Assembly Bill No. 1496

CHAPTER 837

An act to amend Sections 19051, 19055, and 19059.5 of, to amend, repeal, and add Sections 4053, 4059, 4081, 4101, 4105, 4201, 4305.5, 4312, 4331, and 4400 of, to add and repeal Section 4139 of, and to repeal Sections 4034 and 4344 of, and to repeal Article 8 (commencing with Section 4130 of Chapter 9 of Division 2) of, the Business and Professions Code and to add Sections 109948, 109948.1, 110010.1, 110010.2, 111656, 111656.1, 111656.2, 111656.3, 111656.4, 111656.5, 111656.6, 111656.7, 111656.8, 111656.9, 111656.10, 111656.11, 111656.12, and 111656.13 to, the Health and Safety Code, relating to home medical device retail facilities.

[Approved by Governor September 28, 2000. Filed with Secretary of State September 29, 2000.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1496, Olberg. Home medical device retail facilities.

The Pharmacy Law provides for the licensure and regulation of medical device retailers, and the Sherman Food, Drug, and Cosmetic Law provides, generally, for the regulation by the State Department of Health Services of foods, drugs, devices, and cosmetics. These laws make the violation of their provisions crimes.

This bill would delete provisions from the Pharmacy Law governing the licensure and regulation of medical device retailers and provide instead for the licensure and regulation of home medical device retail facilities, as defined, by the State Department of Health Services effective July 1, 2001. This bill would create the Drug and Device Safety Fund into which moneys, as specified, collected by the department in connection with home medical device retail facilities would be deposited for its use upon appropriation by the Legislature.

Because a violation of the bill's provisions pertaining to the Sherman Food, Drug, and Cosmetic Law would be a criminal offense, this bill would create a new crime, thereby imposing a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4034 of the Business and Professions Code is repealed.

SEC. 2. Section 4053 of the Business and Professions Code is amended to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a manufacturer, wholesaler, or medical device retailer if the board shall find that sufficient, qualified supervision is employed by the manufacturer, wholesaler, or medical device retailer to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) Section 4051 shall not prohibit a veterinary food-animal drug retailer from selling or dispensing veterinary food-animal drugs for food-producing animals if the board finds that sufficient qualified supervision is employed by the veterinary food-animal drug retailer to adequately safeguard and protect the public health. Each person applying for an exemption shall meet the following requirements to obtain and maintain that exemption:

(1) The veterinary food-animal drug retailer shall be in the charge of an exempt person who has taken and passed an examination administered by the board and whose certificate of exemption is currently valid.

(2) Each premises maintained by a veterinary food-animal drug retailer shall have a license issued by the board and shall have an exempt person on the premises if veterinary food-animal drugs are furnished, sold, or dispensed.

(3) Only the exempt person shall prepare and affix the label to all veterinary food-animal drugs.

(4) The exempt person shall complete a training program to be approved by the board and qualify through examination on areas covering the essential knowledge necessary to properly read, fill, label, and dispense veterinary food-animal prescriptions.

(c) An exemptee certificate issued pursuant to this section is valid only at the location for which it is issued. The licensee and the exemptee shall each notify the board in writing within 30 days of the date on which the exemptee is no longer employed by the licensee at the location for which the exemptee certificate was issued. The licensee shall not operate without a pharmacist or an exemptee approved for that location by the board.

(d) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 3. Section 4053 is added to the Business and Professions Code, to read:

4053. (a) Subdivision (a) of Section 4051 shall not apply to a manufacturer or wholesaler if the board shall find that sufficient, qualified supervision is employed by the manufacturer or wholesaler to adequately safeguard and protect the public health, nor shall Section 4051 apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

(b) Section 4051 shall not prohibit a veterinary food-animal drug retailer from selling or dispensing veterinary food-animal drugs for food-producing animals if the board finds that sufficient qualified supervision is employed by the veterinary food-animal drug retailer to adequately safeguard and protect the public health. Each person applying for an exemption shall meet the following requirements to obtain and maintain that exemption:

(1) The veterinary food-animal drug retailer shall be in the charge of an exempt person who has taken and passed an examination administered by the board and whose certificate of exemption is currently valid.

(2) Each premises maintained by a veterinary food-animal drug retailer shall have a license issued by the board and shall have an exempt person on the premises if veterinary food-animal drugs are furnished, sold, or dispensed.

(3) Only the exempt person shall prepare and affix the label to all veterinary food-animal drugs.

(4) The exempt person shall complete a training program to be approved by the board and qualify through examination on areas covering the essential knowledge necessary to properly read, fill, label, and dispense veterinary food-animal prescriptions.

(c) An exemptee certificate issued pursuant to this section is valid only at the location for which it is issued. The licensee and the exemptee shall each notify the board in writing within 30 days of the date on which the exemptee is no longer employed by the licensee at the location for which the exemptee certificate was issued. The licensee shall not operate without a pharmacist or an exemptee approved for that location by the board.

(d) This section shall become operative on July 1, 2001.

