California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814
Phone (916) 445-5014
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

Contact Person: Patricia Harris (916) 445-5014

LICENSING COMMITTEE

September 10, 2003
Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019
(818) 843-6000
9:00 a.m. – 12 noon

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Candy Place at telephone number (916) 445-5014, at least 5 working days prior to the meeting. Opportunities are provided to the public to address the committee on each agenda item.

A. Call to Order **9:00 a.m.**

B. Discussion on the Implementation of the Joint Legislative Sunset Review Bill – SB 361(Pending)
- **Presentation by Tracy A. Ferrel, Ph.D. – Chief, DCA Office of Examination Resources and Competency Committee Chair RoseAnn Jankowski, Pharm.D. on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and California's Multi-State Jurisprudence Examination (MPJE)**
- **Proposed Regulation Amendments to Implement NAPLEX and the MPJE (CCR, title 16, sections 1719, 1720, 1720.1, 1721, 1723.1, 1724, 1727, 1728)**
- **Proposed Regulation Amendments to Implement the Program Modifications for Pharmacy Technicians (CCR, title 16, sections 1749 and 1793 et seq.)**

C. Request for Comments to Update the Program Requirements for Intern Pharmacists (CCR, title 16, sections 1727 and 1728)

D. Competency Committee Report on the June 2003 California Pharmacist Licensure Examination

E. Proposed Modifications to Statutes for Site Licenses
- **Revisions to Wholesaler Statutes**
- **Purchase of Dangerous Drugs and Devices**
- **Issuance of Site License to a Residence**
- **Issuance of Site License to a Specific Location**
- **Exemptee Requirement for Manufacturers**

F. Proposed Approval Process for Security Printers of Controlled Substance Prescription Documents Pursuant to SB 151 (Pending)

G. Update on the Implementation of the Injectable Sterile Compounding Program for Pharmacies

H. Comments from the Public on Items Not on the Agenda

Adjournment **12 noon**

Meeting materials will be available on the board's website by September 3, 2003 -- www.pharmacy.ca.gov

Agenda Item B

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: September 2, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Implementation of the Joint Legislative Sunset Review Bill – SB 361(Pending)**

SB 361 (Figueroa) is the legislative vehicle for the Board of Pharmacy sunset extension and contains statutory recommendations approved by the Joint Legislative Sunset Review Committee. Anticipating that the Governor will sign the legislation, the following is an overview of what the board is doing to implement the NAPLEX and develop a California Multi-State Pharmacy Jurisprudence Examination (MPJE). In addition, it will be necessary for the board to modify its regulations on the examination process and the pharmacy technician program.

Implementation of NAPLEX and California's MPJE

SB 361 will allow an applicant who has passed the NAPLEX and the California MPJE on or after January 1, 2004, to be licensed as a pharmacist. Specifically, the bill requires the board when developing the MPJE to include all of the following:

- examination items to demonstrate the candidate's proficiency in patient communication skills
- aspects of contemporary standards of practice for pharmacists in California including, but not limited to, the provision of pharmacist care and the application of clinical knowledge to typical pharmacy practice situations that are not evaluated by the NAPELX

The bill also requires the board to work with the Office of Examination Resources or with an equivalent organization to develop the state jurisprudence examination to ensure that applicants for licensure are evaluated on their knowledge of applicable state laws and regulations.

Tracy Ferrel, Ph.D., Chief of the Office of Examination Resources for the Department of Consumer Affairs has been guiding the Board of Pharmacy on the development of California's MPJE. The first step was to create a content outline for the MPJE. Working closely with Dr. Ferrell, Competency Committee Chair Roseanne Jankowski and Assistant Executive Officer Virginia Herold performed a very thorough comparison of

the content outlines for the current NAPLEX and the California pharmacist licensure examination. Based on this review, Dr. Ferrel developed a draft content outline for the MPJE. In August, the Competency Committee revised this draft and approved the final examination content outline for California's MPJE. The committee also determined the number of items per examination and the cognitive level of the questions, reviewed questions in the existing pool for appropriateness and began writing new questions. The goal is to have the question pool ready by December 1, 2003.

Dr. Ferrel will be at the Licensing Committee meeting to present an overview of this process and to answer questions. **(Attachment 1 - California MPJE Content Outline.)**

Operationally, staff have been working with the National Associations of Boards of Pharmacy (NABP) on the transition to NAPLEX and the MPJE. Licensing Program Manager Anne Sodergren will be trained this month on the NAPLEX systems. There will be some modifications to California's application process and forms. These changes are necessary to streamline the process and make it more efficient for the applicant, the board and the schools. **(Attachment 2 – Flow Chart on the Application Process and Draft Forms)**

An applicant for licensure in California must also apply concurrently to NABP to take NAPLEX or to have a NAPLEX score transferred to California, and to take the California MPJE. It will be the board's determination whether an applicant is eligible in California to take the take the NAPLEX and/or the California MPJE. The NAPLEX/MPJE Registration Bulletin can be obtain from NABP's website.

Current law (B&P Code sec. 4200.1) requires an applicant who fails to pass the pharmacist licensure examination after four attempts to complete a minimum of 16 semester units of pharmacy coursework before he/she can take the licensure examination for a fifth time. It appears that this law still applies; however clarification has been sought from the board's staff counsel Dana Winterrowd. Therefore, if an applicant has failed the pharmacist licensure examination 4 times, he/she would not be eligible in California to take the NAPLEX and the California MPJE after January 1, 2004. Even if the applicant took and passed NAPLEX in another state, he/she would not be eligible to take California's MPJE until the requirement of 4200.1 is met.

Proposed Regulation Amendments to Implement NAPLEX and California MPJE

With the passage of SB 361, it will be necessary for the board to amend its regulations so that they are consistent with the new statutory provisions and the proposed modifications to the application process. The following is an overview of some of the proposed changes:

- 1719 – The primary change in this section is the requirement that an applicant for the examination must complete the required 1,500 hours prior to applying for the examination. This is proposed to streamline the application process
- 1720 – Changes are technical except that a foreign graduate applicant must take the pharmacist licensure examination within one year of application instead of the

5-year period allowed now.

- 1720.1 – Graduates of foreign pharmacy schools who apply to take the California pharmacist licensure examination must be certified by the Foreign Pharmacy Graduate Examination Committee. This certification will streamline the board's application process for foreign graduates. This certification will provide the board with the graduate's transcripts, which the current process doesn't. Also, the certification process entails passing the TSE consistent with the board's current regulatory requirement.
- 1721- These are technical changes. If an applicant engages in dishonest conduct during an examination is not allowed to take the next examination for two years, must surrender his/her intern card and cannot be issued a pharmacy technician permit.
- 1723.1 – Technical changes
- 1724 – NAPLEX and MPJE scores are communicated as pass/fail. This regulation change is consistent with the guidance provided by the Office of Examination Resources. The board currently establishes its passing score by a criterion-referenced method. The process for establishing the pass score for California's MPJE will not change from current practice.
- 1727 – Technical Changes
- 1728 - Sections (c) and (d) were moved to 1719.

