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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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

DATE: October 5, 2010

LOCATION: First Floor Hearing Room
Department of Consumer Affairs
Sacramento, CA 95834

BOARD MEMBERS PRESENT:

Greg Lippe, Chair
Kenneth Schell, PharmD
Deborah Veale, PharmD

BOARD MEMBERS ABSENT:

Ryan Brooks

STAFF PRESENT:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, Supervising Inspector
Carolyn Klein, Legislation and Regulations Manager
Kristy Schieldge, DCA Staff Counsel

Call to Order

Chair Lippe called the meeting to order at 1:35 p.m.

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

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.

At the April Board Meeting board staff were directed to (1) review and assess the three accreditation agencies seeking board approval as accrediting agencies for sterile injectable compounding

pharmacies, (2) bring staff's report to a future Licensing Committee Meeting, and (3) bring the committee's recommendations to the board for action at a future meeting.

The committee was advised that Joint Commission on Accreditation of Healthcare Organizations (JCAHO) was the only accreditation agency in attendance at the meeting.

Supervising Inspector Janice Dang provided background of the criteria used to evaluate the accreditation agencies as well as the findings of the random unannounced inspections completed by the board. Dr. Dang provided background information on JCAHO and how that organization performs its accreditation. Janice provided her findings on review of JCAHO's process as it relates to the board's criteria. She provided specific information on JCAHO's performance and expectations detailed in the board's criteria.

Mark Crafton, representing JCAHO provided an overview of their accreditation process and indicated that typically a survey can be conducted in 4-6 weeks of the opening on a new facility, but it depends on the nature of the change. If the services are being provided by a current accredited facility "original hospital," then the next inspection would be completed as part of the next regular triennial survey. JCAHO indicated that it depends of the services that are going to be provided at the new site and provided examples of when a new survey would not be required based upon their rules

Executive Officer Herold framed the issue for the committee members and provided background. Ms. Herold stated that JCAHO is already in the statute and as such evaluation of this agency is not necessarily required under existing law. Ms. Herold discussed the disparity between how our board regulates sterile injectable compounding pharmacy and sought clarification on how a new satellite pharmacy under common ownership with a pharmacy already accredited by JCAHO. Specifically Ms. Herold asked if JCAHO may extend an accreditation to a new satellite pharmacy if the services provided are similar to the already accredited hospital without doing an inspection. Mr. Crafton answered yes.

JCAHO indicated that they now perform a periodic performance review – similar to the board's self-assessment program. The results of this review are required to be filed with JCAHO. He also indicated that JCAHO completes a 5% random surveys annually as well as completes "for cause" survey where they believe the quality and safety is compromised.

Ms. Herold inquired if the committee feels that a pharmacist should participate in the JCAHO survey. The committee discussed the issue and spoke in support of this requirement.

Public Comment
Dr. Gray, representing Kaiser Permanente, stated that the committee may want to discuss how this requirement would be implemented if the hospital has a drug room in lieu of a pharmacy as well as seek clarification from JCAHO if it extends accreditation to a hospital licensed by California Department of Public Health.

Motion: Request that JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey.

M/S: Schell/Veale

Support: 2 Oppose: 0 Abstain: 1

2. Proposed Regulations to Modify Application Requirements for Intern Pharmacists, Pharmacy Technicians and Pharmacists to Require "Self-Query" Reports From the Healthcare Integrity and Protection Data Bank (HIPDB)

Chair Lippe stated that at the July Board Meeting, the board approved two proposals to (1.) require pharmacists and pharmacist interns and (2.) require pharmacy technicians to provide a "self query" report from the National Practitioners Data Bank-- Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as a condition of application for licensure in California. The process for pharmacy technicians will be discussed under the next agenda item.

The committee was advised that it is not unusual for a pharmacist applicant or intern to also be licensed in other jurisdictions. As part of the application process for both the intern and pharmacist exam applications, applicants are required to self-disclose several items. The intern application includes several questions surrounding whether prior disciplinary action has ever been taken in this state or any other. The pharmacist exam application includes several of the same types of questions as well as information about licensure in other states. This information is all self-certified by the applicant. In addition, the board requires license verification from any state where a pharmacist applicatn stateis he or she is also licensed.

Public Comment
Dr. Gray sought clarification on which exams this would apply to. Staff clarified that because the regulation references section 4200 of the Business and Professions Code, it would apply for the application for the CPJE and NAPLEX exam

Motion: Authorize the Executive Officer to initiate the rulemaking processes to adopt the language that has been proposed. (language below)

Amend Section 1728. Requirements for Examination.

