



**Legislation and Regulation Committee Report
January 21, 2004**

**Andrea Zinder, Chair
Dave Fong, Member**

FOR ACTION

Action Item 1 – The Legislation and Regulation Committee (committee) recommends that the board sponsor a provision in the 2004 omnibus bill to correct usage errors in Section 4101. The proposed changes are technical.

Discussion: The proposed changes update usage to reflect the requirement that wholesalers designate an “exemptee-in-charge” and correct the name of veterinary food-animal drug retailers in this section.

Amend Section 4101 of the Business and Professions Code, to read:

4101. (a) Any pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.
- (b) ~~Any exemptee who takes charge of, or acts as manager of,~~ An exemptee-in-charge of a wholesaler or veterinary ~~food-drug animal~~ food-animal drug retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.
- ~~(c) This section shall become operative on July 1, 2001.~~

Action Item 2 – The committee recommends that the board sponsor a provision in the 2004 omnibus bill to correct a usage error in Section 11155 of the Health and Safety Code. The proposed change is technical.

Discussion: The proposed change would replace “physician” with “prescriber.” This change reflects the reality that practitioners other than physicians are authorized to prescribe controlled substances.

Amend Section 11155 of the Health and Safety Code, to read:

11155. Any prescriber ~~physician~~, who by court order or order of any state or governmental agency, or who voluntarily surrenders his controlled substance privileges, shall not possess, administer, dispense, or prescribe a controlled substance unless and until such privileges have been restored, and he has obtained current registration from the appropriate federal agency as provided by law.

Action Item 3 – The committee recommends that the board sponsor a provision in the 2004 omnibus bill to correct an erroneous code section reference in Section 11159.1 of the Health and Safety Code. The proposed change is technical.

Amend Section 11159.1 of the Health and Safety Code, to read:

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article ~~13 3.5~~ (commencing with Section ~~4180 4063~~) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article ~~but~~ and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article ~~13 3.5~~ (commencing with Section ~~4180 4063~~) of Chapter 9 of Division 2 of the Business and Professions Code. Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

Action Item 4 – The committee recommends that the board sponsor a provision in the 2004 omnibus bill to correct errors in Section 11207 of the Health and Safety Code and to clarify that a pharmacy technician may assist a pharmacist in filling controlled substance prescriptions.

Discussion:

Amend Section 11207 of the Health and Safety Code, to read:

11207. (a) ~~No person other than a registered pharmacist as defined in Section 4036 of the Business and Professions Code under the laws of this state or an intern pharmacist, as defined in Section 4030 4038.4 of the Business and Professions Code, who is under the personal supervision of a pharmacist, shall compound, prepare, fill or dispense a prescription for a controlled substance.~~

(b) Notwithstanding subdivision (a), a pharmacy technician may perform those tasks permitted by Section 4115 of the Business and Professions Code when assisting a pharmacist dispensing a prescription for a controlled substance.

NO ACTION

The proposed text of those proposed regulations that have been subject to an informational hearing and are ready to begin formal rulemaking is included in Attachment A. Notices for these regulations will be published as soon as possible within the restrictions established by Executive Order S-2-03.

The following attachments are included relating to Executive Order S-2-03:

Attachment B – Copy of the Executive Order

Attachment C – A memo summarizing the board’s compliance with the executive order.

Attachment D – A copy of the exemption request submitted for the sterile compounding regulation.

Attachment E – The report submitted by the board regarding the review of existing standards of general application.

Attachment F – The report submitted by the board regarding the review of all rulemaking since January of 1999.

Pending Regulations

Section 1751 – Sterile Compounding

Summary: This regulation will establish guidelines for the compounding of sterile drug products.

Status: Suspended

Regulations Awaiting Notice

Section 1707.5 – Hospital Central Fill

Summary: This regulation will permit central refill operations for hospitals.

Status: Awaiting Notice.

Section 1709.1 - Pharmacist-in-Charge at Two Locations

Summary: This regulation will permit a pharmacist to serve as pharmacist-in-charge at two locations.

Status: Awaiting Notice.

Section 1711 – Patient Notification

Summary: This regulation will modify the patient notification provisions of the board’s quality assurance regulation to require notification to the patient if the drug was actually taken or if it resulting in a clinically significant delay in therapy.

Status: Awaiting notice.

Section 1715 – Pharmacy Self Assessment

Summary: This regulation will update the pharmacy self assessment form to reflect recent changes in pharmacy law.

Status: Informational Hearing Required

Section 1717.4 and 1717.2 – Electronic Prescriptions & Electronic Records

Summary: This regulation will make any needed changes to board regulations to conform to changes in patient privacy laws.

Status: Awaiting notice

Section 1717.4 – Authentication of Electronic Prescriptions

Summary: This regulation will require pharmacists to authenticate electronic prescriptions.

Status: Awaiting notice

Section 1719 et seq. – Pharmacist Examination

Summary: This regulation will update existing requirements for the pharmacist examination and make those changes necessary to conform with the provisions of Senate Bill 361.

Status: Awaiting Notice

Section 1793.3 – “Clerk-Typist” Ratio

Summary: This regulation will eliminate the clerk/typist ratio.

Status: Informational hearing held, action deferred until January 2004 board meeting to accommodate staff workload and ongoing negotiations regarding a statutory revision to ancillary staff ratios.

Section 100 Filing – This filing will conform existing board regulations to the numerous changes in Pharmacy Law made by 2003 legislation.

Status: Awaiting Notice

Status of Bills with a Board Position

AB 261 (Maddox) Increases penalties for operating a "backroom pharmacy."

Board Position: **Support**

Status: Dead

AB 746 (Matthews) Requires the board to revoke a license after a second conviction for Medi-Cal fraud.

Board Position: **Support**

Status: Senate Rules Committee

AB 1363 (Berg) Establishes requirements for needle exchange programs.

Board Position: **Support**

Status: Two-year bill

AB 1460 (Nation) Permits pharmacists to perform CLIA waived tests to monitor drug therapy. Board Position: **Support**

Status: Two-year bill

SB 393 (Aanestad) Permits "tech check tech" in hospitals.

Board Position: **Support**

Status: Two-year bill

SB 506 (Sher) Requires the board to track wholesale distribution of antibiotic drugs.

Board Position: **Oppose**

Status: Two-year bill

Bills of Interest

AB 57 (Bates) Places MDMA into Schedule II.
Status: Assembly Inactive File

AB 521 (Diaz) Requires pharmacists to notify patients of harmful drug interactions.
Status: Two-year bill.