SEC. 4. Section 4059 of the Business and Professions Code is amended to read:

4059. (a) No person shall furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. No person shall furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(b) This section shall not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler or pharmacy to each other or to a physician, dentist, podiatrist, or veterinarian, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and

the buyer, the drug or device and its quantity. This section shall not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, and a description of the device and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Health Services. The physician prescribing the dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist or may furnish topical pharmaceutical agents authorized for use pursuant to paragraph (5) of subdivision (a) of Section 3041 to an optometrist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A medical device retailer shall dispense, furnish, transfer, or sell a dangerous device only to another medical device retailer, a pharmacy, a physician, a licensed health care facility, a licensed physical therapist, or a patient or his or her personal representative.

(g) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Examining Committee of California to perform tissue penetration in accordance with Section 2620.5.

(h) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device

without a prescription of a physician, dentist, podiatrist, or veterinarian.

(i) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

(j) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 5. Section 4059 is added to the Business and Professions Code, to read:

4059. (a) No person shall furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. No person shall furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(b) This section shall not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler or pharmacy to each other or to a physician, dentist, podiatrist, or veterinarian, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device and its quantity. This section shall not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, and a description of the device and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Health Services. The physician prescribing the

dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist or may furnish topical pharmaceutical agents authorized for use pursuant to paragraph (5) of subdivision (a) of Section 3041 to an optometrist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Examining Committee of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

(i) This section shall become operative on July 1, 2001.

SEC. 6. Section 4081 of the Business and Professions Code is amended to read:

4081. (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, medical device retailer, 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 any pharmacy, wholesaler, veterinary food-animal drug retailer, or medical device retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee 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 exemptee had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 7. Section 4081 is added to the Business and Professions Code, to read:

4081. (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 any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or exemptee, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge or exemptee 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 exemptee had no knowledge, or in which he or she did not knowingly participate.

(d) This section shall become operative on July 1, 2001.

SEC. 8. Section 4101 of the Business and Professions Code is amended to read:

4101. (a) Any pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.

(b) Any exemptee who takes charge of, or acts as manager of, a wholesaler, medical device retailer, or veterinary food-drug animal retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.

(c) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 9. Section 4101 is added to the Business and Professions Code, to read:

4101. (a) Any pharmacist who takes charge of, or acts as pharmacist-in-charge of a pharmacy or other entity licensed by the board, who terminates his or her employment at the pharmacy or other entity, shall notify the board within 30 days of the termination of employment.

(b) Any exemptee who takes charge of, or acts as manager of, a wholesaler or veterinary food-drug animal retailer, who terminates his or her employment at that entity shall notify the board within 30 days of the termination of employment.

(c) This section shall become operative on July 1, 2001.

SEC. 10. Section 4105 of the Business and Professions Code is amended to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer, medical device retailer, or wholesaler, the exemptee, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 11. Section 4105 is added to the Business and Professions Code, to read:

4105. (a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any

entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the exemptee, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) This section shall become operative on July 1, 2001.

SEC. 12. Article 8 (commencing with Section 4130) of Chapter 9 of Division 2 of the Business and Professions Code is repealed.

SEC. 13. Section 4139 is added to the Business and Professions Code, to read:

4139. (a) Licenses to conduct a medical device retailer issued or renewed by the California State Board of Pharmacy prior to July 1, 2001, shall remain valid until one year after the date of the issuance or renewal of the license. On or after July 1, 2001, the California State Board of Pharmacy shall not issue or renew a medical device retailer license. Thereafter, entities seeking licensure as a home medical device retail facility shall apply to the State Department of Health Services.

(b) This section shall remain in effect only until July 1, 2002, and as of January 1, 2003, is repealed, unless a statute, which is enacted before January 1, 2003, deletes or extends that date.

SEC. 14. Section 4201 of the Business and Professions Code is amended to read:

4201. (a) Each application to conduct a pharmacy, wholesaler, medical device retailer, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the

application shall state the information as to each person beneficially interested therein.

(b) As used in this section, and subject to subdivision (c), the term ‘‘person beneficially interested’’ means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, medical device retailer, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, medical device retailer, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other provision of law, the medical device retailer license shall authorize the holder thereof to operate as a medical device retailer and to sell and dispense dangerous devices.

(i) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

(k) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 15. Section 4201 is added to the Business and Professions Code, to read:

4201. (a) Each application to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, shall be made on a form furnished by the board, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein.

(b) As used in this section, and subject to subdivision (c), the term ''person beneficially interested'' means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that no natural person shall be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) In any case where the applicant is a partnership or other unincorporated association, is a limited liability company, or is a corporation, and where the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, or veterinary food-animal drug retailer, if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other provision of law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other provision of law, the wholesale license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other provision of law, the veterinary food-animal drug retailer license shall authorize the holder thereof to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.

(i) For licenses referred to in subdivisions (f), (g), and (h), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board.

(j) This section shall become operative on July 1, 2001.