(Attachment 3 – Proposed Regulation Changes Regarding the Qualifications for the Pharmacist Licensure Examination)

Requested Action: To recommend that the Board of Pharmacy approve the proposed regulation changes and move them to hearing

Amendments to Implement the Program Modifications for Pharmacy Technicians

SB 361 included statutory changes to the pharmacy technician program that were recommendations from the board's Pharmacy Manpower Task Force. These changes include the requirement that an applicant for registration as a pharmacy technician has obtained an associate's degree in pharmacy technology. This was changed from an associate arts degree in a field of study directly related to the duties performed by a pharmacy technician. Certification by the Pharmacy Technician Certification Board was added as a qualifier and the experience provision was eliminated. Also, the statute was clarified to allow a graduate from a pharmacy school recognized by the board to be eligible for registration instead of requiring that an applicant be eligible for the board's pharmacist licensure examination.

The regulation amendments are consistent with the provisions of SB 361 and include technical clean up of the language that has not been done since the original adoption in 1990. The changes are:

- 1749 – Moves the technician fees to the same schedule of all other board application and licensing fees. Technical only
- 1793 - Technical changes

- 1793.1 – Moves (g) to 1793.7 and eliminates (h) which is duplicative of existing law
- 1793.2 – Duplicative of existing statute
- 1793.3 – No change. Proposed changes are being considered by the Legislative/Regulatory Committee
- 1793.4 – Eliminates experience as a qualification consistent with SB 361 changes
- 1793.5 – Duplicative of existing statute
- 1793.6 – Amendment removes the specificity of the theoretical and practical aspects of the 240 hours of training
- 1793.7 – Removes the duplicative sections of statute and adds (g) from 1793.1

(Attachment 4 – Proposed Regulation Changes Regarding the Pharmacy Technicians)

Requested Action: To recommend that the Board of Pharmacy approve the proposed regulation changes and move them to hearing

Attachment 1

California State Board of Pharmacy

California Exam Detailed Content Outline

1. Provide Medication to Patients in Compliance with California Law (30 Percent)

A. Organize and Evaluate Information as Communicated by the Prescriber, Prescriber's Authorized Agent, or Patient

1. Assess prescription/medication order for completeness, correctness, authenticity, and legality
2. Assess prescription/medication order for reimbursement eligibility
3. Evaluate the pharmaceutical information needs of the patient/patient's representative

B. Dispense Medications in Compliance with California Law

1. Enter prescription information into patient profile
2. Document preparation of medication in various dosage forms
3. Prepare label(s) for prescription containers
4. Select auxiliary label(s) for container(s)
5. Prior to dispensing, perform the final check of the medication (e.g., correct drug, dose, route, directions)

2. Monitor, Communicate, and Manage Patient Outcomes (30 Percent)

A. Improve Patient Understanding, and Counsel Patients in Compliance with California Law

1. Assess the patient's knowledge of the disease and treatment
2. Determine the need for a referral
3. Counsel patient/patient's representative regarding prescription medication therapy
4. Counsel patient/patient's representative regarding herbal/alternative therapies
5. Verify the patient's/patient representative's understanding of the information presented

B. Monitor, Communicate, and Manage Patient Outcomes

1. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals
2. Adjust patient’s drug therapy according to written protocols developed with prescriber(s)

3. Manage Operations in Accordance with California Law (60 Percent)

A. Obtain and Document Pharmaceuticals, Devices and Supplies

1. Maintain a borrow/loan system in compliance with legal requirements
2. Maintain a record-keeping system of items purchased/received/returned in compliance with legal requirements and professional standards

California State Board of Pharmacy
California Exam Detailed Content Outline

B.	**Perform Quality Assurance/Improvement to Enhance Patient Safety and Meet Legal Requirements**
1.	Measure, assess and improve the accuracy of medication dispensing by pharmacy staff
2.	Measure, assess and improve patient compliance/adherence with medication regimens
3.	Measure, assess and improve the disease-management outcomes of patient populations
C.	**Manage Operations, Human Resources and Information Systems**
1.	Monitor the practice site and/or service area for compliance with federal, state and local laws, regulations and professional standards
2.	Develop and implement policies and procedures for pharmacy technicians
3.	Supervise the work of pharmacists, pharmacy technicians and/or other pharmacy staff
4.	Ensure the availability of patient-related information (e.g., patient profiles, medication administration records)
D.	**Establish and Manage Medication Use Systems in Accordance with Patient Safety Guidelines and California Law**
1.	Apply therapeutic interchange (i.e., therapeutic substitution) guidelines
2.	Establish and maintain a system by which adverse drug reactions are documented, analyzed, evaluated and reported
3.	Establish and maintain a system for medication error reporting including root cause analysis

Total: 90 Questions, including 15 nonscored, pretest items

Attachment 2

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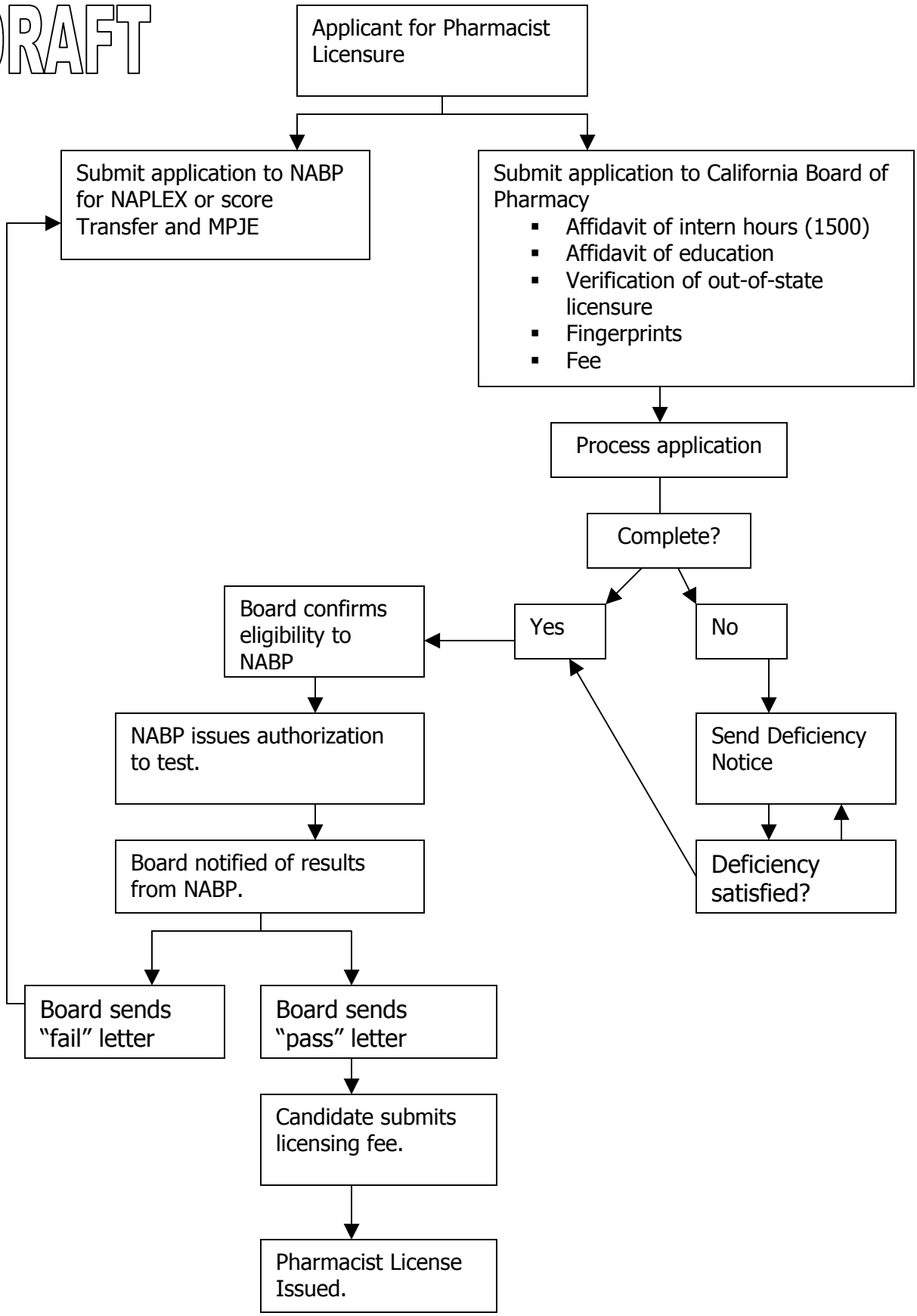
Applicant for Pharmacist Licensure
Submit application to NABP for NAPLEX or score Transfer and MPJE
Submit application to California Board of Pharmacy
Affidavit of intern hours (1500)
Affidavit of education
Verification of out-of-state licensure
Fingerprints
Fee
Process application
Complete?
Yes
No
Board confirms eligibility to NABP
NABP issues authorization to test.
Board notified of results from NABP.
Send Deficiency Notice
Deficiency satisfied?
Board sends "fail" letter
Board sends "pass" letter
Candidate submits licensing fee.
Pharmacist License Issued.

