



California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Virginia Herold
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LEGISLATION AND REGULATION COMMITTEE

California State Board of Pharmacy Department of Consumer Affairs Notice of Public Meeting October 24, 2007

This board meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Karen Abbe at (916) 574-7946, at least five working days prior to the meeting.

Opportunities are provided to the public to address the board on each open agenda item. Board members who are not on the committee may attend the meeting as observers.

Agenda

DATE: October 24, 2007

PLACE: San Jose DoubleTree Hotel (near San Jose Airport)
2050 Gateway Place
San Jose, CA 95110
(408) 453-4000

Wednesday, October 24, 2007

- A. CALL TO ORDER** ***4:05 p.m.**
- B. Requests for Legislative and Regulatory Proposals for 2008**
- 1. Previously Discussed Proposed Legislation**
 - a. Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – B&PC 4052.8
 - b. Furnishing Dangerous Drugs During an Emergency – B&PC 4062
 - c. Temporary Permit for Damaged Pharmacies – B&PC 4110
 - 2. Proposed Legislation**
 - a. Who May Order Dangerous Drugs or Devices, Exceptions (technical change) – B&PC 4059.5
 - b. PIC reporting requirements – B&PC Sections 4101, 4113 & 4305
 - c. Amendment Furnishing Dangerous Drugs by a Pharmacy – B&PC 4126.5
 - d. Requirements for Renewal of Pharmacist License involving CE – B&PC 4231
 - e. Entry Into Pharmacists Recovery Program, Administrative Fee - B&PC 4362
 - f. Controlled Substance Utilization Review and Evaluation System, Clinic Reporting – H&SC 11165
 - g. References Update for statutory medications referencing B&PC 4052

**Times are approximate and are subject to change
Committee materials will be available on the board's Web site by October 17, 2007.*

3. Proposed Regulations

- a. Graduate of Foreign Pharmacy Schools (technical change) – 16 CCR 1720.1

C. Public Requests for Future Legislation and Regulatory Proposals

The public is encouraged to bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct the problems.

Adjournment

5:15 p.m.



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Date: October 17, 2007

To: Legislation and Regulation Committee

Subject: Proposed Legislation for 2008

The Licensing Committee has submitted the following two proposals for discussion at this meeting. In the interest of preparing a full listing of proposed legislation for 2008 they are included for information only. (See Licensing tab section for copies of the proposals.)

- Amendment to section 4052 and adding section 4052.8 to allow for immunizations by a pharmacist pursuant to the published recommendations of the Advisory Committee on Immunization Practices (ACIP). Should the board vote to support this legislative proposal, board staff along with experts in the field will facilitate a cooperative effort to elicit support from associations and organizations to ensure the successful passage of this key proposal to improve the quality of care for Californians.
- Amendment to sections 4062 and 4110 will allow for the use of mobile pharmacies. Should the board vote to support this legislative proposal board staff will contact the Office of Emergency Services to elicit support for this proposal.



Date: October 16, 2007

To: Legislation and Regulation Committee

Subject: Proposed Legislation for 2008 – Omnibus Provisions

Consistent with the board's strategic objective 3.3, board staff and counsel have completed a comprehensive review of the legal requirements surrounding the requirements of a pharmacist-in-charge (PIC) as well as a designated representative-in-charge (DRIC). As a result of this review, several omnibus changes are being recommended to include some technical changes as well as refine the definitions of the pharmacist-in-charge and designated representative-in-charge and clarify the reporting requirements when a change of PIC or DRIC occurs.

Below is a list of the specific recommended changes as well as a brief statement about the specific proposed change. The proposed language is included in **Attachment 1**.

- Section 4022.5 – Designated Representative; Designated Representative-in-Charge
This section requires amendment to clarify the definition of "designated representative-in-charge" as well as the responsibilities of a licensee serving as such.
- Section 4036.5 – Pharmacist-in-Charge
A new section is needed to refine the term "pharmacist-in-charge" as well as the responsibilities a pharmacist serving as such.
- Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.
This section requires amendment to clarify when a pharmacist-in-charge or designated representative-in-charge must notify the board that he or she ceased to serve in such a capacity.
- Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications
This section requires amendment to clarify the procedures to be followed by a pharmacy when identifying a pharmacist-in-charge as well as the procedures to notify the board when a change in pharmacist-in-charge has

occurred. In addition this section allows for the use of an interim pharmacist-in-charge, for a period not greater than 120 days, when a pharmacy is unable to identify a permanent new pharmacist-in-charge within 30 days as required.