SEC. 16. Section 4305.5 of the Business and Professions Code is amended to read:

4305.5. (a) Any person who has obtained a license to conduct a wholesaler, medical device retailer, or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) Any person who has obtained a license to conduct a wholesaler, medical device retailer, or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee, and who continues to operate the licensee in the absence of a pharmacist or an exemptee approved for that location, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

(c) Any pharmacist or exemptee who takes charge of, or acts as manager of a wholesaler, medical device retailer, or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 17. Section 4305.5 is added to the Business and Professions Code, to read:

4305.5. (a) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, shall notify the board within 30 days of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(b) Any person who has obtained a license to conduct a wholesaler or veterinary food-animal drug retailer, who willfully fails to notify the board of the termination of employment of any pharmacist or exemptee who takes charge of, or acts as manager of the licensee, and who continues to operate the licensee in the absence of a pharmacist or an exemptee approved for that location, shall be subject to summary suspension or revocation of his or her license to conduct a pharmacy.

(c) Any pharmacist or exemptee who takes charge of, or acts as manager of a wholesaler or veterinary food-animal drug retailer, who terminates his or her employment at the licensee, shall notify the board within 30 days of the termination of employment. Failure to notify the board within the 30-day period shall constitute grounds for disciplinary action.

(d) This section shall become operative on July 1, 2001.

SEC. 18. Section 4312 of the Business and Professions Code is amended to read:

4312. (a) The board may void the license of a wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer if the licensed premises remains closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may void a license after a shorter period of closure. To void a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If no written objection is received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may void the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) In the event that the license of a wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer is voided pursuant to subdivision (a) or revoked pursuant to Article 9 (commencing with Section 4300), or a wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer, notifies the board of its intent to remain closed or to discontinue

business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer.

(d) In the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) Where a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, ‘‘closed’’ means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

(g) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 19. Section 4312 is added to the Business and Professions Code, to read:

4312. (a) The board may void the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer if the licensed premises remains closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may void a license after a shorter period of closure. To void a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If no written objection is received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may void the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) In the event that the license of a wholesaler, pharmacy, or veterinary food-animal drug retailer is voided pursuant to subdivision (a) or revoked pursuant to Article 9 (commencing with Section 4300), or a wholesaler, pharmacy, medical device retailer, or veterinary food-animal drug retailer, notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a wholesaler, pharmacy, or veterinary food-animal drug retailer fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the wholesaler, pharmacy, or veterinary food-animal drug retailer is located, authorizing the board to enter the wholesaler, pharmacy, or veterinary food-animal drug retailer and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the wholesaler, pharmacy, or veterinary food-animal drug retailer.

(d) In the event that the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) Where a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, ''closed'' means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

(g) This section shall become operative on July 1, 2001.

SEC. 20. Section 4331 of the Business and Professions Code is amended to read:

4331. (a) Any person who is neither a pharmacist nor an exemptee and who takes charge of a medical device retailer, wholesaler, or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) Any person who has obtained a license to conduct a medical device retailer and who fails to place in charge of that medical device retailer a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the compounding or dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) Any person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) Any person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 21. Section 4331 is added to the Business and Professions Code, to read:

4331. (a) Any person who is neither a pharmacist nor an exemptee and who takes charge of a wholesaler or veterinary food-animal drug retailer or who dispenses a prescription or furnishes dangerous devices except as otherwise provided in this chapter is guilty of a misdemeanor.

(b) Any person who has obtained a license to conduct a veterinary food-animal drug retailer and who fails to place in charge of that veterinary food-animal drug retailer a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) Any person who has obtained a license to conduct a wholesaler and who fails to place in charge of that wholesaler a pharmacist or exemptee, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or exemptee, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) This section shall become operative on July 1, 2001.

SEC. 22. Section 4344 of the Business and Professions Code is repealed.

SEC. 23. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) (1) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(2) The fee for a medical device retailer license shall not exceed the fee for a nongovernmental pharmacy license.

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for processing remodeling plans and inspecting a remodeled pharmacy shall be one hundred thirty dollars ($130) and may be increased to one hundred seventy-five dollars ($175).

(d) The fee for the pharmacist examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(e) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(f) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(g) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(h) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(i) The fee for examination and investigation for an exemptee license under Sections 4053 and 4054 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).

(j) The fee for an exemptee license and annual renewal under Sections 4053 and 4054 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(k) The fee for an out-of-state drug distributor’s license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(*l*) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(m) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(n) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not

recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(o) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(p) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(q) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(r) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(s) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(t) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(u) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(v) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(w) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

(x) This section shall remain in effect only until July 1, 2001, and as of January 1, 2002, is repealed, unless a later enacted statute, which is enacted before January 1, 2002, deletes or extends that date.

SEC. 24. Section 4400 is added to the Business and Professions Code, to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be three hundred forty dollars ($340) and may be increased to four hundred dollars ($400).

(b) The fee for a nongovernmental pharmacy or medical device retailer annual renewal shall be one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250).

(c) The fee for processing remodeling plans and inspecting a remodeled pharmacy shall be one hundred thirty dollars ($130) and may be increased to one hundred seventy-five dollars ($175).

(d) The fee for the pharmacist examination shall be one hundred fifty-five dollars ($155) and may be increased to one hundred eighty-five dollars ($185).

