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**Legislation and Regulation Committee**

**Robert Graul, RPh, Chair**
**Bill Powers, Public Member**
**Robert Swart, PharmD**
**Shirley Wheat, Public Member**
**Andrea Zinder, Public Member**

# *ITEM C: LEGISLATION AND REGULATION COMMITTEE REPORT*

## 1. Action on Legislative Proposals Recommended for Sponsorship by the Legislation and Regulation Committee During the Committee Meeting of October 29, 2008.

It is anticipated that during the Legislation and Regulation Committee Meeting scheduled for October 29, 2008, the committee will consider legislative proposals for board sponsorship in 2009. Below is a list of some of the proposals that will be considered by the committee.

OMNIBUS PROVISIONS PREVIOUSLY APPROVED BY THE BOARD – SB 1779 (Senate Business and Professions Committee)

**FOR ACTION**: A motion and vote from the board is necessary to formally approve the proposed language to be included in the omnibus provisions.

As the governor vetoed the board's omnibus bill, board staff recommends inclusion of all of the following provisions again. Any committee recommendations will be discussed during the board meeting.

**Use of Mobile Pharmacies**

Section 4062 Furnishing Dangerous Drugs During an Emergency
This section allows for the use of a mobile pharmacy in the event of a declared natural disaster if certain criteria are met.

Section 4110 License Required, Temporary Permit Upon Transfer of Ownership
This section allows for the use of a mobile pharmacy on a temporary basis when a pharmacy is destroyed or damaged.

**Pharmacist-in-Charge and Designated Representative in Charge**

Amend Sections 4022.5, 4101, 4113, 4160, 4196, 4305, 4329, 4330 and Add section 4036.5
The Board of Pharmacy is proposing changes to several sections of the Business and Professions Code to clarify the reporting requirements to document a change in the Pharmacist-In-Charge (PIC). The PIC is responsible for the overall operations in a pharmacy. There are also similar changes for the Designated Representative-in-Charge (DRC) of a wholesaler or veterinary food-animal drug retailer. This proposal would also define the term "pharmacist-in-charge" currently referenced throughout pharmacy law as well as place into statute the approval process currently used by the board when evaluating a pharmacy application for approval of a proposed PIC or DRC.

**Corrections to Sections Referencing Prior Business and Professions Code § 4052**

Omnibus changes based on recodification of Business and Professions Code section 4052

In 2006 Business and Professions Code section 4052 was recodified into four sections. The below B&PC and H&SC sections reference old section 4052 and require update.

- 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

**General Omnibus Provisions**

Amend Section 4059.5 - Who May Order Dangerous Drugs or Devices, Exceptions
A technical change to this section clarifies that a designated representative must sign for and receive delivery of drugs by a wholesaler. This is important for accountability of drug purchases and receipt in wholesale operations.

Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
This section corrects a drafting error that occurred in Senate Bill 1307 (Chapter 857, statutes of 2004). The term "exemptee-in-charge" was incorrectly updated to "representative-in-charge" and requires correction to the appropriate term "designated representative-in-charge."

Amend Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy
This section clarifies specifically who in the supply chain may receive dangerous drugs furnished by a pharmacy.

Amend Section 4161 – Nonresident Wholesaler: When License Required: Application
This section clarifies that any person that sells, brokers or distributes dangerous drugs or devices within California must be licensed.

Amend Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee
This section addresses the need to authorize the board 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. This authority already exists when a pharmacist fails to certify completion of continuing education as part of the renewal application.

Amend Section 4362 – Entry Into Program; Discipline Exceptions
This section specifies the administrative co-pay participants pay as part of their participation in the PRP. The board subsidizes the administrative cost, however requires the participant to also pay a portion of the administrative costs of the program. The current administrative co-pay, $75.00, is set by contract only. The board has not sought a change in this co-pay in over 10 years, and has continually absorbed the additional monthly administrative fee, currently about $230/month per participant.

This section allows the board the ability to waive a participant's co-pay for demonstrated financial hardship.

Amend H&SC Section 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature
This section requires amendment to mandate that a clinic that dispenses schedule III and schedule IV controlled substances must report weekly to CURES, similar to the requirements for pharmacies and prescribers who dispense controlled drugs as specified.

A copy of each proposal is in **ATTACHMENT 1.**

NEW OMNIBUS PROVISIONS

**FOR ACTION**: A vote from the board is necessary to formally approve the proposed language to be included in the omnibus provisions if recommended to do so by the Legislation and Regulation Committee.

Add Section 4013 – Subscriber Alert
This section needs to be added to require all board licensed facilities to join the board's e-mail notification list.

Amend Section 4112 – Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
This section requires amendment to explicitly state that a person cannot act as a nonresident pharmacy unless he or she has obtained a license from the state.

Amend Section 4401 – Pharmacists: Biennial Renewal
This section needs amendment to require pharmacists to notify the board of any misdemeanor or felony convictions, or whether any disciplinary action has been taken, as specified subsequent to the licensee's last renewal.

Amend Section 4403 – Reissuance Without Payment of Fees Prohibited

This section needs amendment to require pharmacy technicians and designated representatives to notify the board of any misdemeanor or felony convictions, or whether any disciplinary action has been taken, as specified subsequent to the licensee's last renewal.

**ATTACHMENT 2** contains the draft language for these sections.

OTHER LEGISLATIVE PROPOSALS FOR BOARD SPONSORSHIP

**FOR ACTION**: A vote from the board is necessary to formally approve the proposed language to be included in the omnibus provisions if recommended to do so by the Legislation and Regulation Committee.

Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices

At the April 2007 Board Meeting, the board voted to pursue a statutory change to allow a pharmacist to initiate and administer immunizations pursuant to the published recommendations of the Advisory Committee on Immunization Practices.

Beginning in November 2007, board staff worked with stakeholders to address questions as well as to elicit support for this proposal. However, in April 2008, after consideration it was decided not to move the proposal this year. It is being brought before the board for consideration and possible sponsorship in 2009.

Included in **ATTACHMENT 3** is the most recent draft of the language as well as the Adolescent and Adult Schedules.

Request from the California Pharmacy Foundation for Clarification of Business and Professions Code section 4076.

At the July 2008 Board Meeting, the board heard a request from Dr. Steve Gray, representing the California Pharmacy Foundation. The Foundation is requesting that the board sponsor legislation that will clarify a pharmacist's authorization within Business and Professions Code section 4076(a)(10) and allow a pharmacist to place the "purpose" of the medication on the label that is affixed to every prescription container dispensed to a patient. One of the Foundation's primary focuses is on the reduction of medication errors and they believe that clarifying when and how a pharmacist is authorized to place the additional information within the prescription label will improve patient outcomes.

It was recommended that this matter be referred to the Legislation and Regulation Committee for discussion and to recommend if it is feasible to pursue this proposal in 2009 with its anticipated legislative calendar.

Draft language for this proposal is included in **ATTACHMENT 4**.

## 2. Update of the Committee's Strategic Plan for 2008/09

There are no recommended changes to the committee's strategic plan.

## 3. FIRST QUARTERLY REPORT ON COMMITTEE GOALS FOR 2008/09

The update on the first quarterly report on committee's strategic goals for 2008/09 is included in **ATTACHMENT 5**.

# Attachment 1

## *Omnibus Language included in SB 1779*

**Omnibus Provisions from 2008**

# Business and Professions Code Amendments

## § 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.

**§ 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 Section 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.

**§ 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.

**§ 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.

**§ 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.

**§ 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~~ a 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.

## § 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.

## § 4062. Furnishing Dangerous Drugs During and Emergency

(a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or

device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency the board will allow for the deployment of a mobile pharmacy to impacted areas to ensure the continuity of patient care if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing;
(2) The mobile pharmacy retains records of dispensing as required in subdivision (a);
(3) A licensed pharmacist is on the premises, and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed;
(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy;
(5) The mobile pharmacy is located within the declared disaster area or affected areas; and
(6) The mobile pharmacy ceases the provisions of services within forty-eight (48) hours following the termination of the declared emergency.