- Section 4160 – Wholesaler Licenses
This section requires amendment to clarify the procedures to be followed by a wholesaler when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.
- Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
This section requires amendment to clarify the procedures to be followed by a veterinary food-animal drug retailer when identifying a designated representative-in-charge as well as the procedures to notify the board when a change in the designated representative-in-charge has occurred.
- Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
This section requires amendment to specify that failure to meet notification requirements will constitute grounds for disciplinary action.
- Section 4329 – Nonpharmacists; Prohibited Acts
This section requires amendment to include the prohibition of a nonpharmacist from acting as a supervisor or pharmacist-in-charge.
- Section 4330 – Proprietors; Prohibited Acts
This section requires amendment to clarify that any pharmacy owner that subverts or tends to subvert the efforts of a pharmacist-in-charge is guilty of a misdemeanor.

In addition to the changes listed above all of the following proposals are also recommended omnibus provisions for 2008. Copies of the exact language are in **Attachment 2**.

- Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.
A technical change to this section is necessary to clarify that a designated representative must sign for and receive delivery of drugs by a wholesaler.
- Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section requires amendment to clarify specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

- Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section requires amendment to expand the board's authority to also include the board's ability to automatically inactivate a pharmacist license when a pharmacist who certifies completion of the required CE as part of a renewal, fails to provide proof either as part of an audit or investigation
- Section 4362 – Entry Into Pharmacists Recovery Program
This section requires amendment to specify the administrative co-pay participants pay.
- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to require that a clinic that dispensed schedule III and schedule IV controlled substances must report to CURES.

In 2006 Business and Professions Code section 4052 was recodified into four sections. The below B&PC and H&SC sections reference 4052 and require update. The proposed language is in **Attachment 3**.

- Section 733 – Dispensing Prescription Drugs and Devices
- Section 4027 – Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities
- Section 4040 – Prescription; Content Requirements
- Section 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- Section 4060 – Controlled Substance – Prescription Required, Exceptions
- Section 4076 – Prescription Container – Requirements for Labeling
- Section 4111 – Restrictions on Prescriber Ownership
- Section 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue a Prescription



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ARNOLD SCHWARZENEGGER, GOVERNOR

Date: October 17, 2007

To: Legislation and Regulation Committee

Subject: Proposed Regulations

Section 100 Changes

Board staff is recommending to the board the following Section 100 changes for board consideration. A copy of the proposed language is included in **Attachment 4**.

16 CCR § 1715.5. Implementation of Electronic Monitoring of Schedule II Prescriptions

This regulation defines the information that must be reported to CURES. This section currently references schedule II controlled substances and requires updating to reflect the expansion of CURES reporting requirements to include schedule III and IV controlled substances.

16 CCR § 1720.1. Graduates of Foreign Pharmacy School

This regulation defines the certification requirement for graduates of foreign pharmacy schools. This section requires amendment to correct the name of the certification. Specifically, the correct language shall refer to the Foreign Pharmacy Graduate Examination Committee.

Attachment 1

Proposed Revisions to PIC/DRIC Statutes

- 4022.5 – Designated Representative; Designated Representative-in-Charge
- 4036.5 – Pharmacist-in-Charge
- 4101 – Pharmacist-in-Charge; Designated Representative-in-Charge; Termination of Status; Duty of Notify the Board
- 4113 – Pharmacist-in-Charge; Approval. Responsibilities; Notifications
- 4160 – Wholesaler License
- 4196 – Veterinary Food-Animal Drug Retailer Licenses, Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked
- 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action
- 4329 – Nonpharmacists; Prohibited Acts
- 4330 – Proprietors; Prohibited Acts

Proposed Revisions to PIC/DRIC Statutes

§ 4022.5. Designated representative; designated representative-in-charge

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties in Sections 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board who is as the supervisor or manager of a responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

§ 4036.5. Pharmacist-in-charge

"Pharmacist-in-charge" means a pharmacist proposed by a pharmacy and approved by the board as the supervisor or manager responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

§ 4101. Persons in charge of pharmacy or exemptees Pharmacist-in-charge; designated-representative-in-charge; termination of employment status; duty to notify board

(a) ~~A pharmacist who takes~~ may take charge of, ~~or acts and act as the~~ pharmacist-in-charge of a pharmacy ~~or other entity licensed by the board~~ upon application by the pharmacy and approval by the board. Any pharmacist-in-charge who terminates his or her employment at the pharmacy, gives up or is stripped of his or her role as pharmacist-in-charge, or otherwise ceases to act as the pharmacist-in-charge of the pharmacy or other entity, shall notify the board in writing within 30 days of the termination of employment date of such change in status.