(e) The fee for regrading an examination shall be seventy-five dollars ($75) and may be increased to eighty-five dollars ($85). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(f) The fee for a pharmacist license and biennial renewal shall be one hundred fifteen dollars ($115) and may be increased to one hundred fifty dollars ($150).

(g) The fee for a wholesaler license and annual renewal shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(h) The fee for a hypodermic license and renewal shall be ninety dollars ($90) and may be increased to one hundred twenty-five dollars ($125).

(i) The fee for examination and investigation for an exemptee license under Sections 4053 and 4054 shall be seventy-five dollars ($75) and may be increased to one hundred dollars ($100), except for a veterinary food-animal drug retailer exemptee, for whom the fee shall be one hundred dollars ($100).

(j) The fee for an exemptee license and annual renewal under Sections 4053 and 4054 shall be one hundred ten dollars ($110) and may be increased to one hundred fifty dollars ($150), except that the fee for the issuance of a veterinary food-animal drug retailer exemptee license shall be one hundred fifty dollars ($150), for renewal one hundred ten dollars ($110), which may be increased to one hundred fifty dollars ($150), and for filing a late renewal fifty-five dollars ($55).

(k) The fee for an out-of-state drug distributor’s license and annual renewal issued pursuant to Section 4120 shall be five hundred fifty dollars ($550) and may be increased to six hundred dollars ($600).

(*l*) The fee for registration and annual renewal of providers of continuing education shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(m) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(n) The fee for evaluation of applications submitted by graduates of foreign colleges of pharmacy or colleges of pharmacy not recognized by the board shall be one hundred sixty-five dollars ($165) and may be increased to one hundred seventy-five dollars ($175).

(o) The fee for an intern license or extension shall be sixty-five dollars ($65) and may be increased to seventy-five dollars ($75). The fee for transfer of intern hours or verification of licensure to another state shall be fixed by the board not to exceed twenty dollars ($20).

(p) The board may, by regulation, provide for the waiver or refund of the additional fee for the issuance of a certificate where the certificate is issued less than 45 days before the next succeeding regular renewal date.

(q) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change is thirty dollars ($30).

(r) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, is sixty dollars ($60) and may be increased to one hundred dollars ($100).

(s) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(t) The fee for any applicant for a clinic permit is three hundred forty dollars ($340) and may be increased to four hundred dollars ($400) for each permit. The annual fee for renewal of the permit is one hundred seventy-five dollars ($175) and may be increased to two hundred fifty dollars ($250) for each permit.

(u) The board shall charge a fee for the processing and issuance of a registration to a pharmacy technician and a separate fee for the biennial renewal of the registration. The registration fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50). The biennial renewal fee shall be twenty-five dollars ($25) and may be increased to fifty dollars ($50).

(v) The fee for a veterinary food-animal drug retailer license shall be four hundred dollars ($400). The annual renewal fee for a veterinary food-animal drug retailer shall be two hundred fifty dollars ($250).

(w) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty dollars ($30).

(x) This section shall become operative on July 1, 2001.

SEC. 25. Section 19051 of the Business and Professions Code is amended to read:

19051. Every upholstered-furniture retailer, unless he or she holds an importer's license, a furniture and bedding manufacturer's license, a wholesale furniture and bedding dealer's license, a custom upholsterer's license, or a retail furniture and bedding dealer's license shall hold a retail furniture dealer's license.

(a) This section does not apply to a person whose sole business is designing and specifying for interior spaces, and who purchases specific amenable upholstered furniture items on behalf of a client, provided that the furniture is purchased from an appropriately licensed importer, wholesaler, or retailer. This section does not apply to a person who sells ''used'' and ''antique'' furniture as defined in Sections 19008.1 and 19008.2.

(b) This section does not apply to a person who is licensed as a home medical device retail facility by the State Department of Health Services, provided that the furniture is purchased from an appropriately licensed importer, wholesaler, or retailer.

SEC. 26. Section 19055 of the Business and Professions Code is amended to read:

19055. Every bedding retailer, unless he or she holds an importer's license, an upholstered-furniture and bedding manufacturer's license, a wholesale upholstered-furniture and bedding dealer's license, or a retail furniture and bedding dealer's license, shall hold a retail bedding dealer's license.

(a) This section does not apply to a person whose sole business is designing and specifying for interior spaces, and who purchases specific amenable bedding items on behalf of a client, provided that the bedding is purchased from an appropriately licensed importer, wholesaler, or retailer.

(b) This section does not apply to a person who is licensed as a home medical device retail facility by the State Department of Health Services, provided that the bedding is purchased from an appropriately licensed importer, wholesaler, or retailer.

SEC. 27. Section 19059.5 of the Business and Professions Code is amended to read:

19059.5. Every sanitizer shall hold a sanitizer's license unless he or she is licensed as a home medical device retail facility by the State Department of Health Services.

