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

Licensing Committee Report

Clarence Hiura, Chair
Ruth Conroy, Member
John Tilley, Member
Richard Benson, Member

Report of June 9, 2004

FOR ACTION

RECOMMENDATION 1

That the Board of Pharmacy amend the continuing education statute and regulations as requested by the Pharmacy Foundation of California.

Discussion

The California Pharmacists Association submitted a request to the Board of Pharmacy that it consider amendments to the CE statute and regulations. 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

(Attachment A)

NO ACTION

Implementation of North American Pharmacist Licensure Examination (NAPLEX and California Pharmacist Jurisprudence Examination (CPJE)

The transition to the NAPLEX and CPJE has been completed with the recent licensure of 248 pharmacists. Since January 1, 2004, (when the statute took effect), the board has processed 1,792 applications and 1,507 candidates have been determined eligible to take the examinations. So far, 654 candidates have taken the CPJE. The pass/fail information and other statistical data for both the NAPLEX and CPJE examinations will be provided during the Competency Committee report.

The transition to this new examination format has been challenging and staff will continue to work to streamline this new labor-intensive process. While the board has not been without its critics, tremendous efforts by staff to implement the program timely should not go unnoticed. This was a major change in program operations (the board has been giving its own examination forever) and this new change was done without additional staff. In fact, the board had lost staff in its licensing and enforcement programs. Moreover, the board was ready to implement the CPJE in December; however, contracts were not in place for the CPJE and NAPLEX until March. There was further delay when by mid-May only 266 candidates (out of the 1,000 eligible candidates) had taken the CPJE. This delayed the releasing of the CPJE results because 400 candidates were needed to take the examination in order to validate the questions.

Also, the licensing unit has experienced a substantial increase in telephone, faxed and in-person inquiries regarding the examination process. Many candidates are confused and want to be walked through the application process. Staff has been working hard to ensure timely processing and licensure of pharmacist applicants. Every effort is being made to assist applicants to the extent that the board can without impacting the application process. The application process for licensure examination has been updated and is on the board's Web site. **(Attachment B)**

One-Year Evaluation of the Licensing Program for Pharmacies the Compound Injectable Sterile Drug Products

Supervising Inspector Dennis Ming presented to the Licensing Committee an overview and evaluation on the successful implementation of the sterile compounding licensing program. The program was implemented in January 2003, as the result of legislation. **(Attachment C)**

Implementation of the Statewide Protocol for Pharmacists to Dispense Emergency Contraception and Recommendation to Pursue Adoption of an Emergency Regulation

SB 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy

and the Medical Board of California. **(Attachment D)**

The protocol is available on the board's Web site and has been provided to the pharmacists associations for distribution. However, in order for the board to enforce the protocol, it must be adopted as a regulation. The proposed regulation has been noticed for adoption at this board meeting.

It was noted during the discussion that the board was provided some changes to Appendix 1 of the protocol, which is the list of brands and doses of oral contraceptive tablets used for emergency contraception. Medical Board of California will be notified of the corrections and the protocol will be revised accordingly.

California Pharmacy Manpower Statistics

Attached are pharmacy manpower statistics for California as of December 2003. **(Attachment E)**

Report on the Workgroup on Compounding

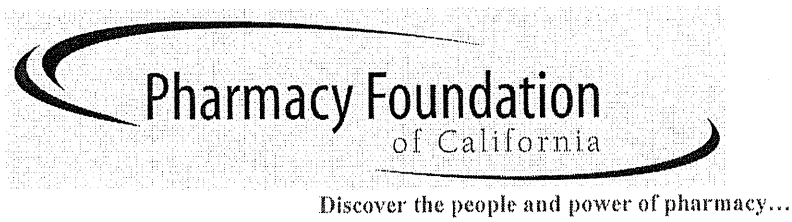
Last April, the Board of Pharmacy agreed to form a workgroup with the Department of Health Services, State Food and Drug Branch to address pharmacy-compounding issues. The workgroup held its second meeting on June 9, 2004 and over 30 individuals participated. **(Attachment F)**

Meeting Summary of June 9, 2004 (Attachment G)

Competency Committee Report (Attachment H)

Final Report on Committee Strategic Objectives for 2003/04 (Attachment I)

ATTACHMENT A



May 12, 2004

Patricia Harris
Executive Officer
California State Board of Pharmacy
400 R Street, Suite 4070
Sacramento, California 95814

Re: Request for Regulatory Changes regarding the AES Program

Dear Patty,

Beginning on January 1, 2004, the activities of the Accreditation Evaluation Service (AES) were moved from the California Pharmacists Association to the California Pharmacists Association Educational Foundation. In addition, the California Pharmacists Association Educational Foundation began doing business as the Pharmacy Foundation of California. In order to provide AES with a more descriptive and appropriate name, we are also changing the name of AES to "California Accreditation for Pharmacy Education" or CAPE.

To conform the current Pharmacy Law with these changes, we are asking the Board of Pharmacy to pursue a few minor changes to the pharmacy regulations that deal with pharmacist continuing education. At the same time, we are asking that other non-substantive changes be incorporated to reflect the current terminology and operational standards of both AES and the Accreditation Council for Pharmacy Education (ACPE). To assist the Board, we have included recommended language that incorporates these proposed changes.

A summary of the changes:

Changes made to CCR Title 16, Division 17, Article 4:

- Change the term "continuing pharmaceutical education" to "continuing pharmacy education" throughout the regulations.
- Changing AES from a "continuing education provider and coursework review component of the California Pharmacists Association" to "an accrediting agency for providers of continuing pharmacy education in California"
- Changing the role of AES and ACPE from "approvers" to "accreditors"
- Changing "ownership" of AES from CPhA to CPhA Educational Foundation DBA Pharmacy Foundation of California

4030 Lennane Drive **Sacramento, California 95834** **916 779-1410**

- Correcting what appears to be incorrect language from "organization" to "accreditation agency".
- Changing the review/audit requirement to a minimum of once a year from a minimum of 10%.
- Changing the term "certificates of completion" to "statements of credit"
- Updating the requirement of the provider to furnish statements of credit to "all enrollee" to "participants who complete all the requirements for course completion".
- Adding that material must still be "current" in order for it to be valid for CE, rather than a blanket 3 year shelf life.
- Change the name of Accreditation Evaluation Service (AES) to California Accreditation for Pharmacy Education (CAPE).

It is our desire and intent to implement these changes as soon as possible. Please advise us if there are any problems with these proposed changes or our immediate implementation of them. If we can be of any additional assistance in seeing these changes incorporated, or if there are any questions or other concerns about this request, please call me at (916) 779-1410 ext. 323. We will assume that if we don't hear from you that this is acceptable to the Board.

Thank you for your assistance.

Sincerely,

Lynn Rolston
Executive Director

Carlo Michelotti, RPh, MPH
CEO, CPhA

CA Code of Regulations

TITLE 16. Professional And Vocational Regulations
Division 17. California State Board of Pharmacy
Article 4. Continuing Education

Article 4. Continuing Education

§1732. Definitions.

As used in this article:

(a) An accreditation agency is an organization which evaluates and accredits providers of continuing ~~pharmaceutical~~ pharmacy education, monitors the quality of their educational activities, and audits continuing education coursework.

(b) The Accreditation Council for Pharmacy Education (ACPE) is the national accrediting agency for providers of continuing ~~pharmaceutical~~ pharmacy education.

(c) The ~~Accreditation Evaluation Service~~ CA Accreditation for Pharmacy Education is an accrediting agency for providers of continuing pharmacy education in California.~~is the continuing education provider and coursework review component of the California Pharmacists Association.~~

(d) A recognized provider is anyone whose qualifications as a continuing education provider have been accredited ~~approved~~ by an accreditation agency approved by the Board.

(e) An hour consists of at least 50 minutes of contact time.

NOTE

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

§1732.05. Accreditation Agencies.

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

(1) The Accreditation Council for Pharmacy Education

(2) The ~~Accreditation Evaluation Service~~ California Accreditation for Pharmacy Education of the California Pharmacists Association Educational Foundation DBA Pharmacy Foundation of California.

(b) Upon written application to the Board, any other organization will be approved by the board if:

(1) the organization submits a plan demonstrating that it has the capacity to evaluate each continuing education provider in accordance with the 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.

(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.

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

(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.

(E) When an ~~approved~~ accredited 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.

(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.

(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, post-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.

(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:

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.

(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.

(2) The ~~organization~~ accreditation agency agrees to perform the following:

(A) Maintain a list of the names and addresses of the persons designated as responsible for their accredited provider's C.E. program. The accreditation agency shall require that any change in the designated responsible person's identity shall be reported to the agency within 15 days of the effective date of such change.

(B) Notify the Board of names, addresses and responsible party of each provider.

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

(D) Review at least ~~a ten percent (10%) sample of coursework, as determined by the Board, but not less than~~ 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 and, on request, report the findings of such reviews to the Board.

(E) 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; and

(F) Verify attendance of licentiates at specific presentations upon request of the Board.

(c) Substantial failure of an approved accreditation agency to evaluate continuing education providers as set forth in (b)(1) or to perform in accordance with the terms of its agreement as described in (b)(2) shall constitute cause for revocation of approval by the Board.

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

§1732.1. Requirements for Recognized 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~~ accreditation as a provider prior to offering any such courses.

(b) 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. All continuing education coursework shall be:

(1) accurate and timely;

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

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

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

(5) based on stated educational goals and objectives.

(d) All providers shall furnish ~~certificates of completion~~ statements of credit to all ~~enrollees~~ participants who complete all the requirements for course completion. The ~~certificate~~ statement 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) Each recognized provider shall notify the accreditation agency, on forms approved by the board, within 15 days of the first time each new C.E. course is offered or presented

(f) All providers shall maintain records of attendance at or completion of their continuing education programs for four (4) years.

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

§1732.2 Coursework From Non-Recognized-Providers

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

education by ~~is accepted by~~ the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California ~~California State Board of Dental Examiners as meeting their requirements, which meets the standards of relevance to pharmacy practice, and which is not offered by an approved provider as set forth in section 1732.1(c), may be approved~~ shall, upon satisfactory completion, be considered approved continuing education for pharmacists. ~~for credit for pharmacists. upon written petition to the Board.~~

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

§1732.3. Coursework Approval for Providers.

(a) Unless denied by the accreditation agency upon audit, all coursework offered by California recognized providers is considered as approved in California.

(b) On a random basis established by the Board or in response to complaints about a particular provider or requests by the 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. 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 those defining relevance to pharmacy practice and educational quality stated in Section 1732.1(c).

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

(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.

NOTE
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 coursework, each recognized provider shall submit such materials as are required by the accreditation agency or the Board of Pharmacy.

NOTE
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 pharmacist shall submit with the application for renewal proof satisfactory to the Board that,

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~~ statements of credit for four (4) years following completion of the program.