(b) ~~An exemptee~~ A designated representative or a pharmacist may take charge of and act as the designated representative-in-charge of a wholesaler or veterinary food drug-animal retailer upon application by the wholesaler or veterinary food drug-animal retailer and approval by the board. Any designated representative-in-charge who terminates his or her employment, gives up or is stripped of his or her role as designated representative-in-charge, or otherwise ceases to act as the designated representative-in-charge at that entity, shall notify the board in writing within 30 days of the termination of employment date of such change in status.

§ 4113. Pharmacists-in-charge; designation approval; responsibilities; notifications

~~(a) Every pharmacy shall designate a pharmacist-in-charge and within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was designated be supervised or managed by a pharmacist-in-charge. As part of its initial application for a license, and for each renewal, each pharmacy shall, on a form designed by the board, provide identifying information and the California license number for a pharmacist proposed to serve as the pharmacist-in-charge. The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.~~

(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.

(c) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist ceases to be a pharmacist-in-charge is terminated, gives up or is stripped of that role, or in any other manner ceases to act as pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

(d) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead supply on that form the name of any pharmacist who is an employee, officer or administrator of the pharmacy or the entity which owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity which owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge, with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

§ 4160. Wholesaler Licenses

(a) A person may not act as a wholesaler of any dangerous drug or dangerous

device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) A separate license shall be required for each place of business owned or operated by a wholesaler. Each license shall be renewed annually and shall not be transferable.

~~(d) The board shall not issue or renew a wholesaler license until the wholesaler identifies a designated representative in charge and notifies the board in writing of the identity and license number of that designated representative. Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler.~~

~~(e) A wholesaler shall identify and notify the board of a new designated representative in charge within 30 days of the date that the prior designated representative in charge ceases to be the designated representative in charge. A pharmacist may be identified as the designated representative in charge. Every wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge is terminated, gives up or is stripped of that role, or in any other manner ceases to act as designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.~~

(e f) A drug manufacturer licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(f g) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a wholesaler.

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

§ 4196. Veterinary Food-Animal Drug Retailer Licenses; persons allowed in areas where drugs stored, possessed, or repacked

(a) No person shall conduct a veterinary food-animal drug retailer in the State of California unless he or she has obtained a license from the board. A license shall be required for each veterinary food-animal drug retailer owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a veterinary food-animal drug retailer in more than one location. The license shall be renewed annually and shall not be transferable.

(b) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct a veterinary food-animal drug retailer.

(c) No person other than a pharmacist, an intern pharmacist, a designated representative, an authorized officer of the law, or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the permit issued by the board pursuant to Section 4041, wherein veterinary food-animal drugs are stored, possessed, or repacked. A pharmacist or designated representative shall be responsible for any individual who enters the veterinary food-animal drug retailer for the purpose of performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the veterinary food-animal drug retailer.

~~(d) The board shall not issue or renew a veterinary food-animal retailer license until the veterinary food-animal drug retailer identifies a designated representative in-charge and notifies the board in writing of the identity and license number of that designated representative. Every veterinary food-animal drug retailer shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the veterinary food-animal drug retailer's compliance with state and federal laws governing veterinary food-animal drug retailers. As part of its initial application for a license, and for each renewal, each veterinary food-animal drug retailer shall, on a form designed by the board, provide identifying information and the California license number for a designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a veterinary food-animal drug retailer license without identification of an approved designated representative-in-charge for the veterinary food-animal drug retailer.~~

~~(e) Each veterinary food-animal drug retailer shall identify, and notify the board of, a new designated representative in-charge within 30 days of the date that the prior designated representative in-charge ceases to be the designated representative in-charge. A pharmacist may be identified as the designated representative in-charge. Every veterinary food-animal drug retailer shall notify the board in writing, on a~~

form designed by the board, within 30 days of the date when a designated representative-in-charge is terminated, gives up or is stripped of that role, or in any other manner ceases to act as designated representative-in-charge, and shall on the same form propose another designated representative or pharmacist to take over as designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the veterinary food-animal drug retailer shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(e f) For purposes of this section, designated representative-in-charge means a person granted a designated representative license pursuant to Section 4053, or a registered pharmacist, who is the supervisor or manager of the facility.