SEC. 28. Section 109948 is added to the Health and Safety Code, to read:

109948. (a) ''Home medical device retail facility'' is an area, place, or premises, other than a licensed pharmacy, in and from which prescription devices, home medical devices, or home medical device services are sold, fitted, or dispensed pursuant to prescription. ''Home medical device retail facility'' includes, but is not limited to, any area or place in which prescription devices, home medical devices, or home medical device services are stored, possessed, prepared, manufactured, or repackaged, and from which the

prescription devices, home medical devices, and home medical device services are furnished, sold, or dispensed at retail.

(b) ''Home medical device retail facility'' shall not include any area in a facility licensed by the department where floor supplies, ward supplies, operating room supplies, or emergency room supplies of prescription devices are stored or possessed solely for treatment of patients registered for treatment in the facility or for treatment of patients receiving emergency care in the facility.

(c) ''Home medical device retail facility'' shall not include any area of a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of Division 2 where the supplies specified in subdivision (c) of Section 4057 of the Business and Professions Code are stored or possessed solely for treatment of patients by a licensed home health agency or licensed hospice, as long as all prescription devices are furnished to these patients only upon the prescription or order of health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

SEC. 29. Section 109948.1 is added to the Health and Safety Code, to read:

109948.1. (a) ''Home medical device services'' means the delivery, installation, maintenance, replacement of, or instruction in the use of, home medical devices used by a sick or disabled individual to allow the individual to be maintained in a residence.

(b) ''Home medical device'' means a device intended for use in a home care setting including, but not limited to, all of the following:

(1) Oxygen and oxygen delivery systems.

(2) Ventilators.

(3) Continuous Positive Airway Pressure devices (CPAP).

(4) Respiratory disease management devices.

(5) Hospital beds and commodes.

(6) Electronic and computer driven wheelchairs and seating systems.

(7) Apnea monitors.

(8) Low air loss continuous pressure management devices.

(9) Transcutaneous Electrical Nerve Stimulator (TENS) units.

(10) Prescription devices.

(11) Medical gases for human consumption.

(12) Disposable medical supplies including, but not limited to, incontinence supplies as defined in Section 14125.1 of the Welfare and Institutions Code.

(13) In vitro diagnostic tests.

(14) Any other similar device as defined in regulations adopted by the department.

(c) The term ''home medical device'' does not include any of the following:

(1) Devices used or dispensed in the normal course of treating patients by hospitals and nursing facilities, other than devices delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical devices to an individual's residence.

(2) Prosthetics and orthotics.

(3) Automated external defibrillators (AEDs).

(4) Devices provided through a physician's office incident to a physician's service.

(5) Devices provided by a licensed pharmacist that are used to administer drugs that can be dispensed only by a licensed pharmacist.

(6) Enteral and parenteral devices provided by a licensed pharmacist.

SEC. 30. Section 110010.1 is added to the Health and Safety Code, to read:

110010.1. ''Prescription device'' means any device limited to prescription use under Section 111470.

SEC. 31. Section 110010.2 is added to the Health and Safety Code, to read:

110010.2. ''Prescription drug'' means any drug limited to prescription use under Section 111470.

SEC. 32. Section 111656 is added to the Health and Safety Code, to read:

111656. (a) No person shall conduct a home medical device retail facility business in the State of California unless he or she has obtained a license from the department. A license shall be required for each home medical device retail facility owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a home medical device retail facility in more than one location. The license shall be renewed annually and shall not be transferable. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to home medical device retail facilities.

(b) Applications for a home medical device retail facility license shall be made on a form furnished by the department. The department may require any information it deems reasonably necessary to carry out the purposes of this section.

(c) A warehouse owned by a home medical device retail facility the primary purpose of which is storage, not dispensing of prescription devices to patients, shall be licensed at a fee one-half of that for a home medical device retail facility. There shall be no separate or additional license fee for warehouse premises owned by a home medical device retail facility that are physically connected to the retail premises or that share common access.

(d) The department may, at its discretion, issue a temporary license when the ownership of a home medical device retail facility is transferred from one person to another upon any conditions and

for the periods of time as the department determines to be in the public interest. A temporary license fee shall be established by the department at an amount not to exceed the annual fee for renewal of a license to conduct a home medical device retail facility.

(e) Notwithstanding any other provision of law, a licensed home medical device retail facility may furnish a prescription device to a licensed health care facility for storage in a secured emergency pharmaceutical supplies container maintained within the facility in accordance with facility regulations of the State Department of Health Services set forth in Title 22 of the California Code of Regulations.

(f) The licensure requirements of this section shall not apply to the following entities or practitioners, unless the entities or practitioners furnish home medical devices or home medical device services through a separate entity including, but not limited to, a corporate entity, division, or other business entity:

(1) Home health agencies that do not have a Part B Medicare supplier number.

(2) Hospitals, excluding providers of home medical devices that are owned or related to a hospital.

(3) Manufacturers and wholesale distributors, if not selling directly to the patient.

(4) Health care practitioners authorized to prescribe or order home medical devices or who use home medical devices or who use home medical devices to treat their patients.

(5) Licensed pharmacists and pharmacies. Pharmacies that sell or rent home medical devices shall be governed by the provisions of Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code and any rules and regulations adopted by the California State Board of Pharmacy.

(6) Licensed hospice programs.