NOTE
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 licensure renewal on the grounds of emergency or hardship by applying to the Board in writing, on a 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.

NOTE
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. Following such reconsideration, the provider may request review of the accreditation agency's decision by the full Board of Pharmacy

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

CA B&P Code 4232.

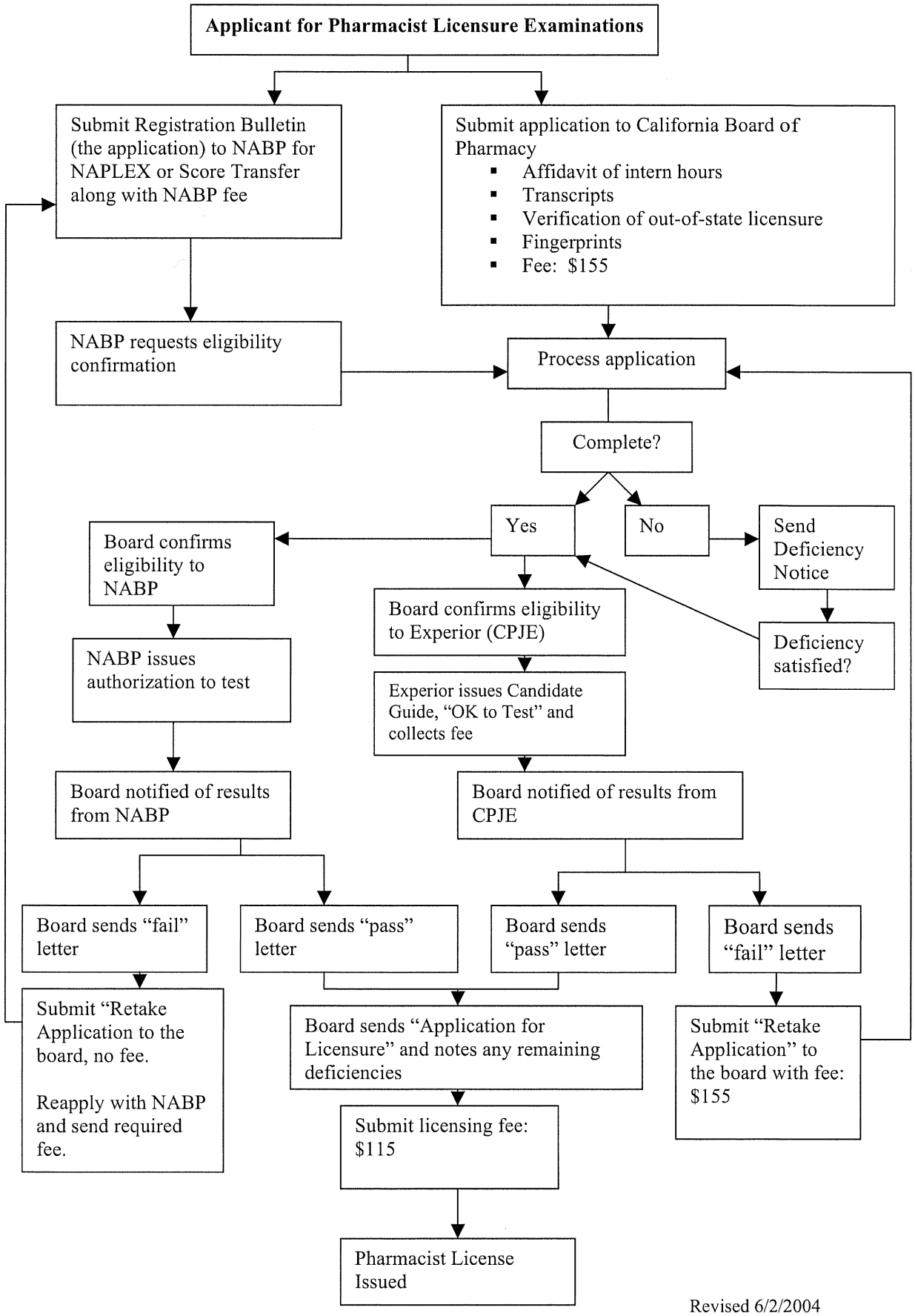
(a) The courses shall be in the form of postgraduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses, and other similar methods of conveying continuing professional ~~pharmaceutical~~ pharmacy education.

(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.

BOARD OF PHARMACY
CALIFORNIA CODE OF REGULATIONS
AMEND TITLE 16, DIVISION 17

ATTACHMENT B



Revised 6/2/2004

ATTACHMENT C

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

June 9, 2004

To: Licensing Committee

From: Dennis Ming, Supervising Inspector

RE: Sterile Compounding License Renewal Process – Status Report

Since the inception of the Sterile Compounding Licensing program in July, 2003, the Board of Pharmacy has received and processed **238** applications and has approved **184** Sterile Compounding licenses, of which **16** are out of state, for an average of **77%.**

The top three reasons for delays in approving applications when received are:

1. Lack of adequate/detailed policies and procedures required for compliance with California Code of Regulations 1751.
2. Incomplete applications relative to corporate officers, owners, etc. (amendments required)
3. Pharmacy permit pending (non resident and resident)

Inspections for new applications are completed within 3 weeks of assignment to a Compliance Team inspector.

As required by Business and Professions Code, Section 4127.1, subdivision (C), *"A license to compound injectable sterile drug products may not be renewed until the location has been inspected by the board and found to in compliance with this article and regulations adopted by the board".*

Starting in April, 2004, the board began re-inspections of pharmacies previously issued a Sterile Compounding License. To date **31** pharmacies issued Sterile Compounding licenses in 2003 were re-inspected. None were found to be out of compliance and none were denied renewal of their sterile compounding license. All were found to be in compliance for purposes of renewal.

To maintain continuity in the licensing and inspection process, the re-inspections were assigned to inspectors who conducted the initial licensing inspection. A separate checklist was created to assist the inspector in comparing results of the initial licensing inspection to the observations made during the re-inspection (attachment I). The results of the re-inspection as well as the status of the pharmacy during the initial licensing inspection were discussed with each

licensee/owner. This process enabled the inspector to identify areas of on-going compliance as well as trends/patterns in non-compliance with California Code of Regulations, Section 1751.

Once completed, the inspectors faxed copies of the completed inspection report as well as the checklist to the Supervising Inspector for review.

Initial results of the re-inspection process are as follows (per CCR 1751):

CCR 1751: Compounding Area for Parenteral Solutions: All of the pharmacies maintained on an on-going basis, the environment for the compounding sterile injectable drugs in compliance with this section.

CCR 1751.1 Laminar Flow Biological Safety Cabinet: One or two of the pharmacies converted from standard class 100 laminar air flow cabinets to class 100 barrier isolators in anticipation of the implementation of revised California Code of Regulations Section 1751 which requires specific environments in which to compound sterile injectable drugs from a non-sterile source. Pharmacies maintained annual certification of the laminar airflow hoods.

CCR 1751.2: Labeling Requirements: Pharmacies maintained compliance with this regulation. Pharmacies who contract with another pharmacy to compound sterile injectable drugs (Business and Professions Code Section 4123) were required to have the label of the compounding and dispensing pharmacy on the container.

CCR 1751.3: Record Keeping: Record keeping as required under current regulation will be changed when the revision to 1751(R) are finally approved and implemented. An area where record keeping was not strictly adhered to was radiopharmacies whose products are primarily intended for one time use and often for diagnostic purposes. In these cases, strict adherence to the record keeping requirements was not always possible or practical. Revisions to CCR 1751 will address and resolve these issues regarding record keeping requirements.

CCR 1751.4: Protective Clothing: This section was intended for pharmacies preparing cytotoxic (chemotherapeutic) medications for injection and for those pharmacies, compliance was on going.

CCR 1751.5: Training of Staff, Patient and Caregiver: Since the inception of the sterile compounding regulations, pharmacies were made more aware of the requirement to train and document competencies of the staff relative to utilizing aseptic technique etc. in the preparation of sterile injectable drugs. Records are being maintained; however, this area should be carefully monitored during the re-inspection process to ensure complete compliance.

CCR 1751.6: Disposal of Waste Material: Pharmacies were observed disposing of waste material from the preparation of sterile injectable drugs in an appropriate manner. Pharmacies compounding chemotherapeutic drugs disposed of residue in the appropriate chemo containers.

CCR 1751.7: Quality Assurance: This section has been the most problematic for pharmacies to maintain compliance. Results of the re-inspection demonstrate that a few pharmacies neglected

to maintain records of cleaning, calibration of equipment, process validation, and end product testing. Some were confused as to how many tests should be done and how often. It would be beneficial to provide feed-back to licensees either in future issues of the SCRIPT or on the Board of Pharmacy web site on how to maintain compliance with quality assurance in pharmacies compounding sterile injectable drugs. None of the pharmacies that were observed to be weak in compliance with this section were issued written warnings of non-compliance; rather they were instructed by the inspector in how to improve their compliance.

CCR 1751.8: Policies and Procedures: Pharmacies maintained their written policies and procedures and a few have submitted revisions for review upon receiving the renewal notice from the board.

CCR 1751.9: Reference Materials: Pharmacies have maintained compliance with this section in having the necessary resource information for compounding sterile injectable drugs.

Future Plans and Action:

1. Continue to conduct new and re-inspections for pharmacies applying for a sterile compounding license.
2. Provide additional information to the Executive Officer regarding the impact on inspector workload in conducting annual re-inspections of pharmacies compounding sterile injectable drugs relative to areas of compliance and non-compliance.
3. Continue to provide consultative/educational services to licensees to achieve and/or maintain compliance with sterile compounding regulations.
4. Modify the current sterile compounding checklist on the board web site to reflect the revisions in CCR 1751 (when approved for implementation).

ATTACHMENT D

Pharmacists Protocol for Dispensing Emergency Contraception

Senate Bill 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

On the following page is the approved protocol. Pharmacists may use this protocol after they have completed one hour of continuing education credit in emergency contraception (a requirement of the new law).

Prior legislation (Senate Bill 1169, Chapter 900, Statutes of 2001) permits pharmacists to furnish emergency contraception medications to patients based on a protocol with a single licensed prescriber. Existing protocols developed with a prescriber remain valid.

The protocol was prepared with the intent to keep it simple and to comply with the statutory requirements established by Senate Bill 490.

The statutory provisions for pharmacists furnishing emergency contraception are found in California Business and Professions Code section 4052.

Protocol for Pharmacists Furnishing Emergency Contraception (EC)

Authority: Section 4052 of the California Business and Professions Code authorizes a pharmacist to furnish emergency contraception pursuant to a protocol approved by the Board of Pharmacy and the Medical Board of California. Use of the following protocol satisfies that requirement.