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

§ 4305. Licensees conducting pharmacies; Pharmacist-in-charge; notice to board; disciplinary action

~~(a) Any person who has obtained a license to conduct a pharmacy, shall notify the board within 30 days of the termination of employment of any pharmacist who takes charge of, or acts as manager of the pharmacy. Failure by any pharmacist to notify the board in writing that he or she has ceased to act as pharmacist-in-charge of a pharmacy, or by any pharmacy to notify the board in writing that a pharmacist-in-charge is no longer acting in that capacity, within the 30-day period specified by sections 4101 and 4113, shall constitute grounds for disciplinary action.~~

~~(b) Operation of a pharmacy for more than 30 days without supervision or management thereof by a pharmacist-in-charge shall constitute grounds for disciplinary action.~~

~~(b c) Any person who has obtained a license to conduct a pharmacy, who willfully fails to timely notify the board of the termination of employment of that any pharmacist who takes charge of, or acts as manager the pharmacist-in-charge of the pharmacy has ceased to act in that capacity, and who continues to permit the compounding or dispensing of prescriptions, or the furnishing of drugs or poisons, in his or her pharmacy, except by a pharmacist subject to the supervision and management of a responsible pharmacist-in-charge, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.~~

~~(c) Any pharmacist who takes charge of, or acts as manager of a pharmacy, who terminates his or her employment at the pharmacy, shall notify the board within 30 days of termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.~~

§ 4329. Nonpharmacists; prohibited acts

Any nonpharmacist who takes charge of or acts as supervisor, manager, or pharmacist-in-charge of any pharmacy, or who compounds or dispenses a prescription or furnishes dangerous drugs except as otherwise provided in this chapter, is guilty of a misdemeanor.

§ 4330. Proprietors; prohibited acts

(a) Any person who has obtained a license to conduct a pharmacy, who fails to place in charge of the pharmacy a pharmacist, or any person, who by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, or the furnishing of dangerous drugs, in his or her pharmacy, except by a pharmacist, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(b) Any nonpharmacist pharmacy owner who commits any act that would subvert or tend to subvert the efforts of the pharmacist-in-charge to comply with the laws governing the operation of the pharmacy is guilty of a misdemeanor.

Attachment 2

Proposed Omnibus Language

- 4059.5 – Who May Order Dangerous Drugs or Devices, Exceptions
- 4126.5 – Furnishing Dangerous Drugs by Pharmacy
- 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
- 4362 – Entry Into Pharmacists Recovery Program
- H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to the Legislature

Proposed Omnibus Provisions for 2008

Business and Professions Code Amendments

§ 4059.5. Who may order dangerous drugs or devices, exceptions

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may must sign for and receive the delivery.

(b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.

(c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

- (1) The drugs are placed in a secure storage facility in the same building as the pharmacy.
- (2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.
- (3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.
- (4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

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

§ 4126.5. Persons or organizations that pharmacies may furnish with dangerous drugs; violations; offset of amounts due; definitions

(a) A pharmacy may furnish dangerous drugs only to the following, and only the following may receive dangerous drugs furnished by a pharmacy:

(1) A wholesaler owned or under common control by the wholesaler from whom the dangerous drug was acquired.

(2) The pharmaceutical manufacturer from whom the dangerous drug was acquired.

(3) A licensed wholesaler acting as a reverse distributor.

(4) Another pharmacy or wholesaler to alleviate a temporary shortage of a dangerous drug that could result in the denial of health care. A pharmacy furnishing dangerous drugs pursuant to this paragraph may only furnish a quantity sufficient to alleviate the temporary shortage.

(5) A patient or to another pharmacy pursuant to a prescription or as otherwise authorized by law.

(6) A health care provider that is not a pharmacy but that is authorized to purchase dangerous drugs.

(7) To another pharmacy under common control.