Staff does not anticipate significant activity on any of the remaining two-year bills with the exception of Senate Bill 393 (“tech check tech”) and copies of these bills have been omitted accordingly.

Quarterly Status Report on Committee Goals for 2003-04

For your information, an update of the Committee’s progress in accomplishing its strategic objectives is attached to this report (Attachment G).

Meeting Summary for January 8, 2004

For your information the summary for the January 8, 2004 meeting of the Legislation and Regulation Committee meeting is attached to this report (Attachment H). The committee scheduled its next meeting for April 5, 2004 at 10:30 a.m. in Sacramento.

Attachment A

**Board of Pharmacy
Proposed Amendments**

**Title 16, Section 1710, Hospital Central Fill
Title 16, Section 1711, Patient Notification
Title 16, Section 1717.1, Common Electronic Files
Title 16, Section 1717.4, Authenticity of Prescriptions
Title 16, Section 1749, Fees
Title 16, Article 11, Ancillary Personnel**

Amend Section 1710:

1710. ~~Inpatient~~-Hospital Pharmacy.

(a) For purposes of Business and Professions Code Section 4111, an inpatient hospital pharmacy is a hospital pharmacy pursuant to Business and Professions Code Section 4029 which solely or predominantly furnishes drugs to inpatients of that hospital. A hospital pharmacy which predominantly furnishes drugs to inpatients of that hospital may furnish drugs to outpatients or employees of that hospital or to walk-in customers, provided that sales to walk-in customers do not exceed one (1) percent of all the pharmacy's prescriptions.

(b) A hospital pharmacy may process an order for filling patient cassettes by another pharmacy within this state, provided:

(1) The pharmacy that is to fill the cassettes either has a contract with the ordering hospital pharmacy or has the same owner as the ordering inpatient hospital pharmacy.

(2) The filled cassette is delivered directly from the filling pharmacy to the ordering hospital pharmacy.

(3) Each cassette or container meets the requirements of Business and Professions Code section 4076.

(4) Both pharmacies are responsible for ensuring that the order has been properly filled.

(5) Both pharmacies shall maintain complete and accurate records of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy.

(6) Prescription information shall be electronically transferred between the two pharmacies.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4029, 4111, 4118 and 4380, Business and Professions Code.

Amend Section 1711:

1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

~~(c) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form. Unless the pharmacist has already been notified of a medication error by the prescriber or the patient, the pharmacist shall immediately communicate to the patient and the prescriber the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.~~

(c) (1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

- (2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:
(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.
(B) Communicate to the prescriber the fact that a medication error has occurred.
- (3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.
- (4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.
- (d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.
- (e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:
1. the date, location, and participants in the quality assurance review;
 2. the pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);
 3. the findings and determinations generated by the quality assurance review; and,
 4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.
- The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.
- (f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created.
- (g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.
- (h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.
- ~~(i) This section shall become operative on January 14, 2002.~~

Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000.
Reference: Section 4125, Business and Professions Code.

Amend Section 1717.1:

1717.1. Common Electronic Files.

- (a) For dangerous drugs other than controlled substances: Two or more pharmacies may establish and use a common electronic file to maintain required dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file.
- (b) For controlled substances: To the extent permitted by Federal law, two or more pharmacies may establish and use a common electronic file of prescriptions and dispensing information.
- (c) All common electronic files must contain complete and accurate records of each prescription and refill dispensed.
- (d) Common electronic files as authorized by this section shall not permit disclosure of confidential medical information except as authorized by the Confidentiality of Medical Information Act (Civil Code 56 et seq.).
- (e) Pharmacies maintaining a common electronic file authorized by this section shall develop and implement written policies and procedures designed to prevent the unauthorized disclosure of confidential medical information.

Authority cited: Sections 4005, 4075 and 4114, Business and Professions Code. Reference: Sections 4005, 4019, 4027, 4050, 4051, 4052, 4075, 4114, 4116 and 4117, Business and Professions Code and Sections 56.10 and 56.11 of the Civil Code.

Amend Section 1717.4:

1717.4. Electronic Transmission of Prescriptions.

- (a) Except as otherwise prohibited by law, prescriptions may be transmitted by electronic means from the prescriber to the pharmacy.
- (b) An electronically transmitted prescription which meets the requirements of this regulation shall be deemed to be a prescription within the meaning of Business and Professions Code section 4040.
- (c) An electronically transmitted prescription order shall include the name and address of the prescriber, a telephone number for oral confirmation, date of transmission and the identity of the recipient, as well as any other information required by federal or state law or regulations. The prescriber's address, license classification and federal registry number may be omitted if they are on file and readily retrievable in the receiving pharmacy.
- (d) An "interim storage device" means as electronic file into which a prescription is entered for later retrieval by an authorized individual. Any interim storage device shall, in addition to the above information, record and maintain the date of entry and/or receipt of the prescription order, date of transmission from the interim storage device and identity of the recipient of such transmission. The interim storage device shall be maintained so as to ensure against unauthorized access and use of prescription information, including dispensing information.
- (e) A pharmacy receiving an electronic image transmission prescription shall either receive the prescription in hard copy form or have the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. Any hard copy of a prescription shall be maintained on paper of permanent quality.
- (f) An electronically transmitted prescription shall be transmitted only to the pharmacy of the patient's choice. This requirement shall not apply to orders for medications to be administered in an acute care hospital.
- (g) Electronic equipment for transmitting prescriptions (or electronic transmittal technology) shall not be supplied or used so as to violate or circumvent Business and Professions Code section 4000 et seq., Health and Safety Code section 11150 et seq., or any regulations of the board.
- (h) Any person who transmits, maintains or receives any prescription or prescription refill, orally, in writing or electronically, shall ensure the security, integrity, authenticity, and confidentiality of the prescription and any information contained therein.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4019, 4040, 4071, 4072 and 4075, Business and Professions Code; and Section 11150, et seq., Health and Safety Code.