**§ 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.

**§ 4081. Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory**

(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized

officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

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

**§ 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~~ 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~~ 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.

**§ 4110 License Required, Temporary Permit Upon Transfer of Ownership**

(a) No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred.
(b) The board may, at its discretion, issue a temporary permit, when the ownership of a pharmacy is transferred from one person to another, upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be established by the board at an amount not to exceed the annual fee for renewal of a permit to

conduct a pharmacy. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.

(c) The board may allow the temporary use of a mobile pharmacy, when a pharmacy is destroyed or damaged and when needed to protect the health and safety of the public and the following conditions are met:

(1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.

(2) The mobile pharmacy is under the control and management of the Pharmacits-in-Charge of the pharmacy that was destroyed or damaged.

(3) A licensed pharmacist is on the premises while drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction or damage and an expected restoration date.

(6) Within three (3) calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration to the permanent pharmacy.

(7) The mobile pharmacy is not operated for more than forty-eight (48) hours following the restoration of the pharmacy.

## § 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.

**§ 4113. Pharmacist~~s~~-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 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.

**§ 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.

**§ 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 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 ~~five hundred fifty dollars ($550)~~ six hundred dollars ($600) ~~or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products~~. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.

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

**§ 4161. Out-of-State Distributor; Requirements**

(a) A person located outside this state that *(1)* ships, *sells,* mails, or delivers dangerous drugs or dangerous devices into this state *or (2) sells, brokers, or distributes dangerous drugs or devices within this state* shall be considered a nonresident wholesaler.
(b) A nonresident wholesaler shall be licensed by the board prior to shipping, *selling,* mailing, or delivering dangerous drugs or dangerous devices to a site located in this state *or selling, brokering, or distributing dangerous drugs or devices within this state* .
(c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, *sold,* mailed, or delivered to a site located in this state *or sold, brokered, or distributed within this state*. A license shall be renewed annually and shall not be transferable.
(d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
(1) Its agent for service of process in this state.
(2) Its principal corporate officers, as specified by the board, if any.
(3) Its general partners, as specified by the board, if any.
(4) Its owners if the applicant is not a corporation or partnership.
(e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
(f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
(g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
(h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.
(i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
(j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident 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.
(k) 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 five hundred fifty dollars ($550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound injectable sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
(l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

**§ 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.

**§ 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 who 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.~~

**§ 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 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.

**§ 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.

**§ 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 $125 monthly to cover a portion of the administrative costs borne by the board to contract for these services. 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

### § 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.

### § 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 2

## *Proposed Omnibus Language*

## Proposed New Omnibus Provisions

### 4013 Subscriber Alert

(a) By July 1, 2010 all board licensed facilities must join the board's e-mail notification list within 60 days of obtaining a license or at the time of license renewal.
(b) After July 1, 2010, any facility licensed by the board must update their e-mail address with the board's e-mail notification list within 30 days when a change in the e-mail address occurs.

### 4112. Nonresident Pharmacy: Registration; Provision of Information to Board; Maintaining Records; Patient Consultation

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.
(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. ~~All nonresident pharmacies shall register with the board~~. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.
(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.
(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.
(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.
(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.
(g) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section
4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is

shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.
(h) The registration fee shall be the fee specified in subdivision (a) of Section 4400.
(i) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.
(j) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

**4401. Pharmacist: Biennial Renewal**

(a) Every pharmacist who desires to retain his or her license on the books of the board shall biennially pay to the executive officer of the board the renewal fee, established by the board, within the limits prescribed by this chapter. In return for the payment of the renewal fee, a certificate of renewal shall be issued.
(b) As part of the renewal, a pharmacist must notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.

**4403. Reissuance Without Payment of Fees Prohibited**

(a) The board shall not reissue or renew any license without the payment of the fees required by this chapter and the payment of all fees that are delinquent at the time that the application is made.
(b) As part of the renewal, a pharmacy technician must notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.
(c) As part of the renewal, a designated representative must notify the board whether he or she has been convicted, as defined in Section 490, of a misdemeanor or felony, or whether any disciplinary action has been taken by any regulatory or licensing board in this or any other state, subsequent to the licensee's last renewal.

# Attachment 3

- ***Draft Language for Immunization Proposal***
- ***Adult and Adolescent Immunization Schedule***

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

2) Transmit a valid prescription to another pharmacist.

3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

6) Manufacture, measure, fit to the patient, or sell and repair dangerous devices or furnish instructions to the patient or the patient's representative concerning the use of those devices.

7) Provide consultation to patients and professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals.

8) Furnish emergency contraception drug therapy as authorized by Section 4052.3.

9) Initiate and administer immunizations ~~pursuant to a protocol with a prescriber~~ as authorized by Section 4052.8.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

4052.8 (a) A pharmacist may initiate and administer immunizations pursuant to a protocol with a prescriber. A pharmacist may also initiate and administer immunizations pursuant to the current Recommended Adult (19+ years) and Adolescent (7-18 years) Immunization Schedules, provided by the Centers for Disease Control and Prevention (CDC) pursuant to published recommendations of the CDC Advisory Committee on Immunization Practices (ACIP).

(b) Prior to initiating and administering an immunization pursuant to this section, a pharmacist shall have completed the American Pharmacists Association pharmacy-based immunization certificate program or another pharmacy-based immunization training certificate program endorsed by the Centers for Disease Control and Prevention or the American Council of Pharmaceutical Education.

(c) A pharmacist initiating and administering any immunization pursuant to this section shall also complete 3 hours of immunization-related continuing education coursework annually. Failure at any time to meet this requirement shall, in addition to any other sanctions, require the pharmacist to re-take the training identified in subdivision (b) prior to administration of any further immunization(s).
(d) A pharmacist shall at all times maintain current Basic Life Support certification.
(e) At the time of administration of an immunization, the pharmacist shall:

(1) Provide the patient or patient's agent with the appropriate Vaccine Information Statement for each immunization administered; and
(2) Provide documentation of administration of the immunization to the patient and patient's physician or primary care provider, if one can be identified.

(f) Any pharmacist initiating and administering vaccines pursuant to this section may initiate and administer epinephrine by injection for severe allergic reactions.
(g) Any adverse event shall be reported to the Vaccine Adverse Event Reporting System within the U.S. Department of Health and Human Services.
(h) The pharmacist shall maintain an immunization administration record, which includes, but is not limited to, the name of the vaccine, expiration date, date of administration, manufacturer and lot number, administration site and route, Vaccine Information Statement date, and the name and title of the person administering, for the longer of the following periods:

(1) Ten years from the date of administration; or
(2) If less than 18 years at the time of administration, three years beyond the patient's eighteenth birthday.

(i) Upon receipt of a vaccine as authorized by this section, a pharmacist is responsible to assure that proper vaccine temperatures are maintained during subsequent storage and handling to preserve potency.

# Recommended Adult Immunization Schedule

**Note: These recommendations must be read with the footnotes that follow.**

## Figure 1. Recommended adult immunization schedule, by vaccine and age group United States, October 2007 – September 2008

| VACCINE ▼ / AGE GROUP ▶ | 19–49 years | 50–64 years | ≥65 years |
|---|---|---|---|
| Tetanus, diphtheria, pertussis (Td/Tdap)[1,*] | 1 dose Td booster every 10 yrs; Substitute 1 dose of Tdap for Td | | |
| Human papillomavirus (HPV)[2,*] | 3 doses females (0, 2, 6 mos) | | |
| Measles, mumps, rubella (MMR)[3,*] | 1 or 2 doses | 1 dose | |
| Varicella[4,*] | 2 doses (0, 4–8 wks) | | |
| Influenza[5,*] | | 1 dose annually | |
| Pneumococcal (polysaccharide)[6,7] | 1–2 doses | | 1 dose |
| Hepatitis A[8,*] | 2 doses (0, 6–12 mos or 0, 6–18 mos) | | |
| Hepatitis B[9,*] | 3 doses (0, 1–2, 4–6 mos) | | |
| Meningococcal[10,*] | 1 or more doses | | |
| Zoster[11] | | | 1 dose |

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

Report all clinically significant postvaccination reactions to the Vaccine Adverse Event Reporting System (VAERS). Reporting forms and instructions on filing a VAERS report are available at www.vaers.hhs.gov or by telephone, 800-822-7967.