(b) Notwithstanding any other provision of law, a violation of this section ~~by either a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities or a person engaged in a prohibited transaction with a pharmacy whose primary or sole business is filling prescriptions for patients of long-term care facilities~~ may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

(c) Amounts due from any person under this section on or after January 1, 2005, shall be offset as provided under Section 12419.5 of the Government Code. Amounts received by the board under this section shall be deposited into the Pharmacy Board Contingent Fund.

(d) For purposes of this section, "common control" means the power to direct or cause the direction of the management and policies of another person whether by ownership, by voting rights, by contract, or by other means.

For purposes of subdivision (b) of this section and subdivision (s) of Section 4301, "long-term care facility" shall have the same meaning given the term in Section 1418 of the Health and Safety Code.

§ 4231. Requirements for renewal of pharmacist license; clock hours; exemption for new licensee

(a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that he or she has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.

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

(c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

(d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a) the board shall automatically cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

§ 4362. Entry into the Pharmacists Recovery Program

(a) A pharmacist or intern pharmacist may enter the pharmacists recovery program if:

- (1) The pharmacist or intern pharmacist is referred by the board instead of, or in addition to, other means of disciplinary action.
- (2) The pharmacist or intern pharmacist voluntarily elects to enter the pharmacists recovery program.

(b) A pharmacist or intern pharmacist who enters the pharmacists recovery program pursuant to paragraph (2) of subdivision (a) shall not be subject to discipline or other enforcement action by the board solely on his or her entry into the pharmacists recovery program or on information obtained from the pharmacist or intern pharmacist while participating in the program unless the pharmacist or intern pharmacist would pose a threat to the health and

safety of the public. However, if the board receives information regarding the conduct of the pharmacist or intern pharmacist, that information may serve as a basis for discipline or other enforcement by the board.

(c) A pharmacist or intern pharmacist enrolled in the pharmacists recovery program shall be responsible to pay an administrative co-pay of \$100 monthly to cover a portion of the administrative costs borne by the board to contract for these services.

(1) This fee may be waived, reduced, or deferred by the board or its designee if the participant demonstrates a financial hardship.

Health and Safety Code Amendment

§ 11165. Controlled Substance Utilization Review and Evaluation System: Establishment; Operations; Funding; Reporting to Legislature

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The Department of Justice may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

- (1) Full name, address, and the telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
- (2) The prescriber's category of licensure and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
- (3) Pharmacy prescription number, license number, and federal controlled substance registration number.
- (4) NDC (National Drug **Code**) number of the controlled substance dispensed.
- (5) Quantity of the controlled substance dispensed.
- (6) ICD-9 (diagnosis **code**), if available.
- (7) Number of refills ordered.
- (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
- (9) Date of origin of the prescription.
- (10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

Attachment 3

Section 4052 Recodification Omnibus Language

- 733 – Dispensing Prescription Drugs and Devices
- 4027 – Skilled Nursing Facility – Intermediate care Facility – Other Health Care Facilities
- 4040 – Prescription; Content Requirements
- 4051 – Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist
- 4060 – Controlled Substance – Prescription Required, Exceptions
- 4076 – Prescription Container – Requirements for Labeling
- 4111 – Restrictions on Prescriber Ownership
- 4174 – Dispensing by Pharmacist Upon Order of Nurse Practitioner
- H&SC 11150 – Persons Authorized to Write or Issue A Prescription

**Omnibus Provisions Resulting from
Recodification of B&PC 4052**

BUSINESS AND PROFESSIONS CODE

§ 733. Dispensing Prescription Drugs and Devices

(a) No licentiate shall obstruct a patient in obtaining a prescription drug or device that has been legally prescribed or ordered for that patient. A violation of this section constitutes unprofessional conduct by the licentiate and shall subject the licentiate to disciplinary or administrative action by his or her licensing agency.

(b) Notwithstanding any other provision of law, a licentiate shall dispense drugs and devices, as described in subdivision (a) of Section 4024, pursuant to a lawful order or prescription unless one of the following circumstances exists:

(1) Based solely on the licentiate's professional training and judgment, dispensing pursuant to the order or the prescription is contrary to law, or the licentiate determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition.

(2) The prescription drug or device is not in stock. If an order, other than an order described in Section 4019, or prescription cannot be dispensed because the drug or device is not in stock, the licentiate shall take one of the following actions:

(A) Immediately notify the patient and arrange for the drug or device to be delivered to the site or directly to the patient in a timely manner.

