome explained that initial accreditation will be denied if deficiencies identified during the initial review are not corrected by the second visit.

No public comment was provided.

MOTION: Recommend to the board that ACHC and CHAP be reapproved as accreditation agencies for three years pending receipt of the requested information.

M/S: Schell/Veale

Support: 4 Oppose: 0 Abstain: 0

Additional Discussion

Ms. Herold advised that ACHC and CHAP should be prepared to provide a presentation to the full board at the February 2011 Board Meeting. She encouraged both agencies to conduct annual inspections of the pharmacies they accredit.

Dr. Dang reviewed a response from the Joint Commission that had been requested by the board at the October 2010 Board Meeting regarding survey teams that include a pharmacist and their findings.

Ms. Herold advised that she will request that this response be refined to answer the questions specified by the board.

There was no additional public comment.

2. Update on the Board's Psychometric Evaluation for the ExCPT and PTCB Examinations

Background

Business and Professions Code 139 requires a psychometric assessment description of the occupational analysis serving as the basis for the examination and an assessment of the appropriateness of prerequisites for admittance to the examination.

Chair Report

Chair Lippe provided that the department's Office of Professional Examination Services will be conducting these evaluation assessments of the Pharmacy Technician Certification Board (PTCB) and Exam for the Certification of Pharmacy Technicians (ExCPT) for the board.

Chair Lippe provided that upon completion, the committee will be advised of the findings at which time it may recommend a change to the statutory requirements for licensure detailed in B&PC 4202.

Discussion

Ms. Veale asked if there is an expected date of completion for the evaluation.

Ms. Herold provided that the evaluation should be completed in June 2011. She discussed some of the challenges encountered in trying to secure an evaluator as the state requires that this work be done by a state employed psychometric evaluator.

Ms. Herold advised that the PTCB has never been validated by California. She suggested that the board consider adding both exams to the law book if they both meet minimum standards.

Public Comment

A member of the public sought clarification regarding externship requirements for pharmacy technician students.

Ms. Shellans provided that this item must be requested as an agenda item for a future meeting for discussion.

3. Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Chair Report

Chair Lippe provided that at several prior meetings of the board or its committees, including the last two meetings of the Licensing Committee, there was general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. He discussed that specific areas are required in other disciplines.

Discussion

Ms. Herold provided that prior discussions have included the need to earn CE in emergency response, patient consultation or in maintaining control of a pharmacy's drug inventory.

Dr. Schell discussed the challenge of evaluating course content to ensure it is achieving the objective. He stated that certain content may not be relevant or applicable to all pharmacists in all areas of practice.

Ms. Veale suggested that the CE hour requirement be broken down into required subjects and discretionary subjects. She explained that a licensee will be required to complete the specified hours of the required subjects; but, can choose relevant subjects from 3 main categories that relate to their practice to complete the remaining discretionary hours. Ms. Veale indicated that the licensee will be required to certify that they have completed these hours and will be subject to random audits.

Mr. Brooks suggested that the board contract with a vendor to provide online courses.

Ms. Shellans reviewed the litigation issues and challenges involved with securing such a contract through the states contracting process. She indicated that it would be more efficient to establish minimum standards for course content that course providers would be required to follow.

Ms. Herold provided that to establish such a requirement would require either a legislative or regulation change.

Mr. Brooks suggested that staff research possible providers in this area and conduct a review of necessary implementation.

Ms. Shellans recommended that the committee request direction from the board regarding whether specific content areas for CE should be pursued. She stated that if approved, the committee can determine implementation.

Dr. Schell left the meeting room at 2:58 p.m.

No public comment was provided.

MOTION: Recommend that the board pursue specific content areas for continuing education. If recommendation is approved, authorize staff to investigate implementation.

M/S: Veale/Brooks

Support: 3 Oppose: 0 Abstain: 0

4. Update on the Board's Efforts to Implement 16 California Code of Regulations Section 1702, Mandatory Submission of Fingerprints for Pharmacists

Background

Earlier this year, the board established new requirements for pharmacist renewal that were placed into CCR Section 1701. This regulation was approved by the Office of Administrative Law and is scheduled to take effect on December 7, 2010.

The regulation specifies that as a condition of renewal, a pharmacist must disclose on the renewal form any arrest or conviction, as specified, since the licensee's last renewal; that a pharmacist applicant must pay the actual cost of compliance with the submission of fingerprints; a requirement that the licensee retain proof of compliance, as specified; and that failure to comply with the fingerprint requirement will result in an application for renewal being considered incomplete.

The board was advised the beginning of November that due to the on-going fiscal crisis and hiring restrictions within State government, effective Monday, November 8, 2010, the California Department of Justice (DOJ) no longer has the resources to take phone calls or process follow-up inquiries from regulatory entities who have submitted a criminal offender record information search request through the DOJ or the Federal Bureau of Investigation (FBI).

Board staff requested intervention by the department as its impact affects all boards and bureaus within the department. The board has not received any information thus far.

Chair Report

Chair Lippe provided that the board's efforts to coordinate with the DOJ to establish the necessary changes required to implement these requirements have been unsuccessful.

Discussion

Ms. Herold provided that the board has experienced opposition in allowing the coding for different licensure types and distinguishing those from reprints. She discussed the workload involved with identifying prints and matching them to the appropriate applicant.