Information on how to file a Vaccine Injury Compensation Program claim is available at www.hrsa.gov/vaccinecompensation or by telephone, 800-338-2382. To file a claim for vaccine injury, contact the U.S. Court of Federal Claims, 717 Madison Place, N.W., Washington, D.C. 20005; telephone, 202-357-6400.

Additional information about the vaccines in this schedule, extent of available data, and contraindications for vaccination is also available at www.cdc.gov/vaccines or from the CDC-INFO Contact Center at 800-CDC-INFO (800-232-4636) in English and Spanish, 24 hours a day, 7 days a week.

Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.

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# Figure 2. Vaccines that might be indicated for adults based on medical and other indications United States, October 2007 – September 2008

| VACCINE ▼ / INDICATION ▶ | Pregnancy | Immuno-compromising conditions (excluding human immunodeficiency virus [HIV]), medications, radiation[13] | HIV infection[2,12,13] CD4+ T lymphocyte count <200 cells/μL | HIV infection[2,12,13] CD4+ T lymphocyte count ≥200 cells/μL | Diabetes, heart disease, chronic pulmonary disease, chronic alcoholism | Asplenia[12] (including elective splenectomy and terminal complement component deficiencies) | Chronic liver disease | Kidney failure, end-stage renal disease, receipt of hemodialysis | Health-care personnel |
|---|---|---|---|---|---|---|---|---|---|
| Tetanus, diphtheria, pertussis (Td/Tdap)[1,*] | 1 dose Td booster every 10 yrs | | | | | | | | |
| | | Substitute 1 dose of Tdap for Td | | | | | | | |
| Human papillomavirus (HPV)[2,*] | | 3 doses for females through age 26 yrs (0, 2, 6 mos) | | | | | | | |
| Measles, mumps, rubella (MMR)[3,*] | Contraindicated | | | 1 or 2 doses | | | | | |
| Varicella[4,*] | Contraindicated | | | 2 doses (0, 4–8 wks) | | | | | |
| Influenza[5,*] | 1 dose TIV annually | | | | | | | | 1 dose TIV or LAIV annually |
| Pneumococcal (polysaccharide)[6,7] | | 1–2 doses | | | | | | | |
| Hepatitis A[8,*] | 2 doses (0, 6–12 mos, or 0, 6–18 mos) | | | | | | | | |
| Hepatitis B[9,*] | | 3 doses (0, 1–2, 4–6 mos) | | | | | | | |
| Meningococcal[10,*] | 1 or more doses | | | | | | | | |
| Zoster[11] | Contraindicated | | | | 1 dose | | | | |

*Covered by the Vaccine Injury Compensation Program.

For all persons in this category who meet the age requirements and who lack evidence of immunity (e.g., lack documentation of vaccination or have no evidence of prior infection)

Recommended if some other risk factor is present (e.g., on the basis of medical, occupational, lifestyle, or other indications)

These schedules indicate the recommended age groups and medical indications for which administration of currently licensed vaccines is commonly indicated for adults ages 19 years and older, as of October 1, 2007. Licensed combination vaccines may be used whenever any components of the combination are indicated and when the vaccine's other components are not contraindicated. For detailed recommendations on all vaccines, including those used primarily for travelers or that are issued during the year, consult the manufacturers' package inserts and the complete statements from the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/pubs/acip-list.htm).

**The recommendations in this schedule were approved by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP), the American Academy of Family Physicians (AAFP), the American College of Obstetricians and Gynecologists (ACOG), and the American College of Physicians (ACP).**

DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

# Footnotes

## Recommended Adult Immunization Schedule · United States, October 2007 – September 2008

For complete statements by the Advisory Committee on Immunization Practices (ACIP), visit www.cdc.gov/vaccines/pubs/ACIP-list.htm.

**1. Tetanus, diphtheria, and acellular pertussis (Td/Tdap) vaccination**

Tdap should replace a single dose of Td for adults aged <65 years who have not previously received a dose of Tdap. Only one of two Tdap products (Adacel®[sanofi pasteur]) is licensed for use in adults.

Adults with uncertain histories of a complete primary vaccination series with tetanus and diphtheria toxoid–containing vaccines should begin or complete a primary vaccination series. A primary series for adults is 3 doses of tetanus and diphtheria toxoid–containing vaccines; administer the first 2 doses at least 4 weeks apart and the third dose 6–12 months after the second. However, Tdap can substitute for any one of the doses of Td in the 3-dose primary series. The booster dose of tetanus and diphtheria toxoid–containing vaccine should be administered to adults who have completed a primary series and if the last vaccination was received ≥10 years previously. Tdap or Td vaccine may be used, as indicated.

If the person is pregnant and received the last Td vaccination ≥10 years previously, administer Td during the second or third trimester; if the person received the last Td vaccination in <10 years, administer Tdap during the immediate postpartum period. A one-time administration of 1 dose of Tdap with an interval as short as 2 years from a previous Td vaccination is recommended for postpartum women, close contacts of infants aged <12 months, and all health-care workers with direct patient contact. In certain situations, Td can be deferred during pregnancy and Tdap substituted in the immediate postpartum period, or Tdap can be administered instead of Td to a pregnant woman after an informed discussion with the woman.

Consult the ACIP statement for recommendations for administering Td as prophylaxis in wound management.

**2. Human papillomavirus (HPV) vaccination**

HPV vaccination is recommended for all females aged ≤26 years who have not completed the vaccine series. History of genital warts, abnormal Papanicolaou test, or positive HPV DNA test is not evidence of prior infection with all vaccine HPV types; HPV vaccination is still recommended for these persons.

Ideally, vaccine should be administered before potential exposure to HPV through sexual activity; however, females who are sexually active should still be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types receive the full benefit of the vaccination. Vaccination is less beneficial for females who have already been infected with one or more of the HPV vaccine types.

A complete series consists of 3 doses. The second dose should be administered 2 months after the first dose; the third dose should be administered 6 months after the first dose.

Although HPV vaccination is not specifically recommended for females with the medical indications described in Figure 2, "Vaccines that might be indicated for adults based on medical and other indications," it is not a live-virus vaccine and can be administered. However, immune response and vaccine efficacy might be less than in persons who do not have the medical indications described or who are immunocompetent.

**3. Measles, mumps, rubella (MMR) vaccination**

*Measles component:* Adults born before 1957 can be considered immune to measles. Adults born during or after 1957 should receive ≥1 dose of MMR unless they have a medical contraindication, documentation of ≥1 dose, history of measles based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) have been recently exposed to measles or are in an outbreak setting; 2) have been previously vaccinated with killed measles vaccine; 3) have been vaccinated with an unknown type of measles vaccine during 1963–1967; 4) are students in postsecondary educational institutions; 5) work in a health-care facility; or 6) plan to travel internationally.

*Mumps component:* Adults born before 1957 can generally be considered immune to mumps. Adults born during or after 1957 should receive 1 dose of MMR unless they have a medical contraindication, history of mumps based on health-care provider diagnosis, or laboratory evidence of immunity.

A second dose of MMR is recommended for adults who 1) are in an age group that is affected during a mumps outbreak; 2) are students in postsecondary educational institutions; 3) work in a health-care facility; or 4) plan to travel internationally. For unvaccinated health-care workers born before 1957 who do not have other evidence of mumps immunity, consider administering 1 dose on a routine basis and strongly consider administering a second dose during an outbreak.