(7) Licensed nursing homes.

(8) Licensed veterinarians.

(9) Licensed dentists.

(10) Emergency medical services provider.

SEC. 33. Section 111656.1 is added to the Health and Safety Code, to read:

111656.1. (a) After January 1, 2002, prior to issuing a license required by Section 111656, the department shall inspect each place of business to determine ownership, adequacy of facilities, and personnel qualifications. The department shall inspect each licensee at least annually thereafter. Nothing in this section shall prohibit the department from inspecting any medical device retail facility prior to January 1, 2002.

(b) The annual license fee for a home medical device retail facility shall be eight hundred fifty dollars ($850) until adjusted pursuant to subdivision (c).

(c) The annual license fee required by Sections 111656 and 111630 shall be adjusted annually, commencing July 1, 2003, by the department so that license fee revenues cover the estimated licensing program costs. Adjusted fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(d) Commencing July 1, 2003, the department shall by July 30 of each year, publish the amount of fees to be charged as adjusted pursuant to this section. This adjustment of fees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(e) Commencing January 1, 2003, the department shall, on or before January 10 of each year, provide the Legislature with a report recommending fee rates. The report shall describe the estimated licensing program costs for the next fiscal year to carry out the licensing, regulating, inspecting, and other duties and responsibilities of the department in carrying out the provisions of this article. The department shall describe the projected license fee amount so that license fee revenues cover the estimated licensing program costs. Projected fee amounts shall take into account the resources required for inspections and other activities to support licensing during the previous year and shall take into account projected workload and changes in department overhead costs during the upcoming year.

(f) The Drug and Device Safety Fund is hereby created as a special fund in the State Treasury. All moneys collected by the department under this section and Sections 111656.7, 111656.8, 111656.12, and 111630, and fines and penalties collected by the department in the enforcement of this article, shall be deposited in the fund for use by the department upon appropriation by the Legislature for the purposes of providing funds necessary to carry out and implement the provisions of this article relating to drugs and devices.

SEC. 34. Section 111656.2 is added to the Health and Safety Code, to read:

111656.2. (a) The following standards shall apply to all home medical device retail facilities:

(1) Each retail facility shall store prescription devices in a secure, lockable area.

(2) Each retail facility shall maintain the premises, fixtures, and equipment in a clean and orderly condition.

(3) Each retail facility shall maintain the premises in a dry, well-ventilated condition, free from contamination or other conditions that may render home medical devices unfit for their intended use.

(b) The department may by regulation impose any other standards pertaining to the acquisition, storage, and maintenance of prescription devices or other goods or to the maintenance or condition of the licensed premises of any home medical device retail facility as the department determines are reasonably necessary.

SEC. 35. Section 111656.3 is added to the Health and Safety Code, to read:

111656.3. (a) Each home medical device retail facility shall have written policies and procedures related to home medical device handling and, if authorized by the department pursuant to Section 111656.4, the dispensing of prescription devices. Those written policies and procedures shall be adequate to assure compliance with this article and shall include, but not be limited to:

(1) Training of staff, patients, and caregivers.

(2) Cleaning, storage, and maintenance of home medical devices necessary to prevent damage or contamination and to assure their operation in accordance with manufacturer specifications.

(3) Emergency services. If home medical device malfunction may threaten a patient's health, access to emergency services 24 hours per day, 365 days per year shall be available for device maintenance or replacement.

(4) Maintaining all records required by this article and any regulations adopted pursuant to the provisions of this article.

(5) Storage and security requirements to assure that prescription devices are dispensed in accordance with this article.

(6) Quality assurance.

(b) The home medical device retail facility shall make consultation available to the patient or primary caregiver about the proper use of devices and related supplies furnished by the home medical device retail facility. The home medical device retail facility shall notify the patient or primary care giver that this consultation is available.

(c) Each home medical device retail facility shall ensure all personnel who engage in the taking of orders for, the selling of, or the fitting of prescription devices, if authorized by the department pursuant to Section 111656.4, shall have training and demonstrate initial and continuing competence in the order-taking, fitting, and sale of prescription devices that the home medical device retail facility furnishes pursuant to Section 111656.4.

(d) Each home medical device retail facility shall prepare and maintain records of training and demonstrated employee competence required under this article for employees of the home medical device retail facility. The records shall be maintained for three years from and after the last date of employment.

(e) Each home medical device retail facility shall have an ongoing, documented quality assurance program that includes, but is not limited to, the following:

(1) Monitoring personnel performance to assure compliance with this article.

(2) Storage, maintenance, and dispensing of prescription devices to assure that prescription devices are dispensed in accordance with this article.

(f) The records and documents specified in subdivisions (a) and (e) shall be maintained for three years from the date of making. The records and documents described in subdivisions (a), (d), and (e), shall be open to inspection at all times during business hours by authorized agents of the department or an inspector from the California State Board of Pharmacy for the purpose of investigating a pharmacist.