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APPLICATION FOR PHARMACIST LICENSURE EXAMINATION

All items of information in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for registration under the California Pharmacy Law. The official responsible for information maintenance is the executive officer, telephone (916) 445-5014, 400 R Street, Suite 4070, Sacramento, California 95814-6237. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Civil Code section 1798.3.

LAST NAME	FIRST NAME	MIDDLE NAME	FORMER NAME

ADDRESS OF RECORD	NUMBER	STREET	APT NUMBER

CITY	STATE	ZIP CODE

RESIDENCE ADDRESS: IF DIFFERENT FROM ABOVE		
CITY	STATE	ZIP CODE

TAPE A PHOTOGRAPH TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION

NO POLAROID OR SCANNED IMAGES

HOME PHONE NUMBER	WORK PHONE NUMBER	EMAIL ADDRESS
( )	( )	

DATE OF BIRTH	DRIVER LICENSE NUMBER	STATE	SOCIAL SECURITY NUMBER *

UNIVERSITY, COLLEGE OR SCHOOL OF PHARMACY ATTENDED

Name of university, college or school	Country	Date of Graduation	Degree

DO NOT WRITE BELOW

Photo: ☐	DOJ Clear ☐	Exam History				**CASHIERING ONLY**	
FP Cards ☐	FBI Clear ☐	Date	Exam #	**NAPLEX**	MPJE	**APPLICATION FEE**	
Rules ☐						Receipt No.	
AFFIDAVITS						Date Received	
Graduation ☐	O/S Exp ☐					Amount	
FPGEC ☐						**LICENSE FEE**	
Intern Hours _____						Receipt No	
LICENSURE VERIFY						**Date Received**	
						Amount	
						License No	
		Requalified ☐ Date _____				Date Issued	

* Once you are licensed with the board the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code section 6250 et seq.) and will be placed on the Internet upon licensure. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is a box number you must also provide your residence address as an alternate address that will not be available to the public.

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List all state(s) where you have been or are currently registered as a pharmacist			
State	**Registration number**	**Active or inactive**	**Expiration date**

List all experience earned in and out-of-state. Indicate whether experience was earned as an INTERN or PHARMACIST.				
Dates From To	Name of employer	Location	Total hours experience	Hours earned as:
				Intern ☐ Pharmacist ☐
				Intern ☐ Pharmacist ☐
				Intern ☐ Pharmacist ☐

ALL APPLICANTS MUST ANSWER THE FOLLOWING QUESTIONS:

1. Have you ever taken the California pharmacist licensure exam? ☐ Yes ☐ No
   If "yes," provide exam date(s). _____
2. Have you ever applied for and not taken the exam? ☐ Yes ☐ No
   If "yes," provide exam date(s). _____
3. Are you a registered intern pharmacist in California? ☐ Yes ☐ No
   If "yes," provide California intern number. _____
4. Are you a registered pharmacy technician in California? ☐ Yes ☐ No
   If "yes," provide pharmacy technician registration number. _____
5. Have you ever been registered as a pharmacist in California? ☐ Yes ☐ No
   If "yes," provide California pharmacist license number. _____
6. Have you ever been expelled from a pharmacist licensure exam administered in this state or any other state? **If "yes," provide the date and state**. _____ ☐ Yes ☐ No
7. Have you previously taken a pharmacist exam which was not graded or had exam results withheld on grounds of dishonest conduct during an examination in this state or any other state? ☐ Yes ☐ No
   If "yes," provide the date and state _____
8. Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health and safety risks? **If "yes," attach a statement of explanation. If "no," proceed to #10**. ☐ Yes ☐ No
9. Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program? **If "yes," attach a statement of explanation.** ☐ Yes ☐ No

   If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for licensure.
10. Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances? ☐ Yes ☐ No

    If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? **Attach a statement of explanation**.

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11. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States or any state laws or local ordinances? You must include all misdemeanor and felony convictions, regardless of the age of the conviction, including those which have been set aside under Penal Code section 1203.4. Traffic violations of $500 or less need not be reported. **If "yes," attach an explanation including the type of violation, the date, circumstances, location and the complete penalty received.** ☐ Yes ☐ No

12. Has disciplinary action ever been taken against your pharmacist license or intern permit in this state or any other state? **If "yes," attach a statement of explanation**. ☐ Yes ☐ No

13. Have you ever had an application for a pharmacist license or an intern permit denied in this state or any other state? **If "yes," attach a statement of explanation**. ☐ Yes ☐ No

14. Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied by a governmental authority in this state or any other state? **If "yes," provide the name of company, type of permit, type of action, year of action and state.** ☐ Yes ☐ No

Name of person or company	Type of permit	Type of action	Year of action	State

You must provide a written explanation for all affirmative answers. Failure to do so will ultimately result in this application being deemed withdrawn as incomplete.

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NOTARIZED APPLICANT AFFIDAVIT

I, _____, hereby attest to the fact that I am the applicant whose signature appears below. I understand that falsification of the information on this form may constitute grounds for denial or revocation of the license. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I personally completed this application and have read and understand the instructions attached to this application.

_____ _____
Signature of Applicant Date

Signature of Notary: _____

Subscribed and sworn to before me this _____ day of _____ , 20___

Notary in and for _____ County, State of _____ My certificate expires _____

* Disclosure of your U.S. social security account number is mandatory. Section 30 of the Business and Professions Code, section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

Mandatory Reporter

Under California law each person licensed by the Board of Pharmacy is a “mandated reporter” for child abuse or neglect purposes. Prior to commencing his or her employment, and as a prerequisite to that employment, all mandated reporters must sign a statement on a form provided to him or her by his or her employer to the effect that he or she has knowledge of the provisions of Section 11166 and will comply with those provisions.

California Penal Code section 11166 requires that all mandated reporters make a report to an agency specified in Penal Code section 11165.9 [generally law enforcement agencies] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or neglect. The mandated reporter must make a report to the agency immediately or as soon as is practicably possible by telephone, and the mandated reporter must prepare and send a written report thereof within 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars ($1,000), or by both that imprisonment and fine.