*Rubella component:* Administer 1 dose of MMR vaccine to women whose rubella vaccination history is unreliable or who lack laboratory evidence of immunity. For women of childbearing age, regardless of birth year, routinely determine rubella immunity and counsel women regarding congenital rubella syndrome. Women who do not have evidence of immunity should receive MMR vaccine upon completion or termination of pregnancy and before discharge from the health-care facility.

**4. Varicella vaccination**

All adults without evidence of immunity to varicella should receive 2 doses of single-antigen varicella vaccine unless they have a medical contraindication. Special consideration should be given to those who 1) have close contact with persons at high risk for severe disease (e.g., health-care personnel and family contacts of immunocompromised persons) or 2) are at high risk for exposure or transmission (e.g., teachers; child care employees; residents and staff members of institutional settings, including correctional institutions; college students; military personnel; adolescents and adults living in households with children; nonpregnant women of childbearing age; and international travelers).

Evidence of immunity to varicella in adults includes any of the following: 1) documentation of 2 doses of varicella vaccine at least 4 weeks apart; 2) U.S.-born before 1980 (although for health-care personnel and pregnant women birth before 1980 should not be considered evidence of immunity); 3) history of varicella based on diagnosis or verification of varicella by a health-care provider (for a patient reporting a history of or presenting with an atypical case, a mild case, or both, health-care providers should seek either an epidemiologic link with a typical varicella case or to a laboratory-confirmed case or evidence of laboratory confirmation, if it was performed at the time of acute disease); 4) history of herpes zoster based on health-care provider diagnosis; or 5) laboratory evidence of immunity or laboratory confirmation of disease.

Assess pregnant women for evidence of varicella immunity. Women who do not have evidence of immunity should receive the first dose of varicella vaccine upon completion or termination of pregnancy and before discharge from the health-care facility. The second dose should be administered 4–8 weeks after the first dose.

**5. Influenza vaccination**

*Medical indications:* Chronic disorders of the cardiovascular or pulmonary systems, including asthma; chronic metabolic diseases, including diabetes mellitus, renal or hepatic dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or human immunodeficiency virus [HIV]); any condition that compromises respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration (e.g., cognitive dysfunction, spinal cord injury, or seizure disorder or other neuromuscular disorder); and pregnancy during the influenza season. No data exist on the risk for severe or complicated influenza disease among persons with asplenia; however, influenza is a risk factor for secondary bacterial infections that can cause severe disease among persons with asplenia.

*Occupational indications:* Health-care personnel and employees of long-term care and assisted-living facilities.

*Other indications:* Residents of nursing homes and other long-term care and assisted-living facilities; persons likely to transmit influenza to persons at high risk (e.g., in-home household contacts and caregivers of children aged 0–59 months, or persons of all ages with high-risk conditions); and anyone who would like to be vaccinated. Healthy, nonpregnant adults aged ≤49 years without high-risk medical conditions who are not contacts of severely immunocompromised persons in special care units can receive either intranasally administered live, attenuated influenza vaccine (FluMist®) or inactivated vaccine. Other persons should receive the inactivated vaccine.

**6. Pneumococcal polysaccharide vaccination**

*Medical indications:* Chronic pulmonary disease (excluding asthma); chronic cardiovascular diseases; diabetes mellitus; chronic liver diseases, including liver disease as a result of alcohol abuse (e.g., cirrhosis); chronic alcoholism, chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy [if elective splenectomy is planned, vaccinate at least 2 weeks before surgery]); immunosuppressive conditions; and cochlear implants and cerebrospinal fluid leaks. Vaccinate as close to HIV diagnosis as possible.

*Other indications:* Alaska Natives and certain American Indian populations and residents of nursing homes or other long-term care facilities.

**7. Revaccination with pneumococcal polysaccharide vaccine**

One-time revaccination after 5 years for persons with chronic renal failure or nephrotic syndrome; functional or anatomic asplenia (e.g., sickle cell disease or splenectomy); or immunosuppressive conditions. For persons aged ≥65 years, one-time revaccination if they were vaccinated ≥5 years previously and were aged <65 years at the time of primary vaccination.

**8. Hepatitis A vaccination**

*Medical indications:* Persons with chronic liver disease and persons who receive clotting factor concentrates.

*Behavioral indications:* Men who have sex with men and persons who use illegal drugs.

*Occupational indications:* Persons working with hepatitis A virus (HAV)–infected primates or with HAV in a research laboratory setting.

*Other indications:* Persons traveling to or working in countries that have high or intermediate endemicity of hepatitis A (a list of countries is available at wwwn.cdc.gov/travel/contentdiseases.aspx) and any person seeking protection from HAV infection.

Single-antigen vaccine formulations should be administered in a 2-dose schedule at either 0 and 6–12 months (Havrix®), or 0 and 6–18 months (Vaqta®). If the combined hepatitis A and hepatitis B vaccine (Twinrix®) is used, administer 3 doses at 0, 1, and 6 months.

**9. Hepatitis B vaccination**

*Medical indications:* Persons with end-stage renal disease, including patients receiving hemodialysis; persons seeking evaluation or treatment for a sexually transmitted disease (STD); persons with HIV infection; and persons with chronic liver disease.

*Occupational indications:* Health-care personnel and public-safety workers who are exposed to blood or other potentially infectious body fluids.

*Behavioral indications:* Sexually active persons who are not in a long-term, mutually monogamous relationship (e.g., persons with more than 1 sex partner during the previous 6 months); current or recent injection-drug users; and men who have sex with men.

*Other indications:* Household contacts and sex partners of persons with chronic hepatitis B virus (HBV) infection; clients and staff members of institutions for persons with developmental disabilities; international travelers to countries with high or intermediate prevalence of chronic HBV infection (a list of countries is available at wwwn.cdc.gov/travel/contentdiseases.aspx); and any adult seeking protection from HBV infection.

Settings where hepatitis B vaccination is recommended for all adults: STD treatment facilities; HIV testing and treatment facilities; facilities providing drug-abuse treatment and prevention services; health-care settings targeting services to injection-drug users or men who have sex with men; correctional facilities; end-stage renal disease programs and facilities for chronic hemodialysis patients; and institutions and nonresidential daycare facilities for persons with developmental disabilities.

*Special formulation indications:* For adult patients receiving hemodialysis and other immunocompromised adults, 1 dose of 40 μg/mL (Recombivax HB®), or 2 doses of 20 μg/mL (Engerix-B®) administered simultaneously.

**10.Meningococcal vaccination**

*Medical indications:* Adults with anatomic or functional asplenia, or terminal complement component deficiencies.

*Other indications:* First-year college students living in dormitories; microbiologists who are routinely exposed to isolates of *Neisseria meningitidis*; military recruits; and persons who travel to or live in countries in which meningococcal disease is hyperendemic or epidemic (e.g., the "meningitis belt" of sub-Saharan Africa during the dry season [December–June]), particularly if their contact with local populations will be prolonged. Vaccination is required by the government of Saudi Arabia for all travelers to Mecca during the annual Hajj.

Meningococcal conjugate vaccine is preferred for adults with any of the preceding indications who are aged ≤55 years, although meningococcal polysaccharide vaccine (MPSV4) is an acceptable alternative. Revaccination after 3–5 years might be indicated for adults previously vaccinated with MPSV4 who remain at increased risk for infection (e.g., persons residing in areas in which disease is epidemic).

**11.Herpes zoster vaccination**

A single dose of zoster vaccine is recommended for adults aged ≥60 years regardless of whether they report a prior episode of herpes zoster. Persons with chronic medical conditions may be vaccinated unless a contraindication or precaution exists for their condition.

**12.Selected conditions for which *Haemophilus influenzae* type b (Hib) vaccine may be used**

Hib conjugate vaccines are licensed for children aged 6 weeks–71 months. No efficacy data are available on which to base a recommendation concerning use of Hib vaccine for older children and adults with the chronic conditions associated with an increased risk for Hib disease. However, studies suggest good immunogenicity in patients who have sickle cell disease, leukemia, or HIV infection or who have had splenectomies; administering vaccine to these patients is not contraindicated.

