



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
Arnold Schwarzenegger, GOVERNOR

Licensing Committee Report

Ruth Conroy, Pharm.D., Chair
Clarence Hiura, Pharm.D.
John Tilley, R.Ph.
Richard Benson, Public Board Member

Report of September 22, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy approve the proposed legislative changes as omnibus items for the 2005 legislative session.

Discussion

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.

Another 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.

(Attachment A)

RECOMMENDATION 2

That the Board of Pharmacy approve the proposed legislative changes relating to the continuing education (CE) requirements for the renewal of a pharmacist license.

Discussion

The California Pharmacists Association (CPhA) requested that the statute be amended to change the term “pharmaceutical” to “pharmacy” education throughout the statute and regulation.

The second change is to relocate to statute from regulation the board’s authority to establish the current 30-hour continuing education requirement. 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. 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. 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 under existing law, pharmacists who fail to certify their CE, cannot legally practice now.

(Attachment B)

RECOMMENDATION 3

That the Board of Pharmacy approve the proposed change to CCR, title 16, sec. 1720.1 to implement SB 1913 related to foreign pharmacy school graduates.

Discussion

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. Since the Governor has signed SB 1913, it requires 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. 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, the board needs to amend 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.

A letter will be sent to those individuals with a foreign graduate application on file who currently are not licensed as a pharmacist, notifying them of these changes that will take effect January 1, 2005. (**Attachment C**)

RECOMMENDATION 4

That the Board of Pharmacy approve the proposed change to CCR, title 16, sec. 1728 related to the application process for the pharmacist license examination and the internship requirements.

Discussion

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, amendments are being proposed that:

- 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 graduated 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. (**Attachment D**)

RECOMMENDATION 5

That the Board of Pharmacy approve the proposed omnibus regulation changes to implement SB 1913 and update of licensing requirements.

Discussion

Senate Bill 1913 (Chapter 695, Statutes of 2004) 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. 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.
(Attachment E)

RECOMMENDATION 6

That the Board of Pharmacy approve the proposed changes to the continuing education (CE) regulations.

Discussion

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. One reason for this request was that in January 2004, the activities of the Accreditation Evaluation Service (AES) moved from the California Pharmacists Association (CPhA) to the CPhA Educational Foundation. In addition the following changes were included:

- Change the term “continuing pharmaceutical education” to “continuing pharmacy education”
- Change AES from a “continuing education provider and coursework review component of the California Pharmacists Association” to “the accreditation agency for providers of continuing pharmacy education in California”
- Change the role of AES and ACPE from “approvers” to “accreditors”

- Change the ownership AES to the CPhA Educational Foundation
- Change the language from “organization” to “accreditation agency”
- Change the review/audit requirement 10%
- Change the term “certificates of completion” to “statements of credit”
- Require the provider to furnish the “statement of credit” to participants who complete the requirements for course completion
- Require that the material be current in order for it to be considered valid CE

Upon further review of the CE regulations, it was noted they had not been updated for over 10 years. Therefore, the draft amendments include 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, there are a relatively few changes in the substance of the regulations. The draft is footnoted to indicate the location of existing provisions that were moved and to note those provisions that were altered or eliminated. **(Attachment F)**

NO ACTION

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

The board transitioned to the new examination structure in January 2004 and began administering the California Pharmacist Jurisprudence Examination (CPJE) in March 2004. As of September 1, 2004, 2,303 applications had been received to take the California license exams and 108 of these are retake applications. Since mid-June, 745 individuals have become licensed as pharmacists. 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.

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.

At its April meeting, the board approved the restructuring the Competency Committee. This committee develops and scores the CPJE. The committee will be restructured 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.

The National Association of Boards of Pharmacy also 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. This will also be discussed in the board's next newsletter as well.

Report on the Workgroup on Compounding

Last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues. The workgroup held its third meeting September 22, 2004. At this meeting, the workgroup discussed and provided comments on a draft proposal on general compounding. The proposal establishes a regulatory framework for general compounding by a pharmacy. The workgroup and other interested parties were asked to provide comments by November 1, 2004. **(Attachment G)**

Meeting Summary of September 22, 2004 (Attachment H)

Competency Committee Report – Job Analysis Survey (Attachment I)

Quarterly Status Report on Committee Strategic Objectives for 2004/05 (Attachment J)

ATTACHMENT A

Memorandum

To: Licensing Committee

Date: September 8, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Omnibus Items for 2005

Sections 4005 and 4206 – 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 (a copy of this document is attached for your reference). 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.

Section 4053 -- Exemtees

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.

Section 4127.5 – Fee Exemption

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.

Section 4205 -- Hypodermic Permits

This section details the application requirements for hypodermic licenses. The proposed changes make minor technical changes to eliminate obsolete code section references.

Section 4400 – Fee Provisions

The proposed amendments to Section 4400 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.

Section 4005 of the Business and Professions Code is amended to read:

4005. (a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public. Included therein shall be the right to adopt rules and regulations as follows: for the proper and more effective enforcement and administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of persons and establishments licensed under this chapter; pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed; providing for standards of minimum equipment for establishments licensed under this chapter; and pertaining to the sale of drugs by or through any mechanical device.

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

~~(c) The board may, by rule or regulation, adopt, amend, or repeal rules of professional conduct appropriate to the establishment and maintenance of a high standard of integrity and dignity in the profession. Every person who holds a license issued by the board shall be governed and controlled by the rules of professional conduct adopted by the board.~~

~~(d)~~ The adoption, amendment, or repeal by the board of these or any other board rules or regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

Section 4206 of the Business and Professions Code is repealed.

~~4206. The rules of professional conduct adopted by the board shall be printed as a part of the application for licenses and every applicant shall subscribe thereto when making an application.~~

Section 4053 of the Business and Professions Code is amended to read:

4053. (a) ~~Subdivision (a) of Section 4051 shall not apply to a veterinary food-animal drug retailer or wholesaler that employs a~~ Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall adequately safeguard and protect the public health and safety in the handling, storage and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer., ~~nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).~~

(b) An individual may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

- (1) He or she shall be a high school graduate or possess a general education development equivalent.
- (2) He or she shall have a minimum of one year of paid work experience, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
- (3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
 - (A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
 - (B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
 - (C) Knowledge and understanding of quality control systems.
 - (D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
 - (E) Knowledge and understanding of prescription terminology, abbreviations, dosages and format.
- (4) The board may, by regulation, require training programs to include additional material.
- (5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.

(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.

(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.

(e) This section shall become operative on January 1, 2006.

(f) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

Section 4127.5 of the Business and Professions Code is amended to read:

4127.5. The fee for the issuance of a non-governmental license, or renewal of a license, to compound sterile drug products shall be five hundred dollars (\$500) and may be increased to six hundred dollars (\$600).

Section 4205 of the Business and Professions Code is amended to read:

4205. (a) A license issued pursuant to Section 4110, 4120, ~~4130~~, 4160, or 4161 shall be considered a license within the meaning of Section 4141.

(b) The board may, in its discretion, issue a license to any person authorizing the sale and dispensing of hypodermic syringes and needles for animal use. ~~use for animals and poultry.~~

(c) The application for a license shall be made in writing on a form to be furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of ~~this article~~ Article 9 of this chapter.

(d) A separate license shall be required for each of the premises of any person who sells or dispenses hypodermic syringes or needles at more than one location.

(e) A license shall be renewed annually and shall not be transferable.

(f) The board may deny, revoke, or suspend any license issued pursuant to this article for any violation of this chapter.

Amend Section 4400 of the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

- (a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400).
- (b) The fee for a nongovernmental pharmacy ~~or medical device retailer~~ annual renewal shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250).
- (c) The fee for the pharmacist application and examination shall be one hundred fifty-five dollars (\$155) and may be increased to one hundred eighty-five dollars (\$185).
- (d) The fee for regrading an examination shall be seventy-five dollars (\$75) and may be increased to eighty-five dollars (\$85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars (\$115) and may be increased to one hundred fifty dollars (\$150).
- (f) The fee for a non-governmental wholesaler license and annual renewal shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- (g) The fee for a hypodermic license and renewal shall be ninety dollars (\$90) and may be increased to one hundred twenty-five dollars (\$125).
- (h) ~~The fee for application and investigation for an exemptee license under Section 4053 shall be seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars (\$100).~~
- (1) The fee for the application, investigation and issuance of a license as a designated representative pursuant to Section 4053 shall be one-hundred eighty-five dollars (\$185) and may be increased to two-hundred fifty dollars (\$250). If the applicant is not issued a license as a designated representative, the board shall refund seventy-five dollars (\$75) of the fee.
- (2) The fee for the annual renewal of a license as a designated representative shall be one-hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150).
- ~~(i) The fee for an exemptee license and annual renewal under Section 4053 shall be one hundred ten dollars (\$110) and may be increased to one hundred fifty dollars (\$150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars (\$150), for renewal one hundred ten dollars (\$110), which may be increased to one hundred fifty dollars (\$150), and for filing a late renewal fifty five dollars (\$55).~~
- (1) The fee for the application, investigation and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be two-hundred fifty dollars (\$250). If the applicant is not issued a license as a designated representative, the board shall refund one-hundred dollars (\$100) of the fee.
- (2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one-hundred fifty dollars (\$150).
- (j) The fee for an out-of-state drug distributor's license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars (\$550) and may be increased to six hundred dollars (\$600).
- ~~(k) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).~~

~~(l)~~ The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

~~(m)~~ The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars (\$165) and may be increased to one hundred seventy-five dollars (\$175).