For further details about these requirements, consult Penal Code sections 11164, and following.

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DO NOT CERTIFY THIS PAGE UNTIL AFTER GRADUATION HAS OCCURRED

AFFIDAVIT OF COMPLETION OF COURSEWORK AND GRADUATION FROM AN APPROVED COLLEGE OF PHARMACY

This is to certify that _____ attended the _____ College of Pharmacy, from _____ until _____ and on _____ completed all requirements for graduation from the _____ year program. The degree of _____ was Conferred on him/her on _____

Signed _____ Date _____
(Dean or Registrar)

Address: _____

AFFIX SEAL HERE

_____

_____

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APPLICANT:

- Have the Dean or Registrar complete this form and submit it with your application.
- Foreign College of Pharmacy Graduates – Submit your FPGEC certificate in place of this affidavit.

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LICENSURE VERIFICATION

TO BE COMPLETED BY APPLICANT

(Please print or type)

Name of Applicant				Telephone Number ( )	
Residence Address	Street and Number	City		State	Zip Code
License Number	Date of Birth:	Social Security Number	Date Issued:	Expiration Date:	

TO BE COMPLETED BY STATE BOARD OFFICE

The individual listed above has applied for licensure as a registered pharmacist in the state of California. Before further consideration is given this application, we would appreciate your assistance in completing the information requested below. Upon completion of this form, please return to the applicant in a sealed envelope.

LICENSURE VERIFICATION PROVIDED BY THE STATE OF _____

Applicant's Name		License Number
Type of License Issued: Intern ☐ Pharmacist ☐	Date License issued	Expiration Date of License
License Status: Active ☐ Inactive ☐ Other ☐ If other, please explain:		
License was obtained by: Examination ☐ Reciprocity/Endorcement ☐		
Has applicant been found guilty of any violation for which disciplinary action was taken? Yes ☐ No ☐ If disciplinary action has been taken against this licensee, please provide this office with any documentation regarding the action.		

_____
Signature

Board Seal

_____
Title

_____
Date

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AFFIDAVIT OF INTERN EXPERIENCE

PART 1 - TO BE COMPLETED BY APPLICANT

Complete Part 1 and then forward this form to your current or previous employer(s) to verify your completion of 1,500 hours intern experience.

(please print or type)

Name of Applicant			Telephone Number ( )	
Residence Address	Street and Number	City	State	Zip Code

I ***certify under penalty of perjury under the laws of the state of California that I have complied with California Code of Regulations 1728(b).***

Signature of Applicant _____ Date _____

PART 2 – TO BE COMPLETED BY PRECEPTOR

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Name and Address of Pharmacy

Name of Pharmacy			Pharmacy License Number	
Address of Pharmacy	Street and Number	City	State	Zip Code

Dates of Experience - From: _____ (mm/dd/yy) to: _____ (mm/dd/yy)

Average number of hours per week: _____ Total number of hours: _____

I certify under penalty of perjury under the laws of the state of California that all statements given herein are true, and that the experience gained by this applicant was under my direct supervision and was predominantly related to the practice of pharmacy as required by law.

Signature of Preceptor _____ Title _____ Date _____

Attachment 3

Board of Pharmacy
Draft Regulation Changes
Examination

Article 3. Licentiates in Pharmacy

§1719. ~~Requirements for Admission to~~ Qualifications for Examination.

(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~~ Applicants for the ~~pharmacist licensure~~ examination shall have completed a minimum of ~~1,000~~ 1,500 hours of intern experience prior to applying for the examination. Applicants for the examination shall submit proof of their intern experience on board approved affidavits which shall be certified by the preceptor who supervised the intern while the experience was obtained.[1]
~~(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.~~[2]
(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, shall be exempt from subdivision (b).[3]
(d) Applicants shall have all out-of-state licenses verified by the state in which the license is held. Verifications are to be submitted on board approved affidavits.[4]
(e) For purposes of this division "examination" means North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California.[5]

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 ~~Registration~~ Licensure.

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[1] Relocation of Section 1728 (c).
[2] Requirement to qualify bases on 4200(a)(2)(B) revised the requirement from passing the equivalency exam offered by FPGEC to FPGEC certification as noted in section 1720.1. Passing the Test of Spoken English (TSE) with a score of 50 or greater is a requirement of being FPGEC certified.
[3] Relocation of Section 1728 (d).
[4] Documentation of license verification specified in regulation.
[5] Definition of examination specified in regulation.

(a) An application for ~~the pharmacist licensure~~ examination shall be submitted on the form provided by the Board, and filed with the Board at its office in Sacramento ~~at least (60) days before the date fixed for examination~~.
(b) The fee required by Section 1749(d) shall be paid for each application for examination. The fee is nonrefundable.
(c) An applicant who fails to pay the fee required by Section 1749(f) within ~~two years~~ one year[6] after being notified ~~by the board~~ of ~~his or her~~ their eligibility for a ~~certificate of registration~~ 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~~, including retaking of the examination~~.
(d) ~~Each~~ An applicant for examination whose eligibility is based on the provisions of Business and Professions Code Section 4200(a)(2)(b) and who fails to take the examination within ~~five years~~ one year[7] of the date of filing the application 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.

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

§1720.1. Graduates of Foreign Pharmacy Schools.

~~(a)~~ ~~Each~~ An 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.~~ to the board's satisfaction certification by the Foreign Pharmacy Graduate Examination Committee.[8]
~~(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.~~[9]

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[6] Record retention reduced to one year because the combination of adopting NAPLEX and the associated application changes will result in the board holding applications open for significantly less time and still providing the applicant ample time to pay the fees.
[7] Record retention reduced to one year because the combination of adopting NAPLEX and the FPGEC certification process will result in the board holding foreign graduate applications open for significantly less time. The one-year period is ample time for an applicant to complete the process.
[8] Requirement to qualify bases on 4200(a)(2)(B) revised the requirement from passing the equivalency exam offered by FPGEC to FPGEC certification. One of the requirements of FPGEC certification is a passing TSE score of 50 or greater which was previously required in section 1719(c).
[9] FPGEC provides a copy of applicant's transcript when FPGEC verification is requested by the board.

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

§1721. Dishonest Conduct During Examination.

An applicant for ~~registration~~ examination as a pharmacist who engages in dishonest conduct during the examination shall not have ~~his or her~~ that examination graded and shall ~~be denied the opportunity to take the examination at its next administration~~ not be approved to take the examination for twenty-four months from the date of the incident, and shall surrender ~~his or her~~ their intern card until ~~such time as he or she takes the licensure~~ eligible to take the examination. Such applicant may not be issued a pharmacy technician license until eligible to take the examination.

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

§1723.1. Confidentiality of Examination Questions.

~~Board of Pharmacy~~ Examination questions are confidential, and any applicant for any license~~, permit or exemption certificate~~ issued by the ~~Board~~ board who removes all or part of any qualifying examination from the examination room or area, or who conveys or exposes all or part of any qualifying examination to any other person may be disqualified as a candidate for ~~the~~ a license~~, permit or exemption certificate for which the applicant applies~~.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4059 and 4200, Business and Professions Code.

§1724. Passing Grade in Examination.