**13.Immunocompromising conditions**

Inactivated vaccines are generally acceptable (e.g., pneumococcal, meningococcal, and influenza [trivalent inactivated influenza vaccine]), and live vaccines generally are avoided in persons with immune deficiencies or immune suppressive conditions. Information on specific conditions is available at www.cdc.gov/vaccines/pubs/acip-list.htm.

# Recommended Immunization Schedule for Persons Aged 7–18 Years—UNITED STATES • 2008

***For those who fall behind or start late, see the green bars and the catch-up schedule***

| Vaccine ▼ Age ▶ | 7–10 years | 11–12 years | 13–18 years |
|---|---|---|---|
| Diphtheria, Tetanus, Pertussis[1] | *see footnote 1* | Tdap | Tdap |
| Human Papillomavirus[2] | *see footnote 2* | HPV (3 doses) | HPV Series |
| Meningococcal[3] | MCV4 | MCV4 | MCV4 |
| Pneumococcal[4] | PPV | PPV | PPV |
| Influenza[5] | Influenza (Yearly) | Influenza (Yearly) | Influenza (Yearly) |
| Hepatitis A[6] | HepA Series | HepA Series | HepA Series |
| Hepatitis B[7] | HepB Series | HepB Series | HepB Series |
| Inactivated Poliovirus[8] | IPV Series | IPV Series | IPV Series |
| Measles, Mumps, Rubella[9] | MMR Series | MMR Series | MMR Series |
| Varicella[10] | Varicella Series | Varicella Series | Varicella Series |

Range of recommended ages

Catch-up immunization

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2007, for children aged 7–18 years. Additional information is available at **www.cdc.gov/vaccines/recs/schedules**. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations, including for **high risk conditions: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm**. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at **www.vaers.hhs.gov** or by telephone, **800-822-7967**.

**1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).** *(Minimum age: 10 years for BOOSTRIX® and 11 years for ADACEL™)*
- Administer at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoids (Td) booster dose.
- 13–18-year-olds who missed the 11–12 year Tdap or received Td only are encouraged to receive one dose of Tdap 5 years after the last Td/DTaP dose.

**2. Human papillomavirus vaccine (HPV).** *(Minimum age: 9 years)*
- Administer the first dose of the HPV vaccine series to females at age 11–12 years.
- Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose.
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

**3. Meningococcal vaccine.**
- Administer MCV4 at age 11–12 years and at age 13–18 years if not previously vaccinated. MPSV4 is an acceptable alternative.
- Administer MCV4 to previously unvaccinated college freshmen living in dormitories.
- MCV4 is recommended for children aged 2–10 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups.
- Persons who received MPSV4 3 or more years previously and remain at increased risk for meningococcal disease should be vaccinated with MCV4.

**4. Pneumococcal polysaccharide vaccine (PPV).**
- Administer PPV to certain high-risk groups.

**5. Influenza vaccine.**
- Administer annually to all close contacts of children aged 0–59 months.
- Administer annually to persons with certain risk factors, health-care workers, and other persons (including household members) in close contact with persons in groups at higher risk.
- Administer 2 doses (separated by 4 weeks or longer) to children younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time last season but only received one dose.
- For healthy nonpregnant persons (those who do not have underlying medical conditions that predispose them to influenza complications) ages 2–49 years, either LAIV or TIV may be used.

**6. Hepatitis A vaccine (HepA).**
- Administer the 2 doses in the series at least 6 months apart.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children.

**7. Hepatitis B vaccine (HepB).**
- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

**8. Inactivated poliovirus vaccine (IPV).**
- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age 4 years or older.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

**9. Measles, mumps, and rubella vaccine (MMR).**
- If not previously vaccinated, administer 2 doses of MMR during any visit, with 4 or more weeks between the doses.

**10. Varicella vaccine.**
- Administer 2 doses of varicella vaccine to persons younger than 13 years of age at least 3 months apart. Do not repeat the second dose if administered 28 or more days following the first dose.
- Administer 2 doses of varicella vaccine to persons aged 13 years or older at least 4 weeks apart.

**The Recommended Immunization Schedules for Persons Aged 0–18 Years are approved by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/recs/acip), the American Academy of Pediatrics (http://www.aap.org), and the American Academy of Family Physicians (http://www.aafp.org).**

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# Catch-up Immunization Schedule

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## for Persons Aged 4 Months–18 Years Who Start Late or Who Are More Than 1 Month Behind

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

| Vaccine | Minimum Age for Dose 1 | Minimum Interval Between Doses | | | |
|---|---|---|---|---|---|
| | | Dose 1 to Dose 2 | Dose 2 to Dose 3 | Dose 3 to Dose 4 | Dose 4 to Dose 5 |
| **CATCH-UP SCHEDULE FOR PERSONS AGED 4 MONTHS–6 YEARS** | | | | | |
| Hepatitis B[1] | Birth | 4 weeks | 8 weeks (and 16 weeks after first dose) | | |
| Rotavirus[2] | 6 wks | 4 weeks | 4 weeks | | |
| Diphtheria, Tetanus, Pertussis[3] | 6 wks | 4 weeks | 4 weeks | 6 months | 6 months[3] |
| *Haemophilus influenzae* type b[4] | 6 wks | 4 weeks if first dose administered at younger than 12 months of age<br>8 weeks (as final dose) if first dose administered at age 12-14 months<br>No further doses needed if first dose administered at 15 months of age or older | 4 weeks[4] if current age is younger than 12 months<br>8 weeks (as final dose)[4] if current age is 12 months or older and second dose administered at younger than 15 months of age<br>No further doses needed if previous dose administered at age 15 months or older | 8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months | |
| Pneumococcal[5] | 6 wks | 4 weeks if first dose administered at younger than 12 months of age<br>8 weeks (as final dose) if first dose administered at age 12 months or older or current age 24–59 months<br>No further doses needed for healthy children if first dose administered at age 24 months or older | 4 weeks if current age is younger than 12 months<br>8 weeks (as final dose) if current age is 12 months or older<br>No further doses needed for healthy children if previous dose administered at age 24 months or older | 8 weeks (as final dose) This dose only necessary for children aged 12 months–5 years who received 3 doses before age 12 months | |
| Inactivated Poliovirus[6] | 6 wks | 4 weeks | 4 weeks | 4 weeks[6] | |
| Measles, Mumps, Rubella[7] | 12 mos | 4 weeks | | | |
| Varicella[8] | 12 mos | 3 months | | | |
| Hepatitis A[9] | 12 mos | 6 months | | | |
| **CATCH-UP SCHEDULE FOR PERSONS AGED 7–18 YEARS** | | | | | |
| Tetanus, Diphtheria/ Tetanus, Diphtheria, Pertussis[10] | 7 yrs[10] | 4 weeks | 4 weeks if first dose administered at younger than 12 months of age<br>6 months if first dose administered at age 12 months or older | 6 months if first dose administered at younger than 12 months of age | |
| Human Papillomavirus[11] | 9 yrs | 4 weeks | 12 weeks (and 24 weeks after the first dose) | | |
| Hepatitis A[9] | 12 mos | 6 months | | | |
| Hepatitis B[1] | Birth | 4 weeks | 8 weeks (and 16 weeks after first dose) | | |
| Inactivated Poliovirus[6] | 6 wks | 4 weeks | 4 weeks | 4 weeks[6] | |
| Measles, Mumps, Rubella[7] | 12 mos | 4 weeks | | | |
| Varicella[8] | 12 mos | 4 weeks if first dose administered at age 13 years or older<br>3 months if first dose administered at younger than 13 years of age | | | |

**1. Hepatitis B vaccine (HepB).**
- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

**2. Rotavirus vaccine (Rota).**
- Do not start the series later than age 12 weeks.
- Administer the final dose in the series by age 32 weeks.
- Do not administer a dose later than age 32 weeks.
- Data on safety and efficacy outside of these age ranges are insufficient.

