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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE:	September 22, 2004
TIME:	9:30 a.m. – 12 noon
LOCATION:	Hilton Oakland Airport One Hegenberger Road Oakland, CA 94621
BOARD MEMBERS	Ruth Conroy, Pharm.D., Chair Clarence Hiura, Pharm.D. John, Tilley, RPh.
STAFF PRESENT:	Patricia Harris, Executive Officer Virginia Herold, Assistant Executive Officer Robert Ratcliff, Supervising Inspector Dennis Ming, Supervising Inspector Dana Winterrowd, Legal Counsel

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m. She explained that committee member Richard Benson was unable to attend the meeting.

Proposed Omnibus Legislative Changes for 2005

Chief of Legislation and Regulation Paul Riches explained the proposed omnibus legislative changes for 2005. He stated that sections 4005 and 4206 related to the Rules of Professional Conduct.

Section 4206 [formerly Section 4008.3] requires that each pharmacist sign off on the "rules of professional conduct" as part of their application. This requirement was established in 1959 and was subject to technical amendments in 1965 and 1971. However, this requirement has remained essentially unchanged since that date. Subdivision (c) Section 4005 [formerly Section 4008.2] authorizes the board to adopt these "rules of professional conduct" through the rulemaking process specified in the Administrative Procedures Act.

The current "rules of professional conduct" is a listing of selected regulation sections [1714, 1715.6, 1717, 1761, 1764, 1765, 1793.1] and a statement that the applicant agrees to abide by

these regulations. The statute appears to allow the board to establish "rules of professional conduct" above and beyond those included in the board's statutes and regulations. However, no such document has existed in the memory of any current board staff, which extends back over approximately 25 years.

This requirement provides no additional value for public protection, as the existing law requires the board's licensees to comply with the specified sections and all other applicable sections of the Pharmacy Law. Accordingly, staff is suggesting the repeal of Section 4206, and the relevant portion of Section 4005, to streamline the pharmacist licensure process.

Mr. Riches stated that the next proposed legislative change involves Section 4053. The existing section addresses the issuance of "certificates of exemption" to individuals handling dangerous drugs and dangerous devices in wholesale facilities. Senate Bill 1307 changes current board terminology to reflect usage in other states and names these individuals "designated representatives." The change proposed here makes the section easier to understand and makes no substantive change in law. The proposed language parallels other sections that authorize the issuance of a personal license.

The next proposed change affects section 4127.5. This section sets the fee for the issuance of a sterile compounding license. Existing board practice based on Section 4400 (a) is to exempt government owned and tribally owned pharmacies from this fee. The proposed amendment clarifies that this exemption applies to sterile compounding licenses as well.

Another proposed change would amend section 4025, which details the application requirements for hypodermic licenses. The proposed changes make minor technical changes to eliminate obsolete code section references.

The last proposed change would make technical amendments to section 4400. This section is the fee provisions and would make a range of changes as follows:

1. Eliminates an obsolete reference to medical device retailers.
2. Combines the application and issuance fee for exemptee licenses.
3. Eliminates the fee for approval as an accrediting entity for continuing education consistent with other proposals.
4. Eliminates the fee for the foreign graduate application consistent with other proposals.
5. Makes a number of other technical changes to the section.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed legislative changes as omnibus items for the 2005 Legislative Session.

Proposed Legislative Change to the Pharmacist License Renewal Process Related to the Continuing Education Requirement (Bus. & Prof. Code sec. 4231 and 4232)

Executive Officer Patricia Harris explained that in the course of reviewing the statutes and regulations governing continuing education (CE) for pharmacists, staff also reviewed existing board processes for license renewal related to continuing education. Based on this review, staff

suggested changes to the existing law. The first proposal changes the references to "pharmaceutical education" to "pharmacy education." The California Pharmacists Association (CPhA) requested this change along with numerous other changes to the existing CE regulations.