~~The pharmacist licensure examination consists of two sections, multiple-choice and essay, both of which must be passed by achieving a score of 75 or more on each section. A candidate failing the multiple-choice section shall be given a failing grade for the entire examination without regard to the performance on the essay section.~~

In order to pass the examination an applicant shall be required to obtain a passing score as determined by a criterion-referenced method of establishing the passing point on each part of the examination.[10]

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

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[10] Per Tracy Ferrell of OER, the board should not reference a specific passing score but rather a passing score determined by a criterion-referenced method.

§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~~ issued 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.

§1728. Intern Experience--Requirements for 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.~~ [11]

~~(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.~~

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

[11] Sections1728 (c) and (d) have been relocated to section 1719.

Attachment 4

Board of Pharmacy
Draft Regulation Changes
Technician Licensing

Amend Section 1749 as follows:

§1749. Fee Schedule.

~~Effective July 1, 1999, the~~ 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 is three hundred forty dollars ($340). The fee for the annual renewal of said permit 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 permit is one hundred seventy-five dollars ($175).

~~(c) The fee for processing remodeling plans and inspecting the remodeled area is one hundred thirty dollars ($130).~~[1]

(c) The fee for the issuance of a permit for a pharmacy technician shall be fifty dollars ($50). The fee for the biennial renewal of a pharmacy technician permit shall be fifty dollars ($50). The penalty for failure to renew a pharmacy technician permit is twenty-five dollars ($25).[2]

(d) The fee for an applicant for 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 certificate of registration as a pharmacist 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 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, 4054 and 4133 of the Business and Professions Code are as follows:

(1) For the investigation and examination of an 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 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 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,

[1] The board no longer reviews remodeling plans.

[2] This section was moved from 1793.5 to place all fees into a single section.

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) The fee for the issuance of a clinic permit is three hundred forty dollars ($340). The fee for the annual renewal of 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 medical device retailer is three hundred forty dollars ($340). The fee for the annual renewal of said permit is one hundred seventy-five dollars ($175). The penalty for failure to renew is eighty-seven dollars and fifty cents ($87.50).~~[3]
~~(s)~~ 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(c), 4400(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w), 4401 and 4403, Business and Professions Code.

Amend Section 1793 as follows:

§1793. Definitions.

"Pharmacy technician" means an individual who, under the direct supervision and control of a ~~registered~~[4] pharmacist, performs packaging, manipulative, repetitive, or other nondiscretionary tasks related to the processing of a prescription in a ~~licensed~~[5] pharmacy, but who does not perform duties restricted to a ~~registered~~ pharmacist under section 1793.1.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.1 as follows:

§1793.1. Duties of a ~~Registered~~ Pharmacist.

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

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[3] The board no longer licenses Medical Device Retailers.
[4] "Registered" is removed because it is redundant. A pharmacist is by definition (B&P 4036) a person licensed by the board.
[5] "Licensed" is removed because it is redundant. A pharmacy is by definition (B&P 4037) a place licensed by the board.

(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.~~[6]
~~(h) Perform any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform.~~[7]
~~(i)~~ Perform all functions which require professional judgment.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.2 as follows:

§1793.2. Duties of a Pharmacy Technician.

~~Pharmacy technicians may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of, a registered pharmacist.~~[8]
"Nondiscretionary tasks" as used in Business and Professions Code section 4115, include:
(a) removing the drug or drugs from stock;
(b) counting, pouring, or mixing pharmaceuticals;
(c) placing the product into a container;
(d) affixing the label or labels to the container;
(e) packaging and repackaging.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Repeal Section 1793.4:

§1793.4. Qualifications for Registration as a Pharmacy Technician.

~~Except for the preparation of prescriptions for an inpatient of a hospital or for an inmate of a correctional facility, no person shall act as a pharmacy technician without first being registered with the board. The board shall issue a certificate of registration to an applicant who has met any of the following requirements:~~

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[6] Moved to Section 1793.7.
[7] Eliminated because it is repetitive of existing law.
[8] Eliminated because it is repetitive of existing law (B&P 4115).

~~(a) Has obtained at least an associate of arts degree in one or more fields of study directly related to the duties performed by a pharmacy technician. Directly related fields of study include: health sciences, biological sciences, physical sciences, or natural sciences.~~
~~(b) Has successfully completed a training course specified by the board.~~
~~(c) Is eligible to take the board's pharmacist licensure examination.~~
~~(d) Has at least one year's experience, to include a minimum of 1,500 hours, performing the tasks specified in section 1793.2 while employed or utilized as a pharmacy technician to assist in the preparation of prescriptions for an inpatient of a hospital, for an inmate of a correctional facility, or other experience deemed equivalent by the board.~~
~~(e) A person possesses "experience deemed equivalent by the board" within the meaning of subdivision (d), if he or she has at least 1,500 hours of experience performing the duties specified in section 1793.3 in a pharmacy in the last three years, or has been employed for at least 1,500 hours as a pharmacy technician in another state or by the federal government.~~[9]

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Repeal Section 1793.5:

§1793.5. Application for Registration.

~~The application for registration (Form 17A-5 Rev. 9/94) as a pharmacy technician required by this section is available from the Board of Pharmacy upon request.~~
~~(a) Each application for registration as a pharmacy technician shall include:~~
~~(1) Information sufficient to identify the applicant.~~
~~(2) A description of the applicant's qualifying experience or education, and supporting documentation for that experience or education. Examples of supporting documentation shall include: a certificate of completion issued by the training course provider showing the date of issuance and the number of theoretical and practical hours completed, transcripts, or an experience affidavit (Form 17A-6 or 17A-9 Rev. 9/94) signed by the pharmacist having direct knowledge of the applicant's experience.~~
~~(3) A criminal background check that will require two completed fingerprint cards and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.~~
~~(4) The registration fee shall be fifty dollars ($50) effective July 1, 1995.~~
~~(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.~~
~~(c) The board shall notify the applicant within 30 days whether the application is complete or deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a permit decision.~~
~~(d) Upon review and approval of the application, the board shall issue a certificate of registration as a pharmacy technician for at least one year. Before expiration of the initial certificate of registration, a pharmacy technician must renew the registration certificate with the board. Effective July 1, 1995, the fee is fifty dollars ($50) and the penalty for failure to renew is twenty-five dollars ($25).~~[10]

[9] Eliminated because it is repetitive of existing law (B&P 4202).
[10] Eliminated because the language is outdated and not reflective of SB 361.

Authority cited: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.6 as follows:

§1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) ~~1793.4(b)~~[11] is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) Any other course that provides a training period of at least 240 hours of ~~theoretical and practical~~ instruction covering at least the following:~~, provided that at least 120 of these hours are in theoretical instruction in a curriculum that provides~~:[12]

(1) Knowledge and understanding of different pharmacy practice settings.

(2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

Amend Section 1793.7 as follows:

§1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

~~(a) Any pharmacy which employs a pharmacy technician shall do so in compliance with applicable federal and state laws and regulations governing pharmacy.~~[13]
~~(b)~~

[11] Conforming reference change required by repealing 1793.4.
[12] Changes made to streamline the technician application process.
[13] Eliminated because the language is duplicative of existing law.

(a) Any function performed by a pharmacy technician in connection with the dispensing of a prescription, including repackaging from bulk and storage of pharmaceuticals, must be verified and documented in writing by a pharmacist. Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, the pharmacist shall indicate verification of the prescription by initialing the prescription label before the medication is provided to the patient.