(B) Promptly transfer the prescription to another pharmacy known to stock the prescription drug or device that is near enough to the site from which the prescription or order is transferred, to ensure the patient has timely access to the drug or device.

(C) Return the prescription to the patient and refer the patient. The licentiate shall make a reasonable effort to refer the patient to a pharmacy that stocks the prescription drug or device that is near enough to the referring site to ensure that the patient has timely access to the drug or device.

(3) The licentiate refuses on ethical, moral, or religious grounds to dispense a drug or device pursuant to an order or prescription. A licentiate may decline to dispense a prescription drug or device on this basis only if the licentiate has previously notified his or her employer, in writing, of the drug or class of drugs to which he or she objects, and the licentiate's employer can, without creating undue hardship, provide a reasonable accommodation of the licentiate's objection. The licentiate's employer shall establish protocols that ensure that the patient has timely access to the prescribed drug or device despite the licentiate's refusal to dispense the prescription or

order. For purposes of this section, "reasonable accommodation" and "undue hardship" shall have the same meaning as applied to those terms pursuant to subdivision (l) of Section 12940 of the Government Code.

(c) For the purposes of this section, "prescription drug or device" has the same meaning as the definition in Section 4022.

(d) The provisions of this section shall apply to the drug therapy described in paragraph (8) of subdivision (a) of Section ~~4052~~ 4052.3.

(e) This section imposes no duty on a licentiate to dispense a drug or device pursuant to a prescription or order without payment for the drug or device, including payment directly by the patient or through a third party payer accepted by the licentiate or payment of any required copayment by the patient.

§ 4027. Skilled Nursing Facility – Intermediate Care Facility – Other Health Care Facilities

(a) As used in this chapter, the terms "skilled nursing facility," "intermediate care facility," and other references to health facilities shall be construed with respect to the definitions contained in Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code.

(b) As used in paragraph (4) of subdivision (a) of Section ~~4052~~ 4052.1, "licensed health care facility" means a facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility, as defined in Section 1250 of the Health and Safety Code, operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code.

(c) As used in paragraph (5) of subdivision (a) of Section ~~4052~~ 4052.2, "health care facility" means a facility, other than a facility licensed under Division 2 (commencing with Section 1200) of the Health and Safety Code, that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of the Health and Safety Code, or by an organization under common ownership or control of the health care service plan; "licensed home health agency" means a private or public organization licensed by the State Department of Health Services pursuant to Chapter 8 (commencing with Section 1725) of Division 2 of the Health and Safety Code, as further defined in Section 1727 of the Health and Safety Code; and "licensed clinic" means a clinic licensed pursuant to Article 1 (commencing with Section 1200) of Chapter 1 of Division 2 of the Health and Safety Code.

(d) "Licensed health care facility" or "facility," as used in Section 4065, means a health facility licensed pursuant to Article 1 (commencing with Section 1250) of Chapter 2 of Division 2 of the Health and Safety Code or a facility that is owned or operated by a health care service plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code or by an organization under common ownership or control with the health care service plan.

§ 4040. Prescription; Content Requirements

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section ~~4052~~ 4052.2.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section ~~4052~~ 4052.2 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (3) of subdivision (b) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any

additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

§ 4051. Conduct Limited to Pharmacist; Conduct Authorized by Pharmacist

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section ~~4052~~ 4052.2, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

- (1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.
- (2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.
- (3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

§ 4060. Controlled Substance – Prescription Required, Exceptions

No person shall possess any controlled substance, except that furnished to a person upon the prescription of a physician, dentist, podiatrist, optometrist,

veterinarian, or naturopathic doctor pursuant to Section 3640.7, or furnished pursuant to a drug order issued by a certified nurse-midwife pursuant to Section 2746.51, a nurse practitioner pursuant to Section 2836.1, a physician assistant pursuant to Section 3502.1, a naturopathic doctor pursuant to Section 3640.5, or a pharmacist pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 4052.2. This section shall not apply to the possession of any controlled substance by a manufacturer, wholesaler, pharmacy, pharmacist, physician, podiatrist, dentist, optometrist, veterinarian, naturopathic doctor, certified nurse-midwife, nurse practitioner, or physician assistant, when in stock in containers correctly labeled with the name and address of the supplier or producer. Nothing in this section authorizes a certified nurse-midwife, a nurse practitioner, a physician assistant, or a naturopathic doctor, to order his or her own stock of dangerous drugs and devices.