Purpose: To provide access to emergency contraceptive medication within required limits and ensure that the patient receives adequate information to successfully complete therapy.

Procedure: When a patient requests emergency contraception the pharmacist will ask and state the following:

- Are you allergic to any medications?
- Timing is an essential element of the product's effectiveness. EC should be taken as soon as possible after unprotected intercourse. Treatment may be initiated up to five days (120 hours) of unprotected intercourse. EC effectiveness declines gradually over five days and EC use will not interfere with an established pregnancy.

The pharmacist shall provide the fact sheet and review any questions the patient may have regarding EC. In addition, the pharmacist shall collect the information required for a patient medical record by Section 1707.1 of Title 16 of the California Code of Regulations (reference attached).

Fact Sheet: The pharmacist will provide the patient with a copy of the current EC fact sheet approved by the Board of Pharmacy.

Referrals and Supplies: If emergency contraception services are not immediately available at the pharmacy or the pharmacist declines to furnish pursuant to conscience clause, the pharmacist will refer the patient to another emergency contraception provider. The pharmacist shall comply with all state mandatory reporting laws, including sexual abuse laws.

The pharmacist may provide up to 12 non-spermicidal condoms to each Medi-Cal and Family PACT client who obtains emergency contraception.

Advanced Provision: The pharmacist may dispense emergency contraception medication for a patient in advance of the need for emergency contraception.

EC Product Selection: The pharmacist will provide emergency contraception medication compatible with product information from the list of products appended to this protocol. This list must be kept current and maintained in the pharmacy. Along with emergency contraception products, the list will include adjunctive medications indicated for nausea and vomiting associated with taking EC. Patients will be provided information concerning dosing and potential adverse effects.

Documentation: Each prescription authorized by a pharmacist will be documented in a patient profile as required by law.

Training: Prior to furnishing emergency contraception, pharmacists who participate in this protocol must have completed a minimum of one hour of continuing education specific to emergency contraception.

Appendix 1 -- Brands and Doses of Oral Contraceptive Tablets Used for Emergency Contraception.

Brands and Doses Of Oral Contraceptive Tablets Used For Emergency Contraception

Dedicated Emergency Contraception				
Brand	Manufacturer	Tablets per Dose	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)**
One Dose Regimen				
Plan B	Women's Capital Corporation	2 tablets	0	1.5
Two Dose Regimens				
Plan B	Women's Capital Corporation	1 tablet per dose	0	0.75
Preven	Gynétics	2 tablets per dose	100	0.50
Oral Contraceptive Pills				
Brand	Manufacturer	Tablets per Dose (two doses 12 hours apart *)	Ethinyl Estradiol per Dose (mg)	Levonorgestrel per Dose (mg)*
Levora	Watson	4 white tablets	120	0.60
Ovral	Wyeth	2 white tablets	100	0.50
Ogestrel	Watson	2 white tablets	100	0.50
Nordette	Wyeth	4 light-orange tablets	120	0.60
Tri-Levlen	Berlex	4 yellow tablets	100	0.50
Alesse	Wyeth	5 pink tablets	100	0.50
Aviane	Duramed	5 orange tablets	100	0.50
Triphasil	Wyeth	4 yellow tablets	120	0.50
Levlen	Berlex	4 light-orange tablets	120	0.60
Trivora	Watson	4 pink tablets	120	0.50
Levlite	Berlex	5 pink tablets	100	0.50
Lo/Ovral	Wyeth	4 white tablets	120	0.60

Low-Ogestrel	Watson	4 white tablets	120	0.60
Ovrette	Wyeth	20 yellow tablets	0	0.75

* The progestin in Ovral, Lo/Ovral, and Ovrette is norgestrel, which contains two isomers, only one of which (levonorgestrel) is bioactive; the amount of norgestrel in each dose is twice the amount of levonorgestrel

Appendix 2 -- Sample list of Anti-Emetics for Use with Emergency Contraception.

Anti-nausea Treatment Options for use with Emergency Contraception

Drug	Dose	Timing of Administration
Non-prescription Drugs		
Meclizine hydrochloride (Dramamine II, Bonine)	One or two 25 mg tablets	1 hour before first EC dose; repeat if needed in 24 hours
Diphenhydramine hydrochloride (Benadryl)	One or two 25 mg tablets or capsules.	1 hour before first EC dose; repeat as needed every 4-6 hours
Dimenhydrinate (Dramamine)	One or two 50 mg tablets or 4-8 teaspoons liquid	30 minutes to 1 hour before first ECP dose; repeat as needed every 4-6 hours
Cyclizine hydrochloride (Marezine)	One 50 mg tablet	30 minutes before first EC dose; repeat as needed every 4-6 hours

ATTACHMENT E

State of California

Department of Consumer Affairs

Memorandum

To: **Licensing Committee**

Date: May 25, 2004

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

Subject: **California Pharmacy Manpower Statistics**

Attached for your information are some pharmacy manpower statistics for California. The data is displayed by license type, date and county.

As of December 2003, 5,624 pharmacies were licensed with the board. This is a 6.3% increase from January 2001.

As of December 2003, the board 37,756 pharmacy technicians were registered. This is a 41% increase from December 2001, where there were 26,706 registered pharmacy technicians. Also, provided is the number of pharmacy technicians per pharmacists and per pharmacy.

In 2003, there were 24,256 licensed pharmacists with California addresses. This is a 16% increase from 2001, where 20,905 pharmacists were licensed. Also provided is the number of pharmacists per 100,000 Californians.

Pharmacy License Statistics

Board of Pharmacy Data -- December 2003

County	PHY January 2001	PHY December 2003	% Change	Population 1/1/2001 (DOF Est.)	Population 1/1/2004 (DOF Est.)	% Change	Pop. Per PHY 1/1/2001	Pop. Per PHY 12/1/2003	% Change	Average Sq. Miles per PHY 1/1/2001	Average Sq. Miles per PHY 12/1/2003	% Change
Alameda	206	212	2.9%	1,454,302	1,498,000	3.0%	7,272	7,066	-2.8%	4.0	3.9	-2.8%
Alpine	0	0	0.0%	1,193	1,280	7.3%	0	0	0.0%	-	-	-
Amador	7	7	0.0%	34,400	36,850	7.1%	5,264	5,264	0.0%	86.3	86.3	0.0%
Butte	38	41	7.9%	204,046	212,700	4.2%	5,597	5,188	-7.3%	44.1	40.9	-7.3%
Calaveras	5	6	20.0%	38,476	43,350	12.7%	8,670	7,225	-16.7%	207.4	172.8	-16.7%
Colusa	3	3	0.0%	18,755	20,100	7.2%	6,700	6,700	0.0%	385.4	385.4	0.0%
Contra Costa	142	153	7.7%	930,025	1,003,900	7.9%	7,070	6,561	-7.2%	5.6	5.2	-7.2%
Del Norte	5	5	0.0%	28,022	28,250	0.8%	5,650	5,650	0.0%	246.0	246.0	0.0%
El Dorado	20	22	10.0%	152,942	168,100	9.9%	8,405	7,641	-9.1%	89.6	81.4	-9.1%
Fresno	138	151	9.4%	805,005	862,600	7.2%	6,251	5,713	-8.6%	43.6	39.9	-8.6%
Glenn	4	4	0.0%	27,107	27,750	2.4%	6,938	6,938	0.0%	331.8	331.8	0.0%
Humboldt	24	29	20.8%	127,633	130,000	1.9%	5,417	4,483	-17.2%	168.9	139.7	-17.2%
Imperial	18	21	16.7%	145,285	156,600	7.8%	8,700	7,457	-14.3%	249.0	213.4	-14.3%
Inyo	4	4	0.0%	18,193	18,500	1.7%	4,625	4,625	0.0%	2,556.9	2,556.9	0.0%
Kern	101	115	13.9%	658,935	724,900	10.0%	7,177	6,303	-12.2%	80.8	71.0	-12.2%
Kings	14	15	7.1%	131,218	141,400	7.8%	10,100	9,427	-6.7%	99.4	92.8	-6.7%
Lake	11	11	0.0%	55,691	63,200	13.5%	5,745	5,745	0.0%	120.9	120.9	0.0%
Lassen	4	4	0.0%	33,960	34,850	2.6%	8,713	8,713	0.0%	1,180.2	1,180.2	0.0%
Los Angeles	1605	1669	4.0%	9,884,255	10,103,000	2.2%	6,295	6,053	-3.8%	3.0	2.8	-3.8%
Madera	20	19	-5.0%	117,074	135,300	15.6%	6,765	7,121	5.3%	107.7	113.3	5.3%
Marin	34	34	0.0%	249,671	250,200	0.2%	7,359	7,359	0.0%	24.4	24.4	0.0%
Mariposa	2	2	0.0%	16,143	17,650	9.3%	8,825	8,825	0.0%	731.5	731.5	0.0%
Mendocino	19	19	0.0%	87,591	89,200	1.8%	4,695	4,695	0.0%	204.1	204.1	0.0%
Merced	27	28	3.7%	210,138	232,100	10.5%	8,596	8,289	-3.6%	73.0	70.4	-3.6%
Modoc	2	1	-50.0%	9,794	9,650	-1.5%	4,825	9,650	100.0%	2,101.8	4,203.6	100.0%
Mono	2	2	0.0%	10,914	13,500	23.7%	6,750	6,750	0.0%	1,566.0	1,566.0	0.0%
Monterrey	49	50	2.0%	399,304	421,400	5.5%	8,600	8,428	-2.0%	77.0	75.4	-2.0%
Napa	16	18	12.5%	127,005	131,600	3.6%	8,225	7,311	-11.1%	49.3	43.8	-11.1%
Nevada	14	14	0.0%	91,097	96,100	5.5%	6,864	6,864	0.0%	69.6	69.6	0.0%
Orange	528	531	0.6%	2,828,351	3,017,300	6.7%	5,715	5,682	-0.6%	1.8	1.8	-0.6%
Placer	51	66	29.4%	234,371	292,100	24.6%	5,727	4,426	-22.7%	29.4	22.7	-22.7%
Plumas	5	5	0.0%	20,341	21,100	3.7%	4,220	4,220	0.0%	522.7	522.7	0.0%
Riverside	217	251	15.7%	1,522,855	1,776,700	16.7%	8,188	7,078	-13.5%	33.7	29.1	-13.5%
Sacramento	181	202	11.6%	1,209,472	1,335,400	10.4%	7,378	6,611	-10.4%	5.5	4.9	-10.4%
San Benito	6	5	-16.7%	49,791	57,100	14.7%	9,517	11,420	20.0%	231.8	278.2	20.0%