~~(c)~~

(b) Pharmacy technicians must work under the direct supervision of a registered pharmacist and in such a relationship that the supervising pharmacist is ~~on the premises at all times and is~~[14] fully aware of all activities involved in the preparation and dispensing of medications, including the maintenance of appropriate records.

~~Except for the preparation of prescriptions for an inpatient of a hospital and for an inmate of a correctional facility, a pharmacy technician may perform the duties, as specified in subdivision 1793.2, only under the immediate, personal supervision and control of a registered pharmacist and within the pharmacist's view.~~[15]

~~(d)~~

(c) A pharmacy technician must wear identification clearly identifying him or her as a pharmacy technician.

~~(e)~~

(d) Any pharmacy employing or using a pharmacy technician shall develop a job description and written policies and procedures adequate to ensure compliance with the provisions of Article 11 ~~12~~ of this Chapter, and shall maintain, for at least three years from the time of making, records adequate to establish compliance with these sections and written policies and procedures.

(e) A pharmacist shall 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.[16]

(f) For the preparation of a prescription for an inpatient of a licensed health facility and for a patient of a licensed home health agency, the ratio shall not be less than one pharmacist on duty for a total of two pharmacy technicians on duty. Pursuant to Business and Professions Code section 4115(g)(1), this ratio shall not apply to the preparation of a prescription for an inmate of a correctional facility of the Department of the Youth Authority or the Department of Corrections, or for a person receiving treatment in a facility operated by the State Department of Mental Health, the State Department of Developmental Services, or the Department of Veterans Affairs.

Authority cited: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.
Reference: Sections 4005, 4007, 4038, 4115 and 4202, Business and Professions Code.

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[14] Changes made reflect the law allowing a pharmacy to operate in the temporary absence of the pharmacist (Section 1714.1)

[15] Duplicative of existing law (B&P 4115).

[16] Moved from 1793.1.

Agenda Item C

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: August 27, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Review of Intern Program and Requirements**

One of the Licensing Committee's strategic objectives has been to review the requirements for the Intern Program. Because of other priorities, this committee has not had the opportunity to perform such a review.

Therefore, the purpose of this agenda item is to begin this by soliciting comments on how the intern program should be updated and streamlined operationally. About 10 years ago, to assist the intern and preceptor in complying with the program requirements, the board developed its Intern/Preceptor Manual, which is available to on the board's website.

The Licensing Committee discussed this agenda item at its last meeting. No comments were received in advance of the meeting; however, it was recommended that the internship should include experience obtained under protocol with physicians as allowed by Business and Professions Code section 4052. As suggested at the last meeting, Licensing Committee Chair Clarence Hiura invited the Deans from the California schools of pharmacy to attend this meeting and requested that they bring recommended changes for discussion.

Agenda Item D

California State Board of Pharmacy
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Fax (916) 327-6308

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

NO ACTION
REPORT ONLY

COMPETENCY COMMITTEE REPORT TO THE BOARD MEMBERS FROM THE LICENSING COMMITTEE CLARENCE HIURA, CHAIR AUGUST 28, 2003

1. Report on the June 2003 Examination

On August 15, 2003, the board released the results to the June 2003 pharmacist licensure examination. Of the 1,284 candidates, 649 passed for a passing rate of 50.5%. Detailed passing rate information will be available at the October 2003 board meeting. As of the date of this report, 365 pharmacist licenses have been issued.

Regrade requests are due to the board office by September 5, 2003. Results to regrades will be mailed in the beginning of October 2003.

2. Report on the January 2004 Examination

On January 13 and 14, 2004, the board will administer its January 2004 pharmacist licensure examination at the Hyatt Regency San Francisco Airport Hotel pending no changes in the law occur as a result of SB 361.

Agenda Item E

State of California **Department of Consumer Affairs**

Memorandum

To: **Licensing Committee** **Date: August 27, 2003**

From: **Patricia F. Harris**
Executive Officer
Board of Pharmacy

Subject: **Proposed Modifications to Statutes for Site Licenses**

Proposed Revisions to the Wholesaler Statutes

These proposed changes to the wholesale statutes are primarily technical in nature. The intent is to make the law easier to read and understand. However, there are a couple of substantial changes. The first one is the deletion of current subdivision (b) of 4160. This elimination would require all nonresident wholesalers to be licensed in California. Under current law, if an out-of-state wholesaler distributes dangerous drugs through a California licensed wholesaler, the board does not require that the out-of-state wholesaler be licensed with the board. The second substantial change requires an exemptee-in-charge for all nonresident wholesalers. This requirement is consistent with requirements for in-state wholesalers. **(Attachment 1 – Proposed Language)**

Recommended action: To recommend that the Board of Pharmacy approve the proposed statutory changes

Purchase of Dangerous Drugs and Devices

These proposed statutory changes are also being discussed at the Enforcement Committee meeting on September 17th. The addition of Business and Professions Code section 4168 is intended to address some public protection issues that the Enforcement Committee has been discussing regarding counterfeit drugs, the secondary sourcing of dangerous drugs by wholesalers and the failure to maintain appropriate records. The language provides for specific citation authority for each violation of this section and the ability for the board to collect unpaid fines from non-licensees through the Franchise Tax Board.

This proposed language was also brought to this committee because current law (Business and Professions Codes section 4163) prohibits a manufacturer or wholesaler from furnishing dangerous drugs or devices to an unauthorized person. Proposed 4168(a) would also prohibit the purchasing of dangerous drugs or devices from an unauthorized

person or entity.

Recommended action: To recommend that the Board of Pharmacy approve the proposed statutory changes and/or communicate any concerns to the Enforcement Committee for its consideration

Issuance of Site License to a Residence/Issuance of Site License to a Specific Location

The Licensing Committee is being asked consider the legislative proposal to add Business and Professions Code section 4107. This proposal would prohibit any board-licensed facility from being located in a personal residence. Currently this is not a prohibition and it is problematic in that some wholesale facilities are located in the owner's home. Subdivision (b) makes it clear that that board issues a site permit to one premise and it is a separate operation. **(Attachment 2 – Proposed Language)**

Recommended action: To recommend that the Board of Pharmacy approve the proposed statutory changes

Exemptee Requirement for Manufacturers

This proposal is moving the current requirement from the Business and Professions Code to the Health and Safety Code because Department of Health Services regulates manufacturers. **(Attachment 3 – Proposed Language)**

Recommended action: To recommend that the Board of Pharmacy approve the proposed statutory changes

Attachment 1

Board of Pharmacy
Draft Revisions to Wholesaler Statutes

Amend Section 4160 of the Business and Professions Code, to read:

4160. (a) No person shall act as a wholesaler of any dangerous drug or dangerous device unless he or she has obtained a license from the board.
(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.
~~(b) No selling or distribution outlet, located in this state, of any out-of-state manufacturer, that has not obtained a license from the board, that sells or distributes only the dangerous drugs or the dangerous devices of that manufacturer, shall sell or distribute any dangerous drug or dangerous device in this state without obtaining a wholesaler's license from the board.~~
(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) The board shall not issue or renew a wholesaler license until the wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee.
The exemptee-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. Each wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge. A pharmacist may be designated as the exemptee-in-charge.
(e) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.
(f) A drug manufacturer licensed pursuant to Section 111615 of the Health and Safety Code that only ships drugs of its own manufacture is exempt from this section.