Amend Section 1720:

1720. Application for Examination and ~~Registration~~ Licensure.

- (a) An application for ~~the pharmacist licensure~~ examination shall be submitted on the form provided by the board ~~Board~~, and filed with the board ~~Board~~ at its office in Sacramento ~~at least (60) days before the date fixed for examination~~.
- (b) The fee required by section 1749, subdivision (d) ~~Section 1749(d)~~ shall be paid for each application for examination. The fee is nonrefundable.
- (c) An applicant who fails to pay the fee required by section 1749, subdivision (f) ~~Section 1749(f)~~ within ~~two years one year~~ after being notified by the board ~~board~~ of his or her eligibility for a certificate of registration license as a pharmacist shall be deemed to have abandoned the application and must file a new application and meet all of the requirements which are in effect at the time of reapplication, ~~including retaking of the examination~~.
- (d) Each applicant shall be solely responsible for applying to and complying with the requirements imposed by the administrators of the North American Pharmacist Licensure Examination and the Multi-State Pharmacy Jurisprudence Examination for California for the administration of those examinations.
- (e) ~~An applicant for examination whose eligibility is based on the provisions of Business and Professions Code Section 4200(a)(2)(b) and who does not fail to take the examination within five years~~ one year of the date the applicant is

~~determined by the board to be eligible to take the examination of filing the application shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements which are in effect at the time of reapplication.~~

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

Amend Section 1721:

1721. Dishonest Conduct During Examination.

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

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

Amend Section 1723.1:

1723.1. Confidentiality of Examination Questions.

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

Authority cited: Section 4005, Business and Professions Code. Reference: Sections ~~4059-123~~ and- ~~496~~ 4200, Business and Professions Code.

Amend Section 1724:

1724. Passing Grade in Examination.

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

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

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

Amend Section 1749 as follows:

1749. Fee Schedule.

~~Effective July 1, 1999, the~~ The fees for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with Section 4400 of the Business and Professions Code are hereby fixed as follows:

- (a) The fee for the issuance of a permit to conduct a pharmacy is three hundred forty dollars (\$340). The fee for the annual renewal of said permit is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).
- (b) The fee for the issuance of a temporary permit is one hundred seventy-five dollars (\$175).
- ~~(e) The fee for processing remodeling plans and inspecting the remodeled area is one hundred thirty dollars (\$130).~~
- (c) The fee for the issuance of a pharmacy technician license shall be fifty dollars (\$50). The fee for the biennial renewal of a pharmacy technician license shall be fifty dollars (\$50). -The penalty for failure to renew a pharmacy technician license is twenty-five dollars (\$25).
- (d) The fee for ~~an applicant for~~ application and examination as a pharmacist is one hundred fifty-five dollars (\$155).
- (e) The fee for regrading an examination is seventy-five dollars (\$75).
- (f) The fee for the issuance of an original ~~certificate of registration as a~~ license as a pharmacist is one hundred fifteen dollars (\$115).
- (g) The fee for the biennial renewal of a pharmacist's license is one hundred fifteen dollars (\$115). The penalty fee for failure to renew is fifty-seven dollars and fifty cents (\$57.50).
- (h) The fee for the issuance or renewal of a wholesaler's permit is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (i) The fee for the issuance or renewal of a hypodermic license is ninety dollars (\$90). The penalty for failure to renew is forty-five dollars (\$45).
- (j) The fees for a certificate of exemption under the provisions of sections 4053, 4054 and 4133 of the Business and Professions Code are as follows:
- (1) For the application and investigation ~~and examination~~ of the ~~an~~ applicant, the fee is seventy-five dollars (\$75).
 - (2) For the issuance or renewal of an original certificate for an application approved by the board the fee is one hundred ten dollars (\$110). The penalty for failure to renew is fifty-five dollars (\$55).
- (k) The fee for the issuance or renewal of a license as an out-of-state manufacturer or wholesaler is five hundred fifty dollars (\$550). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (l) The fee for registration as an intern pharmacist or extension of the registration is sixty-five dollars (\$65). The fee for transfer of intern hours or verification of licensure to another state is ten dollars (\$10).
- (m) The fee for the reissuance of any permit, license, certificate or renewal thereof, which has been lost, or destroyed or must be reissued because of name change, is thirty dollars (\$30). The fee for the reissuance of any permit, license, or certificate, or renewal thereof, which must be reissued because of change in the information, other than name change, is sixty dollars (\$60).
- (n) The fee for registration and annual renewal of providers of continuing education is one hundred dollars (\$100). The penalty for failure to renew is fifty dollars (\$50).
- (o) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (p) The fee for evaluation of an application submitted by a graduate of a foreign college of pharmacy or college of pharmacy not recognized by the board is one hundred sixty-five dollars (\$165).
- (q) The fee for the issuance of a clinic permit is three hundred forty dollars (\$340). The fee for the annual renewal of said permit is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).
- ~~(r) The fee for the issuance of a permit for a medical device retailer is three hundred forty dollars (\$340). The fee for the annual renewal of said permit is one hundred seventy-five dollars (\$175). The penalty for failure to renew is eighty-seven dollars and fifty cents (\$87.50).~~
- ~~(s) The fee for the issuance of a permit for a warehouse of a medical device retailer is one hundred seventy dollars (\$170). The fee for the annual renewal of said permit is eighty-seven dollars and fifty cents (\$87.50). The penalty for failure to renew is forty-three dollars and seventy-five cents (\$43.75).~~

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

Amend Section 1793:

1793. Definitions.

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

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

Amend Section 1793.1 as follows:

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

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

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

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

Amend Section 1793.2 as follows:

1793.2. Duties of a Pharmacy Technician.

~~Pharmacy technicians may perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting, and while under the direct supervision and control of, a registered pharmacist.~~

“Nondiscretionary tasks” as used in Business and Professions Code section 4115, include:

- (a) removing the drug or drugs from stock;
- (b) counting, pouring, or mixing pharmaceuticals;
- (c) placing the product into a container;
- (d) affixing the label or labels to the container;
- (e) packaging and repackaging.