San Bernardino	222	248	11.7%	1,689,281	1,886,500	11.7%	8,498	7,607	-10.5%	90.6	81.1	-10.5%
San Diego	388	428	10.3%	2,911,468	3,017,200	3.6%	7,776	7,050	-9.3%	11.7	10.6	-9.3%
San Francisco	142	142	0.0%	801,377	792,700	-1.1%	5,582	5,582	0.0%	1.6	1.6	0.0%
San Joaquin	94	99	5.3%	566,628	630,600	11.3%	6,709	6,370	-5.1%	15.2	14.4	-5.1%
San Luis Obispo	49	52	6.1%	245,191	258,200	5.3%	5,269	4,965	-5.8%	73.8	69.5	-5.8%
San Mateo	88	86	-2.3%	730,029	712,400	-2.4%	8,095	8,284	2.3%	8.4	8.6	2.3%
Santa Barbara	62	70	12.9%	414,155	414,800	0.2%	6,690	5,926	-11.4%	61.1	54.1	-11.4%
Santa Clara	230	244	6.1%	1,736,722	1,731,400	-0.3%	7,528	7,096	-5.7%	5.7	5.3	-5.7%
Santa Cruz	37	39	5.4%	255,021	260,200	2.0%	7,032	6,672	-5.1%	16.4	15.6	-5.1%
Shasta	37	40	8.1%	166,960	175,700	5.2%	4,749	4,393	-7.5%	104.0	96.2	-7.5%
Sierra	1	1	0.0%	3,143	3,520	12.0%	3,520	3,520	0.0%	962.0	962.0	0.0%
Siskiyou	9	10	11.1%	44,184	44,850	1.5%	4,983	4,485	-10.0%	705.3	634.8	-10.0%
Solano	44	46	4.5%	399,026	416,500	4.4%	9,466	9,054	-4.3%	20.6	19.7	-4.3%
Sonoma	65	68	4.6%	450,057	472,700	5.0%	7,272	6,951	-4.4%	27.2	26.0	-4.4%
Stanislaus	70	75	7.1%	441,364	491,900	11.4%	7,027	6,559	-6.7%	21.6	20.2	-6.7%
Sutter	8	13	62.5%	77,878	85,500	9.8%	10,688	6,577	-38.5%	76.1	46.8	-38.5%
Tehama	9	10	11.1%	56,159	58,700	4.5%	6,522	5,870	-10.0%	329.1	296.2	-10.0%
Trinity	3	4	33.3%	13,039	13,450	3.2%	4,483	3,363	-25.0%	1,069.3	802.0	-25.0%
Tulare	50	55	10.0%	367,961	396,800	7.8%	7,936	7,215	-9.1%	96.8	88.0	-9.1%
Tuolumne	10	10	0.0%	52,953	56,900	7.5%	5,690	5,690	0.0%	227.5	227.5	0.0%
Ventura	125	133	6.4%	756,501	802,400	6.1%	6,419	6,033	-6.0%	17.7	16.6	-6.0%
Yolo	18	23	27.8%	162,928	184,500	13.2%	10,250	8,022	-21.7%	56.8	44.5	-21.7%
Yuba	7	9	28.6%	60,711	64,800	6.7%	9,257	7,200	-22.2%	91.9	71.5	-22.2%
Statewide	5290	5624	6.3%	34,336,091	36,143,950	5.3%	6,833	6,427	-5.9%	30.9	29.1	-5.9%

Pharmacy Technician Statistics

Board of Pharmacy Data - December 2003

County	# of Technicians 1/1/2001	# of Technicians 12/1/2003	% Change	Technicians per Pharmacist 1/1/2001	Technicians per Pharmacist 12/1/2003	% Change	Technicians per Pharmacy 1/1/2001	Technicians per Pharmacy 12/1/2003	% Change
Alameda	1149	1603	39.5%	1.3	1.5	17.7%	5.6	7.6	35.6%
Alpine	0	0	0.0%	0.0	0.0	0.0%	0.0	0.0	0.0%
Amador	37	45	21.6%	1.8	1.8	2.2%	5.3	6.4	21.6%
Butte	189	254	34.4%	1.4	1.8	24.9%	5.0	6.2	24.6%
Calaveras	31	44	41.9%	2.2	1.9	-13.6%	6.2	7.3	18.3%
Colusa	9	10	11.1%	1.1	1.1	-1.2%	3.0	3.3	11.1%
Contra Costa	719	1025	42.6%	1.0	1.3	28.8%	5.1	6.7	32.3%
Del Norte	22	23	4.5%	1.4	1.2	-12.0%	4.4	4.6	4.5%
El Dorado	114	151	32.5%	1.1	1.3	18.3%	5.7	6.9	20.4%
Fresno	660	1053	59.5%	1.4	1.9	31.1%	4.8	7.0	45.8%
Glenn	12	23	91.7%	1.7	2.9	67.7%	3.0	5.8	91.7%
Humboldt	110	147	33.6%	1.6	2.1	33.6%	4.6	5.1	10.6%
Imperial	85	109	28.2%	2.7	2.9	7.4%	4.7	5.2	9.9%
Inyo	11	12	9.1%	0.9	0.9	0.7%	2.8	3.0	9.1%
Kern	532	731	37.4%	1.9	2.3	23.1%	5.3	6.4	20.7%
Kings	102	129	26.5%	3.4	3.2	-5.1%	7.3	8.6	18.0%
Lake	41	64	56.1%	1.6	2.7	62.6%	3.7	5.8	56.1%
Lassen	21	31	47.6%	1.5	2.4	59.0%	5.3	7.8	47.6%
Los Angeles	7352	10377	41.1%	1.3	1.6	23.7%	4.6	6.2	35.7%
Madera	106	140	32.1%	3.2	3.4	6.3%	5.3	7.4	39.0%
Marin	86	94	9.3%	0.4	0.4	-6.5%	2.5	2.8	9.3%
Mariposa	9	13	44.4%	1.5	1.9	23.8%	4.5	6.5	44.4%
Mendocino	61	76	24.6%	1.5	1.5	-4.2%	3.2	4.0	24.6%
Merced	140	224	60.0%	2.1	3.0	42.9%	5.2	8.0	54.3%
Modoc	4	5	25.0%	0.8	1.0	25.0%	2.0	5.0	150.0%
Mono	4	6	50.0%	0.8	0.8	-6.3%	2.0	3.0	50.0%
Monterrey	278	343	23.4%	1.6	1.7	9.8%	5.7	6.9	20.9%
Napa	76	100	31.6%	1.1	1.2	6.8%	4.8	5.6	17.0%
Nevada	64	74	15.6%	1.2	1.1	-7.8%	4.6	5.3	15.6%
Orange	1948	2815	44.5%	0.7	0.9	21.1%	3.7	5.3	43.7%
Placer	200	261	30.5%	1.0	0.9	-9.1%	3.9	4.0	0.8%
Plumas	11	13	18.2%	0.8	1.1	28.0%	2.2	2.6	18.2%
Riverside	1420	2004	41.1%	2.4	2.6	11.3%	6.5	8.0	22.0%
Sacramento	1022	1527	49.4%	1.2	1.5	23.5%	5.6	7.6	33.9%
San Benito	36	46	27.8%	3.3	2.9	-12.2%	6.0	9.2	53.3%

San Bernardino	1697	2503	47.5%	2.6	3.4	32.9%	7.6	10.1	32.0%
San Diego	2648	3678	38.9%	1.5	1.8	21.2%	6.8	8.6	25.9%
San Francisco	472	700	48.3%	0.6	0.8	25.3%	3.3	4.9	48.3%
San Joaquin	462	739	60.0%	1.0	1.5	47.6%	4.9	7.5	51.9%
San Luis Obispo	211	247	17.1%	1.2	1.2	0.6%	4.3	4.8	10.3%
San Mateo	466	620	33.0%	0.8	1.0	23.2%	5.3	7.2	36.1%
Santa Barbara	247	323	30.8%	1.3	1.4	13.2%	4.0	4.6	15.8%
Santa Clara	1054	1544	46.5%	0.9	1.2	24.9%	4.6	6.3	38.1%
Santa Cruz	162	188	16.0%	1.2	1.3	6.2%	4.4	4.8	10.1%
Shasta	235	311	32.3%	2.1	2.3	10.6%	6.4	7.8	22.4%
Sierra	0	1	#DIV/0!	0.0	1.0	0.0%	0.0	1.0	#DIV/0!
Siskiyou	28	39	39.3%	1.1	1.1	6.5%	3.1	3.9	25.4%
Solano	418	701	67.7%	2.4	3.5	44.1%	9.5	15.2	60.4%
Sonoma	340	434	27.6%	1.2	1.4	18.4%	5.2	6.4	22.0%
Stanislaus	436	722	65.6%	2.0	3.0	47.8%	6.2	9.6	54.6%
Sutter	58	74	27.6%	1.3	1.4	8.0%	7.3	5.7	-21.5%
Tehama	44	53	20.5%	2.6	2.8	7.8%	4.9	5.3	8.4%
Trinity	14	13	-7.1%	2.8	1.6	-42.0%	4.7	3.3	-30.4%
Tulare	267	332	24.3%	1.8	2.0	11.0%	5.3	6.0	13.0%
Tuolumne	47	59	25.5%	1.3	1.7	25.5%	4.7	5.9	25.5%
Ventura	614	707	15.1%	1.4	1.3	-4.5%	4.9	5.3	8.2%
Yolo	88	140	59.1%	1.0	1.4	42.9%	4.9	6.1	24.5%
Yuba	37	56	51.4%	3.4	3.5	4.1%	5.3	6.2	17.7%
Statewide	26706	37756	41.4%	1.3	1.6	21.8%	5.0	6.7	33.0%