Repeal Section 4161 of the Business and Professions Code:

~~4161. (a) No person shall act as an out-of-state manufacturer or wholesaler of dangerous drugs or dangerous devices doing business in this state who has not obtained an out-of-state dangerous drug or dangerous device distributor's license from the board. Persons not located in this state selling or distributing dangerous drugs or dangerous devices in this state only through a licensed wholesaler are not required to be licensed as an out-of-state manufacturer or wholesaler or have an out-of-state dangerous drug or dangerous device distributor's license.~~
~~(b) Applications for an out-of-state dangerous drug or dangerous device distributor's license shall be made on a form furnished by the board. The board may require any information as the board deems is reasonably necessary to carry out the purposes of the section. The license shall be renewed annually.~~
~~(c) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state manufacturer or wholesaler.~~
~~(d) The Legislature, by enacting this section, does not intend a license issued to any out-of-state manufacturer or wholesaler pursuant to this section to serve as any evidence that the out-of-state manufacturer or wholesaler is doing business within this state.~~

Add Section 4161 to the Business and Professions Code, to read:

4161. (a) Any wholesaler located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
(b) All nonresident wholesalers shall be licensed by the board.
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler. Each license shall be renewed annually and shall not be transferable.
(d) A nonresident wholesaler shall disclose to the board the location, names, and titles of:
(1) Its agent for service of process in this state.
(2) Principal corporate officers as specified by the board.
(3) General partners as specified by the board.
(d) A report containing this information shall be made within 30 days of any change of office, corporate officer, or partner.
(e) All nonresident wholesalers shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section.
(f) All nonresident wholesalers shall maintain records of dangerous drugs or dangerous devices sold, traded or transferred to persons in this state so that the records are in a readily retrievable form.
(g) The nonresident wholesaler shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the wholesaler in compliance with the laws of the state in which it is a resident. Applications for a nonresident wholesaler license shall include a license verification from the licensing authority in the applicant's state of residence.
(h) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler designates an exemptee-in-charge and notifies the board in writing of the identity and license number of that exemptee.
(i) The exemptee-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. Each nonresident wholesaler shall designate, and notify the board of, a new exemptee-in-charge within 30 days of the date that the prior exemptee-in-charge ceases to be exemptee-in-charge.
(j) For purposes of this section, "exemptee-in-charge" means a person granted a certificate of exemption pursuant to Section 4053 or a registered pharmacist who is the supervisor or manager of the facility.
(k) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Repeal Section 4162 of the Business and Professions Code:

~~4162. (a) No person acting as principal or agent for any out-of-state manufacturer, wholesaler, or pharmacy who has not obtained a license from the board, and who sells or distributes dangerous drugs or dangerous devices in this state that are not obtained through a wholesaler who has obtained a license, pursuant to this chapter, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler, pursuant to this chapter, shall conduct the business of selling or distributing dangerous drugs or dangerous devices within this state without registering with the board.~~
~~(b) Registration of persons under this section shall be made on a form furnished by the board. The board may require any information as the board deems reasonably necessary to carry out the purposes of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose dangerous drugs or dangerous devices he or she is selling or distributing.~~
~~(c) The board may deny, revoke, or suspend the person's registration for any violation of this chapter or for any violation of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The board may deny, revoke, or suspend the person's registration if the manufacturer, whose dangerous drugs or dangerous devices he or she is selling or distributing,~~

~~violates any provision of this chapter or any provision of Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code. The registration shall be renewed annually.~~

Amend Section 4163 of the Business and Professions Code, to read:

4163. (a) No manufacturer or wholesaler shall furnish any dangerous drugs or dangerous devices to any unauthorized persons.
(b) Dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices.

Amend Section 4164 of the Business and Professions Code, to read:

4164. All wholesalers licensed by the board ~~and all manufacturers who~~ that distribute controlled substances, dangerous drugs, or dangerous devices within or into this state shall report to the board all sales of dangerous drugs and controlled substances that are subject to abuse, as determined by the board.

Amend Section 4165 of the Business and Professions Code, to read:

4165. ~~(a)~~ Any ~~manufacturer~~ wholesaler licensed by the board who sells or transfers any dangerous drug or dangerous device into this state or who receives, by sale or otherwise, any dangerous drug or dangerous device from any person in this state shall, on request, furnish an authorized officer of the law with all records or other documentation of that sale or transfer.
~~(b) Any manufacturer who fails within a reasonable time, or refuses, to comply with subdivision (a), shall be subject to citation and a fine, an order of abatement, or both, pursuant to Section 125.9 and any regulations adopted by the board, in addition to any other remedy provided by law.~~

Amend Section 4166 of the Business and Professions Code, to read:

4166. (a) Any wholesaler ~~or other distributor~~ that uses the services of any carrier, including, but not limited to, the United States Postal Service or any common carrier, shall be liable for the security and integrity of any dangerous drugs or dangerous devices through that carrier until the drugs or devices are delivered to the transferee at its board-licensed premises.
(b) Nothing in this section is intended to affect the liability of a wholesaler or other distributor for dangerous drugs or dangerous devices after their delivery to the transferee.

Attachment 2

Board of Pharmacy
Draft Changes for Wholesale Violations
August 22, 2003

Add Section 4168 to the Business and Professions Code, to read:

4168. (a) No person or entity shall:

(1) Purchase, trade, sell or transfer dangerous drugs or dangerous devices at wholesale from a person or entity that is not licensed with the board as a wholesaler or pharmacy.

(2) Purchase, trade, sell or transfer counterfeit drugs or devices.

(3) Purchase, trade, sell or transfer dangerous drugs or dangerous devices after the beyond use date on the label.

(4) Fail to maintain records of the acquisition or disposition of dangerous drugs or dangerous devices for at least three years.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) For notifications made on and after January 1, 2005, the Franchise Tax Board, upon notification by the board of a final judgment in an action brought under this section, shall subtract the amount of the fine from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

Attachment 3

Board of Pharmacy
Site Licensing Restriction

Add Section 4107 to the Business and Professions Code, to read:

4107. (a) Effective January 1, 2005,the board may not issue or, effective July 1, 2005, renew a site license, including but not limited to a license to conduct a wholesaler, pharmacy, veterinary food-animal drug retailer, to a facility located in a personal residence.
(b) The board may not issue more than one site license to a single premises. For the purposes of this subdivision, "premises" means a location with its own address and a independent means of ingress/egress.

Attachment 4

Board of Pharmacy
Exemptee Requirement for Manufacturers

Amend Section 111625 of the Health and Safety Code, to read:

111625. (a) A license application shall be completed annually and accompanied by an application fee as prescribed in Section 111630. This fee is not refundable if the license is refused.
(b) A manufacturer licensed pursuant to this article shall not operate without employing sufficient, qualified supervision to adequately safeguard and protect the public health. Either a pharmacist licensed pursuant to Section 4200 of the Business and Professions Code or an individual issued a certificate of exemption pursuant to Section 4053 of the Business and Professions Code shall be deemed to provide sufficient, qualified supervision as required by this subdivision.

Agenda Item F

State of California Department of Consumer Affairs

Memorandum

To: Patricia Harris
Executive Officer

Date: August 25, 2003

From: Paul Riches

Subject: Security Printer Application Review Process

Senate Bill 151 (copy attached) requires the Board of Pharmacy to approve security printers prior to the production of secure prescription forms for controlled substances. This memo will outline a process for the board to use when granting the required approval. This memo addresses the board's processes only. The bill requires coordination of security printer approval between the board and the Department of Justice (DOJ) and board staff will be working with the DOJ to determine details of how their processes and board processes will interact.