Dr. Schell returned to the meeting room at 3:02 p.m.

Chair Lippe suggested the use of a colored envelope to be used in the mailing of reprints.

Ms. Herold discussed that the board does not process its own renewals. She stated that a system is needed that will allow for audit validation.

Dr. Schell left the meeting at 3:06 p.m.

Public Comment

A member of the public sought clarification regarding accurate submission of Livescan prints.

Licensing Manager Debi Mitchell discussed several factors impacting Livescan accuracy including operator error, print quality, and incorrect information. She recommended that the scan and appropriate information including social security number be reviewed by the licensee or applicant before it is submitted by the operator. She advised that if a deficiency letter is sent, the licensee or applicant needs to ensure that this area is corrected.

Ms. Herold provided that her offer to help the DOJ in this process was denied.

5. Discussion of the California Hospital Association's Repopulation After Hospital Evacuation Guidelines and Checklist

Chair Report

Chair Lippe provided that Executive Officer Herold recently served on a panel convened by the California Hospital Association to identify the components needing check off following the evacuation of the hospital but before the hospital can be "repopulated." He indicated that the California Department of Public Health (CDPH) also participated.

Discussion

Ms. Herold discussed that several agencies are involved in the event a hospital needs to be repopulated. She stated that with respect to the pharmacy, if called upon by the CDPH, the board will inspect the pharmacy to validate that there are appropriate safeguards to ensure the safety of the drugs.

Mr. Brooks asked how quickly the board would perform an inspection.

Ms. Herold provided that CDPH or the hospital would contact the board to request an inspection. She indicated that the CDPH makes the determination whether a facility is clear for repopulation, as such, the board's role is relatively minor in this process.

No public comment was provided.

6. Competency Committee Report

Discussion

Ms. Herold provided that each Competency Committee workgroup met once in the fall of 2010 for examination development. She stated that development is going well.

No public comment was provided

7. Update on the Conversion to a New Content Outline for the California Practice Standards and Jurisprudence Examination for Pharmacists in April 2011

Discussion

Ms. Herold provided that pursuant to Business and Professions Code section 139, the board is required to complete an occupational analysis periodically which serves as the basis for the CPJE examination. She stated that to complete this analysis, the committee developed a job analysis survey with the board's contracted psychometric firm. Ms. Herold advised that the results of this survey resulted in the need to slightly change the content outline of the CPJE to ensure it remains valid for California.

Ms. Herold provided that under the leadership of the board's psychometric consultant, the Competency Committee revised the content outline, which was presented to the board at the April 2010 Board Meeting. She stated that after the board approved the revised content outline, the Competency Committee worked with the board's psychometric consultant to ensure the new outline will be used to develop examinations administered after April 1, 2011.

Ms. Herold provided that the new outline and new sample questions will be posted on the board's Web site. She discussed that this typically triggers anxiety for applicants and a delay in their taking the exam which consequently delays the release of the results.

Ms. Veale asked whether applicants will be notified.

Ms. Herold indicated that notification can be provided.

Ms. Veale discussed that the changes are intended to remove duplicity with the NAPLEX exam.

No public comment was provided.

8. Licensing Statistics

Discussion

Ms. Herold reviewed the licensing statistics provided in the committee packet showing the applications received, licenses issued, applications pending and renewals processed since the beginning of the fiscal year. She discussed that these statistics are impacted by the vacancies that have not been filled due to the hiring freeze.

Mr. Brooks expressed concern regarding the hiring freeze considering the fact that the board does not use the general fund.

Ms. Herold discussed that despite being special funded, the board is not exempt to hiring freezes.

The committee discussed the impact on licensees as they are paying fees for services that are impacted by the hiring freeze.

No public comment was provided.

9. Workload and Processing Statistics

Discussion

Ms. Herold reviewed the following current application and mail processing times:

	<u>Applications</u>	<u>Incoming Mail</u>
Pharmacist Exam	14 days	5 days
Pharmacist Intern	5 days	4 days
Pharmacy Technician	55 days	16 days
Site Permits	20 – 60 days	20 days
Change of Permits	150 days	
DOBs	60 days	
Change of PIC	60 days	
Change of DRIC	40 days	

Ms. Herold discussed that these processing times were significantly impacted by the furloughs and the current hiring freeze. She indicated that exemption requests have been submitted; but, have not been acted on.

Licensing Manager Debbie Anderson reviewed the processing procedure. She stated that processing is done in batches and that managers will lend assistance for

processing times longer than 60 days. Ms. Anderson indicated that a quarterly inventory is conducted to ensure appropriate processing.

Mr. Brooks sought clarification regarding electronic submission of applications.

Ms. Anderson indicated that the department is in the development stages for this process. She discussed the BreEZe system and the extensive implementation process involved.

No public comment was provided.

10. Public Comment for Items Not on the Agenda

A member of the public discussed the prevalence of calculation errors. She suggested that a math component be considered as a CE subject.

Ms. Herold stated that this is a significant competency issue. She encouraged this activity be reported to the board.

Ms. Veale suggested that the board consider this topic during the board discussion on specific content areas for CE during the February 2011 Board Meeting.

The meeting was adjourned at 3:36p.m.