Out of State	750
Out of Country	15

Pharmacist Workforce Estimates

Board of Pharmacy Data -- December 2003

County	Total RPH 2001	Total RPH 2003	% Change	Population 1/1/2001 (DOF Est.)	Population 1/1/2004 (DOF Est.)	% Change	Pharmacists Per 100,000 1/1/2001	Pharmacists Per 100,000 12/1/2003	% Change
Alameda	906	1074	18.5%	1,454,302	1,498,000	3.0%	62	72	15.1%
Alpine	0	0	0.0%	1,193	1,280	7.3%	0	0	0.0%
Amador	21	25	19.0%	34,400	36,850	7.1%	61	68	11.1%
Butte	131	141	7.6%	204,046	212,700	4.2%	64	66	3.3%
Calaveras	14	23	64.3%	38,476	43,350	12.7%	36	53	45.8%
Colusa	8	9	12.5%	18,755	20,100	7.2%	43	45	5.0%
Contra Costa	712	788	10.7%	930,025	1,003,900	7.9%	77	78	2.5%
Del Norte	16	19	18.8%	28,022	28,250	0.8%	57	67	17.8%
El Dorado	100	112	12.0%	152,942	168,100	9.9%	65	67	1.9%
Fresno	461	561	21.7%	805,005	862,600	7.2%	57	65	13.6%
Glenn	7	8	14.3%	27,107	27,750	2.4%	26	29	11.6%
Humboldt	70	70	0.0%	127,633	130,000	1.9%	55	54	-1.8%
Imperial	31	37	19.4%	145,285	156,600	7.8%	21	24	10.7%
Inyo	12	13	8.3%	18,193	18,500	1.7%	66	70	6.5%
Kern	285	318	11.6%	658,935	724,900	10.0%	43	44	1.4%
Kings	30	40	33.3%	131,218	141,400	7.8%	23	28	23.7%
Lake	25	24	-4.0%	55,691	63,200	13.5%	45	38	-15.4%
Lassen	14	13	-7.1%	33,960	34,850	2.6%	41	37	-9.5%
Los Angeles	5525	6302	14.1%	9,884,255	10,103,000	2.2%	56	62	11.6%
Madera	33	41	24.2%	117,074	135,300	15.6%	28	30	7.5%
Marin	201	235	16.9%	249,671	250,200	0.2%	81	94	16.7%
Mariposa	6	7	16.7%	16,143	17,650	9.3%	37	40	6.7%
Mendocino	40	52	30.0%	87,591	89,200	1.8%	46	58	27.7%
Merced	67	75	11.9%	210,138	232,100	10.5%	32	32	1.3%
Modoc	5	5	0.0%	9,794	9,650	-1.5%	51	52	1.5%
Mono	5	8	60.0%	10,914	13,500	23.7%	46	59	29.4%
Monterrey	178	200	12.4%	399,304	421,400	5.5%	45	47	6.5%
Napa	69	85	23.2%	127,005	131,600	3.6%	54	65	18.9%
Nevada	55	69	25.5%	91,097	96,100	5.5%	60	72	18.9%
Orange	2710	3233	19.3%	2,828,351	3,017,300	6.7%	96	107	11.8%
Placer	202	290	43.6%	234,371	292,100	24.6%	86	99	15.2%
Plumas	13	12	-7.7%	20,341	21,100	3.7%	64	57	-11.0%
Riverside	600	761	26.8%	1,522,855	1,776,700	16.7%	39	43	8.7%
Sacramento	869	1051	20.9%	1,209,472	1,335,400	10.4%	72	79	9.5%
San Benito	11	16	45.5%	49,791	57,100	14.7%	22	28	26.8%

San Bernardino	658	730	10.9%	1,689,281	1,886,500	11.7%	39	39	-0.7%
San Diego	1752	2007	14.6%	2,911,468	3,017,200	3.6%	60	67	10.5%
San Francisco	774	916	18.3%	801,377	792,700	-1.1%	97	116	19.6%
San Joaquin	452	490	8.4%	566,628	630,600	11.3%	80	78	-2.6%
San Luis Obispo	177	206	16.4%	245,191	258,200	5.3%	72	80	10.5%
San Mateo	591	638	8.0%	730,029	712,400	-2.4%	81	90	10.6%
Santa Barbara	193	223	15.5%	414,155	414,800	0.2%	47	54	15.4%
Santa Clara	1136	1332	17.3%	1,736,722	1,731,400	-0.3%	65	77	17.6%
Santa Cruz	130	142	9.2%	255,021	260,200	2.0%	51	55	7.1%
Shasta	112	134	19.6%	166,960	175,700	5.2%	67	76	13.7%
Sierra	1	1	0.0%	3,143	3,520	12.0%	32	28	-10.7%
Siskiyou	26	34	30.8%	44,184	44,850	1.5%	59	76	28.8%
Solano	171	199	16.4%	399,026	416,500	4.4%	43	48	11.5%
Sonoma	281	303	7.8%	450,057	472,700	5.0%	62	64	2.7%
Stanislaus	216	242	12.0%	441,364	491,900	11.4%	49	49	0.5%
Sutter	44	52	18.2%	77,878	85,500	9.8%	56	61	7.6%
Tehama	17	19	11.8%	56,159	58,700	4.5%	30	32	6.9%
Trinity	5	8	60.0%	13,039	13,450	3.2%	38	59	55.1%
Tulare	150	168	12.0%	367,961	396,800	7.8%	41	42	3.9%
Tuolumne	35	35	0.0%	52,953	56,900	7.5%	66	62	-6.9%
Ventura	453	546	20.5%	756,501	802,400	6.1%	60	68	13.6%
Yolo	88	98	11.4%	162,928	184,500	13.2%	54	53	-1.7%
Yuba	11	16	45.5%	60,711	64,800	6.7%	18	25	36.3%
Total	20905	24256	16.0%	34,336,091	36,143,950	5.3%	61	67	10.2%

Non-Resident RPH

Out of Country	169
Out of State	5251

ATTACHMENT F

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: June 9, 2004

TIME: 1:30 p.m. – 4:00 p.m.

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505

Workgroup Members: Ken Schell, Pharm.D., Chair

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 the workgroup was formed in part to respond to a request from the Department of Health Services to further consider 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.

Compounding Issues

Overview of Pharmacy Law Related to Compounding – Application of USP 797

Dr. Schell stated that at the last meeting, there were questions as to how the recently approved U.S. Pharmacopeia (USP) General Chapter 797 (effective January 1, 2004) on pharmaceutical compounding of sterile preparations might affect California pharmacy practice and the pending regulations promulgated by the board. USP Chapter 797 provides procedures and requirements for compounding sterile preparations. It is intended to be applicable to health care institutions,

pharmacies, physician practice facilities, and other facilities where compounded sterile preparations are prepared, stored and dispensed. Many of the participants had previously voiced the opinion that USP 797 has the force of federal law and may void the board's pending regulations if the USP requirements are more restrictive.

At Dr. Schell's request, the board's liaison counsel with the Attorney General's Office, Deputy Attorney General Joshua Room, made a brief presentation on USP 797. He first noted that there are at least two areas of possible regulation with regard to compounding: regulations aimed at the strength or purity of the resulting drug(s); and regulations aimed at controlling the circumstances in which those drugs are compounded. The Board of Pharmacy has only sought to regulate the latter, and has not yet attempted to regulate drug strength, purity, adulteration, etc. This has typically been the province of the federal government, through the FDA. Because the regulation of compounding is being led by the states, this may constitute a "gap" in regulation.

DAG Room went on to explain that USP 797 is not incorporated by reference into the board's statutes or regulations. The Food and Drug Administration Modernization Act of 1997 (FDAMA) did incorporate the two USP chapters related to compounding, USP 795 and USP 797. USP 795 relates to compounding of nonsterile products and covers most compounding activities of community pharmacies. USP 797 details good practices for compounding sterile products, which includes home IV admixtures, eye drops and similar products. These standards were incorporated into FDAMA; however, since FDAMA was invalidated, the standards currently have no apparent force in federal law. They do remain as elements of the FDA's Enforcement Compliance Guide.

DAG Room stated that since California does not incorporate by reference the standards of USP chapters <795> or <797>, these standards do not control the board's enforcement of its own regulations regarding pharmacy compounding. They are standards that are considered best practices and any compounder would be wise to consider whether they are presently in compliance with USP 797, but the enforcement authority of the board is presently guided by its own separate regulations.

It was noted the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) will be requiring pharmacies to meet the standards of USP 797 for purposes of accreditation.

Overview of California Pharmacy Law on Compounding

Supervising Inspector Dennis Ming identified the pharmacy law that regulates compounding. He directed the group's attention to Bus. & Prof. Code sec. 4127 - 4127.6, CCR, title 16, sec. 1716.1 and 1716.2 and sec. 1751 – 1751.12. He stated that the proposed amendments to the regulations that would update the regulations on compounding of injectable sterile drug products were disapproved by the Office of Administrative (OAL) because of the requirements for building standards in the pharmacy. According to OAL, any changes to building standards must be approved by the Building Standards Commission. The standards were removed from the proposed regulation and placed instead in accompanying legislation. If the legislation is enacted, the building standards would take effect July 2006. The board has noticed this change in the pending regulation for a 15-day comment period and will act on the change at its July meeting.

Supervising Inspector Ming emphasized that current pharmacy regulations only govern the physical circumstances, procedures, and recordkeeping requirements for compounding drugs and do not address quality, strength or end product testing. He stated that this is a "gap" in pharmacy law. Whether a pharmacy compounds one drug for a patient or many, the patient needs to be assured that the compounded drug meets the USP standard.

Identification of Compounding Issues

Compounding versus Manufacturing

The workgroup reviewed the subcommittee report on compounding versus manufacturing. There was general discussion as to the proposed changes made to the compliance guide that the Board of Pharmacy adopted in 1995. The workgroup noted that the subcommittee identified the sections of pharmacy law that defined manufacturer and pharmacy. It was suggested that the subcommittee review these sections of law to determine if the law should be amended to define compounding and the subcommittee may want to incorporate the guideline(s) as part of the definitions in law. The workgroup also asked the subcommittee to address central fill as a definition in pharmacy law. The workgroup further requested that an explanation be provided with the guidelines, particularly as to non-adoption of definitional factors proposed by the FDA.

Non-Prescription Compounding

The workgroup discussed a subcommittee proposal regarding the compounding of non-prescription drugs. It was noted that this is the process whereby a pharmacy compounds from ingredients in a strength that would not normally require a prescription (over the counter strengths). The proposal was modeled after other states and would permit such practice to take place without a prescription and only be available upon request by a patient.

It was noted that when the FDA determines that a drug is nonprescription, then the labeling of that drug is complete enough that it is considered safe for self-use without the oversight of a health practitioner. The board's position is that if a compounded drug is considered a nonprescription drug (because the strengths are equal to that of a nonprescription drug) then it must meet the labeling requirements of the federal FDA.

It was stated that the Board of Pharmacy's position that a prescription is required for compounded nonprescription drugs (even if the strength of compounded drug would not deem it a prescription drug) is contrary to the direction given by DHS, Food and Drug Branch. It was suggested that further clarification be sought from the DHS.

FDA Notice on Compounded Veterinary Medications

Dr. Schell noted that the FDA, Office of Compliance, Center of Veterinary Medicine (CVM) sent a letter to all state boards of pharmacy advising that the compounding of new animal drugs is only permitted if conducted in accordance with the Animal Medical Drug Use Clarification Act (AMDUCA) and its implementing regulations. It was stated that neither the AMDUCA nor

the regulations permit compounding from bulk drugs. Further, they contend that they require that compounding be done by or on the order of a licensed veterinarian, with the context of a valid veterinarian/client/patient relationship and from approved human or veterinary drugs. They further state that in an effort to determine the extent of the illegal veterinary compounding activities CVM is issuing inspection assignments to FDA field offices to inspect certain pharmacies. These pharmacies were selected after evaluating trade complaints and promotional materials submitted to CVM over the last few years.