~~(n)~~

~~(l)~~ The fee for an intern pharmacist license ~~or extension~~ shall be sixty-five dollars (\$65) and may be increased to seventy-five dollars (\$75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars (\$20).

~~(o)~~ ~~(m)~~ The board may, ~~by regulation, provide for the waiver~~ waive or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next ~~succeeding~~-regular renewal date.

~~(p)~~ ~~(n)~~ The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars (\$30).

~~(q)~~ ~~(o)~~ The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars (\$60) and may be increased to one hundred dollars (\$100).

~~(r)~~ ~~(p)~~ It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

~~(s)~~ ~~(q)~~ The fee for any applicant for a non-governmental clinic permit is three hundred forty dollars (\$340) and may be increased to four hundred dollars (\$400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars (\$175) and may be increased to two hundred fifty dollars (\$250) for each permit.

~~(t)~~ ~~(r)~~ The board shall charge a fee for the processing and issuance of a license registration to a pharmacy technician and a separate fee for the biennial renewal of the license registration. The ~~registration~~ license fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50). The biennial renewal fee shall be twenty-five dollars (\$25) and may be increased to fifty dollars (\$50).

~~(u)~~ ~~(s)~~ The fee for a veterinary food-animal drug retailer license shall be four hundred dollars (\$400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars (\$250).

~~(v)~~ ~~(t)~~ The fee for issuance of a retired pharmacist license pursuant to Section 4200.5 shall be thirty dollars (\$30).



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RULES OF PROFESSIONAL CONDUCT
(Please Sign and Return to the Board)

1714 OPERATIONAL STANDARDS AND SECURITY

- (d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

1715.6 REPORTING DRUG LOSS

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

1717. PHARMACEUTICAL PRACTICE

- (a) No medication shall be dispensed on prescription except in a new container which conforms with standards established in the official compendia.
Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-liquid oral products in a clean multiple-drug patient medication package (patient med pak), provided (1) a patient med pak is reused only for the same patient; (2) no more than a one-month supply is dispensed at one time; and (3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
- (b) In addition to the requirements of section 4040, Business and Professions Code, the following information shall be maintained for each prescription on file and shall be readily retrievable:
 - (1) The date dispensed, and the name or initials of the dispensing pharmacist. All prescriptions filled or refilled by an intern pharmacist must also be initialed by the preceptor before they are dispensed.
 - (2) The brand name of the drug or device; or if a generic drug is dispensed, the distributor's name which appears on the commercial package label; and
 - (3) If a prescription for a drug or device is refilled, a record of each refill, quantity dispensed, if different, and the initials or name of the dispensing pharmacist.
 - (4) A new prescription must be created if there is a change in the drug, strength, prescriber or directions for use, unless a complete record of all such changes is otherwise maintained.
- (c) Promptly upon receipt of an orally transmitted prescription, the pharmacist shall reduce it to writing, and initial it, and identify it as an orally transmitted prescription. If the prescription is then dispensed by another pharmacist, the dispensing pharmacist shall also initial the prescription to identify him or herself.
All orally transmitted prescriptions shall be received and transcribed by a pharmacist prior to compounding, filling, dispensing or furnishing.
Chart orders as defined in section 4019 of the Business and Professions Code are not subject to the provisions of the subsection.
- (d) A pharmacist may furnish a drug or device pursuant to a written or oral order from a prescriber licensed in the State other than California in accordance with Business and Professions Code section 4005.
- (e) No licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.
However, a licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by a

patient or at the hospital, institution, medical office or clinic at which the patient is present. The Board may in its sole discretion waive this application of the regulation for good cause shown.

- (f) A pharmacist may transfer a prescription for Schedule III, IV, or V controlled substances to another pharmacy for refill purposes in accordance with Title 21, Code of Federal Regulations, Section 1306.26.

Prescriptions for other dangerous drugs which are not controlled substances may also be transferred by direct communication between pharmacists or by the receiving pharmacist's access to prescriptions or electronic files that have been created or verified by a pharmacist at the transferring pharmacy. The receiving pharmacist shall create a written prescription, identifying it as a transferred prescription; and record the date of transfer and the original prescription number. When a prescription transfer is accomplished via direct access by the receiving pharmacist, the receiving pharmacist shall notify the transferring pharmacy of the transfer. A pharmacist at the transferring pharmacy shall then assure that there is a record of the prescription as having been transferred, and the date of transfer. Each pharmacy shall maintain inventory accountability and pharmacist accountability and dispense in accordance with the provisions of Section 1716.

Information maintained by each pharmacy shall at least include:

- (1) Identification of pharmacist(s) transferring information;
 - (2) Name and identification code or address of the pharmacy from which the prescription was received or to which the prescription was transferred, as appropriate;
 - (3) Original date and last dispensing date;
 - (4) Number of refills and date originally authorized;
 - (5) Number of refills remaining but not dispensed;
 - (6) Number of refills transferred.
- (g) The pharmacy must have written procedures that identify each individual pharmacist responsible for the filling of a prescription and a corresponding entry of information into an automated data processing system, or a manual record system, and the pharmacist shall create in his/her handwriting or through hand-initialing a record of such filling, not later than the beginning of the pharmacy's next operating day. Such record shall be maintained for at least three years.

1761. ERRONEOUS OR UNCERTAIN PRESCRIPTIONS

- (a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity, or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription.
- (b) Even after conferring with the prescriber, a pharmacist shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know that said prescription was not issued for a legitimate medical purpose.

1764. UNAUTHORIZED DISCLOSURE OF PRESCRIPTIONS

No pharmacist shall exhibit, discuss, or reveal the contents of any prescription, therapeutic effect thereof, the nature, extent, or degree of illness suffered by any patient or medical information furnished by the prescriber with any person other than the patient or his or her authorized representative, the prescriber or other licensed practitioner then caring for the patient, another licensed pharmacist serving the patient, or a person duly authorized by law to receive such information.

1765. COMMISSIONS, GRATUITIES, REBATES

An unlawful commission, gratuity or rebate prescribed by this article and Business and Professions Code Section 650 includes the rendering by a pharmacist or pharmacy of consultant pharmaceutical services such as those required pursuant to Title 22, Division 5, Chapters 3 and 4 (skilled nursing facilities and intermediate care facilities) to a licensed health care facility for no cost, nominal cost, or below reasonable cost, if that pharmacist or pharmacy obtains patients, clients or customers and/or their prescription order from that licensed facility or entity.

The determination of the value of consultant pharmaceutical services rendered shall include, but not be limited to, the value of all goods and services furnished by the pharmacist or pharmacy to a licensed health care facility.

1793.1 DUTIES OF A REGISTERED PHARMACIST

Only a registered pharmacist, or an intern pharmacist acting under the supervision of a registered pharmacist, may:

- (a) Receive a new prescription order orally from a prescriber or other person authorized by law.
- (b) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.
- (c) Identify, evaluate and interpret a prescription.
- (d) Interpret the clinical data in a patient medication record system or patient chart.
- (e) Consult with any prescriber, nurse or other health care professional or authorized agent thereof.
- (f) Supervise the packaging of drugs and check the packaging procedure and product upon completion.
- (g) Be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.
- (h) Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.
- (i) Perform all functions which require professional judgement.

I hereby agree to abide by the Rules of Professional Conduct as they may, from time to time, be revised by the California State Board of Pharmacy.

Print Name of Applicant _____

Signature of Applicant _____ **Date** _____

ATTACHMENT B

Memorandum

To: Licensing Committee

Date: September 8, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Continuing Education Legislation

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. The proposed changes attached to this memo are the product of that review. The proposal makes the following substantial changes to existing law:

1. Change references to “pharmaceutical education” to “pharmacy education.”

Discussion: This change was requested by CPhA along with numerous changes to existing CE regulations being discussed at this meeting.