**3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).**
- The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
- DTaP is not indicated for persons aged 7 years or older.

**4. *Haemophilus influenzae* type b conjugate vaccine (Hib).**
- Vaccine is not generally recommended for children aged 5 years or older.
- If current age is younger than 12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or ComVax® [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.
- If first dose was administered at age 7–11 months, administer 2 doses separated by 4 weeks plus a booster at age 12–15 months.

**5. Pneumococcal conjugate vaccine (PCV).**
- Administer one dose of PCV to all healthy children aged 24–59 months having any incomplete schedule.
- For children with underlying medical conditions, administer 2 doses of PCV at least 8 weeks apart if previously received less than 3 doses, or 1 dose of PCV if previously received 3 doses.

**6. Inactivated poliovirus vaccine (IPV).**
- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age 4 years or older.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for persons aged 18 years and older.

**7. Measles, mumps, and rubella vaccine (MMR).**
- The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
- If not previously vaccinated, administer 2 doses of MMR during any visit with 4 or more weeks between the doses.

**8. Varicella vaccine.**
- The second dose of varicella vaccine is recommended routinely at age 4–6 years but may be administered earlier if desired.
- Do not repeat the second dose in persons younger than 13 years of age if administered 28 or more days after the first dose.

**9. Hepatitis A vaccine (HepA).**
- HepA is recommended for certain groups of children, including in areas where vaccination programs target older children. See *MMWR* 2006;55(No. RR-7):1–23.

**10. Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).**
- Tdap should be substituted for a single dose of Td in the primary catch-up series or as a booster if age appropriate; use Td for other doses.
- A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose. A booster (fourth) dose is needed if any of the previous doses were administered at younger than 12 months of age. Refer to ACIP recommendations for further information. See *MMWR* 2006;55(No. RR-3).

**11. Human papillomavirus vaccine (HPV).**
- Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

Information about reporting reactions after immunization is available online at **http://www.vaers.hhs.gov** or by telephone via the 24-hour national toll-free information line 800-822-7967. Suspected cases of vaccine-preventable diseases should be reported to the state or local health department. Additional information, including precautions and contraindications for immunization, is available from the National Center for Immunization and Respiratory Diseases at **http://www.cdc.gov/vaccines** or telephone, **800-CDC-INFO (800-232-4636)**.



CS113897

# Attachment 4

## *Draft Language to Amend B&PC Section 4076*

**Proposal to Amend B&PC 4076**

**§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 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~~ purpose 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, t~~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.

# Attachment 5

## *First Quarterly Report on Committee Goals for 2008/09*

# LEGISLATION AND REGULATION COMMITTEE

Goal 3: Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Outcome: Improve the health and safety of Californians.

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| 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: | 1. Secure extension of board's sunset date.<br>*Sept. 30, 2006:* *Governor signs **SB 1476** which delays the board's sunset date two years (until 2010), and requires the board's sunset report in 2008.*<br>*June 2007:* *SB 963 (Ridley-Thomas) is amended to alter the sunset review process.*<br>*July 2008:* *SB 963 (Ridely-Thomas) is amended to alter the sunset review process. Board staff attend a stakeholders meeting with committee staff to discuss amendments.*<br>2. Sponsor legislation to update pharmacy law.<br>*Sept. 30, 2006:* *Governor signs **SB 1475** containing provisions that:*<br>*(a) Allow a check-off box on electronic prescriptions that if marked by a prescriber, would prevent generic substitution at a pharmacist's discretion (B&P 4073).*<br>*(b) Clarify requirements for reporting to the board when a licensee is impaired to the extent it affects the licensee's safe practice or who has stolen or diverted drugs (B&P 4104).*<br>*(c) Establish the authority to issue a temporary sterile injectable compounding license following a change in ownership (B&P 4127.8).*<br>*(d) Exempt government-owned wholesalers from having to post a $100,000 bond (B&P 4162).*<br>*(e) Exempt drug manufacturers who hold a biologics license application from the FDA from having to post a $100,000 bond otherwise required for nonresident wholesalers (B&P 4162.5).*<br>*(f) Make technical changes in the licensure requirements for clinics (B&P 4180 - 4182, 4190 - 4192).*<br>*June 2007:* *Senate Business and Professions Committee omnibus bill (**SB 1048**) is amended to include board provisions that:*<br>*(a) Revise section to include schedule IV controlled substances to the CURES reporting requirements for hospitals. (B&P 4068)*<br>*(b) Allow board inspectors to embargo a prescription drug when the inspector has probable cause that it is misbranded. (B&P 4084)*<br>*(c) Change the term "exemptee" to "designated representative." (B&P) 4101*<br>*(d) Revise section to specify temporary license fee of $550. Current law does not specify the temporary fee. (B&P 4160 (f) & 4161 (k))*<br>*(e) Extend bonding requirements for wholesalers from 2011 to 2015 to match the extension given to implement the e-pedigree requirements, restoring provisions in SB 1476 chaptered out by SB 1475. (B&P 4162 & 4162.5)* |

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| | *(f) Change in the name of the exam to more accurately reflect the requirements described in B&P 4200.2. The new name will be the "California Practice Standards and Jurisprudence Examination for Pharmacists" (CPJE). (B & P 4200, 4200.1 & 4200.2)*<br>*(g) Revise requirements for intern licenses to allow the board the discretion to extend the duration of an intern license. (B&P 4208)*<br>*(h) Allow the board to cite and fine licensees for violations of Health and Safety Code sections 150200-150206 which authorize a county to establish by local ordinance, a repository and distribution program for specified unused medications from skilled nursing homes to medically indigent patients served by government-owned pharmacies. (B&P 4314 & 4315)* |
| ***Oct. 2007:*** | *Governor signs SB 1048 (Chapter 588, Statutes of 2007) containing board omnibus provisions.* |
| ***Oct. 2007:*** | *Legislation and Regulation Committee considers omnibus provisions for introduction in 2008. Four types of changes are discussed.*<br>*(1) Omnibus changes specific to the PIC and DRC requirements*<br>• *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*<br>• *Section 4036.5 – Pharmacist-in-Charge*<br>• *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*<br>• *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*<br>• *Section 4160 – Wholesaler Licenses*<br>• *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*<br>• *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*<br>• *Section 4329 – Nonpharmacists; Prohibited Acts*<br>• *Section 4330 – Proprietors; Prohibited Acts*<br>*(2) Omnibus changes to allow for the use of mobile pharmacies*<br>• *Section 4062 Furnishing Dangerous Drugs During an Emergency.*<br>• *Section 4110 License Required, Temporary Permit Upon Transfer of Ownership.*<br>*(3) General omnibus changes*<br>• *Section 4059.5 Who May order Dangerous Drugs or Devices, Exceptions.*<br>• *Section 4081 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory*<br>• *Section 4126.5 – Furnishing Dangerous Drugs by Pharmacy.*<br>• *Section 4231 – Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee.*<br>• *Section 4362 – Entry Into Pharmacists Recovery Program.*<br>*H&SC 11165 – Controlled Substance Utilization Review and Evaluation System: Establishment; Operation; Funding; Reporting to Legislature.* |

(4) *Omnibus changes based on recodification of Business and Professions Code section 4052*

- *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*

*Jan. 2008:* *Staff provides language to Senate Business and Professions Committee for inclusion in omnibus bill.*
*Board approved language for omnibus bill.*

*April 2008:* *Some provisions of omnibus bill not included:*

- *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*
- *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*
- *Section 4160 – Wholesaler Licenses*
- *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*
- *Section 4362 – Entry Into Pharmacists Recovery Program.*

*Oct. 2008:* *Governor vetoes SB 1779*

3. **Advocate the board's role and its positions regarding pharmacists' care and dispensing of dangerous drugs and devices (AB 2408).**