The second recommendation is to relocate to statute from regulation the board's authority to establish the current 30-hour continuing education requirement. It was explained that the current statute allows the board to set the number of CE hours required for renewal by regulation up to a maximum of 30 hours. Current board regulations specify the maximum 30 hours for renewal. Given this situation, there is no need for both statute and regulation to set the CE hour requirement.

The next proposed change is to modify the existing CE exemption from the first two years following graduation to the first renewal of a pharmacist license. It was discussed that the existing statute exempts recent graduates from complying the CE renewal requirement. Given that pharmacists moving to California from other states who graduated from pharmacy school more than two years ago must study for both the NAPLEX and the CPJE to become licensed, staff believes that such preparation for the exams should be given equal weight as 30 hours of CE. The revised language would exempt both recent graduates and those becoming licensed in California after graduation.

The last recommended change would specify that pharmacists who fail to provide proof of completed CE (currently proof is a signed statement attesting to completion) within 60 days of the renewal date will be issued an inactive license. It was explained that currently pharmacists who fail to certify their continuing education credits but do pay the renewal fee are unable to practice but have an uncertain license status. Their license is not delinquent (because the fee has been paid) and can remain in this uncertain status indefinitely. Their license is not subject to subsequent renewal. Existing law provides for an inactive pharmacist license, which prohibits the licensee from practicing but is subject to renewal. A pharmacist with an inactive license can reactivate that license at any time upon payment of the renewal fee and providing evidence of the required 30 hours of CE. Issuing an inactive license to these CE delinquencies will resolve the ambiguity of their license status and ease the administrative burden to the board for processing these renewals.

Concern was expressed that such a change may place an unfair burden to employers because a pharmacist with an "inactive" license would not be allowed to practice. It was noted that pursuant to current law, pharmacists who fail to certify their CE, couldn't legally practice now.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed legislative changes relating to the continuing education requirements for the renewal of a pharmacist license.

Proposed Regulation Change to Implement SB 1913 Related to the Foreign Pharmacy School Graduates and the Certification Process by the Foreign Pharmacy Graduate Examination Committee (CCR, title 16, sec. 1720.1)

Licensing Program Manager Anne Sodergren explained that Section 4200 (a)(2)(B) requires an applicant for licensure as a pharmacist who has graduated from a foreign pharmacy school to, among other things, receive a grade satisfactory to the board on an examination designed to measure equivalency. She stated that SB 1913, if enacted, would require a graduate from a foreign pharmacy school to obtain full certification from the Foreign Pharmacy Graduate Examination Committee (FPGEC). This certification is designed to assess the educational equivalence of foreign pharmacy graduates. Forty-six states currently require FPGEC certification. She stated that the certification requirements include:

- Graduation from a pharmacy program that requires at least a four-year curriculum if education was completed prior to January 1, 2003, or a five-year curriculum after January 2003. An evaluation of the academic program is complete to ascertain whether it meets certain minimum criteria of length and content.
- Proof of licensure in the country the candidate earned the pharmacy degree.
- Passing scores on the Foreign Pharmacist Graduate Equivalency Examination, Test of Spoken English (50, the same as the board's requirement) and Test of English as a Foreign Language.

As a result of this change, the board will no longer require the submission of a foreign graduate application for the evaluation of foreign transcripts.

To ensure consistency with the statutory changes, staff is proposing an amendment to CCR 1720.1. The proposed amendment clarifies that the certification obtained by the FPGEC satisfies the educational requirements detailed in B & P Code section 4200.

She explained that a letter will be sent to those individuals with a foreign graduate application on file who are not licensed as a pharmacist, notifying them of these changes that will take effect January 1, 2005.

The Licensing Committee recommended that the Board of Pharmacy amend CCR, title 16. sec. 1720.1.