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

Repeal Section 1793.4:

1793.4. Qualifications for Registration as a Pharmacy Technician.

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

- (a) ~~Has obtained at least an associate of arts degree in one or more fields of study directly related to the duties performed by a pharmacy technician. Directly related fields of study include: health sciences, biological sciences, physical sciences, or natural sciences.~~

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

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

Amend Section 1793.5:

1793.5. Pharmacy Technician Application. ~~for Registration.~~

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

- (a) Each application for registration as a pharmacy technician shall include:
 - (1) Information sufficient to identify the applicant.
 - (2) A description of the applicant's qualifications ~~qualifying experience or education~~, and supporting documentation for those qualifications. ~~that experience or education. Examples of supporting documentation shall include: a certificate of completion issued by the training course provider showing the date of issuance and the number of theoretical and practical hours completed, transcripts, or an experience affidavit (Form 17A-6 or 17A-9 Rev. 9/94) signed by the pharmacist having direct knowledge of the applicant's experience.~~
 - (3) A criminal background check that will require submission of fingerprints in a manner specified by the board ~~two completed fingerprint cards~~ and the fee authorized in Penal Code section 11105(e). In addition, a signed statement whether the applicant has ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or local ordinance.
 - ~~(4) The registration fee shall be fifty dollars (\$50) effective July 1, 1995.~~
- (b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.
- (c) The board shall notify the applicant within 30 days ~~whether if an~~ the application is complete or deficient; and what is needed to correct the deficiency. Once the application is complete, the board will notify the applicant within 60 days of a license permit decision.
- (d) ~~Upon review and approval of the application, the board shall issue a certificate of registration as a pharmacy technician for at least one year. Before expiration of the a pharmacy technician license initial certificate of registration, a pharmacy technician must renew the that license by payment of the fee specified in Section 1749, subdivision (c). registration certificate with the board. Effective July 1, 1995, the fee is fifty dollars (\$50) and the penalty for failure to renew is twenty-five dollars (\$25).~~

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

Amend Section 1793.6 as follows:

1793.6. Training Courses Specified by the Board.

- A course of training that meets the requirements of Business and Professions Code section 4202 (a)(2) ~~1793.4(b)~~ is:
- (a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,
 - (b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or
 - (c) Any other course that provides a training period of at least 240 hours of theoretical and practical instruction covering at least the following; ~~provided that at least 120 of these hours are in theoretical instruction in a curriculum that provides:~~

- (1) Knowledge and understanding of different pharmacy practice settings.
- (2) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.
- (3) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.
- (4) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.
- (5) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.
- (6) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.
- (7) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

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

Amend Section 1793.7 as follows:

1793.7. Requirements for Pharmacies Employing Pharmacy Technicians.

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

~~(b)~~

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

~~(c)~~

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

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

~~(d)~~

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

~~(e)~~

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

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

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

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

Attachment B

Executive Order

EXECUTIVE DEPARTMENT

STATE OF CALIFORNIA



EXECUTIVE ORDER S-2-03 by the Governor of the State of California

WHEREAS, State Government should be dedicated to provide certainty for the regulated communities as well as meaningful and fair public participation in government decisions which impact the cost of doing business in California;

WHEREAS, the express language of the California Administrative Procedure Act declares that "There has been an unprecedented growth in the number of administrative regulations in recent years;"

WHEREAS, the increased costs associated with California's regulatory environment have diminished competition in the national and global marketplaces for the State's goods and services;

WHEREAS, the California Administrative Procedure Act requires that state Agencies proposing to adopt, amend, or repeal any administrative regulation must assess the potential for economic impact on California business enterprises and individuals;

WHEREAS, the California Administrative Procedure Act requires that all adopted regulations be easily understandable, the least burdensome and effective alternative, be consistent with underlying legislative authority and minimize the economic impact to the regulated communities;

WHEREAS, the California Administrative Procedure Act also provides that Agency policy enforced as if it were a regulation, but which has not been adopted, amended or repealed subject to public notice and comment, is contrary to law and public policy because it subverts open government; and

WHEREAS, with the onerous impact of over-regulation on the daily lives of Californians, it is time to reassess the system of State Government that is perceived to work against businesses and inhibit growth and economic prosperity.

NOW, THEREFORE, I, ARNOLD SCHWARZENEGGER, Governor of the State of California, by virtue of the power and authority vested in me by the Constitution and statutes of the State of California, do hereby issue this order to become effective immediately:

1. Each Agency, department, board, commission and office of the executive branch (hereinafter referred to as "Agency" or "Agencies") shall:

a) Subject to any exceptions the Director of the Department Finance allows for emergency or other situations relating to health and safety, request, pursuant to the California Administrative Procedure Act, the immediate return of any proposed regulation, including emergency regulations, for final adoption, amendment, or repeal or other processing by the Office of Administrative Law (OAL) for further review for a period not to exceed 180 days;

b) Subject to the exceptions described in paragraph 1 a) above, cease processing, pursuant to the California Administrative Procedure Act, any proposed regulatory action, including emergency regulations, for further review for a period not to exceed 180 days;

c) Pursuant to law and the extent necessary to comply with this Executive Order, suspend or postpone the effective date of any adopted, amended or repealed regulations published in the California Regulatory Notice Register but not yet effective;

d) Reassess the regulatory impact on business of any proposed regulation for adoption, amendment or repeal described in paragraphs 1 a)-c), above, pursuant to California Government Code section 11346.3 and submit a preliminary report to the Legal Affairs Secretary within 90 days of the date of this Executive Order; and

Affairs Secretary within 90 days of the date of this Executive Order; and

e) Submit a report of all regulations adopted, amended or repealed by each Agency since January 6, 1999 to the Legal Affairs Secretary within 90 days of the date of this Executive Order which specifically addresses the following:

- 1) The impact of the adopted, amended or repealed regulations on California businesses as required by California Government Code section 11346.3;
 - 2) The authority for the adopted, amended, or repealed regulations pursuant to California Government Code sections 11342.1 and 11342.2; and
 - 3) Conformity of the adopted, amended, or repealed regulations with the criteria set forth in California Government Code section 11349.1, of necessity, authority, clarity, consistency, reference and non-duplication.
2. Within 30 days of the date of this Executive Order, each Agency shall assess and identify any present issuance, utilization, enforcement or attempt at enforcement of any guideline, criterion, bulletin, manual, instruction, order, or standard of general application which has not been adopted as a regulation in potential violation of California Government Code section 11340.5(a) and submit its findings to OAL pursuant to California Government Code section 11340.5(b) and the Legal Affairs Secretary;
3. Upon submitting the findings of paragraph 2, above, to OAL and the Legal Affairs Secretary, any Agency utilizing such guideline, criterion, bulletin, manual, instruction, order or standard of general application in the normal course of business until OAL makes its determination to the Governor pursuant to California Government Code section 11340.5(c) shall do so on an opinion-only basis which will not carry the force of law;
4. Within five working days of the date of this Executive Order, the Director of OAL shall submit to the Legal Affairs Secretary a list of all regulations pending 30 day review under California Government Code section 11349.3, as well as any emergency regulations filed within the last 60 days with OAL pursuant to California Government Code sections 11346.1 and 11349.6;
5. The Director of the Office of Administrative Law shall, as soon as is practicable, appoint an advisory body consisting of no more than five (5) persons knowledgeable in regulatory matters to advise the Office of the Governor on how the regulatory process can be improved in California. The term of the advisory body shall expire on or before July 30, 2004; and
6. Agency Secretaries and other Cabinet level positions will be responsible for ensuring compliance with the provisions of this Executive Order. For those departments that do not have Cabinet level representation, the Department of Finance will be responsible for ensuring compliance with the provisions of this Executive Order; and
7. The regulatory relief described herein shall be accomplished through existing resources.