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:
  (1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:
    (A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.
    (B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.
    (C) Experience in both community pharmacy and institutional pharmacy practice settings.
    (D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.
  (2) Satisfactory proof that the applicant graduated from a recognized school of pharmacy.
  (3) Fingerprints to obtain criminal history information from both the Department of Justice and the United States Federal Bureau of Investigation pursuant to Business and Professions Code section 144.
  (4) A signed copy of the examination security acknowledgment.
  (5) A sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application for examination as a pharmacist is submitted to the board.

(b) Applicants who hold or held a pharmacist license in another state shall provide a current license verification from each state in which the applicant holds or held a pharmacist license prior to being authorized by the boar to take the examinations.
(c) Applicants who graduated from a foreign school of pharmacy shall provide the board with satisfactory proof of certification by the Foreign Pharmacy Graduate Examination Committee prior to being authorized by the board to take the examinations.

Add section 1727.2 to 16 CCR:

Every applicant for a pharmacist intern license shall submit as part of the application process, a sealed, original Self Query Report from the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB), dated no earlier than 60 days before the date an application is submitted to the board.

M/S: Schell/Veale

Support: 3 Oppose: 0 Abstain: 0

3. Proposal to Initiate a Regulation Change To Update the Pharmacy Technician Application

Chair Lippe provided an overview of the issue. At the July Board Meeting, the board directed staff to make modifications to the pharmacy technician application that will reduce the number of deficiencies in submitted applications and to add a requirement that a "self query" report from the National Practitioners Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) be added as an application requirement.

Further, at the July Board Meeting, the board was advised that about 50 percent of the technician applications submitted to the board have one or more deficiencies. This slows the processing of the application and delays licensure for qualified applicants. Staff believes that the proposed modifications will help reduce processing time for applicants and ensure that those technicians disciplined by other states are known to the board before California issues a pharmacy technician application.

The committee requested clarification from board staff on the nature of the deficiencies and solutions being offered. Staff Manager Debi Mitchell highlighted some of the changes that are being incorporated into the revised form. She indicated that some of the changes being offered are to ensure consistent use of language between statute and regulation, e.g. "license" vs. "registration."

Ms. Herold also highlighted to committee members that the processing time on the application information will reflect a 60 day processing time.

The committee discussed the use of "registration" versus "license" and directed staff to ensure that all references should use the term "license."

Public Comment

Dr. Gray advised the committee that use of the term "licensee" has implications that the term "registration" does not. Specifically, in Division 2, a licensee is responsible for reporting requirements for elder and child abuse.

Motion: Authorize the executive officer take all steps necessary to initiate the rulemaking to update the application form and HIPDB self-query report as presented. (language below)

Amend 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

The application for a pharmacy technician license (Form 17A-5 (Rev. ~~9/94~~ 01/11)) required by this section is available from the Board of Pharmacy upon request.

(a) Each application for ~~registration as~~ a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.

(4) A sealed original Self-Query from the National Practitioner Data Bank -- Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is/has been submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within ~~30~~ 60 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in ~~Section 1749, subdivision (c)~~ subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, and 4400 Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, ~~and~~ 4202, 4207, 4402, and 4400 Business and Professions Code, Section 11105 of the Penal Code, and sections 1706.2. and 1793.6. of Title 16 of the California Code of Regulations.

M/S: Veale/Schell

Support: 3 Oppose: 0 Abstain: 0

(The application being incorporated by reference in this regulation is attached, following this meeting summary.)

4. Request from PETNET Solutions for a Waiver of Security Requirements for Pharmacies to Permit Afterhours Maintenance of Equipment Without a Pharmacist Present.

Josh Nutting, Pharm.D, representing PETNET Solutions provided background to the committee on the basis for their request. Specifically, PETNET was seeking a waiver of Business and Professions Code, Chapter 9, Division 2, Article 7, Section 4116(a) to allow personnel listed as Cyclotron Operator/Engineer on the Radioactive Material License access to the permitted space (pharmacy area) during non-operational hours without the presence of a pharmacist for the sole purpose of maintenance and repair of the cyclotron, automated synthesis equipment, and quality control testing equipment.

PETNET was also seeking a waiver to California Code of Regulations, Division 17, Title 16, Article 2, Section 1714(d) and (f) to allow the CO (Cyclotron Operator/Engineer) access to the permitted pharmacy space by issuing cipher lock combination numbers to the CO and to allow an applicant for a licensed premises or for a renewal of that license to certify that it meets the requirements of Section 1714 and to attach a copy of the waiver to the application, should the board grant a waiver, or comply with other actions as determined by the board.

Dr. Nutting stated that the longer the company waits to conduct the maintenance following a work day, the lower the radiation fields. Business operations need to run 24 hours a day and, since the pharmacy closes at 4 p.m., no pharmacy operations that occur from 4 p.m. to 10 p.m. Under current regulation, PetNet is required to have a pharmacist come in a sit for 4 hours in order to meet regulation requirements.