Security printers seeking the board's approval shall complete the application forms and submit them to the board. The application shall contain the following information:

(1) Name of applicant
(2) Address of applicant
(3) Telephone number
(4) Type of Ownership
(5) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms. Soft copies only?
(6) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers. Soft copies only?
(7) The location, name, and title of the applicant's agent for service of process in this state
(8) The location, names and title of all principal corporate officers, if any; or, all managing general partners, if any.
(9) A signed statement indicating whether the applicant, principal corporate officers, or managing general partners have ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.
(10) The applicant shall also provide fingerprints as required by the board.

Board of Pharmacy Processing:

(1) Applications will be forwarded to the licensing unit for review.
(2) Licensing unit will notify applicant in writing of deficiencies.
(3) When the application is complete (including fingerprint clearances), the application file is submitted to a supervising inspector for review as follows:

(a) If the supervising inspector approves the application, a copy of the file and a letter from the Board of Pharmacy indicating its approval is sent to the Department of Justice (DOJ) for review.

(b) If the DOJ approves or fails to take action within 30 days, then the security printer application is approved and a letter is generated to the applicant indicating approval.
    (b1) The name and contact information of the approved security printer is added to the master list maintained on the board website. Where are complaints filed?

(c) If the DOJ rejects the applicant, then a letter is sent to the applicant by the DOJ indicating denial of their application.
    (c1) The DOJ notifies the board of the denial and the grounds for the denial.

(d) If the supervising inspector rejects the application, then a letter is sent to the applicant indicating denial of their application.

The legislation provides the following as grounds for denying the approval:

(1) The applicant has been convicted of a crime.
(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.
(3) The applicant committed any act that would constitute a violation of this division.
(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.
(5) The Board of Pharmacy or Department of Justice determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.
(6) The Board of Pharmacy or Department of Justice determines that the applicant has submitted an incomplete application.

California State Board of Pharmacy
400 R Street, Suite 4070, Sacramento, CA 95814-6237
Phone (916) 445-5014
Fax (916) 327-6308
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GRAY DAVIS, GOVERNOR

APPLICATION FOR SECURITY PRESCRIPTION PRINTER

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for registration under the California Pharmacy Law. The official responsible for information maintenance is the Executive Officer, telephone (916) 445-5014, 400 R Street, Suite 4070, Sacramento, California 95814-6237. The information may be transferred to another governmental agency such as a law enforcement agency if necessary for it to perform its duties. Each individual has the right to review the files or records maintained on them by our agency, unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

(Please print or type)

Name of Business:			Telephone Number: ( )
Address of Business: Number and Street	City	State	Zip Code

Indicate type of ownership: Individual ☐ Partnership ☐ Corporation ☐

Name of agent for service of process in California		Agent's telephone number ( )	
Agent's California address (P.O. Box not acceptable)	City	State	Zip Code

Owners/Partners/Corporate Officers

Name	Residence Address	Telephone number	Title

Have any of the above named persons ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, any state or local jurisdiction? Include all misdemeanor and felony convictions, regardless of the age of the conviction, including those which have been set aside and/or dismissed under Penal Code section 1000 or 1203.4. (Traffic violations of $500 or less need not be reported.) If "yes," please attach an explanation which must include the type of violation, the date, circumstances and location, and the complete penalty received. ☐ Yes ☐ No

Continue on reverse side

For Office Use Only

☐ Policies & Procedures ☐ Policies & Procedures	BOP Approved _____ BOP Denied _____	To DOJ _____ DOJ Approved _____ DOJ Rejected _____

Certification of Applicant – Please read carefully and sign below

Under penalty of perjury, under the laws of the state of California, each person whose signature appears below, certifies that: (1) He/she is the applicant, or one of the owners or managers of the applicant corporation, named in the foregoing application, duly authorized to make this application on its behalf; (2) that he/she has read the foregoing application and knows the contents thereof and that each and all statements therein made are true; (3) that no person other than the applicant or applicants has any direct or indirect interest in the applicant's or applicants' business to be conducted under the license(s) for which this application is made, and (4) all supplemental statements are true and accurate.

Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date
Signature of corporate officer, partner or owner	Name (please print)	Title	Date

Agenda Item G

California State Board of Pharmacy
STATE AND CONSUMER SERVICES AGENCY
400 R Street, Suite 4070, Sacramento, CA 95814
DEPARTMENT OF CONSUMER AFFAIRS
Phone (916) 445-5014
GRAY DAVIS, GOVERNOR
Fax (916) 327-6308

August 28, 2003

Patricia Harris
Executive Officer
California State Board of Pharmacy

RE: Status Report: Sterile Compounding Licensing Process

As of August 28, 2003, the Board of Pharmacy has received 174 applications for Sterile Compounding licenses. One hundred and twenty six (73%) of the applications have been issued a Sterile Compounding License. Approximately 48 of the applications (27%) are pending for deficiencies such as incomplete applications, poorly written policies and procedures, and, in the case of out-of-state applications, a lack of a non-resident pharmacy permit.

The following is a breakdown of the applications processed by month:

Month:	Number of Application Processed:
April	9
May	27
June	107
July	26
August	5
Total:	174

At the inception of the program, it was planned the expiration date of the Sterile Compounding License would coincide with the expiration date of the pharmacy license so the licensee would receive only one mailing advising them of the need to renew both licenses. However, during the

first six months of the Sterile Compounding licensing program, there were identified 68 pharmacies who were recently inspected, paid the initial application fee, and issued a Sterile Compounding license whose pharmacy license will expire on or before January 1, 2004. At the approval of the Executive Director, these pharmacies will be sent a letter advising them their Sterile Compounding license expiration date will be extended until their next pharmacy expiration date in 2004 at which time they will be subject to a renewal fee and re-inspection in accordance with Business and Professions Code Section 4127.1 subdivision (c). This will reduce the concerns from the licensees about repaying a fee within a short period and also result in better utilization of inspector resources by eliminating the need to re-inspect pharmacies within a 2-3 month time span.

Pharmacies whose applications are received after August 1st and where it is discovered during the initial inspection process that sterile injectable drugs were compounded and dispensed in the absence of a Sterile Compounding License will be in violation of Business and Professions Code Section 4127.1 subdivision (a).

Future Plans and Action:

1. Continue to monitor and trend the number of applications received versus those approved.
2. Send Sterile Compounding License expiration date extension letters to pharmacies whose pharmacy license expires on or before January 1, 2004.
3. Modify the sterile compounding checklist in the Board of Pharmacy website after the revised California Code of Regulation Section 1751 is finally approved for implementation.
4. Continue to send inspectors on sterile compounding inspections as applications are received.
5. Meet with inspectors to discuss the compliance of radio-pharmacies relative to California Code of Regulation Section 1751 prior to conducting renewal inspections.
6. Continue to assist licensees in the development of policies and procedures to meet compliance with California Code of Regulations Section 1751.
7. Conduct inspections in pharmacies identified as compounding and dispensing sterile injectable drugs who have not applied for a Sterile Compounding License.

Submitted by:

Dennis Ming, Pharm.D.
Supervising Inspector.