I FURTHER DIRECT that as soon as hereafter possible, this order shall be filed with the Office of the Secretary of State and that widespread publicity and notice be given to this order.



IN WITNESS WHEREOF I have hereunto set my hand and caused the Great Seal of the State of California to be affixed this the seventeenth day of November 2003.

/s/ Arnold Schwarzenegger

Governor of California

Attachment C

Memorandum

To: Board Members

Date: January 12, 2004

From: Paul Riches

Subject: Executive Order S-2-03

Executive Order S-2-03 requires state agencies to take several actions related to rulemaking activity.

1. Regulatory Review – The board is required to review all rulemakings adopted since January 6, 1999 based on existing statutory criteria to assure their compliance with those criteria. This review is required to be completed by February 17, 2004 and submitted to the Governor’s Legal Affairs Secretary.

2. Rulemaking Moratorium – All state agencies must suspend rulemaking activity for 180 days to provide the administration with adequate time to review pending proposals. The only immediate effect of this moratorium for the board is delaying the recently approved rulemaking on sterile compounding standards. This proposal must be submitted to the Office of Administrative Law for review by February 20, 2004 or it expires.

The board requested an exemption to the moratorium for this rulemaking because of its impact on the public health and safety, but the administration denied the request. Accordingly, the board will have to begin this process again. Staff recommends resubmitting the issue to the Licensing Committee to consider at its next meeting. The USP has recently published its revised chapter on sterile compounding and that document should be considered before initiating a new rulemaking process.

3. Review of Existing Board Standards – All state agencies must review existing standards of practice to identify any potential “underground” regulations. An “underground” regulation exists when a state agency applies a general standard to all affected persons without adopting that general standard through a formal rulemaking procedure. With the assistance of counsel, board staff reviewed existing standards and practices. The review did not uncover any potential “underground” regulations and a copy of the memo indicating this result to the Governor’s Legal Affairs Secretary is attached for your information.

During the review process, counsel advised the board that several of the guidance documents the board has published in the past required revisions and updates. Those guidance documents have been removed from the board’s website pending the completion of the revision process.

Attachment D

Memorandum

To: **Michael C. Genest**
Chief Deputy Director, Department of Finance
via
George Valverde Acting Secretary, State & Consumer
Services Agency
&
Kathleen Hamilton, Director, Department of Consumer
Affairs

Date: December 5, 2003

From: Patricia Harris, Executive Officer

Subject: Executive Order S-2-03: Request for Exception
Regarding Proposed Regulations - Exemption for Sterile
Compounding Standards

The California State Board of Pharmacy (the "Board") submits this *Request for Exception to Stay of Regulation Processing Imposed by Executive Order S-2-03*, in conformity with that memorandum dated November 20, 2003, issued by Donna Arduin, Director of Finance:

A. Subject Matter of Regulatory Action

1. The subject regulatory action concerns Standards for Pharmacy Compounding of Injectable Sterile Drug Products (hereinafter simply "Standards"). A true and correct copy of the proposed Standards approved by the Board at the Board's October 2003 meeting are attached hereto and are marked, "Exhibit 1."
2. Chapter 827 of the Statutes of 2001 (hereinafter simply "Chapter 827," see also Senate Bill 293) required the Board to adopt new standards for pharmacy compounding of injectable sterile drug products ("ISDPs"). The Standards implement, interpret, and make specific the requirements of that law.

B. Impact of Regulatory Action on Public, including Business

1. The Standards, if enacted, will apply only to those pharmacies that choose to compound ISDPs. The Standards are directed to promoting high degrees of reliability relative to the sterility of ISDPs used in this State.
2. The authors of S.B.293 (Torlakson (D) and Figueroa (D)) stated that the bill (now chapter 827) was intended to address a tragic incident in Walnut Creek in which three people died and twelve were hospitalized. (Senate Analysis, S.B.293.) According to the authors, an independent pharmacy was responsible for compounding a cortisone-based injectable drug which was tainted with meningitis bacteria due to a careless disregard and lack of knowledge by pharmaceutical staff regarding proper protocol for preparing sterile compounded drugs. (*Ibid.*) The bill requires pharmacies engaging in sterile drug compounding to obtain a special license for this practice, to ensure that drug compounding is performed in a safe manner. (*Ibid.*)

3. The Standards approved by the Board represent the result of over one year's effort contributed by numerous members of the pharmacy community and the Board. The Board conducted numerous open public meetings to hear and to address concerns of the pharmacy community regarding the Standards. As a result of those meetings, the Board revised and refined the Standards to address, and in many cases accommodate, the concerns of the pharmacy community.
4. The Standards would compel only those pharmacies that choose to compound ISDPs, to meet infrastructure requirements and to follow specified procedures directed to assuring the sterility of injectable drug products. In turn, those infrastructure requirements would provide opportunities to manufacturers, wholesalers, shippers and vendors to provide the infrastructure components needed by compounding pharmacies.

C. Reason why the Regulatory Process Should Not be Suspended Pending Review

1. As set forth above, the Standards are required by the terms of Chapter 827. In this regard, Section 2 of Chapter 827 provides, in pertinent part:

“SEC. 2. Article 7.5 (commencing with Section 4127) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.5. Injectable Sterile Drug Products

4127. The board shall adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy.”

2. The Legislative Counsel's Digest for Chapter 827 provides, in relevant part:

“The bill would require the board to adopt necessary regulations regarding injectable sterile drug products.”

3. Denial of this Request would prevent the Board from complying with the mandate of Chapter 827 and, as more fully discussed below, would delay the public protection to be provided by the enactment of the Standards.

D. Suggested Time Frame for Decision on Request for Exception:

1. January 20, 2004.

E. Justification for Suggested Time Frame:

1. **The Notice of Rulemaking regarding the Standards was published on February 21, 2003. Thus, the last day to submit the Standards to the Office of Administrative Law is February 20, 2004.**
2. A time frame of January 20, 2004, for decision on this Request for Exception would provide a 30 day allowance for the accommodation of the procedural details that would likely be needed to navigate the Standards to the Director of the Department of Consumer Affairs, and if approved, on to the Office of Administrative Law for review and publication.