2. Eliminate the board’s authority to establish the continuing education required by regulation and establish the current 30 hour continuing education requirement in statute.

Discussion: 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 hours requirement.

3. Modify the existing CE exemption from the first two years following graduation to the first renewal of a pharmacist license.

Discussion: 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 substantially after graduation.

4. Specifies 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.

Discussion: 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 reactive 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.

Section 4231 of the Business and Professions Code is amended to read:

4231. (a) The board shall not renew a pharmacist license issue any renewal certificate unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy pharmaceutical education during the two years preceding the application for renewal. The continuing education required by this article shall consist of the number of clock hours, not to exceed 30 clock hours, designated by regulation adopted by the board. This section shall not apply to licensees during the first two years immediately following their graduation from a college of pharmacy or department of pharmacy of a university recognized by the board.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education within 60 days of the license expiration date, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by complying with Section 704 of the Business and Professions Code.

Section 4232 of the Business and Professions Code is amended to read:

4232. (a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional pharmaceutical pharmacy education.

(b) The subject matter shall be pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state.

(c) The subject matter of the courses may include, but shall not be limited to, the following: pharmacology, biochemistry, physiology, pharmaceutical chemistry, pharmacy administration, pharmacy jurisprudence, public health and communicable diseases, professional practice management, anatomy, histology, and any other subject matter as represented in curricula of accredited colleges of pharmacy.

ATTACHMENT C

Memorandum

To: Licensing Committee

Date: October 6, 2004

From: Anne Sodergren
Board of Pharmacy

Subject: Proposed Regulation Changes to Implement SB 1913 – Foreign Pharmacy Graduate Requirements

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. SB 1913, currently on the governor's desk, if enacted a graduate from a foreign pharmacy school will be required 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.

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 or complete evaluations of foreign transcripts.

To ensure consistency with the statutory changes, the board is proposing the attached amendment to CCR 1720.1. The proposed amendment clarifies that the certification obtained by the FPGEC satisfies the educational requirements detailed in Section 4200.

The board is preparing a letter to those with a foreign graduate application on file who have not yet been licensed as a pharmacist, notifying them of these changes that will take effect January 1, 2005.

§1720.1. Graduates of Foreign Pharmacy Schools.

Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate Examination Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a).

~~(a) Each applicant for admission to the pharmacist licensure examination, whose eligibility is based upon the provisions of Business & Professions Code section 4200(a)(2)(B), shall be required to demonstrate that the education obtained at the foreign school is equivalent to that required of domestic graduates by receiving a grade satisfactory to the board on the Foreign Pharmacy Equivalency Examination administered by the National Association of Boards of Pharmacy:~~

~~(b) Each applicant for admission to the pharmacist licensure examination whose collegiate study was in a foreign country shall provide transcripts and other reference material sufficient for the board to evaluate an applicant's collegiate equivalency pursuant to Business and Professions Code section 4200(a)(3). If the applicant cannot provide documents sufficient to determine collegiate equivalency, the board may accept the findings of a foreign credentials evaluation service. This service shall be required at the discretion of the board and may include authentication, translation and or evaluation of such documents as deemed necessary by the board. Any costs for the review shall be paid directly to the evaluation service by the applicant.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Section Sections 851 and 4200, Business and Professions Code.

ATTACHMENT D

Memorandum

To: Licensing Committee

Date: October 6, 2004

From: Anne Sodergren
Board of Pharmacy

Subject: Proposed Regulation Changes to Implement SB 1913 – Application Process for the Pharmacist Licensure Examination and Intern Experience Requirements

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 added to statute detailing the intern requirements an applicant must satisfy before applying for the pharmacist licensure examinations. This statute in part moves the intern requirements previously only listed in the board's regulation CCR 1728.

To clarify the specific intern requirements, the board is proposing the attached amendment to CCR 1728. The proposed amendments change the intent of the regulation from listing intern requirements to also detailing requirements for the examination.

Specifically the following changes are made:

- 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 graduated from a recognized school of pharmacy.
- Require both a state and federal criminal history.

To implement these changes, the board is revising procedures and affidavits.

§1728. Intern Experience==Requirements for Examination, Licensure:

(a) ~~Minimum Hours: All intern pharmacists must complete 1,500 hours of experience as a prerequisite to licensure:~~

~~(1) First Year Maximum: A maximum of 250 of the 1,500 hours may be obtained during the first year of pharmacy education in a program sponsored by a school of pharmacy recognized by the Board.~~

~~(2) Preceptor Supervision: A minimum of 900 of the required 1,500 hours must be obtained in a pharmacy under the supervision of a preceptor.~~

~~(3) Board Approved Experience: A maximum of 600 of the required 1,500 hours may be granted at the discretion of the Board for other experience which substantially relates to the practice of pharmacy.~~

(b) ~~Required Areas of Experience: Effective January 1, 1986 all applicants for licensure must complete experience in both community pharmacy and institutional pharmacy practice in settings in the following areas:~~

~~(1) Receiving and interpreting the prescription;~~

~~(2) Patient medication profiles;~~

~~(3) Prescription preparation;~~

~~(4) Consultation;~~

~~(5) Record-keeping;~~

~~(6) Over the counter products;~~

~~(7) Drug information.~~

(c) ~~Proof of Experience: All intern pharmacists are required to submit proof of their experience on Board approved affidavits which shall be certified by the preceptor under whose immediate supervision such experience was obtained.~~

(d) ~~Out-of-State Exemption: One who is licensed as a pharmacist in any state and who has practiced as a pharmacist in that state for at least one year, as certified by the Board of Pharmacy of that state, shall be exempt from the pharmaceutical requirements of this section.~~

(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.
- (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 board 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.

Authority cited: Sections 851, and 4005 and 4114, Business and Professions Code.
Reference: Sections 144, 851, 4114 and 4200, Business and Professions Code.

ATTACHMENT E

Memorandum

To: Licensing Committee

Date: September 9, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: SB 1913 Regulation Clean-up

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. Below is proposed regulation language developed by to staff to update board regulations. Many of the changes are minor or technical but a number of the changes are substantive.

Section 1706.2 – This relocates existing provisions regarding the abandonment of applications into the section addressing that issue.

Section 1719 – This section recognizes schools of pharmacy that are accredited by or granted candidate status by the ACPE [this change 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.

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 [see item D on this agenda]. The amendments also eliminate the fee for registering continuing education accreditation entities to be consistent with changes proposed for continuing education regulations [see item G on this agenda].

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

§1706.2. Abandonment of Application Files.

- (a) An applicant for a ~~permit license~~ to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy manufacturer, wholesaler, supplier, out-of-state distributor, or clinic, medical device retailer or warehouse of a medical device retailer who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements ~~which are~~ in effect at the time of reapplication.
- (b) An applicant for a pharmacy technician license registration who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.
- (c) An applicant who fails to pay the fee for licensure as a pharmacist required by Section 1749(f) within one year after being notified by the board of his or her eligibility be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.
- (d) An applicant to take the pharmacist licensure examinations who fails to take the examinations within twelve months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections ~~4029, 4033, 4034, 4037, 4043, 4110, 4112, 4115, 4120, 4127.1, 4160, 4190 and 4200, 4201, 4202, 4203, 4204, and 4205,~~ Business and Professions Code.

Article 3. Licentiatees in Pharmacy Pharmacist Candidates

§1719. ~~Requirements for Admission to Examination.~~ Recognized Schools of Pharmacy.

As used in this division, “recognized school of pharmacy” means a school of pharmacy accredited, or granted candidate status, by the Accreditation Council for Pharmacy Education or otherwise recognized by the board.

- (a) ~~Applicants for the pharmacist licensure examination shall have completed all requirements for graduation from a school of pharmacy accredited by the American Council on Pharmaceutical Education or recognized by the Board.~~
- (b) ~~All candidates for the pharmacist licensure examination shall have completed a minimum of 1,000 hours of experience prior to applying for the examination.~~
- (c) ~~All candidates for the pharmacist licensure examination who are graduates of a foreign pharmacy school (any school located outside the United States of America) must demonstrate proficiency in English by achieving a score specified by the board on the Test of Spoken English administered by the Educational Testing Service. For candidates taking the Test of Spoken English after June 30, 1995, a score of at least 50 must be achieved. For candidates taking the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections ~~851, 4005 and 4200~~ of the Business and Professions Code.

§1720. Application for Examination and Licensure.

(a) An application for the pharmacist licensure examinations examination shall be submitted on the form provided by the board, and filed with the board at its office in Sacramento.

(b) The fee required by section 1749, subdivision (d) shall be paid for each application for initial examination and for any application to retake the examination described in Section 4200.2 of the Business and Professions Code. The fee is nonrefundable.