The committee sought clarification on the safeguards in place and was advised that some equipment could be locked up when the pharmacy was closed.

The committee was advised that the board does not have the authority to waive a statutory requirement. Ms. Herold offered that a possible solution would be a legislative change. Ms. Herold suggested that a narrowly drafted statutory change to Business and Professions Code section 4116, may allow PETNET to obtain the authorization it seeks. Ms. Herold indicated that should section 4116 be amended, the board could then consider the waiver request to California Code of Regulations Section 1714.

There was no additional committee discussion and no public comment.

5. <u>Discussion about a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas.</u>

Chair Lippe provided background on this issue. Specifically, the committee was advised that at several prior meetings of the board or its committees, including the last meeting of the Licensing Committee, there was general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. To establish such a requirement would take either a legislative or regulation change.

Pharmacists are required to earn 30 hours of approved continuing education credit every two years as a condition of renewal. Requirements for continuing education in both statute and regulation follow this page. Pharmacy technicians are not required to earn CE to maintain board licensure, although to be certified by the Pharmacy Technician Certification Board (a method to qualify for initial registration), they have a CE requirement

The committee discussed previous content required continue education as well as the requirements in other states that specify course content. Dr. Veale suggested that patient consultation may be one area to consider, especially given the board's efforts in improving patient safety.

Dr. Schell spoke in support of the concept. Dr. Schell indicated that coursework in ethics may be of value and that the board sees too many inventory issues that result in discipline and that this may also be appropriate.

Dr. Veale indicated that the committee needs to determine what the goal of the specific CE requirement – to respond to enforcement related issues or is it patient care issues.

Public Comment:
Steve Gray, representing Kaiser, and Lynn Rolston, representing CPhA, provided public comment. Dr. Gray indicated that there are chronic problems e.g. inventory diversion and prevention, as well as issues surrounding changes in law, e.g., quality assurance programs. Dr. Gray suggested that subject matter identified by the board to fill in gaps in education that can be evaluated periodically. He suggested that substance abuse, inventory management and disaster response could be ongoing. However issues such as compounding regulations, would not require ongoing CE, but perhaps on a short term to ensure pharmacists are educated on the changes in the law. Dr. Gray stated that the board may need to also specify that only live CE accredited by the board be acceptable.

Lynn Rolston indicated that continuing education offerings have changed and expanded the type of coursework that the board accepts, that it almost requires that certain topics need to be required by the board to ensure quality. She also spoke in support on in-person courses for specified courses. She spoke in support of the board requiring CE when a significant law changes e.g., compounding regulations.

Chair Lippe concluded that this issue requires further discussion and requested that the time be brought back to a future committee meeting.

There was no additional committee discussion or public comment.

6. Department of Consumer Affairs' Request that Health Care Boards Evaluate the Federal Healthcare Reform Act's Impact on Present and Future Licensees and their Licensing Acts

Ms. Herold indicated that in March, the Federal Health Care Reform Act was enacted federally and advised the committee that since that time, the director has asked that the board examine how it will affect how health care is delivered in California, particularly to prepare for larger number of patients.

Ms. Herold advised that committee that a presentation will be given to the board during the October Board Meeting to provide information on pharmacy-related issues.

There was no additional committee discussion and no public comment.

7. Competency Committee Report

Chair Lippe advised the committee that a quality assurance review of the CPJE was initiated on August 2, 2010. Mr. Lippe indicated that this process is done periodically to ensure the reliability of the CPJE examination. As of the date of this report, the quality assurance review has been completed and results have been released.

The committee was also advised that both Competency Committee workgroups met in August 2010 at the annual meeting to discuss examination development. Each Competency Committee workgroup will also meet once in the fall of 2010 for examination development. Each workgroup will ensure the new outline will be used to develop examinations administered after April 1, 2011.

There was no additional committee discussion and no public comment.

8. Licensing Statistics

The committee reviewed the licensing statistical report provided with the meeting materials.

Dr. Veale requested clarification on the number of pending exam applications and was advised that staff will better define what is included in the numbers presented in the report.

There was no additional committee discussion and no public comment.

9. Public Comments for Items Not on the Agenda

Eric Mahone requested clarification on the identification requirements established by the board for exam administration purposes. He suggested that the board consider the risk vs. benefit to a middle name not matching on the two required forms of identification required.

Staff counsel advised the committee that there could not be discussion on this item as it was not agendized, but encouraged Mr. Mahone to speak with the board's Executive Officer at the conclusion of the meeting.

There was no additional public comment.

The meeting was adjourned at 3:45 p.m.