F. Consequences of not Granting Exception within Suggested Time Frame:

1. Absence of Public Protection

Business and Professions Code section 4001.1 states:

“Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.”

Failure to implement the proposed regulations would adversely impact public health and safety. The proposed regulations will improve the safety and quality of ISDPs compounded in California pharmacies.

Denial of this Request would result in the absence of public protection contemplated by Chapter 827 and the Standards.

2. Legislative Mandate

Denial of this Request could be interpreted as disregard of the legislative mandate of Chapter 827, discussed above.

3. Lost Effort

Should this *Request for Exception* not be granted, the Board would, by lapse of time as discussed above, lose the opportunity to complete the current proposed action.

Wherefore, the Board respectfully requests that the Director of Finance approve this Request.

G. Suspension by OAL, of the Approval, Pending DOF Review

This rulemaking file has not been submitted to OAL for review at this point. Accordingly, no request for OAL to suspend review is necessary.

H. Conclusion (include contact information)

The Board of Pharmacy respectfully requests an exception for this rulemaking. If you have any further questions please feel free to contact me at (916) 445-5014 ext. 4004 or by email at Patricia_Harris@dca.ca.gov.

Attachment E

Memorandum

To: John Smith, Interim Director
Office of Administrative Law

Date: December 17, 2003

Peter Siggins, Legal Affairs Secretary
Governor's Office

Via: Ron Joseph, Interim Director
Department of Consumer Affairs

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

Subject: Executive Order S-2-03, Paragraph Two

In compliance with Executive Order S-2-03, paragraph two, the California State Board of Pharmacy (Board) has performed a thorough review of all forms, applications, informative materials, and Website documents and has determined that the Board does not have any standards of general application that have not been adopted either by statute or by regulation.

I trust this has met the requirements for reporting the information. Please contact me at (916) 445-5014, extension 4004, if you have any questions.

Attachment F

	Date Adopted*	Current Economic Impact? (If yes, discuss separately)	Authority: Cite the provision of law which permits or obligates your agency to adopt, amend or repeal the regulation.	Necessity: Briefly describe the reason why this regulation was needed.	Consistency: Explain why the regulation is not in conflict with existing provisions of law.	Reference: Cite the law which was implemented, interpreted or made specific by the regulation.	Clarity: Explain whether the regulation can be easily understood by those persons affected by it.	Non-duplication: Explain why the regulation does not serve the same purpose as another statute or regulation.
16CCR1707 Off-Site Storage of Records	October 20, 2000	YES _____ NO <u> X </u>	Business and Professions Code section 4005	The regulation established criteria for the board to grant a waiver of the requirement that all records of acquisition and disposition of dangerous drugs be maintained at the license premises.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code sections 4081, 4105 and 4333	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1707.2 Notice to Consumers	September 8, 2002	YES _____ NO <u> X </u>	Business and Professions Code sections 4005 and 4122	This regulation modified existing requirements regarding a notice that pharmacies must either post in the premises or provide on a written receipt. Many patients do not fully understand how to take their medications appropriately and the health impact and costs are staggering. To this end, the board modified the required notice to consumers to feature key questions patients should ask their pharmacist.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code sections 4005 and 4122.	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.

16CCR1707.4 Central Refill Pharmacies	July 1, 2000	YES _____ NO <u> X </u>	Business and Professions Code section 4005	The regulation provided standard labeling and documentation requirements that assure patients of which pharmacy filled the prescription and assure the privacy of patient information.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code section 4063, 4076, 4081 and 4333	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1711 Quality Assurance Programs	January 14, 2002	YES _____ NO <u> X </u>	Business and Professions Code section 4005 and section 2 of Chapter 677, Statutes of 2000	This regulation fulfilled the board's obligation to adopt regulations specifying the requirements for quality assurance programs in pharmacies that was established in Senate Bill 1339 (Chapter 677, Statutes of 2000). These regulations are designed to establish quality assurance programs that will effect a reduction in the incidence of medication errors in pharmacies.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions section 4125	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1714.1 Pharmacy Operation	January 1, 2000	YES _____ NO <u> X </u>	Business and Professions Code section 4005, 4115 and 4116	The regulation was required to implement provisions of Senate Bill 188 which permitted pharmacists to take regularly scheduled lunch breaks.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code sections 4009, 4115, 4115.5 and 4116. Labor Code sections 512 and 1186	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.

<p>16CCR1714.5</p> <p>Exempt Dangerous Drugs and Dangerous Devices</p>	<p>May 9, 2001</p>	<p>YES _____</p> <p>NO <u> X </u></p>	<p>Business and Professions Code section 4005</p>	<p>The board promulgated this regulation to designate those dangerous drugs and dangerous devices may be stored outside a pharmacy by certain entities. Previously this list was maintained in statute, but that was changed to have the list established in regulations by the board.</p>	<p>The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.</p>	<p>Business and Professions Code section 4057</p>	<p>The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.</p>	<p>The regulation was reviewed by OAL and found to meet the standard of non-duplication.</p>
<p>16CCR1715</p> <p>Self-Assessment</p>	<p>September 23, 2001</p>	<p>YES _____</p> <p>NO <u> X </u></p>	<p>Business and Professions Code section 4005</p>	<p>Pharmacists were using an outdated version of the forms that detail the periodic self-assessment of pharmacy operations. These forms are designed to provide comprehensive information regarding compliance requirements for federal and state laws to each pharmacy in a readily understandable format. The previous self-assessment form was out of date.</p>	<p>The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.</p>	<p>Business and Professions Code sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4133, 4305, 4330, 4332 and 4333.</p>	<p>The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.</p>	<p>The regulation was reviewed by OAL and found to meet the standard of non-duplication.</p>