~~(c) An applicant who fails to pay the fee required by section 1749, subdivision (f) within one year after being notified by the board of his or her eligibility for a license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

(d) Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.

~~(e) An applicant for examination who does not take the examination within one year of the date the applicant is determined by the board to be eligible to take the examination shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

NOTE:

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200, Business and Professions Code.

§1725. Acceptable Pharmacy Coursework for Examination Candidates with Four Failed Attempts.

(a) Coursework that meets the requirements of section 4200.1 of the Business and Professions Code is any pharmacy coursework offered by a pharmacy recognized school of pharmacy, ~~approved by the American Council on Pharmaceutical Education or recognized by the board.~~

(b) A final examination must be a part of the course of study.

(c) When a candidate applies for reexamination after four failed attempts, he or she shall furnish evidence of successful completion of at least 16 semester units or the equivalent of pharmacy coursework. Evidence of successful completion must be posted on a transcript from the pharmacy school sent directly to the board.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4200.1, Business and Professions Code.

§1726. ~~Preeceptor-~~ Supervision of Intern Pharmacists.

(a) The pharmacist supervising an intern pharmacist shall be responsible for all professional activities performed by the intern under his or her supervision. ~~A preeceptor is a pharmacist~~

~~registered in any state whose license is not revoked, suspended or on probation in any state in which he or she is now or has been registered.~~

~~(b) The preceptor pharmacist supervising an intern pharmacist shall supervise the intern's activities to provide the experience necessary to make for the intern pharmacist to become proficient in the practice of pharmacy. provision of pharmaceutical services.~~

~~(c) The preceptor shall be responsible for all professional activities performed by the intern under his or her supervision.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1727. Intern Pharmacist.

~~(a) An intern pharmacist is a person who holds a valid intern card.~~

~~(b) An intern card shall be issued for a period of:~~

~~(1) One to five years for the person who is currently enrolled in a school of pharmacy recognized by the Board.~~

~~(2) One year to a person who is a graduate of a school of pharmacy recognized by the Board.~~

~~(3) One year to a foreign graduate who has met educational requirements described in Business and Professions Code Section 4200.~~

~~(4) One year to an out of state licentiate who is awaiting the administration of the next licensure examination.~~

~~(c) Registration as an intern may be renewed or extended at the sole discretion of the Board for:~~

~~(1) Persons who have not completed experience requirements.~~

~~(2) Persons who have completed experience requirements but have not taken or passed the licensure examination. Intern cards shall not be extended or renewed for a person who failed the licensure examination three or more times.~~

~~(d) An intern shall notify the Board within 30 days of any change of address. An intern shall return his or her intern card, by registered mail, within thirty (30) days of a change of eligibility status.~~

~~(e) An intern pharmacist may perform all functions of a pharmacist at the discretion and under the supervision of a preceptor in accordance with Business and Professions Code Section 4114.~~

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4030, 4114 and 4200, Business and Professions Code.

§1749. Fee Schedule.

The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with Section 4400 of the Business and Professions Code are hereby fixed as follows:

(a) The fee for the issuance of a ~~permit to conduct a~~ pharmacy license is three hundred forty dollars (\$340). The fee for the annual renewal of ~~said permit~~ pharmacy license is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).

(b) The fee for the issuance of a temporary pharmacy permit is one hundred seventy-five dollars (\$175).

(c) The fee for the issuance of a pharmacy technician license shall be fifty dollars (\$50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars (\$50). The penalty for failure to renew a pharmacy technician license is twenty-five dollars (\$25). (d) The fee for application and examination as a pharmacist is one hundred fifty-five dollars (\$155).

(e) The fee for regrading an examination is seventy-five dollars (\$75).

(f) The fee for the issuance of an original pharmacist license is one hundred fifteen dollars (\$115).

(g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars (\$115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents (\$57.50).

(h) The fee for the issuance or renewal of a wholesaler's license ~~permit~~ is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).

(i) The fee for the issuance or renewal of a hypodermic license is ninety dollars (\$90). The penalty for failure to renew is forty-five dollars (\$45).

(j) The fees for a certificate of exemption under the provisions of sections 4053; or 4054 ~~and~~ 4133 of the Business and Professions Code are as follows:

(1) For the application and investigation of the applicant, the fee is seventy-five dollars (\$75).

(2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars (\$110). The penalty for failure to renew is fifty-five dollars (\$55).

(k) The fee for the issuance or renewal of a license as an out-of-state distributor ~~manufacturer or wholesaler~~ is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).

(l) The fee for ~~registration as an intern pharmacist~~ license ~~or extension of the registration~~ is sixty-five dollars (\$65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars (\$10).

(m) ~~The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars (\$30). The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars (\$60).~~

(n) ~~The fee for registration and annual renewal of providers of continuing education is one hundred dollars (\$100). The penalty for failure to renew is fifty dollars (\$50).~~

(~~o~~) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.

(~~p~~) ~~The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars (\$165).~~

(~~q~~) (o) The fee for the issuance of a clinic license ~~permit~~ is three hundred forty dollars (\$340). The fee for the annual renewal of a clinic license ~~said permit~~ is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).

(~~r~~) ~~The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars (\$170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents (\$87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents (\$43.75).~~

Authority cited: Sections 163.5 and 4005, Business and Professions Code. Reference: Sections 163.5, 4005, 4110, 4112(h), 4120, 4130, 4196, 4200(e), 4400(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (p), (q), (r), (s), (t), (u), (v), (w), 4401 and 4403, Business and Professions Code.

§1750. Fee Schedule--Health and Safety Code.

~~The fee for issuance and renewal of a warehouse license as provided by Section 11127 of the Health and Safety Code is one hundred dollars (\$100). The penalty for failure to renew is twenty five dollars (\$25).~~

Authority cited: Section 4005, Business and Professions Code; and Section 11127, Health and Safety Code. Reference: Section 11127, Health and Safety Code.

ATTACHMENT F

Memorandum

To: Licensing Committee

Date: September 9, 2004

From: Paul Riches
Chief of Legislation and Regulation

Subject: Continuing Education Regulations

Below is a draft of changes to board regulations governing continuing education. CPhA provided the board with suggested amendments to these regulations to update terminology used by the continuing education community. The attached draft includes both the CPhA amendments and a reorganization and clean-up of the existing regulations. The changes represent a substantial reorganization of existing regulatory provisions but there are relatively few changes in the substance of the regulations. The draft is footnoted to indicate the location of existing provisions that were moved and to note those provisions that were altered or eliminated.

Article 4. Continuing Education

§1732. Definitions.

As used in this article:

- (a) ~~An accreditation~~ “Accreditation agency” means is an organization which evaluates and accredits providers of continuing pharmaceutical education for pharmacists, ~~monitors the quality of their educational activities, and audits continuing education coursework.~~
- (b) ~~The American Council on Pharmaceutical Education (ACPE) is the national accrediting agency for providers of continuing pharmaceutical education.~~¹
- (c) ~~The Accreditation Evaluation Service is the continuing education provider and coursework review component of the California Pharmacists Association.~~²
- (d) ~~A recognized provider is anyone whose qualifications as a continuing education provider have been approved by an accreditation agency approved by the Board.~~³
- (e) ~~An hour consists of~~ “Hour” means at least 50 minutes of contact time.
- (c) “Provider” means a person who has been accredited by an approved accreditation agency or accredited by the board to provide a specific continuing education course.

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

§1732.05. Accreditation Agencies for Continuing Education.

(a) The following organizations are approved ~~by the Board as continuing education and accreditation agencies:~~

¹ Duplicates provision in Section 1732.05 (a).

² Duplicates provision in Section 1732.05 (a).

³ “Non-recognized provider” is eliminated. Providers are accredited by accreditation agencies or specific courses are accredited by the board.