*Sept. 30, 2006:* *Governor signs AB 2408. Amendments taken in August remove provisions that would have described the professional services provided by pharmacists, and authorized pharmacists outside California to provide pharmacists' care services to patients in California if licensed here or working within the framework of a nonresident pharmacy. Remaining provisions restructure pharmacist protocol provisions and several other changes.*

4. **Secure statutory standards for pharmacies that compound medications (AB 595).**

*Aug. 2006:* *Amendments made to remove opposition of DHS regarding pharmacy contracting with another pharmacy for compounded drugs triggers opposition from pharmacy organizations. Board drops AB 595, but will advance regulations developed for compounding pharmacies in the future.*

5. Secure implementation of e-pedigrees on prescription drugs dispensed in California (SB 1476).

*Sept. 30, 2006:* *Governor signs SB 1476 which contains board amendments to delay implementation of the e-pedigree requirements until 2009, or upon board action, until 2011. Amendments also require interoperability, serialization, returned drug products to retain the initiating pedigree, require notice to the board of suspected or actual counterfeiting, and continuation of the pedigree through repackaging operations.*

6. Advocate the board's position on pending legislation affecting pharmacy practice and/or the board's jurisdiction.

*AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.*
*AB 249 (Eng) Healing Arts: Settlement Agreements.*
*AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.*
*AB 1025 (Bass) Professions and Vocations: Denial of Licensure.*
*SB 472 (Corbett) Prescription Drugs: Labeling Requirements.*
*SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.*
*SB 606 (Scott) Pharmaceutical Information: Clinical Data Trial.*
*SB 963 (Ridely-Thomas) Regulatory Boards: Operations.*
*SB 966 (Simitian) Pharmaceutical Drug Disposal.*

*Oct. 2007:* ***Governor signs the following:***
*AB 110 (Chapter 707, Statutes of 2007) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects.*
*SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.*
*SB 966 (Chapter 542, Statutes of 2007) Pharmaceutical Drug Disposal.*

*Oct. 2007:* ***Governor vetoes the following:***
*AB 249 (Eng) Healing Arts: Settlement Agreements.*
*AB 543 (Plescia) Ambulatory Surgical Centers: Licensure.*
*AB 1025 (Bass) Professions and Vocations: Denial of Licensure.*
*SB 615 (Oropeza) Pharmacy Technicians: Scholarship Fund.*

*Jan. 2008:*
1. *AB 501 (Swanson) Pharmaceutical Devices*
2. *AB 865 (Davis) State Agencies: Live Customer Service Agents*
3. *AB 1436 (Hernandez) Nurse Practitioner Scope of Practice*
4. *AB 1587 (de la Torre) and SB 843 (Calderon) Medical Information Marketing*
5. *SB 963 (Ridley Thomas) Regulatory Boards: Sunset Review*
6. *AB 1 X (Nunez) Health Care Reform*

*April 2008:*
1. *AB 501 (Swanson) Pharmaceutical Devices*
2. *AB 865 (Davis) State Agencies*
3. *AB 1394 (Krekorian) Counterfeit: Trademarks*
4. *AB 1436 (Hernandez) Nurse Practitioners Scope of Practice*
5. *AB 1587 (de la Torre) Personal Information: Pharmacy*
6. *AB 2122 (Plescia) Surgical Clinics: licensure*
7. *SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review*
8. *SB 1270 (Cedillo) Pharmacy: dangerous drugs and devices predigree*
9. *SB 1594 (Steinberg) Bleeding disorders clotting products*

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| | *July 2008:* | 1. *AB 501 (Swanson) Pharmaceutical Devices*<br>2. *AB 865 (Davis) State Agencies*<br>3. *AB 1394 (Krekorian) Counterfeit: Trademarks*<br>4. *AB 1436 (Hernandez) Nurse Practitioners Scope of Practice*<br>5. *AB1574 (Plescia) Surgical Clinics: Licensure*<br>6. *AB 1587 (de la Torre) Personal Information: Pharmacy*<br>7. *SB 963 (Ridley-Thomas) Regulatory Boards: Sunset Review*<br>8. *SB 1270 (Cedillo) Pharmacy: dangerous drugs and devices predigree* |
| | *Oct. 2008:* | ***Governor signs the following:***<br>1. *AB 1394 (Chapter 431, Statutes of 2008) Counterfeit: Trademarks*<br>2. *SB 963 (Chapter 385, Statutes of 2008) Regulatory Boards: Sunset Review*<br>***Governor vetoes the following:***<br>1. *AB 501 (Swanson) Pharmaceutical Devices*<br>2. *AB 865 (Davis) State Agencies*<br>3. *AB1574 (Plescia) Surgical Clinics: Licensure* |

7. Expand the conditions under which a pharmacist may administer an immunization independent of physician protocol.

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| *March 2007:* | *Licensing Committee considers and approves concept. More work is required.* |
| *June 2007:* | *Licensing Committee considers draft language and requests additional refinements to proposal for consideration at September 2007 committee meeting.* |
| *Sept. 2007:* | *Licensing Committee forwards to full board legislative proposal.* |
| *Oct. 2007:* | *Board approved draft legislation* |
| *Nov. 2007:* | *Staff meeting with stakeholders to elicit support for the proposal.* |
| *Dec. 2007:* | *Staff develop fact sheets and work with experts in immunizations.* |
| *Jan. 2008:* | *Seeking coalition to support initiative. Will pursue proposal in 2009.* |

8. Advocate the board's role as an advocate for consumers by redesigning prescription label for all medicines dispensed to California patients.

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| *Oct. 2007:* | *Governor signs SB 472 (Chapter 470, Statutes of 2007) Prescription Drugs: Labeling Requirements.* |
| *Oct. 2007:* | *Subcommittee of the board is created to facilitate changes to regulation. Members include: Dr. Schell, Chair; Dr. Ravnan; Dr. Conroy; Dr. Swart; and President Powers.* |
| *Jan. 2008:* | *Shirley Wheat added to the subcommittee.* |
| *Apr. 2008:* | *First public forum held in Fremont.* |
| *May 2008:* | *Staff develop survey form to distribute to consumers to solicit input*<br>*Staff attend Senior Seminar, interview attendees about prescription label and distribute surveys.* |
| *June 2008:* | *Staff attends community events, interview attendees about prescription label and distribute surveys.* |
| *July 2008:* | *Staff attends community events, interview attendees about prescription label and distribute surveys.* |
| *Oct. 2008:* | *Staff continues to attend community events, interview attendees about prescription label and distribute surveys.*<br>*Public Education Committee updated on the status of survey results.* |

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| Objective 3.2 | Annually identify and respond with regulatory changes to keep pharmacy regulations current and consistent with the board's mission. |
| Measure: | Percentage successful enactment of promoted regulatory changes. |
| Tasks: | 1. Authorize technicians to check technicians in inpatient pharmacies with clinical pharmacist programs (sections 1793.7-1793.8).<br>*Aug. 2006:* *Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.*<br>*Nov. 2006:* *Rulemaking file submitted to the Office of Administrative Law .*<br>*Jan. 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.*<br>2. Authorize the use of prescription drop boxes and automated delivery machines for outpatient pharmacies (sections 1713 and 1717(e)).<br>*Aug. 2006:* *Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.*<br>*Jan. 2007:* *Regulation takes effect following approval by the Office of Administrative Law.*<br>3. Make technical changes in pharmacy regulations to keep the code updated.<br>*Dec. 2006:* ***Board notices regulation for 45 days of public comment.***<br>Section 1775.4 contested citations<br>Section 1706.2 criteria for abandonment of files<br>*Jan. 2007:* ***Board adopts regulations.***<br>Section 1775.4 contested citations<br>Section 1706.2 criteria for abandonment of files<br>*Feb. 2007:* ***Rulemaking file compiled and undergoing review by the Department of Consumer Affairs.***<br>Section 1775.4 contested citations<br>Section 1706.2 criteria for abandonment of files<br>*April 2007:* *Section 1775.4 contested citations. DCA determines no regulation is needed to accomplish the requirement to allow 1 rescheduling of an office conference. This regulation is withdrawn.*<br>*June 2007:* *Changes to 1706.2 take effect following approval by the Office of Administrative Law.*<br>4. Repeal the requirement to post a notice regarding electronic files (section 1717.2).<br>*July 2006:* *Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.*<br>*Oct. 2006:* *Board approves regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration review.*<br>*March 2007:* *Office of Administrative Law approves rulemaking. Regulation takes effect.*<br>5. Revise and update Disciplinary Guidelines revision and update (section 1760).<br>*Aug. 2006:* *Final changes to Disciplinary Guidelines being compiled by staff.*<br>*Dec. 2006:* *Disciplinary Guidelines is being reformatted into strikeout and underscore version for eventual release for public comment.*<br>*June 2007:* *Enforcement Committee reviews Disciplinary Guidelines and requests additional time to review before being submitted to the board.*<br>*Sept. 2007:* *Enforcement Committee approves Disciplinary Guidelines and recommends board approval.*<br>*Oct. 2007:* *Board approves Disciplinary Guidelines for 45-day comment period.*<br>*Feb. 2008:* *Regulation released for 45 days of public comment.*<br>*April 2008:* *Board Adopts regulation.*<br>*Sept. 2008:* *Rulemaking file submitted for review by the administration.* |