A letter was sent from the American Pharmacists Association, International Academy of Compounding Pharmacists and the National Community Pharmacists Association expressing serious concern with the CVM letter and regarding what was perceived as a change in the FDA enforcement policy. The signatories urged the FDA to retract the letter.

The workgroup discussed concern by the various pharmacy organizations about the FDA's position regarding the compounding of veterinary drugs and efforts to address these concerns with the agency.

Next Meeting Date

Dr. Schell stated that the next meeting date for the Workgroup on Compounding Issues is September 22, 2004, in Oakland.

Adjournment

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

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
Meeting Summary

DATE: June 9, 2004

TIME: 9:30 a.m. – 12 noon

LOCATION: Hilton Burbank Airport & Convention Center
2500 Hollywood Way
Burbank, CA 91505-1019

BOARD MEMBERS Clarence Hiura, Pharm.D., Chair
Ruth Conroy, Pharm.D.

STAFF PRESENT: Patricia Harris, Executive Officer
Virginia Herold, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Dennis Ming, Supervising Inspector

Call to Order

Committee Chair Clarence Hiura called the meeting to order at 9:30 a.m. He explained that committee members John Tilley and Richard Benson were excused from the meeting.

Request for Changes to Business and Professions Code section 4232 and CCR, title 16, section 1732 – 1732.7 Relating to Continuing Education (CE)

The California Pharmacists Association submitted a request to the Board of Pharmacy that it consider amendments to the CE statute and regulations. 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

The Licensing Committee recommended that the Board of Pharmacy amend the continuing education statute and regulations as requested by the Pharmacy Foundation of California.

Report on the Implementation of the North American Pharmacy Licensure Examination (NAPLEX) and the California Specific Examination

Assistant Executive Officer Virginia Herold reported that as of May 28, 2004, the board has qualified 1,134 applicants to take the pharmacist licensure examination (the NAPLEX and CPJE). However, as of May 24, 2004, only 284 applicants had taken the CPJE. She stated that the board had processed 1,545 applications out of the 1,673 applications received. There were 128 applications to process with 411 deficient applications pending.

Ms. Herold added that the board will be releasing the CPJE scores in approximately two weeks with the goal of issuing pharmacist licenses by mid-June. She stated that the board has been releasing NAPLEX scores and does so on a weekly basis. She reported on the pass rate for the NAPLEX.

Ms. Herold advised the Licensing Committee that staff has experienced a substantial increase in telephone, faxed and in-person inquiries regarding the examination process. Even with the board's limited resources, staff has been performing extraordinarily to ensure timely processing and licensure of pharmacist applicants. Every effort is being made to assist applicants to the extent that the board can without impacting the application process.

Request from the Schools of Pharmacy to discuss the Intern Requirements

Committee Chair Clarence Hiura reported that on April 20, 2004, President John Jones received a letter from the Dean of UCSF, School of Pharmacy, Dr. Mary Anne Koda-Kimble. She wrote the letter on behalf of her fellow California School of Pharmacy Deans. The purpose of the letter was to express concern about the proposed changes to the licensure requirements contained in SB 1913, and to request that the board initiate an open dialogue with them on how the 1,500 hours of pharmacy internship would be defined.

It was explained to Dean Koda-Kimble that SB 1913 is not changing the 1,500 experience requirement that is currently specified in regulation, California Code of Regulations (CCR), title 16, sec. 1728. Specifically SB 1913 is moving the intern requirements from regulation to statute

(B&P Code sec. 4030), the length of time and circumstances that an intern pharmacist license may be issued (B&P Code sec. 4208), that the intern pharmacist must complete the 1,500 hours prior to applying for the pharmacist licensure examination and that the experience must comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy education (B&P Code sec. 4209).

In her letter, Dean Koda-Kimble discussed the 1,500-intern requirement that is required by section 1728. Pharmacist interns must complete a minimum of 900 hours in a pharmacy under the supervision of a preceptor. Then the board can grant at its discretion a maximum of 600 hours for other experiences that substantially relates to the practice of pharmacy. California pharmacy students are granted the 600 hours for completing the School's Advanced Pharmacy Practice Experiences (APPEs or clerkships).

There was concern by the schools that SB 1913 changes the 1,500 intern requirement so that California pharmacy students would not be required to complete any intern hours of pharmacy practice experience beyond those associated with their formal curriculum in the school of pharmacy. The bill does not make this change.

The Licensing Committee initiated review of the intern program last June as part of its strategic objective. The program was discussed at subsequent meetings until December, when the committee recommended to the board that the intern requirements be placed in statute. The board acted on this recommendation at its January 2004 meeting. It was noted that once SB 1913 passes, the board will need to amend CCR 1728, to make it consistent with the new statutory changes.

The Licensing Committee discussed the intern requirements. The committee advised that it would review CCR 1728 at its next meeting in September and encouraged the schools to submit any recommendations at that time.

Report on the Implementation of the Licensure Program for Pharmacies that Compound Sterile Injectable Drug Products – One-year Evaluation

Supervising Inspector Dennis Ming reported that since the inception of the sterile compounding licensing program in July, 2003, the Board of Pharmacy has received and processed 238 applications and has approved 184 Sterile Compounding licenses, of which 16 are out of state. This is 77%. He stated that the three main reasons for the delays in approving applications are: the lack of adequate/detailed policies and procedures required for compliance with the regulations, incomplete applications relative to pharmacy ownership and pending licensure of the pharmacy.

Dr. Ming stated that inspections for new applications are completed within 3 weeks of assignment to an inspector. In April, the board began the re-inspection of these pharmacies prior to renewal and to date, 31 pharmacies were re-inspected. All the pharmacies were in compliance and sterile compounding pharmacy permits were renewed.

To maintain continuity in the licensing and inspection process, the re-inspections were assigned to inspectors who conducted the initial licensing inspection. A separate checklist was created to assist the inspector in comparing results of the initial licensing inspection to the observations made during the re-inspection. The results of the re-inspection were discussed with each licensee. This process enabled the inspector to identify areas of on-going compliance as well as trends/patterns in non-compliance with the regulations.

He stated that the initial results of the re-inspection process were as follows:

CCR 1751: Compounding Area for Parenteral Solutions: All of the pharmacies maintained on an on-going basis, the environment for the compounding sterile injectable drugs in compliance with this section.

CCR 1751.1 Laminar Flow Biological Safety Cabinet: One or two of the pharmacies converted from standard class 100 laminar air flow cabinets to class 100 barrier isolators in anticipation of the implementation of revised California Code of Regulations Section 1751 which requires specific environments in which to compound sterile injectable drugs from a non-sterile source. Pharmacies maintained annual certification of the laminar airflow hoods.

CCR 1751.2: Labeling Requirements: Pharmacies maintained compliance with this regulation. Pharmacies who contract with another pharmacy to compound sterile injectable drugs (Business and Professions Code Section 4123) were required to have the label of the compounding and dispensing pharmacy on the container.

CCR 1751.3: Record Keeping: Record keeping as required under current regulation will be changed when the revision to 1751 are finally approved and implemented. An area where record keeping was not strictly adhered to was radio pharmacies whose products are primarily intended for one time use and often for diagnostic purposes. In these cases, strict adherence to the record keeping requirements was not always possible or practical. Revisions to CCR 1751 will address and resolve these issues regarding record keeping requirements.

CCR 1751.4: Protective Clothing: This section was intended for pharmacies preparing cytotoxic (chemotherapeutic) medications for injection and for those pharmacies, compliance was on going.

CCR 1751.5: Training of Staff, Patient and Caregiver: Since the inception of the sterile compounding regulations, pharmacies were made more aware of the requirement to train and document competencies of the staff relative to utilizing aseptic technique etc. in the preparation of sterile injectable drugs. Records are being maintained; however, this area should be carefully monitored during the re-inspection process to ensure complete compliance.

CCR 1751.6: Disposal of Waste Material: Pharmacies were observed disposing of waste material from the preparation of sterile injectable drugs in an appropriate manner. Pharmacies compounding chemotherapeutic drugs disposed of residue in the appropriate chemo containers.

CCR 1751.7: Quality Assurance: This section has been the most problematic for pharmacies to maintain compliance. Results of the re-inspection demonstrate that a few pharmacies neglected to maintain records of cleaning, calibration of equipment, process validation, and end product testing. Some were confused as to how many tests should be done and how often. It would be beneficial to provide feed-back to licensees in either the board's newsletter or on its Web site on how to maintain compliance with quality assurance in pharmacies compounding sterile injectable drugs. None of the pharmacies that were observed to be weak in compliance with this section were issued written warnings of non-compliance; rather they were instructed by the inspector in how to improve their compliance.

CCR 1751.8: Policies and Procedures: Pharmacies maintained their written policies and procedures and a few have submitted revisions for review upon receiving the renewal notice from the board.

CCR 1751.9: Reference Materials: Pharmacies have maintained compliance with this section in having the necessary resource information for compounding sterile injectable drugs.

Supervising Inspector Ming concluded his report by providing a future action plan for the program, which is to:

- continue to conduct new and re-inspections for pharmacies applying for a sterile compounding license.
- provide additional information to the executive officer regarding the impact on inspector workload in conducting annual re-inspections of pharmacies compounding sterile injectable drugs relative to areas of compliance and non-compliance.
- continue to provide consultative/educational services to licensees to achieve and/or maintain compliance with sterile compounding regulations.
- modify the current sterile compounding checklist on the board web site to reflect the revisions in CCR 1751 (when approved for implementation).

Implementation of the Statewide Protocol for Pharmacists to Dispense Emergency Contraception and Recommendation to Pursue Adoption of an Emergency Regulation

SB 490 (Chapter 651, Statutes of 2003) permits pharmacists to furnish emergency contraception medications based on a statewide protocol adopted by the California State Board of Pharmacy and the Medical Board of California.

The protocol is available on the board's Web site and has been provided to the pharmacists associations for distribution. However, in order for the board to enforce the protocol, it must be adopted as a regulation. The proposed regulation has been noticed for adoption at the July board meeting.

It was noted during the discussion that the board was provided some changes to Appendix 1 of the protocol, which is the list of brands and doses of oral contraceptive tablets used for

emergency contraception. Staff will be exploring the process it must follow to update this appendix.

California Pharmacy Manpower Statistics

Ms. Harris explained that the pharmacy manpower statistics for California was provided for information purposes. She noted that as of December 2003, 5,624 pharmacies were licensed with the board. This is a 6.3% increase from January 2001.

As of December 2003, the board 37,756 pharmacy technicians were registered. This is a 41% increase from December 2001, where there were 26,706 registered pharmacy technicians. Also provided was the number of pharmacy technicians per pharmacists and per pharmacy.