(1) ~~The Accreditation Council for Pharmacy Education, American Council on Pharmaceutical Education~~

(2) ~~The Pharmacy Foundation of California.⁴ Accreditation Evaluation Service of the California Pharmacists Association~~

(b) ~~Upon written application to the Board, any other organization will be approved by the board⁵ if: Accreditation agencies shall:~~

~~(1) the organization submits a plan demonstrating that it has the capacity to evaluate Evaluate each continuing education provider seeking accreditation in accordance with the provider's ability to comply with the requirements of Section 1732.1.~~

~~following criteria:~~

~~(A) Topics and subject matter shall be pertinent to the practice of pharmacy as specified in section 4232 of the Business and Professions Code and section 1732.1(c) of the California Code of Regulations.⁶~~

~~(B) Each continuing education course shall have written educational goals and specific learning objectives which are measurable and which serve as a basis for an evaluation of the program's effectiveness.⁷~~

~~(C) Speakers shall be competent in the subject matter and shall be qualified by education, training and/or experience.⁸~~

~~(D) Each continuing education course shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the instructional objectives for each course and a summary containing the main points for each topic.⁹~~

~~(E) When an approved provider works with others on the development, distribution and/or presentation of continuing education programs (joint sponsorship), there shall be procedures to identify and document the functions of each participating party.¹⁰~~

~~(F) Promotional materials shall meet the requirements specified in section 1732.3(d) of the California Code of Regulations. Advertisements shall also include at least the following:~~

~~1. the educational goals and specific learning objectives of the program.~~

~~2. the nature of the targeted audiences that may best benefit from participation in the program.~~

~~3. the speakers and their credentials.¹¹~~

~~(G) An evaluation mechanism shall be used. The mechanism shall allow all participants to assess their achievement in accordance with the program's learning objectives. Self-evaluation mechanisms may include, but are not limited to, pre- and post-testing, pre-testing along with group discussion and critique of answers, patient case-study discussions and problem-solving exercises.~~

~~The provider shall also develop a mechanism for each participant to evaluate the continuing education course.¹²~~

~~(H) Where the method of educational delivery does not translate into contact hours, such as home study programs and other mediated instructional approaches, there shall be procedures for the determination of hours of credit for courses. Procedures used to determine the amount of time required for participants to successfully complete the program shall be documented and defensible. Acceptable procedures include:~~

⁴ Changed to reflect the reorganization of AES into the Pharmacy Foundation of California.

⁵ This draft explicitly recognizes two accrediting agencies and would require a regulation change to add new accrediting agencies. The board has not approved a new accrediting agency in many years (if ever).

⁶ Eliminated because it is repetitive of Section 4232 and Section 1732.3.

⁷ Moved to section 1732.3 relating to CE course requirements.

⁸ Moved to section 1732.3 relating to CE course requirements.

⁹ Moved to section 1732.3 relating to CE course requirements.

¹⁰ This provision is eliminated as it is unnecessary.

¹¹ Moved to Section 1732.1 relating to CE providers.

¹² Moved to Section 1732.3 relating to CE course requirements.

1. assessing the amount of time the activity would require if it were delivered in a more formal and structured live program format; or,
2. pilot testing the activity with a group of pharmacists who are representative of the target audience and ascertaining the mean average length of time for completion for only those participants who successfully complete the program; or,
3. determination by an advisory panel, consisting of individuals qualified by experience and training in the development and administration of continuing education.¹³

(I) The provider shall be required to maintain records of each enrollee's participation in continuing education programs.

1. For live programs, acceptable documentation of participation includes attendance rosters, sign-in sheets, completed program evaluation forms, or signed verification forms.
2. For home study and other mediated instructional approaches—acceptable documentation of participation includes:
 - a. use of a post-testing procedure in which a pre-established proficiency level is established and certificates are awarded only upon attainment of the pre-specified minimum proficiency level;
 - b. in the case of study groups, the successful completion of the program may be attested to by all participants; or
 - c. completion and submission, by the individual participant, of a written evaluation or critique of both the program and its applicability to the participant's practice of pharmacy. The evaluation shall be of sufficient length and detail to demonstrate successful completion of the program and a reasoned consideration of its applicability to the participant's professional practice.¹⁴

(2) The organization agrees to perform the following: (A) Maintain a list of the name and address names and addresses of the persons designated as person responsible for the provider's C.E. continuing education program. The accreditation agency shall require that any change in the designated-responsible person's identity shall be reported to the accreditation agency within 15 days of the effective date of such change.

(B) Notify the Board of

(3) Provide the board with the names, addresses and responsible party of each provider, upon request.

(C)

(4) Respond to complaints from the board Board, providers or from California pharmacists concerning activities of any of its approved accredited providers or their coursework.

(D)

(5) Review at least a ten percent (10%) sample of coursework, as determined by the Board, but not less than¹⁵ one course per year offered by each provider approved accredited by the agency for compliance with the agency's requirements and requirements of the board Board and, on request, report the findings of such reviews to the board Board.

(E)

(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 Board; and

(F)

¹³ Moved to Section 1732.1 and simplified.

¹⁴ Moved to Section 1732.1 and simplified.

¹⁵ Change requested by CPhA to conform with existing standards in the continuing education community.

~~(7) Verify the attendance of licentiates completion at of a specific continuing education course by an individual pharmacist presentations upon request of this article, the Board.~~
(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in subdivision (b)(1) or to perform in accordance with the terms of its agreement as described in (b)(2) shall constitute cause for revocation of its approval as an accreditation agency by the board Board.

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

§1732.1. Requirements for Recognized Accredited Providers.

~~(a) Anyone seeking to provide continuing education courses as a recognized provider for California pharmacists shall apply to a Board approved accreditation agency for recognition as a provider prior to offering any such courses. No person shall provide continuing pharmacy education without being accredited by an approved accreditation agency or having the course accredited by the board pursuant to Section 1732.2.~~

~~(b) Providers shall ensure that each continuing education course complies with the requirements of Section 1732.3.~~

~~Upon satisfactory completion of the accreditation requirements of the accreditation agency and receipt of written approval therefrom, a continuing education provider may represent itself as a California recognized provider of continuing education material for pharmacists.~~

~~(c) The provider is responsible for assuring the educational quality of its coursework. Coursework shall be relevant to the practice of pharmacy and shall be related (1) to the scientific knowledge or technical skills required for the practice of pharmacy, or (2) to direct and/or indirect patient care, or (3) to the specific management and operation of a pharmacy practice.¹⁶ All continuing education coursework shall be:~~

~~(1) accurate and timely;¹⁷~~

~~(2) presented in an orderly fashion conducive to the learning process;¹⁸~~

~~(3) complete and objective, and not reflecting predominantly the commercial views of the provider or of anyone giving financial assistance to the provider;¹⁹~~

~~(4) specifically applicable and pertinent to the practice of pharmacy; and~~

~~(5) based on stated educational goals and objectives.²⁰~~

~~(d) All providers~~

~~(c) Providers shall furnish certificates of completion statements of credit²¹ to all participants that complete a continuing education course. enrolees. The certificate statement of credit shall contain the name of the enrollee, name and number of the provider, title of the course, number of completed hours, date of completion, expiration date of the coursework, course number, if applicable and the name of the accrediting agency.~~

~~(e)~~

~~(d) Each recognized provider shall notify the accreditation agency, on forms approved by the board, within at least 15 days in advance of the first time each new C.E. course is offered or presented.~~

~~(f) All providers~~

~~(e) Providers shall maintain records of attendance at or completion of their continuing education courses programs for four (4) years.~~

¹⁶ Recast and moved to Section 1732.3.

¹⁷ Eliminated as redundant since CE courses must be "relevant" to the practice of pharmacy and outdated or inaccurate information would not meet the relevance standard.

¹⁸ Eliminated because the provision is unreasonably vague.

¹⁹ Moved to Section 1732.3.

²⁰ Eliminated as repetitive of other sections requiring specific learning objectives.

²¹ Change requested by CPhA to conform to current terminology.

(f) Providers shall include the following information in promotional materials regarding continuing education courses:

- (1) Provider's name.
- (2) The number of hours awarded for completion of the course
- (3) The course's date of expiration
- (4) The provider number assigned by the accreditation agency.
- (5) The name of the provider's accrediting agency.
- (6) The learning objectives of the program.
- (7) The nature of the targeted audiences that may best benefit from participation in the program.
- (8) The speakers and their credentials.

(g) Providers shall have written procedures for determining the credit hours awarded for the completion of continuing education courses.

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

§1732.2. Coursework from Non-Recognized Providers. Board Accredited Continuing Education.

~~(a) Non-recognized providers or pharmacists~~ Individuals may petition the ~~Board~~ board to allow continuing education credit for specific coursework which is not offered by a ~~recognized~~ provider but meets the standards of Section 1732.3. ~~relevance to pharmacy practice and educational quality, as set forth in subdivision (c) of section 1732.1.~~

(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.

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

§1732.3. Coursework Approval for Providers. Requirements for Continuing Education Courses

(a) Unless denied by the accreditation agency upon audit, all coursework offered by ~~California~~ ~~recognized~~ providers ~~is considered as approved in California.~~ may be used to satisfy the continuing education required by Section 1732.5.