<p>16CCR1717 & 16CCR1745</p> <p>Medication Delivery and Partial Refill</p>	<p>March 12, 2003</p>	<p>YES _____</p> <p>NO <u> X </u></p>	<p>Business and Professions Code section 4005</p>	<p>The amendment to this section permits pharmacies to deliver dispensed prescriptions for pickup by the patient at a later time if the patient receives care at the location. This practice eases the delivery of medications to hard to serve populations who do not reside in a community with ready access to a pharmacy. The time period for dispensing a prescription for Schedule II controlled substances was increased to 14 days by Chapter 878, Statutes of 1998. This regulation was updated to reflect the new time limit.</p>	<p>The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.</p>	<p>Business and Professions Code sections 4005 and 4301 and Health and Safety Code section 11055, 11153, 11154, 11164, 11166, and 11200</p>	<p>The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.</p>	<p>The regulation was reviewed by OAL and found to meet the standard of non-duplication.</p>
<p>16CCR1717.3</p> <p>Preprinted Multiple Checkoff Prescriptions</p>	<p>August 31, 2001</p>	<p>YES _____</p> <p>NO <u> X </u></p>	<p>Business and Professions Code section 4005</p>	<p>Using preprinted blanks has been proven to eliminate potential medication errors. Prescribers found existing regulations that mandated using one blank per medication prescribed were burdensome and costly. This regulation permitted more than one drug to be prescribed on each form.</p>	<p>The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.</p>	<p>Business and Professions Code section 4040 and Health and Safety Code section 11164</p>	<p>The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.</p>	<p>The regulation was reviewed by OAL and found to meet the standard of non-duplication.</p>

16CCR1720.1 Foreign Graduates	March 13, 2003	YES _____ NO <u> X </u>	Business and Professions Code section 4005	Existing methods used to evaluate transcripts from foreign pharmacy graduates is fair and equitable, but a specialized foreign credential evaluation service that can authenticate, translate and or evaluate transcripts can be more effective and efficient in making such an evaluation in some circumstances. This regulation allows such an option.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code section 4200	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication
16CCR1732.2 Coursework From Non-Recognized Providers	August 27, 2003	YES _____ NO <u> X </u>	Business and Professions Code section 4005	The board determined that the the regulatory action would facilitate the process for pharmacists fulfilling their continuing education requirement by accepting continuing education approved by: the Medical Board of California, the California Board of Podiatric Medicine, the California Board of Registered Nursing or the Dental Board of California.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code section 4232.	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1748.3 Medical Device Retailers	January 16, 2000	YES _____ NO <u> X </u>	Business and Professions Code section 4005 and 4131	The regulation was needed to ensure that the board has unfettered access to records relating to the distribution of dangerous devices as required by law.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code sections 4130 and 4131	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.

16CCR1749 & 1749.1 Fees	April 20, 1999	YES _____ NO <u> X </u>	Business and Professions Code section 163.5 and 4005	The regulation was required to lower licensing fees to allow the board to reduce its operating reserve.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code Sections 163.5, 4005, 4110, 4112(h), 4120, 4130, 4196, 4200(c), 4400(a), (b), (c), (d), (e), (f), (g), (h), (i), (j), (k), (l), (m), (n), (o), (q), (r), (s), (t), (u), (v), (w), 4401 and 4403	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1760 Disciplinary Guidelines	November 3, 2001	YES _____ NO <u> X </u>	Business and Professions Code section 4005 and section 11425.50 of the Government Code	The regulation is based upon the board's desire to 1) overcome the problems experienced by those who use the guidelines due to the structure of the text, 2) incorporate law changes and 3) correct drafting errors contained in the original document.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code sections 4300 and 4301, and Government Code section 11425.50(e).	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1775 & 1775.1 Citation and Fine	March 31, 2000	YES _____ NO <u> X </u>	Business and Professions Code section 129.5, 148 and 4005	The regulation was needed to enforce continuing education requirements for pharmacists.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code section 129.5 and 148	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.

<p>16CCR1775 et seq.</p> <p>Citation and Fine</p>	<p>July 22, 2001</p>	<p>YES _____</p> <p>NO <u> X </u></p>	<p>Business and Professions Code sections 125.9, 148, and 4005</p>	<p>Increasing complaint volume and ongoing difficulties in achieving compliance with routine licensure requirements demonstrated the need for added enforcement options. Prior to this regulation, the board had to choose between admonition and disciplinary action against a licensee when imposing sanctions for violations. Expanded citation and fine authority provided the board with appropriate options for violations that warrant more severe sanction than admonition but are not appropriate for formal disciplinary action.</p>	<p>The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.</p>	<p>Business and Professions Code sections 125.9 and 148</p>	<p>The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.</p>	<p>The regulation was reviewed by OAL and found to meet the standard of non-duplication.</p>
<p>16CCR1775 et seq.</p> <p>Citation and Fine</p>	<p>October 11, 2003</p>	<p>YES _____</p> <p>NO <u> X </u></p>	<p>Business and Professions Code sections 125.9, 148, 685 and 4005 and Civil Code section 56.36</p>	<p>The regulation revised the board’s system for issuing citations to make the process more consistent with the procedures used by other boards within the Department of Consumer Affairs. The changes removed board members from the process for issuing citations and make all board members eligible to hear any appeals of citations.</p>	<p>The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.</p>	<p>Business and Professions Code sections 125.9, 148 and 685 and Civil Code section 56.36</p>	<p>The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.</p>	<p>The regulation was reviewed by OAL and found to meet the standard of non-duplication</p>

16CCR1777 et seq. Citations and Fines	November 22, 2002	YES _____ NO <u> X </u>	Business and Professions Code section 4005	The regulation implemented the citation and fine provisions of Senate Bill 19 (Chapter 526, Statutes of 1999) regarding violations of the Confidentiality of Medical Information Act and Senate Bill 1828 (Chapter 681, Statutes of 2000) regarding internet dispensing of dangerous drugs and dangerous devices.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code section 4067 and Civil Code section 56.36	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.
16CCR1783 Wholesale Transactions	September 25, 1999	YES _____ NO <u> X </u>	Business and Professions Code section 4005	This regulation eliminated confusion for wholesalers and manufacturers of dangerous drugs regarding who is legally permitted to purchase dangerous drugs.	The regulation was reviewed by the Office of Administrative Law (OAL) and found to be consistent with existing statutes.	Business and Professions Code sections 4043, 4059, 4059.5, 4080, 4081, 4120, 4160, 4161, 4163 4304. Health and Safety Code section 11209	The regulation was reviewed by OAL and found to meeting existing legal requirements for clarity.	The regulation was reviewed by OAL and found to meet the standard of non-duplication.

*- In, 2003, the board submitted a Section 100 filing that made numerous technical changes to Title 16, Article 17 of the California Code of regulations.

Attachment G

Legislation and Regulation Committee
Strategic Plan Update for January 2004

Goal 3:	<u>Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.</u>
Outcome:	Improve the health and safety of Californians.