In 2003, there were 24,256 licensed pharmacists with California addresses. This is a 16% increase from 2001, where 20,905 pharmacists were licensed. Also provided is the number of pharmacists per 100,000 Californians.

Adjournment

Licensing Committee Chair Clarence Hiura adjourned the meeting at 11:45 a.m.

ATTACHMENT H

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	16	22	71	72	54	2	157	145	171	349	430	n/a	1489
Intern pharmacist	89	195	405	240	184	75	88	154	117	87	100	n/a	1734
Pharmacy technician	555	500	793	562	658	942	654	335	394	477	455	n/a	6325
Foreign educated pharmacists (evaluations)	4	9	98	33	15	18	18	67	47	20	20	n/a	349
Pharmacy	38	35	51	24	37	23	36	26	42	43	33	41	429
Sterile Compounding	20	10	6	6	10	7	9	2	6	6	10	9	101
Clinics	12	22	14	16	19	13	11	5	19	10	5	12	158
Hospitals	1	2	3	0	3	1	5	1	1	3	0	3	23
Nonresident Pharmacy	9	4	6	4	6	2	4	4	3	8	0	0	50
Licensed Correctional Facility	0	1	0	0	0	0	0	1	0	0	0	0	2
Hypodermic Needle and Syringes	4	9	5	4	4	4	7	7	5	4	7	3	63
Out of State Distributor	5	9	6	2	6	6	6	7	9	10	9	6	81
Wholesalers	8	6	7	5	8	12	16	11	6	4	9	7	99
Veterinary Food-Animal Drug Retailer	1	0	0	0	0	0	0	0	0	0	0	0	1
Exemptees	51	47	61	39	33	25	37	33	47	56	29	40	498
Issued													
Pharmacist	11	421	167	88	29	8	5	8	4	9	1	239	990
Intern pharmacist	79	201	285	301	153	63	81	68	79	59	29	95	1493
Pharmacy technician	660	1105	456	903	483	621	1173	548	649	494	483	401	7976
Pharmacy	37	51	47	39	32	22	20	32	34	23	32	59	428
Sterile Compounding	95	11	6	6	0	1	13	11	10	3	1	15	172
Clinics	17	12	16	33	14	5	17	7	13	8	7	5	154
Hospitals	1	7	3	2	1	1	1	0	0	1	5	2	24
Nonresident Pharmacy	2	9	10	8	2	8	10	3	1	1	2	11	67
Licensed Correctional Facility	0	1	0	0	1	0	0	0	0	0	0	0	2
Hypodermic Needle and Syringes	2	3	6	6	1	2	3	2	6	4	9	2	46
Out of State Distributor	6	11	5	7	8	4	2	7	1	8	5	3	67
Wholesalers	28	6	9	8	2	10	9	7	7	10	3	8	107
Veterinary Food-Animal Drug Retailer	0	0	0	5	1	0	0	0	0	1	0	0	7
Exemptees	58	45	49	41	18	14	57	38	18	46	42	41	467

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending													
Pharmacist Examination	u/a	u/a	u/a	u/a	u/a	u/a	u/a	u/a	131	u/a	u/a	158	131
Intern pharmacist	u/a	u/a	11	u/a	u/a	32	u/a	u/a	44	u/a	u/a	49	44
Pharmacy technician													
Foreign educated pharmacists (evaluations)	u/a	u/a	18	u/a	u/a	33	u/a	u/a	11	u/a	u/a	40	11
Pharmacy	69	72	74	59	43	44	60	54	54	73	72	69	69
Sterile Compounding	54	53	53	53	50	56	52	42	37	40	49		
Clinics	61	79	77	60	44	52	46	44	42	44	42	42	42
Hospitals	40	10	10	8	7	7	11	12	11	13	8	10	10
Nonresident Pharmacy	54	40	34	30	33	27	21	22	19	22	25	24	24
Licensed Correctional Facility	0	0	0	8	0	0	0	1	0	0	0	0	0
Hypodermic Needle and Syringes	5	14	8	5	8	10	14	15	13	14	5	8	8
Out of State Distributor	46	51	41	29	23	24	28	25	35	37	37	40	40
Wholesalers	42	48	27	24	27	28	35	29	39	26	26	25	25
Veterinary Food-Animal Drug Retailer	1	1	1	1	0	0	0	1	1	1	0	0	0
Exemptees	114	103	104	88	156	167	147	142	171	181	168	167	167
Change of Pharmacist-in-Charge													
Received	170	170	224	164	192	137	152	171	189	174	164	183	2090
Processed	114	207	218	158	183	108	165	196	132	163	153	204	2001
Pending	139	102	108	114	123	152	139	114	171	182	193	172	172
Change of Exemptee-in-Charge													
Received			3	6	4	3	0	5	3	3	4	5	36
Processed			3	3	3	3	0	4	3	0	4	5	28
Pending			0	3	4	0	0	1	1	3	1	1	1
Change of Permits													
Received	49	57	60	27	30	35	28	38	24	32	67	43	490
Processed	55	10	121	34	18	19	13	5	70	57	97	53	552
Pending	135	182	121	114	126	142	157	190	144	119	74	133	133
Discontinuance of Business													
Received	9	8	16	6	21	14	14	9	22	11	8	11	149
Processed	0	33	11	33	15	0	18	0	35	0	24	13	182
Pending	47	22	27	0	6	20	16	25	12	23	7	5	5

Board of Pharmacy Licensing Statistics - Fiscal Year 2003/04

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Renewals Received													
Pharmacist	2567	1115	1236	1408	898	1469	1292	994	1215	1302	542		14038
Pharmacy technician	1964	971	1216	1352	939	1425	1345	1161	1373	1474	695		13915
Pharmacy	970	180	836	506	194	379	426	500	873	643	199		5706
Sterile Compounding	0	0	0	0	0	2	3	5	12	14	9		45
Clinics	89	49	36	38	42	61	64	51	73	74	40		617
Nonresident Pharmacy	25	12	9	13	9	12	21	13	11	20	12		157
Hypodermic Needle and Syringes	33	15	20	28	18	26	25	16	16	21	9		227
Out of State Distributor	44	12	22	21	15	26	23	20	36	32	15		266
Wholesalers	76	24	29	30	20	41	43	33	27	33	16		372
Veterinary Food-Animal Drug Retailer	4	6	2	0	1	0	1	1	2	1	0		18
Exemptees	252	74	103	124	76	155	158	132	135	142	86		1437

ATTACHMENT I

Licensing Committee

2003-2004
Final Report
July 1, 2003 – June 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 is in the testing phase and should be fully implemented by November 1, 2003. Therefore, some of the information are estimates and will be notated with an asterisk.

Tasks:

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

Note: Pharmacists examination applications are not being processed because of the changes outlined in SB 361. 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
Pharmacy Intern	689	499	359*	187**	3	7-10	10-14	10
Pharmacy Technicians	1848	2162	1206*	932**	15	13	5-7	5-10
Foreign Graduates	111	66	132*	40**	n/a	n/a	n/a	n/a
Pharmacies	131	88	104	123	7	13	6	13
Non-Resident Pharmacy	19	12	11	8	23	25	27	42
Wholesaler	21	25	20	20	7	8	18	20
Veterinary Drug Retailer	1	0	0	0	n/a	33	0	0
Exemptee	159	97	118	125	6	4	30	32
Out-of-State Distributor	20	14	21	25	15	18	13	15
Clinics	48	48	35	27	8	9	6	8
Hypo Needle & Syringe	18	12	8	14	5	17	7	9
Sterile Compounding	36	23	17	25	7	7	3	5

* denotes updated to include March 2004 information available at time of report development.
**denotes April and May 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	3	3	3	3-5
Pharmacy Intern	3	7-10	7-10	10-15
Pharmacy Technician	14	17	5-10	10
Foreign Graduate	n/a	n/a	n/a	n/a
Pharmacies	19	15	16	13
Non-Resident Pharmacy	25	44	67	17
Wholesaler	12	8	21	8
Veterinary Drug Retailer	n/a	7	0	2
Exemptee	38	38	17	17
Out-of-State Distributor	12	11	11	4
Clinics	19	12	20	4
Hypo Needle & Syringe	7	2	2	9

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

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist	1	1	1	1-2
Pharmacy Intern	1	1	1	5
Pharmacy Technician	10	10	5-7	5
Foreign Graduate	n/a	n/a	n/a	n/a
Pharmacies	14	16	9	10
Non-Resident Pharmacy	64	13	34	34
Wholesaler	4	3	6	3
Veterinary Drug Retailer	n/a	1	0	1
Exemptee	1	27	3	3
Out-of-State Distributor	9	2	4	5
Clinics	12	6	1	10
Hypo Needle & Syringe	6	2	3	3

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

	Q1	Q2	Q3	Q4
Pharmacist	599	125	17	249
Pharmacy Intern	565	517	228	183
Pharmacy Technician	2221	2007	2370	1378
Foreign Graduate	n/a	n/a	n/a	n/a
Pharmacies	147	99	95	122
Non-Resident Pharmacy	21	18	15	14
Wholesaler	43	20	23	21
Veterinary Drug Retailer	0	1	0	1
Exemptee	152	82	155	129
Out-of-State Distributor	22	17	10	16
Clinics	45	52	34	20
Hypo Needle & Syringe	11	9	11	15
Sterile Compounding				19

5. **Withdrawn licenses to applicants not meeting board requirements.**

	Q1	Q2	Q3	Q4
Pharmacy Technician	10	5	6	2
Pharmacies	4	5	1	3
Non-Resident Pharmacy	2	3	4	3
Clinics	0	10	13	6
Sterile Compounding				4

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.**

9/03 *Discussed at Licensing Committee Meeting. No recommendations were made. Will revise intern reporting affidavits.*

12/03 *Discussed proposed statutory changes and Licensing Committee recommended board approval.*

1/04 *Board approved proposed statutory changes. Will be added to 2004 omnibus bill. Board recognized the School of Pharmacy at Lake Erie College of Osteopathic Medicine for purposes of issuing an intern registration to a student from this school. Staff to develop process to approve new schools of pharmacy not ACPE accredited.*

2/04	*Intern provisions added to SB 1913.*
4/04	*Board approved recommended change to regulation.*
3/04	*Discussed proposed regulation change to issue an intern registration to an applicant enrolled in school of pharmacy that has a "candidate" status with ACPE. Licensing Committee recommended board approval.*

2. Implement changes to the Pharmacy Technician Program.

a. Use PTCB as a qualifying method for registration.

b. Eliminate clerk-typist from pharmacist supervisory ratio.

c. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology.