(b) On a random basis ~~established by the Board~~ or in response to ~~complaints about a particular provider or~~ requests by the ~~board~~ Board, the accreditation agency shall review selected coursework. ~~Within 15 days of receipt of written notification, the provider shall submit to the accreditation agency all material deemed necessary by the Committee to review the course.²²~~ The material shall be forwarded to a reviewer to judge the quality of the program on the basis of factors established by the accreditation agency in addition to the requirements of this section. ~~those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(e).~~

(c) A recognized provider's coursework shall be valid for up to three years following the initial presentation provided that the information is still current.

²² The board no longer has a continuing education committee.

~~(d) A recognized provider's advertisements for approved coursework shall clearly indicate the provider's name, the coursework's number of hours, date of expiration, the provider number assigned by the accreditation agency and the name of the accrediting agency.²³~~

(d) Continuing education courses shall comply with the following:

(1) Courses shall have specific, measurable learning objectives which serve as a basis for an evaluation of the program's effectiveness.

(2) Speakers, or those developing the content of the course, shall be competent in the subject matter and shall be qualified by education, training and/or experience.

(3) Courses shall have a syllabus which provides a general outline of the course. The syllabus shall contain at a minimum, the learning objectives for each course and a summary containing the main points for each topic.

(4) Courses shall include a mechanism that allows all participants to assess their achievement in accordance with the program's learning objectives.

(e) (1) Continuing education courses shall be relevant to the practice of pharmacy as provided in this section and in Section 4232 of the Business and Professions Code and related to one or more of the following:

(A) The scientific knowledge or technical skills required for the practice of pharmacy.

(B) Direct and/or indirect patient care.

(C) The management and operation of a pharmacy practice.

(2) Continuing education courses shall not reflect the commercial views of the provider or of any person giving financial assistance to the provider.

Authority cited: Sections 4005, 4206 and 4232, Business and Professions Code. Reference: Section 4232, Business and Professions Code.

§1732.4. Provider Audit Requirements.

Upon written request from the accreditation agency, relating to an audit of continuing education course coursework, each ~~recognized~~ provider shall submit such materials as are required by the accreditation agency.

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

§1732.5. Renewal Requirements for Pharmacist.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Article, each applicant for renewal of a pharmacist license shall submit with the application for renewal proof satisfactory to the board Board that, that the applicant has completed 30 hours of continuing education in the prior 24 months. subsequent to the last renewal thereof, he or she has completed 30 hours of approved continuing education.

(b) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course. the program.

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

§1732.6. Exemptions.

Pharmacists may seek exemption from the continuing education requirements for ~~license~~ renewal on the grounds of emergency or hardship by applying to the board Board in writing, ~~on a~~

²³ Moved to Section 1732.1.

~~form provided for that purpose~~, setting forth the reasons why such exemption should be granted. Exemptions may be granted for such reasons as illness or full-time enrollment in a health professional school.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4234, Business and Professions Code.

§1732.7. Complaint Mechanism.

A provider may request reconsideration of any adverse action taken against the provider or its coursework by an accreditation agency. Following such reconsideration, the provider may request review of the accreditation agency's decision by the board. ~~full Board of Pharmacy~~.

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

ATTACHMENT G



California State Board of Pharmacy

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

**LICENSING COMMITTEE
WORKGROUP ON COMPOUNDING
Meeting Summary**

DATE: September 22, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Hilton Oakland Airport
One Hegenberger Road
Oakland, CA 94621

Workgroup Members: Ken Schell, Pharm.D., Chair
John Tilley, R.Ph.

Staff Present: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Dennis Ming, Supervising Inspector
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General

Call to Order/Introductions

Chair of the workgroup, Dr. Schell, called the meeting to order at 1:30 p.m. Individuals attending the meeting were all invited to participate and were asked to introduce themselves.

Dr. Schell stated that this is the third meeting of the workgroup. He acknowledged and thanked the participants for their commitment and involvement. While the workgroup was initially formed in part to respond to a request from the Department of Health Services to identify the criteria used by the board to determine when a compounding pharmacy should be considered a manufacturer, it is the board's goal to work with the compounding profession in trying to respond to the request from DHS as well as to identify "gaps" in pharmacy law related to pharmacy compounding, and to address them.

General Compounding Proposal

Board Supervising Inspector Dennis Ming and Chief of Legislation and Regulation Paul Riches presented a concept proposal on general compounding. Dr. Ming explained that the concept draft was developed by he and Mr. Riches using documents prepared by the law subcommittee formed from this workgroup, compounding guidelines from the National Association of Boards

of Pharmacy (NABP), compounding requirements developed by the Texas State Board of Pharmacy, and California pharmacy law(s).

The workgroup discussed the concept draft and provided suggestions to clarify various provisions. Mr. Riches requested that any additional comments be provided by November 1st.

Subcommittee on Law - *Compounding versus Manufacturing*

The subcommittee on law presented their draft revisions of compounding guidelines that the Board of Pharmacy adopted in 1995. These guidelines were developed using the FDA Compliance Policy Guides in effect at the time and their original purpose was to provide the factors to be considered by board inspectors that may suggest that a pharmacy that claims to be compounding may actually be engaged in manufacturing.

The workgroup reviewed the subcommittee's revisions to the factors. It was noted that the general concept draft developed by Dr. Ming and Mr. Riches includes a definition of compounding, which currently is not defined in pharmacy law. The concept draft also requires that the pharmacist have a professional relationship with both the prescriber and the patient. Moreover, the general compounding draft addresses the issues of central fill (where a pharmacy may contract with another pharmacy to compound non-sterile drug products pursuant to a prescription), recordkeeping requirements, labeling, quality assurance requirements for the compounding process and the compounded drug, and requirements for facilities and equipment. The concept draft also specifies that the chemicals, drug products and components must be used and stored according to official United States Pharmacopoeia compendia specifications. There also was discussion regarding the compounding of OTC products and whether a prescription is required. It is the board's position that a prescription would be required whenever a pharmacy compounds a drug product. A drug product is defined broadly enough to include OTC compounding.

In response to questions about the relative roles of the Board of Pharmacy, the federal Food and Drug Administration and its California counterpart(s), it was explained to the workgroup that the Board of Pharmacy regulates the practice of pharmacy, which includes compounding. It is, however, ultimately within the authority of the federal and state FDA to license and regulate manufacturers and it is within their purview to determine when an entity must be licensed as a manufacturer. It was noted that compounding is included in the definition of manufacturing but a pharmacy that engages in compounding is not required to be registered as a manufacturer so long as the compounding is done within the pharmacy practice (upon prescription from a practitioner for a patient who is under the care of that practitioner). Because the FDA is concerned with public safety, it is reassessing pharmacy compounding.

The board is seeking to establish guidelines that provide uniformity in compounding in California. Better definition and regulation of the practice of compounding is primarily for the purpose of public safety. It may also solidify the role of compounding in pharmacy practice, and thereby diminish the likelihood that pharmacies compounding within their practice of pharmacy will be required to register as manufacturers. However, the board can offer no such guarantee.

Moreover, counsel advised that the proposed “factors” for distinguishing compounding from manufacturing would at best be considered “guidelines,” and as such, do not have the force of law. Absent adoption by regulation, they may also be underground regulations.

It was reiterated during the meeting that the Board of Pharmacy’s priority mandate is to protect the public and this mandate extends to the compounding of prescription drugs. It would appear that the general compounding draft provides the regulation necessary to guarantee that those pharmacies that compound prescription drugs meet specific standards to assure patient safety.

Next Meeting Date

Dr. Schell stated that the next meeting date for the Workgroup on Compounding is December 1, 2004, in Burbank.

Adjournment

Dr. Schell thanked the participants for attending and adjourned the meeting at 4:00 p.m.

**CONCEPT DRAFT
GENERAL COMPOUNDING**

Part 1 - Definitions

- (a) "Compounding" means any the following activities occurring in a pharmacy:
 - (1) Altering the dosage form or delivery system of a drug.
 - (2) Altering the strength of a drug.
 - (3) Combining active ingredients.
 - (4) Preparing a drug from bulk chemicals.
- (b) "Strength" means the amount of active ingredient in each unit of the drug.
- (c) "Quality" means the drug is free of any contaminants only contains those active ingredients indicated on the label.
- (d) "Integrity" means the drug will retain its effectiveness until the beyond use date noted on the label.