Objective 3.1:	Annually identify and respond with legislative changes to keep pharmacy laws current and consistent with the board's mission.
Measure:	100 percent successful enactment of promoted legislative changes
Tasks:	<ol style="list-style-type: none"> 1. Secure extension of board's sunset date. Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361) 2. Sponsor legislation to strengthen and update licensing requirements for pharmacy technicians. Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361) 3. Sponsor legislation to add enforcement options for non-compliance issues. Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361) 4. Sponsor legislation to update pharmacy law to standardize terminology regarding cancellation of licenses, waiving pharmacy law requirements during declared emergencies. Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361) 5. Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices. <u>Advocacy:</u> AB 1196, SB 151, SB 175, SB 361, SB 490, SB 545, SB 774 <u>Technical Assistance:</u> AB 262, AB 746, AB 1196, SB 151, SB 175, SB 292, SB 361, SB 490, SB 545, SB 774, SB 907 6. Sponsor clean-up language to B & P Code section 4312. Completed 9/25/03 - Chapter 539, Statutes of 2003 (SB 361) 7. Sponsor public meetings 4 times a year to solicit comments on areas needing legislative changes. Public meetings held on March 27, 2003 and September 11, 2003. Public meeting scheduled for April 5, 2004.

<p>Objective 3.2:</p>	<p>Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission.</p>
<p>Measure:</p>	<p>Percentage successful enactment of promoted regulatory changes</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Strengthen standards for compounding sterile injectable drug products. In process. Rulemaking approved by board in October 2003. Rulemaking suspended by S-2-03. 2. Authorize the executive officer the authority to issue citations and fines. Completed. Regulation effective October 11, 2003. 3. Eliminate the clerk typist ratio. September 2003 - Informational hearing held. Action deferred. 4. Allow pharmacists to be pharmacist-in-charge of two locations simultaneously. September 2003 - Informational hearing held. Rulemaking awaiting publication of notice. 5. Update pharmacy Self-Assessment document. 6. Allow central filling by hospital pharmacies. September 2003 - Informational hearing held. Awaiting publication of notice. 7. Revise regulations concerning electronic prescribing to conform to AB 2245, and require that the pharmacist confirm the authenticity of any electronic prescription in which there is an uncertainty or ambiguity. September 2003 - Informational hearing held. Awaiting publication of notice.

<p>Objective 3.3:</p>	<p>Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2005.</p>
<p>Measure:</p>	<p>Number of areas of pharmacy law reviewed</p>
<p>Tasks:</p>	<ol style="list-style-type: none"> 1. Evaluate electronic prescribing laws involving controlled substances. 2. Evaluate the prescribing and dispensing of veterinary drugs. Completed – Chapter 250, Statutes of 2003 (SB 175) 3. Evaluate group dispensing by prescribers. August 2003 - Draft legislation developed in concert with the Medical Board. Awaiting board action.

Attachment H

MEETING SUMMARY
LEGISLATION AND REGULATION COMMITTEE
DATE: JANUARY 8, 2004
LOCATION: TELECONFERENCE

BOARD MEMBERS PRESENT:

ANDREA ZINDER, CHAIR
DAVE FONG

BOARD STAFF PRESENT:

PATRICIA HARRIS
PAUL RICHES

The meeting was convened at 8:35 a.m.

Legislation

The committee considered amending Section 4101 of the Business and Professions Code to update terminology regarding exemptees and to correct a usage error.

The committee recommended to the board that the changes to Section 4101 be included in the 2004 omnibus bill.

The committee considered amending Section 11155 of the Health and Safety Code to update the law to reflect that physicians are not the only practitioners permitted to prescribe controlled substances.

The committee recommended to the board that the change to Section 11155 be included in the 2004 omnibus bill.

The committee considered amending Section 11159.1 of the Health and Safety Code to correct an erroneous code section references. The committee also requested that staff evaluate the need for any other clarifications in the section.

The committee recommended to the board that the changes to Section 11159.1 be included in the 2004 omnibus bill.

The committee considered amending Section 11207 of the Health and Safety Code to update usage and correct an erroneous code section reference. The committee also discussed further amending this section to clarify that a pharmacy technician may assist a pharmacist in preparing a controlled substance prescription.

The committee recommended to the board that the technical changes recommended by staff and the clarification regarding pharmacy technicians be included in the 2004 omnibus bill.

The committee reviewed items for inclusion in the 2004 omnibus bill already approved by the board. A discussion of changes to Section 4076 raised other issues regarding the labeling requirements including the inclusion of dosage form and route of administration on the required prescription label. The committee

concluded that such changes were significant and warranted discussion during the next public meeting of the committee.

The committee was provided with an update on a potential omnibus provision to clarify the license status of the UC Davis Veterinary Medical Hospital. Staff is communicating with UC Davis to obtain agreement on language. The board approved such a provision in July 2003.

Regulations Update

The committee was updated on how the board is complying with the regulatory review requirements of Executive Order S-2-03.

Future Meetings.

The committee agreed to conduct its next meeting on April 5, 2004 at 10:30 a.m. in Sacramento.

Adjournment

The committee adjourned at 9:30 a.m.

Attachment I



MEMORANDUM

DATE: January 13, 2004

TO: Paul Riches
Chief of Legislation and Regulation
Board Of Pharmacy

FROM: Kristy Wiese, Deputy Director
Division of Legislative and Regulatory Review

SUBJECT: Status of the Implementation of SB 907 –Naturopathic Doctors

In response to your request, this is to advise you that the Department is moving forward in implementing SB 907 (Chapter Statutes of 2003), which established the Bureau of Naturopathic Medicine. The Legislation provided that fees would be collected prior to the actual implementation of the Bureau.

Regulations to implement the provisions of SB 907 have been drafted, but were placed on “hold” while an exemption request was submitted for approval to pursue a regulatory package. It was recently clarified that the regulatory package does not require an exemption approval. The regulatory package (Initial Statement of Reasons) is being finalized for internal review and then will proceed through the usual rulemaking process.

The Initial Statement of Reasons includes an application for licensure, which will be used as the mechanism for the collection of licensing fees. Once fees are collected the Department will certify that there is sufficient funding to continue implementing the other provisions of SB 907 that may include the establishment of the bureau, staffing and processing of applications of licensure. We anticipate that this process will take a few months, at least.

Prior to the completion of that process, the Bureau will not be issuing licenses.

Until such a time that the Bureau is operational and is issuing licenses to qualified naturopaths, naturopaths may not prescribe or engage in any other activity allowed by the bill.

If you have any additional questions regarding the status of the Bureau of Naturopathic Medicine, please contact me at 327-5196 or Terri A. Ciau at 323-2582. Terri is coordinating the implementation of the new Bureau on behalf of the Department.