9/03	*Governor signed SB 361. New changes will be implemented 11/04. Regulation changes are proposed to the board. Application forms have been revised.*
10/03	*Board approved proposed regulation changes. Regulation proposal pending with Legislative/Regulation Committee.*
12/03	*New application forms made available on website.*
1/04	*New program requirements are implemented.*

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

9/03	*Governor signed SB 361 to implement NAPLEX and California specific exam to be administered quarterly via computer. The Licensing Committee recommended regulation changes to implement new examination program.*
10/03	*Board approved proposed regulation changes.*
12/03	*Proposed regulation changes are pending with the Legislative/Regulation Committee.*
12/03	*Revised application and instruction forms.*
12/03	*Finalized contracts for the new examinations.*
1/04	*Started processing applications for pharmacist licensure examination.*
3/04	*Contract for California specific examination was approved.*
4/04	*NAPLEX contract was approved.*

3/04	*California applicants began taking the NAPLEX and CPJE.*
6/04	*1,311 California applicants have taken the NAPLEX and 654 have taken the CPJE.*
	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.
9/03	*Developed content outline for California specific exam and made available on board's website. Additional test questions identified by Competency Committee for inclusion in Candidate's Review Guide.*
12/03	*Worked on new Candidate Review Guide for the California specific examination.*
3/04	*Candidate Review Guide for California specific examination and update on examination process added to the board's Web site.*
4/04	*Presented to the graduating class on the exam process.*
5/04	*Presentation to the graduating class on the exam process.*
6/04	*Reported on the process at Licensing Committee Meeting and provided new flow chart.*
	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.
8/03	*Competency Committee met for two days and finalized content outline. Reviewed question bank.*
9/03	*Competency Committee met for two days and developed questions.*
10/03	*Competency Committee met for two days and developed questions.*
11/03	*Competency Committee met for three days and developed questions.*
2/04	*Competency Committee met for two days and developed questions.*

3/04	*Competency Committee met for two days and developed questions.*
3/04	*Licensing Committee recommended that Competency Committee be restructured to a two-tier structure that would be a group of item writers to develop questions for the CPJE and a core committee that would develop and oversee the CPJE administration.*
4/04	*Board approved new Competency Committee structure. Will recruit for item writers in next board newsletter.*
5/04	*Competency Committee met for two days and developed questions.*
	7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.
9/03	*Reported that 126 sterile compounding licenses have been issued since July 1.*
12/03	*Reported that 151 sterile compounding licenses have been issued since July 1.*
4/04	*Reported that 185 sterile compounding licenses have been issued since July 1.*
6/04	*Reported that 204 sterile compounding licenses have been issued since July 1.*
6/04	*Prepared and presented a one year evaluation of program.*
	8. Issue temporary permits whenever change of ownership occurs.
9/03	*1st Quarter - 24 temporary permits issued.*
1/04	*2nd Quarter – 12 temporary permits issued.*
4/04	*3rd Quarter – 32 temporary permits issued*
6/04	*4th Quarter – 16 temporary permits issued*
	9. Establish means for licensee to renew permits on line.
8/03	*NABP is establishing a program that will allow states to establish criteria for licenses to be renewed on line through NABP. The board has requested Legal Affairs to review this as a possible option for the board.*
5/04	*Reported to the Department Office of Information Services that this is a technology priority for the board.*
	10. Implement Changes to Facilities Licensure Requirements

9/03	*Proposed statutory changes to the licensure requirements for wholesale facilities. Recommended board support requirements.*
9/03	*Proposed statutory changes that would clarify the licensure requirements for facilities. Would prohibit facilities from being located in a personal residence and clarifies that the board issues a permit at one premise which is a separate operation. Recommended board support.*
10/03	*Board approved proposed statutory changes for wholesale facilities and other licensure requirements.*
12/03	*Statutory proposals are pending with the Legislative/Regulation Committee.*
1/04	*SB 1307 was introduced regarding the licensure of wholesalers and non-resident wholesalers.*
6/04	*Application requirements for all applicants placed in SB 1913 (omnibus legislation.)*
	11. Review the Ownership of Pharmacies
10/03	*Board determined that a Limited Liability Company can own a pharmacy.*
4/04	*Requested counsel review law regarding prescriber ownership.*
	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.
3/04	*Recommend that this provision be extended to the board's next sunset review in 2006 due to the change in examination format. Obtained clarification from counsel that with new examination format, an applicant has 4 opportunities to pass NAPLEX and 4 opportunities to pass CPJE.*
3/04	*Board is required to report to the Legislature by December 31, 2004, the effect of this law in 4 areas. Draft report will be provided at April Board meeting.*
4/04	*Draft report provided to board and approved extension of the statutory provision.*
6/04	*Amendments placed in SB 1913 (omnibus bill.)*
	13. Evaluate application requirements for all licenses.
3/04	*Proposed a change for inclusion in the 2004 omnibus bill to give clear statutory authority to request information needed to evaluate the qualifications of any applicant.*

4/04	*Board approved recommendation and amendments will be placed in SB 1913 (omnibus bill.)*
6/04	*Amendments placed in SB 1913 (omnibus bill.)*

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:	**1. Explore the need to regulate pharmacy benefit managers.**
9/03	*Ad Hoc Committee held 3rd meeting. Requested completion of Sunrise Questionnaire. Recommended that the board not take action.*
10/03	*Board agreed with recommendation, but will continue to "watch" the issue.*
4/04	*Board took an oppose unless amended on AB 1960 because it placed the requirements for PBMs in the board's code section.*
	2. Explore the need to regulate drugs labeled for "veterinary use only."
9/03	*SB 175 was introduced and signed (Chapter 250, Statutes 2003).*
	3. Explore the importation of drugs from foreign countries.
7/03	*Discussed at July Enforcement Committee and board meetings.*
9/03	*Discussed at September Enforcement Committee.*
10/03	*Discussed at October Board meeting.*
12/03	*Discussed at December Enforcement Committee meeting.*
1/04	*Discussed at January Board meeting.*
3/04	*Discussed at March Enforcement Committee meeting.*
4/04	*Board did not take a position on legislation that allowed the importation of drugs to California consumers.*
4/04	*Discussed at April Board meeting.*
6/04	*Discussed at June Enforcement Committee Meeting.*
	4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.
9/03	*Legislation and Regulation Committee held informational hearing – Completed.*
	5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding

12/03	*Licensing Committee requested participation of Board Members John Tilley and Ken Schell and Supervising Inspector Dennis Ming.*
3/04	*Held first meeting of Workgroup on Compounding and developed list of issues to address.*
6/04	*Held second meeting of Workgroup on Compounding.*
	6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)
12/03	*Recommended approval of protocol submitted by the Pharmacy Access Partnership and ACOCT.*
1/04	*Board approved protocol*
1/04	*Medical Board of California (MBC) did not act on protocol and delegated to committee to review and address concerns.*
3/04	*Reported status that MBC had not yet provided a revision. Advised that protocol must be adopted as regulation.*
4/04	*Draft protocol provided by MBC and approved by the board.*
5/04	*MBC approved protocol.*
5/04	*Protocol placed on board's Web site.*
6/04	*Protocol noticed as a regulation.*
	7. 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.
1/04	*UCSF presented the final report on the study on the evaluation of pharmacy technicians in a unit-dose distribution system. The study began May 1998 and ended December 31, 2003.*
3/04	*CSMC is requesting a waiver in order to conduct a sequel study with UCSF to evaluate the impact of pharmacist in the prevention of medication errors with prescribing and administering of medications instead of checking unit-dose cassettes.*
4/04	*Board approved the waiver for 2 years.*

Objective 2.4:		**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2005.**
Measure:		**Percentage of cashiered application and renewal fees within 2 working days.**
Tasks:		**1. Cashier application fees.**
	9/03	*1st Quarter - The average processing time for processing new application fees is 2-3 working days.*
	1/04	*2nd Quarter - The average processing time for processing new application fees is 2-3 working days.*
	4/04	*3rd Quarter – The average processing time for processing new application fees is 2-3 working days.*
	6/04	*4th Quarter – The average processing time for processing new application fees is 2-3 working days.*
		2. Cashier renewal fees.
	9/03	*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.*
	9/03	*1st Quarter - Average processing time for central cashiering is 2-3 weeks.*
	1/04	*2nd Quarter - Average processing time for central cashiering is 2-3 weeks.*
	4/04	*3rd Quarter – Average processing time for central cashiering is 2-3 weeks.*
	6/04	*4th Quarter – Average processing time for central cashiering is 2-3 weeks.*
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:		**1. Respond to requests for licensing verification.**
	9/03	*1st Quarter – Processed 261 license verifications.*
	1/04	*2nd Quarter – Processed 178 license verifications.*
	4/04	*3rd Quarter – Processed 245 licensure verifications.*

6/04	*4th Quarter – Unavailable at time of report development..*

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:		**1. Make address and name changes.**
	9/03	*1st Quarter – Processed 1,994 address changes.*
	1/04	*2nd Quarter – Processed 2,679 address changes.*
	4/04	*3rd Quarter – Processed 1,743 address changes.*
	6/04	*4th Quarter – Processed 1,479 address changes.*
		2. Process discontinuance of businesses forms and related components.
	9/03	*1st Quarter – Processed 34 discontinuance- of-business forms. Processing time is 40 days.*
	1/04	*2nd Quarter - Processed 26 discontinuance- of-business forms. Processing time is 7 days.*
	4/04	*3rd Quarter - Processed 52 discontinuance- of-business forms. Processing time is 24 days.*
	6/04	*4th Quarter - Processed 36 discontinuance- of-business forms. Processing time is 19 days.*
		3. Process changes in pharmacist-in-charge and exemptee-in-charge.
	9/03	*1st Quarter – Processed 539 pharmacist-in-charge changes. Average processing time is 130 days. Processed 3 exemptee-in-charge changes. The average processing time is 14 days.*
	1/04	*2nd Quarter – Processed 225 pharmacist-in-charge changes. Average processing time is 14 days. Processed 6 exemptee-in-charge changes. The average processing time is 8 days.*
	4/04	*3rd Quarter – Processed 380 pharmacist-in-charge changes. Average processing time is 37 days. Processed 7 exemptee-in-charge changes. The average processing time is 7 days.*
	6/04	*4th Quarter – Processed 395 pharmacist-in-charge changes. Average processing time is 13 days. Processed 10 exemptee-in-charge changes. The average processing time is 10 days.*

	4. Process off-site storage applications.
9/03	*Processed 43 off-site storage applications.*
12/03	*Processed 17 off-site storage applications.*
4/04	*Processed 36 off-site storage applications.*
6/04	*Processed 20 off-site storage applications.*
	5. Process change-of-permit applications.
9/03	*1st Quarter – Processed 185 applications. Average processing time is 130 days.*
1/04	*2nd Quarter – Processed 71 applications. Average processing time is 12 days.*
4/04	*3rd Quarter – Processed 120 applications. Average processing time is 40 days.*
604	*4th Quarter – Processed 224 applications. Average processing time is 50 days.*