SEC. 36. Section 111656.4 is added to the Health and Safety Code, to read:

111656.4. Section 4051 of the Business and Professions Code shall not prohibit a home medical device retail facility from selling or dispensing prescription devices if the department finds that sufficient qualified supervision is employed by the home medical device retail facility to adequately safeguard and protect the public health. Each person applying to the department for this exemption shall meet the following requirements to obtain and maintain the exemption:

(a) A licensed pharmacist or an exemptee who has taken and passed an examination administered by the department and whose certificate of exemption is currently valid, shall be in charge of the home medical device retail facility.

(b) The licensed pharmacist or exemptee shall be on the premises at all times that prescription devices are available for sale or fitting unless the prescription devices are stored separately from other merchandise and are under the exclusive control of the licensed pharmacist or exemptee. A licensed pharmacist or an exemptee need not be present in the warehouse facility of a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public.

(c) The department may require an exemptee to complete a designated number of hours of coursework in department-approved courses of home health education in the disposition of any disciplinary action taken against the exemptee.

(d) Each premises maintained by a home medical device retail facility shall have a license issued by the department and shall have a licensed pharmacist or exemptee on the premises if prescription devices are furnished, sold, or dispensed.

(e) A home medical device retail facility may establish locked storage (a lock box or locked area) for emergency or after working hours furnishing of prescription devices. Locked storage may be installed or placed in a service vehicle of the home medical device

retail facility for emergency or after hours service to patients having prescriptions for prescription devices.

(f) The department may by regulation authorize a licensed pharmacist or exemptee to direct an employee of the home medical device retail facility who operates the service vehicle equipped with locked storage described in subdivision (e) to deliver a prescription device from the locked storage to patients having prescriptions for prescription devices. These regulations shall establish inventory requirements for the locked storage by a licensed pharmacist or exemptee to take place shortly after a prescription device has been delivered from the locked storage to a patient.

SEC. 37. Section 111656.5 is added to the Health and Safety Code, to read:

111656.5. (a) No person other than a licensed pharmacist, an intern pharmacist, an exemptee, as specified in Section 111656.4, or an authorized agent of the department or a person authorized to prescribe, shall be permitted in that area, place, or premises described in the license issued by the department wherein prescription devices are stored, possessed, prepared, manufactured, or repacked, except that a licensed pharmacist or exemptee shall be responsible for any individual who enters the medical device retail facility for the purposes of receiving, fitting, or consultation from the licensed pharmacist or exemptee or any person performing clerical, inventory control, housekeeping, delivery, maintenance, or similar functions relating to the home medical device retail facility. The licensed pharmacist or exemptee shall remain present in the home medical device retail facility any time an individual is present who is seeking a fitting or consultation. However, a licensed pharmacist or an exemptee need not be present on the premises of a home medical device retail facility at all times of its operation and need not to be present in a warehouse facility owned by a home medical device retail facility unless the department establishes that requirement by regulation based upon the need to protect the public. The exemptee need not be present if the prescription devices are stored in a secure locked area under the exclusive control of the exemptee and unavailable for dispensing. This subdivision shall apply only to prescription devices.

(b) A ‘‘warehouse’’ as used in this section, is a facility owned by a home medical device retail facility that is used for storage only. There shall be no fitting, display, or sales at that location. A licensed pharmacist or exemptee shall be designated as ‘‘in charge’’ of a warehouse but need not be present during its operation. The licensed pharmacist or exemptee may permit others to possess a key to the warehouse.

(c) Notwithstanding the remainder of this section, a home medical device retail facility may establish a locked facility, meeting the requirements of Section 111656.4, for furnishing prescription

devices to patients having prescriptions for prescription devices in emergencies or after working hours.

(d) The department may establish reasonable security measures consistent with this section as a condition of licensing in order to prevent unauthorized persons from gaining access to the area, place, or premises, or to the prescription devices therein.

(e) The department may by regulation establish labeling requirements for prescription devices sold, fitted, or dispensed by a home medical device retail facility as it deems necessary for the protection of the public.

SEC. 38. Section 111656.6 is added to the Health and Safety Code, to read:

111656.6. Home medical devices for rental purposes shall at all times while under the control of the home medical device retail facility, be maintained in a clean and sanitary condition and in good working order following, where available, manufacturer specifications.

SEC. 39. Section 111656.7 is added to the Health and Safety Code, to read:

111656.7. (a) Without registering as an out-of-state home medical device retail facility, an out-of-state home medical device retail facility shall not sell or distribute prescription devices in this state through any person or media other than a wholesaler who is licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code.

(b) Applications for an out-of-state home medical device retail facility registration shall be made on a form furnished by the department. The department may require any information it deems reasonably necessary to carry out the purposes of this section.

(c) The Legislature by enacting this section does not intend a registration issued to any out-of-state home medical device retail facility pursuant to this section to change or affect the tax liability imposed by Chapter 3 (commencing with Section 23501) of Part 11 of Division 2 of the Revenue and Taxation Code on any out-of-state home medical device retail facility.

(d) The Legislature by enacting this section does not intend a registration issued to any out-of-state home medical device retail facility pursuant to this section to serve as any evidence that the out-of-state home medical device retail facility is doing business within this state.