Part 2 – Requirements

- (a) Prior to compounding a drug, the pharmacist shall establish a professional relationship with the prescriber and patient.
- (b) A drug may not be compounded without a written master formula record that includes at least the following elements:
 - (1) Active ingredients to be used.
 - (2) Inactive ingredients to be used.
 - (3) Process and/or procedure used to prepare the drug.
 - (4) Quality reviews required at each step in preparation of the drug.
 - (5) Post compounding process or procedures required, if any.
 - (6) Beyond use dating requirements.
- (c) The pharmacist shall assure that the compounded drug retains its strength, quality, and integrity.
- (d) All chemicals, drug products, and components must be used and stored according to compendial and other applicable requirements to maintain their strength, quality and integrity.
- (e) The expiration date of the finished product must not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.
- (f) A pharmacy may contract with another pharmacy to compound non-sterile drug products, pursuant to a prescription, for delivery to another pharmacy. The compounded product must be labeled with the following:
 - (1) the name of the pharmacy that compounded the drug
 - (2) the name of the pharmacy that dispensed the drug to the patient in addition
 - (3) the information required by Business and Professions Code Section 4076.
- (g) Pharmacists who compound drugs, or supervise the compounding of drugs, shall be responsible for ensuring that the compounded drug has been prepared, labeled, stored, and delivered properly.

(h) Prior to allowing any drug to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment form for compounding pharmacies developed by the board. The self assessment shall subsequently be performed before July 1 of every odd-numbered year, within 30 days of the designation of a new pharmacist-in-charge, or within 30 days of the issuance of a new pharmacy permit.. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

Part 3 – Records

(a) For each compounded drug a record shall be made that includes at least the following elements:

- (1) The information required of a master formula record.
- (2) The date the drug was compounded.
- (3) The identity of the pharmacy personnel who compounded the drug.
- (4) The identity of the pharmacist reviewing the final product.
- (5) The quantity of each component used compounding a drug.
- (6) The supplier and lot number of each component.
- (7) The equipment used compounding a drug.
- (8) The internal reference (lot) number.
- (9) The expiration date of the final drug.

(c) Pharmacies must maintain written records of the acquisition, storage, and proper destruction of chemicals, drug products, and components used in compounding.

(d) Documentation must be maintained that the chemicals, drug products, and components have been procured from reliable suppliers and certificates of purity or analysis must accompany chemical purchases and be retained in the pharmacy.

(e) Pharmacies must prepare, maintain, and retain all records required by this act for a period of three years from the date the record was created.

Part 4 - Labeling

(a) In addition to labeling information required under Business and Professions Code Section 4076, the label of a compounded drug product shall contain the generic name(s) of the principal active component(s).

(b) A statement that the drug has been compounded by the pharmacy shall be included on the container (auxiliary label may be used).

(c) Drugs compounded into unit-of-use containers shall be labeled with the name of the active component, concentration or strength, volume or weight, and an expiration date.

Part 5 - Policies and Procedures

(a) Pharmacies must provide written documentation of a compounding policy and procedure manual that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures for the facility.

(b) The policy and procedure manual shall be reviewed on an annual basis by the pharmacist-in-charge.

(c) Provisions to notify the staff assigned compounding duties of any changes in the policy and procedure manual must also be included.

- (d) The policy and procedure manual must also include written documentation of a plan for the recall of dispensed compounded products where subsequent verification demonstrates the potential for adverse effects with continued use of the compounded drug.
- (e) Written processes used to maintain, store, calibrate, clean/disinfect equipment used in compounding drug shall be contained in the policy and procedure manual and shall be incorporated as part of the staff training and competency evaluation process.
- (f) The pharmacist-in-charge shall establish policies and procedures to ensure that compounded drugs have the strength indicated by the label.
- (g) The policies and procedures shall include procedures for the recall of compounded drugs.

Part 6 - Facilities and Equipment

- (a) Pharmacies must provide written documentation of facilities and equipment necessary for the safe and accurate compounding of a drug, to also include, where applicable, certification of the facility/equipment.
- (b) Equipment must be stored, used, and maintained in accordance with manufacturers specifications.
- (c) Equipment used in compounding drug products are to be calibrated prior to use to ensure retained accuracy. Documentation of calibration shall be recorded in a written format to include but limited to where applicable, temperature, weight, volume, etc.

Part 7 - Training of Staff, Patient and Caregiver

- (a) Pharmacies must provide written documentation that pharmacy personnel have the skills and training required to correctly understand and perform their assigned responsibilities relating to compounding.
- (b) The training of pharmacy personnel shall be documented and retained as part of an on-going competency evaluation process for pharmacy personnel involved in compounding.
- (c) Pharmacy personnel assigned compounding duties shall demonstrate knowledge about the processes and procedures used to compound drug drugs prior to compounding any drug.

Part 8 - Quality Assurance

- (a) Pharmacies must provide written documentation of the development of and adherence to a quality assurance plan.
- (b) The quality assurance plan must include verification, monitoring, and review of the adequacy of the compounding process and must include documentation of that review by the assigned personnel to demonstrate the compounded drug meets the specified criteria of strength and quality.
- (c) As part of the quality assurance plan, all qualitative/quantitative analysis reports for compounded drug drugs must be retained and collated with the compounding record and master formulation.
- (d) The quality assurance plan shall also include a written process that describes and documents the action taken when a compounded drug fails to meet the minimum standards for quality, strength and integrity.

ATTACHMENT H



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 graduated 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.

ATTACHMENT I

Memorandum

To: Board Members

Date: October 12, 2004

From: Virginia Herold
Assistant Executive Officer

Subject: Competency Committee Report

The Competency Committee has met two times since the July Board Meeting. This committee develops and oversees administration of the California Pharmacist Jurisprudence Examination.

Board President Goldenberg attended the September meeting and personally thanked each member for his or her participation in this important committee and contributions to development of the pharmacist licensure exam.

Examination Statistics:

Since January 2004 (and as of October 6);

2,426 applications have been received by the board to take the CPJE

2,345 applications have been processed

1,952 individuals have been qualified by California to take the pharmacist licensure examinations

1,468 individuals have been matched with NABP's system to take the NAPLEX

135 individuals have been approved to retake the examinations

1,050 individuals have become licensed as pharmacists under this new examination structure (since mid June)

The pass rate of the CPJE is 85 percent.

Job Analysis

Every five years, board policy requires a job analysis of California pharmacists to provide for the validity of the board's licensure examination. The Department of

Consumer Affairs recommends a job analysis be undertaken every three to seven years. It has been five years since the last job analysis.

The Competency Committee has finished pilot testing the job analysis questionnaire that will be mailed in November to 3,000 California-licensed and residing pharmacists. This questionnaire asks pharmacists to identify the tasks they perform and the importance they assign to these tasks. To encourage completion of these questionnaires, the board awards three hours of continuing education credit.

The results of this survey will be used to develop a content outline for future CPJE examinations. The NABP just recently completed the job analysis and new content outline for the NAPLEX, and the board's new content outline will be developed referencing the new NAPLEX content outline (the CPJE will not test the same information as does the NAPLEX).

The new content outline for the CPJE will be developed early in 2005 after the results of the job analysis are compiled, and will be used to construct the CPJE beginning in late Spring. Candidates will be advised about the new content outline before it is used to construct the examinations.

New Committee Structure

The board has begun seeking new members for the Competency Committee. According to a plan approved by the board, the examination development duties currently performed by the Competency Committee will be split into two committees: one group of item writers and another group that will perform item selection, performance review of questions and scoring.

In the next newsletter, the board will have an article encouraging the nomination of new members for the two committees. Prospective members should be pharmacists with approximately five years of pharmacy experience, although there will continue to be some members with more extensive experience. The committees need to be comprised of representatives from a cross section of professional practice and each of California's schools of pharmacy.

The item writers will meet once a year for a one-day training session. The core committee will continue to meet six times annually in two-day meetings, and attendance at these meetings is important.

Pharmacists who are interested in becoming appointed to one of these committees may apply by mailing a cover letter describing his or her area of pharmacy experience or practice, and including the individual's curriculum vitae and three letters of reference from pharmacists who are familiar with the individual's work. The selection of members will be made by the board president.

Exam Contracts

The board's annual contracts for test administration services with Experior Assessments (for the CPJE) and NABP are undergoing review. Essentially the same services are being contracted for as for 2004. Several modifications in test parameters will be incorporated into the CPJE. The board is going to a system similar to that used by the NABP that includes a block to prevent candidates from reviewing items at the end of the exam or permitting them to skip items to return to later. Instead, candidates for both the CPJE and NAPLEX must answer each question as it comes to the candidate; there is no review later. This is a heightened security requirement.

ATTACHMENT J

Licensing Committee
2004-2005
First Quarter Report
July 1, 2004 – September 30, 2004

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2005.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system has been implemented.

Tasks: **1. Review 100 percent of all applications within 7 working days of receipt.**

Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:				Average Days to Process:			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	248				23			
Pharmacist (initial licensing)	498				3			
Pharmacy Intern	316				10			
Pharmacy Technicians	978				5-10			
Foreign Graduates								
Pharmacies	100				6			
Non-Resident Pharmacy	20				22			
Wholesaler	19				39			
Veterinary Drug Retailer	0				0			
Exemptee	140				8			
Out-of-State Distributor	30				7			
Clinics	62				7			
Hypo Needle & Syringe	9				1			
Sterile Compounding	20				2			

* Denotes July and August 2004 information available at time of report development.