Proposed Regulation Change to Implement SB 1913 Related to the Application Process for the Pharmacist Licensure Examination and Intern Experience Requirements (CCR, title 16, sec. 1728)

Ms. Sodergren explained that as part of the board's ongoing efforts to streamline application requirements, a number of changes to the intern pharmacist program have been pursued. Section 4209 is a new section that will be added to statute detailing the intern requirements an applicant must satisfy before applying for the pharmacist licensure examinations. (This was done via SB 1913). This statute in part moves the intern requirements previously listed in the board's regulation CCR 1728.

To clarify the specific intern requirements, staff is proposing amendments to section 1728. The proposed amendments detail the examination and intern requirements. She stated that the changes being proposed are:

- Remove the first year maximum cap on intern hours, (currently 250 hours).
- Remove the seven required areas of experience listed and instead require that the experience satisfy the requirements for the introductory and advanced pharmacy practice experienced established by the ACPE.
- Require proof that the applicant gradated from a recognized school of pharmacy.
- Require both a state and federal criminal history.

To implement these proposed changes, staff will be revising its application procedures and affidavits.

The Licensing Committee recommended that the Board of Pharmacy amend CCR, title 16. sec. 1728.

Proposed Omnibus Regulation Changes to Implement SB 1913 and Update of the Licensing Requirements

Ms. Harris reported that Senate Bill 1913 and the adoption of the NAPLEX requires the board to alter existing regulations relating to the pharmacist licensing process to reflect the new statutes and to streamline board operations. She provided an overview of the proposed regulation language developed by staff to update board regulations. Although a number of the changes are substantive, many are minor or technical.

Section 1706.2 – This amendment relocates existing provisions for the abandonment of applications by pharmacist applicants into this one section. It adds a new provision that will require an individual to take the pharmacist licensure examination(s) within one year of being deemed eligible and will require licensure as a pharmacist within one year of passing the examination. Currently an applicant has two years to become licensed.

Section 1719 – This section recognizes schools of pharmacy that are accredited by or granted candidate status by the ACPE, which is a change that was previously approved by the board. The provisions relating to foreign graduates have been eliminated because of SB 1913, which requires all foreign graduates must be FPGEC certified which includes the existing requirements.

Section 1720 – This section is changed to reflect the current exam structure.

Section 1725 – This section is changed to conform to Section 1719.

Section 1726 – This section is changed to eliminate reference to "preceptor." Preceptor is no longer a relevant term as interns may be supervised by any pharmacist in good standing.

Section 1727 – This section is repealed. Similar provisions have been added to the Business and Professions Code (SB 1913).

Section 1749 – This section is amended to make numerous technical changes. The amendments also include the elimination of the foreign graduate application fee consistent with the changes

made to foreign graduate licensing requirements. The amendments also eliminate the fee for registering continuing education accreditation entities to be consistent with changes proposed for continuing education regulations.

Section 1750 – This section is repealed as the underlying statute was repealed in 2003.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed omnibus regulation changes to implement SB 1913.

Proposed Regulation Change to Update the Continuing Education (CE) Provisions (CCR, title 16, sec. 1732 – 1732.7)

Mr. Riches reported that at the July meeting, the board approved the recommended changes to the CE regulations as proposed by the California Pharmacists Association (CPhA). CPhA provided the board with suggested amendments to these regulations to update terminology used by the continuing education community. When he went to notice the regulation changes for hearing, Mr. Riches noted that the regulation had not been updated for over 10 years. He then proceeded to draft amendments that included the CPhA amendments, a reorganization of the law and clean up of the existing language. While the changes represent a substantial reorganization of the existing regulatory provisions, Mr. Riches reported that there were a relatively few changes in the substance of the regulations. The draft provided to the committee was footnoted to indicate the location of existing provisions that were moved and to note those provisions that were altered or eliminated.

The Licensing Committee recommended that the Board of Pharmacy approve the proposed amendments to the continuing education regulations.

Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Pharmacists Jurisprudence Examination (CPJE) – Status on the Restructuring of the Competency Committee

Assistant Executive Officer Virginia Herold reported that the board transitioned to the new examination structure in January 2004. The board began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. She stated that as of September 1, 2004, 2,303 applications have been received to take the California license exams and 108 of these are retake applications. She also stated that 745 individuals have become licensed as pharmacists since mid-June. A total of 1,838 individuals have been made eligible to take the licensure examinations and 94 individuals have also been requalified to take the exams (they failed one of the exams, and had to requalify). The board has also verified 1,368 individuals as qualified to take the NAPLEX for California to the NABP (and this includes score transfers). The board has administered 1,299 CPJE examinations. The board has performed 17 regrades of the CPJE, which resulted in no change in the score. The CPJE's pass rate is 86 percent.

Ms. Herold explained that there are three ways that an individual may provide a NAPLEX score to the California Board of Pharmacy:

1. The individual becomes qualified by California as eligible to take the pharmacist licensure examinations, with California as the primary state.
2. The individual becomes qualified in another state to take the pharmacist licensure examination, but designates California as a "score transfer" state -- before he or she takes the NAPLEX. Then once California qualifies the individual as eligible to take the licensure examinations here, the NABP will transfer the score to the board.
3. The individual qualifies for the NAPLEX examination in another state and becomes licensed there. Later, at some point, the individual wants to become licensed in California. In some states, the state where the individual is licensed is willing to "assign" the NAPLEX score to California via a process the NABP calls "license transfer" (however, the applicant still needs to fulfill all other requirements for licensure in CA, including passing the CPJE).

Since January, the board has been using options 1 and 2 to obtain NAPLEX scores for eligible candidates. She stated that NABP recently survey all other states regarding option 3 and their willingness to accept a NAPLEX score from California, after an individual is licensed here. The NABP calls this "License Transfer" or "assignment of a score by licensure." Thirty states responded and not all these states indicated that they are willing to do this. The states willing to accept an "assignment of NAPLEX score" from California are: AK, DE, FL, HI, IL, KS, MN, MO, NE, NH, NY, ND, OH, OR, SD, TN, TX, VA, WI. The states that replied "no" are: AZ, AR, GA, ID, LA, MD, NV, PA, WA and WY.

Those that answered yes indicated that they would accept the NAPLEX score earned after 1/1/04 for a pharmacist licensed in California – and they would allow a score earned in their state to be used by California for purposes of licensure. In such cases, these candidates would not need to retake the NAPLEX if they want to become licensed in the other state, although there may be other requirements for licensure (in California, the individual would still need to pass the CPJE if the NAPLEX score was earned after 1/1/04 and transferred here by an agreeable state).

For those states that answered no, there would be no sharing of NAPLEX scores unless a score transfer (option 2) was requested before the individual took the NAPLEX. Instead these candidates would need to retake the NAPLEX.

For those 19 states that didn't respond, the NABP and the board do not know whether NAPLEX scores could be transferred after licensure in one state to another state.

Ms. Herold discussed the status of restructuring the Competency Committee. She stated that the Competency Committee develops and scores the CPJE. At the April Board Meeting, the board agreed with a Licensing Committee recommendation to restructure the Competency Committee into a two-tier structure – a core committee and a group of item writers.

The item writers would develop questions for the examination, and the core committee would select items and refine them for the examination, select cut scores and oversee issues arising from administration of the examination.

The board is now seeking to identify new members for the two committees. In the next board newsletter, the board will seek nominations from interested pharmacists to serve in either capacity.

The board's president will appoint members to the committees. To apply for appointment, an applicant needs to submit one CV/resume and three letters of reference. This material needs to be submitted to the board (Competency Committee Appointments, Board of Pharmacy, 400 R Street, Suite 4070, Sacramento, CA 95814).

The new committee structure should be in place early next year.