SEC. 40. Section 111656.8 is added to the Health and Safety Code, to read:

111656.8. (a) No person acting as principal or agent for any out-of-state home medical device retail facility who has not obtained a registration from the department pursuant to this article and who sells or distributes prescription devices in this state that are not obtained through a wholesaler who has obtained a license pursuant

to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, or that are not obtained through a selling or distribution outlet of an out-of-state manufacturer that is licensed as a wholesaler pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code, shall conduct the business of selling or distributing prescription devices within this state without registering with the department pursuant to this article.

(b) Registration of persons under this section shall be made on a form furnished by the department. The department may require any information as the department deems reasonably necessary to carry out the purposes of this section including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose prescription devices he or she is selling or distributing.

(c) The department may deny, revoke, or suspend the registration of persons registered under this article for any violation of this article or Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code or for any violation of Part 5 (commencing with Section 109875) of Division 104. The department may deny, revoke, or suspend the person's registration if the manufacturer whose prescription devices he or she is selling or distributing violates this article or Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code or Part 5 (commencing with Section 109875) of Division 104.

(d) Registration under this section shall be renewed annually.

SEC. 41. Section 111656.9 is added to the Health and Safety Code, to read:

111656.9. When, in the opinion of the department, a high standard of patient safety, consistent with good patient care, can be provided by the licensure of a home medical device retail facility that does not meet all of the requirements for licensure as a home medical device retail facility, the department may waive any licensing requirements for that medical device retail facility.

SEC. 42. Section 111656.10 is added to the Health and Safety Code, to read:

111656.10. (a) The department may void the license of a home medical device retail facility, if the licensed premises remain closed, as defined in subdivision (e), other than by order of the department. For good cause shown, the department may void a license after a shorter period of closure. To void a license pursuant to this subdivision, the department shall make a diligent, good faith effort to give notice by personal service on the licensee. If no written objection is received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the department may void the license without the necessity of a hearing. If the licensee files a written objection, the

department shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the department shall have all the powers granted in that chapter.

(b) In the event that the license of a home medical device retail facility is voided pursuant to subdivision (a) or revoked or a home medical device retail facility notifies the department of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all prescription devices to another licensee authorized to possess the prescription devices. The licensee transferring the prescription devices shall immediately confirm in writing to the department that the transfer has taken place.

(c) If a home medical device retail facility fails to comply with subdivision (b), the department may seek and obtain an order from the superior court in the county in which the home medical device retail facility is located, authorizing the department to enter the home medical device retail facility and inventory and store, transfer, sell, or arrange for the sale of, prescription devices found in the home medical device retail facility.

(d) In the event that the department sells or arranges for the sale of any prescription devices pursuant to subdivision (c), the department may retain from the proceeds of the sale an amount equal to the cost to the department of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the prescription devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the prescription devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) Where a statute or regulation requires the licensee to file with the department his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the department, and service of notice in this manner shall be deemed completed on the 10th day after the mailing.

(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the department for the remaining proceeds within 30 calendar days after the personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the department into the Drug and Device Safety Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of

Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.

(e) For the purposes of this section, ''closed'' means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

(f) Nothing in this section shall be construed as requiring a home medical device retail facility to be open seven days a week.

SEC. 43. Section 111656.11 is added to the Health and Safety Code, to read:

111656.11. (a) It is unlawful for any person who is neither a licensed pharmacist nor an exemptee to take charge of a home medical device retail facility or to furnish prescription devices except as otherwise provided in this article.

(b) It is unlawful for any person who has obtained a license to conduct a home medical device retail facility to fail to place a licensed pharmacist or exemptee in charge of that home medical device retail facility or for any person to, by himself or herself, or by any other person, permit the compounding or dispensing of prescriptions, except by a licensed pharmacist or exemptee or as otherwise provided in this article.

SEC. 44. Section 111656.12 is added to the Health and Safety Code, to read:

111656.12. (a) The fee for examination and investigation for an exemptee license under Section 111656.4 shall be one hundred dollars ($100).

(b) The fee for an exemptee license and annual renewal under Section 111656.4 shall be one hundred fifty dollars ($150).

(c) The fee for registration as an out-of-state home medical device retail facility or as the principal or agent of an out-of-state home medical device retail facility shall be one hundred fifty dollars ($150).

SEC. 45. Section 111656.13 is added to the Health and Safety Code, to read:

111656.13. (a) Any entity that prior to July 1, 2001, holds a current, valid license as a medical device retailer pursuant to Section 4130 of the Business and Professions Code, shall be deemed to be a licensed home medical device retail facility until the expiration of that license if the entity is in compliance with all applicable criteria for obtaining a license as a home medical device retail facility.

(b) Any entity that was not required to obtain a license as a medical device retailer in order to provide equipment or services prior to July 1, 2001, and that is required to obtain a license as a home medical device retail facility pursuant to Section 111656, shall apply for a license as a home medical device retail facility by July 1, 2001; however, the requirement for licensure shall only apply to those entities on and after January 1, 2002.

SEC. 46. Sections 1, 12, and 22 of this act shall become operative on July 1, 2001.

SEC. 47. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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