2. Process 100 percent of all deficiency documents within 3 working days of receipt.

Average days to process deficiency:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	3-7			
Pharmacist (initial licensing)	3-7			
Pharmacy Intern	10			
Pharmacy Technicians	5-7			
Foreign Graduates				
Pharmacies	9			
Non-Resident Pharmacy	10			
Wholesaler	9			
Veterinary Drug Retailer	0			
Exemptee	3			
Out-of-State Distributor	11			
Clinics	7			
Hypo Needle & Syringe	5			

3. Make a licensing decision within 3 working days after all deficiencies are corrected.

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	1-2			
Pharmacist (initial licensing)	1-2			
Pharmacy Intern	5			
Pharmacy Technicians	5			
Pharmacies	4			
Non-Resident Pharmacy	3			
Wholesaler	3			
Veterinary Drug Retailer	0			
Exemptee	2			
Out-of-State Distributor	4			
Clinics	4			
Hypo Needle & Syringe	6			

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Q1	Q2	Q3	Q4
Pharmacist	536*			
Pharmacy Intern	241*			
Pharmacy Technician	1080*			
Foreign Graduate	N/A			
Pharmacies	121			
Non-Resident Pharmacy	11			
Wholesaler	25			
Veterinary Drug Retailer	3			
Exemptee	122			
Out-of-State Distributor	25			
Clinics	53			
Hypo Needle & Syringe	12			
Sterile Compounding	13			
* Denotes July and August 2004 information available at time of report development.				

5. Withdrawn licenses to applicants not meeting board requirements.

	Q1	Q2	Q3	Q4
Pharmacy Technician	11			
Pharmacies	15			
Non-Resident Pharmacy	13			
Clinics	28			
Sterile Compounding	2			

Objective 2.2: Implement at least 50 changes to improve licensing decisions by June 30, 2005.

Measure: Number of implemented changes.

Tasks: 1. Review Pharmacist Intern Program.

- 9/04 Governor signed SB 1913 that contained new intern provisions to become effective 1/05.
- 9/04 Licensing Committee recommended changes to 1728 to implement SB 1913.
- 9/04 Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.

9/04 *Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*

2. Implement changes to the Pharmacy Technician Program.

1/04 *a. Use PTCB as a qualifying method for registration.
Completed.*

1/04 *b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.
Completed.*

9/04 *c. Eliminate clerk-typist from pharmacist supervisory ratio.
Completed – regulation approved by OAL, change effective 10/3/04.*

3. Administer a pharmacist licensure exam more than twice a year.

3/04 *Completed – CA applicants began taking the NAPLEX and CPJE.*

9/04 *826 California applicants have taken the NAPLEX and 1,006 have taken the CPJE since July 1, 2004.*

4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.

5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.

6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.

8/04 *Competency Committee met for two days and developed question.
Finalized job analysis survey.*

9/04 *Competency Committee met for two days and developed questions.*

9/04 *Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).*

11/04 *Job analysis will be released.*

7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.

6/04 Completed.

9/04 OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.

9/04 Reported that 13 sterile compounding licenses have been issued since July 1, 2004.

8. Issue temporary permits whenever change of ownership occurs.

9/04 1st Quarter – 22 temporary permits issued.

9. Establish means for licensee to renew permits on line.

10. Implement Changes to Facilities Licensure Requirements

9/04 Governor signed SB 1913 that included application requirements for all applicants.

9/04 Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.

9/04 Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.

11. Review the Ownership of Pharmacies

7/04 Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.

12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.

7/04 Draft report provided to the board.

9/04 Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).

9/04 Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.

12/04 Report to the Legislature is due.

13. Evaluate application requirements for all licenses.

- 9/04 Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.*
- 9/04 Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).*
- 9/04 Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.*
- 9/04 Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*
- 9/04 Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.*
- 9/04 Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.*

14. Review the requirement regarding the education of graduates from foreign pharmacy schools.

- 9/04 Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.*
- 9/04 Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*
- 9/04 Sent a letter to all pending foreign graduates advising of law change and suspended application process.*

15. Review the CE requirements for pharmacists.

- 7/04 Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*
- 9/04 Licensing Committee recommended changes to the CE requirements to relocate to statute the 30- hour requirement, to exempt all newly licensed pharmacists from CE requirements for two years and to renew the pharmacist license as "inactive" when a pharmacist fails to certify their CE credits.*
- 9/04 Licensing Committee recommended revisions to the CE regulations.*

	16. Review the regulatory requirements for city and county jails and juvenile facilities.
<i>8/04</i>	<i>Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.</i>
Objective 2.3:	Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2005.
Measure:	Number of public policy initiatives evaluated.
Tasks:	<ol style="list-style-type: none"> 1. Explore the need to regulate pharmacy benefit managers. <ul style="list-style-type: none"> <i>10/03</i> <i>Board concluded not to regulate PBMs.</i> <i>9/04</i> <i>Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.</i> 2. Explore the need to regulate drugs labeled for "veterinary use only." <ul style="list-style-type: none"> <i>9/03</i> <i>SB 175 was introduced and signed (Chaptered 250, Statutes 2003).</i> <i>1/04</i> <i>Completed.</i> 3. Explore the importation of drugs from foreign countries. <ul style="list-style-type: none"> <i>7/04</i> <i>Discussed at July Board meeting.</i> <i>9/04</i> <i>Discussed at September Enforcement Committee meeting.</i> <i>9/04</i> <i>Governor vetoed SB 1149 which would have required the board to approve Web sites for Canadian pharmacies.</i> 4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies. <ul style="list-style-type: none"> <i>9/04</i> <i>OAL approved regulation change and will take effect 10/22.</i> <i>10/04</i> <i>Completed.</i> 5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding.

	<p>9/04 <i>Held third meeting of workgroup on compounding – proposed draft concept on general compounding.</i></p> <p>6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant to SB 490 (Chapter 651, Statutes of 2003.)</p> <p>7/04 <i>Protocol on Web site.</i></p> <p>7/04 <i>Board approved regulation on protocol.</i></p> <p>9/04 <i>Regulation submitted to OAL for approval.</i></p> <p>7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.</p> <p>9/04 <i>Governor signed SB 1913 that provides the authority.</i></p> <p>8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.</p> <p>4/04 <i>Board approved waiver for two years.</i></p>
<p>Objective 2.4:</p> <p>Measure:</p>	<p>Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.</p> <p>Percentage of cashiered application and renewal fees within 2 working days.</p>
<p>Tasks:</p>	<p>1. Cashier application fees.</p> <p>9/04 <i>1st Quarter - The average processing time for processing new application fees is 2-3 working days.</i></p> <p>2. Cashier renewal fees.</p> <p>9/03 <i>The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.</i></p> <p>8/04 <i>Held interviews for renewal cashier because hiring freeze was lifted.</i></p> <p>9/04 <i>1st Quarter - Average processing time for central cashiering is 2-3 weeks.</i></p> <p>10/04 <i>Filled vacancy for renewal cashier.</i></p>

Objective 2.5:	Respond to 95 percent of all requests for verification of licensing information within 5 working days by June 30, 2005.
Measure:	Percentage response for verifying licensing information within 5 working days.
Tasks:	<ol style="list-style-type: none"> 1. Respond to requests for licensing verification. <p><i>9/04 1st Quarter – Processed 227 license verifications.</i></p>
Objective 2.6:	Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.
Measure:	Percentage of licensing records changes within 5 working days
Tasks:	<ol style="list-style-type: none"> 1. Make address and name changes. <p><i>9/04 1st Quarter – Processed 2,478 address changes.</i></p> <ol style="list-style-type: none"> 2. Process discontinuance of businesses forms and related components. <p><i>9/04 1st Quarter – Processed 26 discontinuance- of-business forms. Processing time is 44 days.</i></p> <ol style="list-style-type: none"> 3. Process changes in pharmacist-in-charge and exemptee-in-charge. <p><i>9/04 1st Quarter – Processed 421 pharmacist-in-charge changes. Average processing time is 23 days. Processed 12 exemptee-in-charge changes. The average processing time is 2 days.</i></p> <ol style="list-style-type: none"> 4. Process off-site storage applications. <p><i>9/04 Processed 33 off-site storage applications.</i></p> <ol style="list-style-type: none"> 5. Process change-of-permit applications. <p><i>9/04 1st Quarter – Processed 142 applications. Average processing time is 25 days.</i></p>