6. Self-assessment of a wholesaler by the designated representative (section 1784).

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| *July 2006:* | *Regulation released for 45 days of public comment. Action to be taken at the October Board Meeting.* |
| *Oct. 2006:* | *Board approves regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration review.* |
| *April 2007:* | *Office of Administrative Law approves rulemaking. Regulation takes effect.* |
| *May 2007:* | *Wholesalers are notified of this requirement.* |

7. Exempt the address of records of interns from display on the board's Web site (section 1727.1).

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| *Sept. 2006:* | *Office of Administrative Law approves rulemaking. Regulation takes effect October 2006.* |

8. Modification of building standards for pharmacies – rulemaking by the California Building Standards Commission.

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| *July 2006:* | *Board notified that a new procedure now exists for adopting building standards. Staff will pursue these procedures in 2007.* |
| *June 2007:* | *Board staff submit rulemaking file to the California Building Standards Commission.* |

9. Update Notice to Consumers Poster in conformance with AB 2583 (Chapter 487, Statutes 2006)(Section 1707.2).

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| *Feb. 2007:* | *Board notices regulation for 45 days comment period.* |
| *April 2007:* | *Board considers comments submitted during public comment period and modifies text regulation to reflect comments.* |
| *May 2007:* | *New section 1707.2 released for 45 days of public comment.* |
| *July 2007:* | *Board adopts regulation and compiles rulemaking file. File submitted to the Department of Consumer Affairs to initiate Administration Review.* |
| *Sept. 2007:* | *File submitted to the Office of Administrative Law for review.* |
| *Oct. 2007:* | *Office of Administrative Law approves rulemaking.* |
| *Nov. 2007:* | *Regulation changes takes effect.* |
| *Nov. 2007:* | *Staff solicits design submissions from graphic designers.* |
| *Jan. 2008:* | *Communication and Public Education Committee make recommendations on design submissions.* |

10. Secure changes without regulatory effect (Section 100 changes) to pharmacy regulations to keep them accurate and current.

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| *June 2007:* | *Submitted the following Section 100 changes:*<br>*Section 1707 – Waiver Requirements for Off-Site Storage of Records.*<br>*Section 1709.1 – Replace the term "Exemptee-in-Charge" with "Designated Representative-in-Charge".*<br>*Section 1715 – Self-Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law.*<br>*Section 1719 – Pharmacy Practice.*<br>*Sections 1780.1 and 1781 – Replace the term "Exemptee" with "Designated Representative".*<br>*Section 1786 – Return of Exemptee Certificate.*<br>*Section 1787 – Authorization to Distribute Dialysis Drugs and Devices.*<br>*Section 1790 – Assembling and Packaging.*<br>*1793.8 – Update regulation reference to recodified Business and Professions Code section 4052.* |
| *Aug. 2007:* | *Staff withdraw Section 100 Changes.* |
| *Nov. 2007:* | *Staff resubmit Section 100 Changes* |
| *Dec. 2007:* | *Office of Administrative Law approves Section 100 Changes.* |

11. Increase fees to keep the board's contingency fund solvent and maintain operations.

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| *March 2007:* | *Organization Development Committee reviews proposals and recommends approval.* |
| *April 2007:* | *Board approves the proposal.* |
| *May 2007:* | *Board releases language for the 45-day public comment period.* |
| *July 2007:* | *Board adopts proposed changes for a 15-day comment period and if no negative comments are received board adopts regulations.* |
| *Aug. 2007:* | *File submitted to the Department of Consumer Affairs to initiate Administration Review.* |
| *Oct. 2007:* | *File submitted to the Office of Administrative Law for review.* |
| *Nov. 2007:* | *Office of Administrative Law approves rulemaking.* |
| *Nov. 2007:* | *Staff complete necessary programming changes and begin advising licensees of the change.* |
| *Jan. 1, 2008:* | *New fees take effect.* |

12. Secure regulatory standards for pharmacies that compound.

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| *Dec. 2006:* | *Licensing Committee evaluates proposed compounding regulations developed in 2004. Some modifications may be needed.* |
| *March 2007:* | *Licensing Committee convenes discussion of amendments to compounding regulations. More work is required.* |
| *May 2007:* | *Licensing Committee holds detailed discussion on compounding regulations.* |
| *Sept. 2007:* | *Licensing Committee forwards regulation proposal to the board for review.* |
| *Nov. 2007:* | *Board releases language for the 45-day comment period.* |
| *Jan. 2008:* | *Board held regulation hearing and considers written comments and oral testimony.* |
| *April 2008:* | *Board votes to withdraw rulemaking.* |
| *Aug. 2008:* | *Board releases new language for the 45-day comment period.* |

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| | 13. Establish an ethics course.<br>*April 2007:* *Board establishes a subcommittee to examine the development of an ethics course.*<br>*Oct. 2007:* *Board votes to pursue regulation change to establish program components.*<br>*Sept. 2008:* *Board notices regulation for 45-day comment period.* |

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| Objective 3.3 | Review 5 areas of pharmacy law for relevancy, currency and value for consumer protection by June 30, 2011. |
| Measure: | Number of areas of pharmacy law reviewed. |
| Tasks: | 1. Initiate review of the pharmacist-in-charge requirement.<br>*Aug. 2007:* *Staff and counsel review pharmacist-in-charge and designated representative-in-charge statutes and regulations for reporting requirements and make recommendations to amend various statutes and regulations.*<br>*Oct. 2007:* *Legislation and Regulation Committee reviews draft language to be incorporated into omnibus bill.*<br>*Jan. 2008:* *Board approves omnibus language recommended by Legislation and Regulation Committee.*<br>• *Section 4022.5 – Designated Representative; Designated Representative-in-Charge*<br>• *Section 4036.5 – Pharmacist-in-Charge*<br>• *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*<br>• *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*<br>• *Section 4160 – Wholesaler Licenses*<br>• *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked*<br>• *Section 4305 – Pharmacist-in-Charge; Notice to Board; Disciplinary Action*<br>• *Section 4329 – Nonpharmacists; Prohibited Acts*<br>• *Section 4330 – Proprietors; Prohibited Acts*<br>*April 2008:* The following provisions are not incorporated into omnibus bill.<br>• *Section 4101 – Pharmacist-in-Charge; Designation Representative-in-Charge; Termination of Status; Duty to Notify the Board.*<br>• *Section 4113 – Pharmacist-in-Charge; Approval; Responsibilities; Notifications*<br>• *Section 4160 – Wholesaler Licenses*<br>• *Section 4196 – Veterinary Food-Animal Drug Retailer Licenses; Persons Allowed in Areas Where Drugs are Stored, Possessed, or Repacked* |