§ 4076. Prescription Container – Requirements for Labeling

(a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 4052.2 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.

(3) The name of the patient or patients.

(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either

subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(5) The date of issue.

(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.

(7) The strength of the drug or drugs dispensed.

(8) The quantity of the drug or drugs dispensed.

(9) The expiration date of the effectiveness of the drug dispensed.

(10) The condition for which the drug was prescribed if requested by the patient and the condition is indicated on the prescription.

(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:

(i) Prescriptions dispensed by a veterinarian.

(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.

(iii) Dispensed medications for which no physical description exists in any commercially available database.

(B) This paragraph applies to outpatient pharmacies only.

(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.

(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

§ 4111. Restrictions on Prescriber Ownership

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist authorized to issue a drug order pursuant to subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section ~~4052~~ 4052.2.

§ 4174. Dispensing by Pharmacist Upon Order of a Nurse Practitioner

Notwithstanding any other provision of law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section ~~4052~~ 4052.2.

HEALTH AND SAFETY CODE

§ 11150 – Persons Authorized to Write or Issue a Prescription

No person other than a physician, dentist, podiatrist, or veterinarian, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of either ~~subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of~~ Section ~~4052~~ 4052.2 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nursemidwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

Attachment 4

Proposed Section 100 Changes

- 1715.5
- 1720.1

Proposed Section 100 Changes

Amend §1715.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1715.5 The collection of information authorized by Health and Safety Code section 11165 shall be provided as follows:

(a) For each prescription for a Schedule II, III or IV controlled substance, the dispensing pharmacy shall provide the following information: the full name and address of the patient; the gender and date of birth of the patient; the DEA (Drug Enforcement Administration) number of the prescriber; the triplicate prescription number; the pharmacy prescription number; the pharmacy license number; the NDC (National Drug Code) number and the quantity of the controlled substance; the ICD-9 (diagnosis code), if available; the date of issue of the prescription, the date of dispensing of the prescription, and the state medical license number of any prescriber using the DEA number of a government exempt facility.

(b) The above information shall be provided in the following format:

(1) For each pharmacy with the capacity to do so, by on-line transmission at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(2) For each pharmacy which does not have the capacity to transmit the information on-line, on a three and one-half inch diskette in a ASCII format or one-half inch nine track magnetic 1600 BPI tape or any other medium approved by the Board of Pharmacy, which diskette, tape or medium shall be mailed or delivered to a location specified by The Board of Pharmacy, at least every 30 days and no later than the 18th calendar day of the month following the month in which the prescription is dispensed.

(3) For each pharmacy without the capacity to comply with either subsection (b)(1) or (2), the original triplicate shall be transmitted to the Department of Justice by the end of the month in which the prescription was filled. For each pharmacy which submits hard copy pursuant to this subdivision and which pharmacy averages more than 25 triplicate prescriptions per month in any six months, the Board of Pharmacy or its designee may thereafter require that pharmacy to comply with subsections (b)(1) and (2).

(4) As to a prescription which is partially filled or dispensed, the period for compliance with subsections (1), (2), or (3) shall be measured from the earlier of the following dates and times: the prescription is either (1) completely dispensed or (2) can no longer be dispensed.

(c) Every pharmacy which has made a submission as required by this section by July 18, 1998, shall receive a reduction of \$75 on its next renewal fee for licensure of the pharmacy by the board. Every pharmacy shall be in compliance with this section and Health and Safety Code section 11165 by September 18, 1998.

Authority cited: Sections 4005, Business and Professions Code. Reference: Sections 11164 and 11165, Health and Safety Code.

Amend §1720.1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1720.1 Graduates of foreign pharmacy schools who have been certified by the Foreign Pharmacy Graduate ~~Equivalency~~ Examination Committee shall be deemed by the board to have satisfied the requirements of paragraphs (3) and (4) of Business and Professions Code Section 4200(a). Candidates who have been certified by the Foreign Pharmacy Graduate ~~Equivalency~~ Examination Committee before January 1, 1998, must also provide the board with a score on the Test of Spoken English of least 50. For candidates who took the Test of Spoken English before June 30, 1995, a score of at least 220 must be achieved.

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