Ms. Herold reported that the National Association of Boards of Pharmacy periodically seeks item writers for the NAPLEX examination. The board is interested in forwarding to the NABP the names of individuals interested in serving as NAPLEX item writers. The NABP selects its item writers. She indicated that this would be discussed in the board's next newsletter as well.

Ms. Herold concluded her report by explaining that the board is required to perform a job analysis of the pharmacist profession every three to five years, to maintain the validity of the licensure examination. The Department of Consumer Affairs recommends that a job analysis be conducted every five years. The job analysis identifies the skills, frequency and importance of tasks performed by pharmacists. From these skill statements, the Competency Committee develops a content outline for the examination. All questions for the examination are developed according to this outline.

The board last conducted a job analysis in 1999, so it is now time to conduct a new evaluation. In November, approximately 2,000 pharmacists will be sent questionnaires that include a number of task statements.

The pharmacists surveyed by the board will be asked to identify the tasks that they perform, and the frequency and the importance of the tasks. The responses are confidential and will be compiled by the board's examination consultant. The board will use a system it has used in the past to provide CE credit to those who complete the analysis while maintaining the respondent's confidentiality.

A new content outline should be in place by February or March 2005, and all test items administered by mid-2005 will correspond to the new content outline. Before the new content outline will be implemented, it will be released publicly so that candidates can prepare for the examination. The board's CPJE content outline will not include tasks tested by NAPLEX; these tasks will be removed via analysis of the NAPLEX content outline.

Discussion on How the Board of Pharmacy Can Improve and Facilitate Communications with the Public and Licensees

At the board's July meeting, President Goldenberg stated that one of the priorities for his term is to improve the communication of the board with its licensees and with the public. To this end,

each of the board's committees will hold a public meeting before the October board meeting with this topic listed as a discussed item. The goal is to establish a dialogue with the stakeholders on improving communication, and to bring these to the next board meeting. The committee was provided with a copy of the memorandum that was prepared by the Assistant Executive Officer for the Communication and Public Education Committee. This document provided an overview of the several broad based means of communication that the board has with the public and its licensees.

There was general discussion suggesting ways to increase attendance and participation at board meetings. Such suggestions included holding the board meetings in the evening, to host town hall meetings with the local associations and at health fairs. It was also suggested that the Board President send out personal invitations to the schools of pharmacy and association chapters that are near the board meeting location.

Report on Staff Discussions with the Board of Corrections Regarding Pharmacy Services in City and County Jails and Juvenile Facilities

Supervising Inspector Robert Ratcliff reported that Virginia Herold, Paul Riches and he met with representatives from the Board of Corrections last month regarding the regulation of pharmacy practice in city and county jails and juvenile facilities.

The meeting was held at request of the Board of Corrections and its purpose was to clarify the board's requirements for these facilities. They also discussed CCR, title 15, which contain the minimum standards for local adult and juvenile detention facilities. While these standards are in regulation, the standards are only guidelines.

It was discussed that there are about 50 – 60 Board of Corrections employees that oversight the jails and juvenile facilities, which includes 25 surveyors, five of which survey local detention facilities. The surveyors work with the local health officers who inspect the facilities including pharmacy services and prepare a required annual report. Statewide there are approximately 450 jails and 120 juvenile facilities. These vary in size from very small city facilities to quite large county facilities (jail wards in the counties of Los Angeles, Orange, San Francisco, San Joaquin, San Diego, Contra Costa, and Alameda). Based on board licensing statistics it would appear that most of these facilities, except for the county facilities, are not licensed. It appears that all the facilities, regardless of size, need or provide pharmacy services. Pharmacy services vary from on-site, to mail order, to using a community pharmacy.

Based on this meeting, there appears to be gaps in the law as to the regulation of pharmacy services in these facilities. The board will continue to meet with the Board of Corrections to address these regulatory gaps.

Adjournment

Licensing Committee Chair Ruth Conroy adjourned the meeting at 11:45 a.m.