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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item III: Discussion and Consideration of Actions to Implement Legislation Chaptered in 2017

As reported during the November 2017 Board Meeting, the Governor signed several measures that impact the board's jurisdiction and/or the board's operations. Provided below is a brief summary of each measure and well as implementation activities.

SB 351 (Chapter 623, Statutes of 2017, Roth) Hospital Satellite Compounding Pharmacy: License: Requirements

Summary: Creates options for hospitals that wish to obtain additional licenses from the board for purposes of providing pharmaceutical care. Specifically, the board can now issue hospital satellite compounding pharmacy licenses that will not need to be located in the acute care hospital building. This measure also allows the board to issue a hospital pharmacy license that can be located outside of the general acute care hospital but in another physical plant regulated under the California Department of Public Health's hospital license.

Implementation: Board staff is working with the department's IT staff to make modifications to the existing computer systems to incorporate the new licensing program. In the interim staff will be manually processing applications and issuing licenses. Draft application forms are under review by DCA and will be released upon approval.

SB 443 (Chapter 647, Statutes of 2017, Hernandez) Pharmacy: Emergency Medical Services Automated Drug Delivery System

Summary: Creates an option for county emergency medical services to restock ambulances through use of an emergency medical services automated drug delivery system (EMADDS) that is located within a county operated fire department. As part of the measure, the board can issue a license for the use of the EMADDS as well as a license to a designated paramedic.

Implementation: A service request was submitted to the department to make modifications to the existing computer system to incorporate the new designated paramedic licensing program, and draft application forms are under development. Until programming is completed, staff will be manually processing application and issuing licenses. Because of a lack of funding, integration of the EMADDS into the computer system is not possible, necessitating manual processing in the long term.

SB 547 (Chapter 429, Statutes of 2017, Hill) Professions and Vocations

Summary: Allows the board to hire its own counsel.

Implementation: Dr. Gutierrez, Ms. Herold and Ms. Sodergren met with Director Grafilo and Ryan Marcroft, Deputy Director, Legal Affairs Division.

SB 752 (Chapter 598, Statutes of 2017, Stone) Designated Representative-Reverse Distributor

Summary: Establishes the creation of a designated representative-reverse distributor license and shortens the period an applicant must wait to retake the pharmacist licensure examination to 45 days.

Implementation: A service request was submitted to the department to make modifications to the existing computer system to incorporate the new designated paramedic licensing program. In the interim, staff will be manually processing applications and issuing licenses. The new application form has been approved and will be released after direction on the training programs is provided.

For Board Consideration: Under the provisions related to the designated representative-reverse distributor, one pathway to licensure includes completion of a training program approved by the board that addresses specified areas. Staff recommends that implementation of this item be referred to the Licensing Committee to develop the training requirements for promulgation as regulations upon approval by the full board. In the interim, the board could consider and approve individual training programs. Should the board be interested in approving training programs in the interim, staff request guidance from the board on the type of information that would be beneficial to making such an approval, e.g. minimum hours, confirmation by board staff that required elements are included, practical versus theoretical training, etc.

AB 401 (Chapter 548, Statutes of 2017, Aguiar-Curry) Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy

Summary: Establishes regulatory framework for telepharmacy (via a remote dispensing site pharmacy), establishes mandatory reporting by wholesalers of suspicious drug orders, and establishes the authority for two clinics to operate from a single location.

Implementation: Service requests were submitted to the department to make modifications to the existing computer system to incorporate the new licensing program and co-located clinics. In the interim, staff will be manually processing applications and issuing licenses. Draft application forms are currently being developed.

Further, as part of the requirements for telepharmacy, regulations must be developed to establish the requirements a pharmacy technician must possess to work at such a location. The Licensing Committee will be discussing this issue as part of its committee meeting scheduled for January 16, 2018.

Regarding suspicious ordering notifications from drug wholesalers, the board has already received approximately 50 such notifications.

Copies of each of the chaptered measures follow this memorandum.

Attachments

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SECTION 1. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy ~~also includes~~ *may include* a pharmacy that ~~may be located outside of the hospital in~~ ~~another~~ *is located in any* physical plant that is regulated under ~~a hospital's consolidated license issued pursuant~~ ~~to Section 1250.8~~ *the license of a general acute care hospital as defined in subdivision (a) of Section 1250* of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) "Hospital satellite compounding pharmacy" means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

SEC. 2. *Section 4127.15 is added to the Business and Professions Code, to read:*

4127.15. Subject to the requirements of this section, the board may issue a license to a hospital satellite compounding pharmacy. The license fee and annual renewal fee shall be in an amount established by the board in subdivision (u) of Section 4400. The license shall not be transferable.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(1) A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

(2) The services provided shall be directly related to the services or treatment plan administered in the physical plant.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the hospital satellite compounding pharmacy's policies and procedures for sterile compounding.

(2) Reviews the hospital satellite compounding pharmacy's completed self-assessment form as described in Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

(1) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy as defined in subdivision (a) of Section 4029.

(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty.

(3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding.

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(4) Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.

(5) Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects shall also be, within 12 hours, reported to the MedWatch program of the federal Food and Drug Administration.

SEC. 3. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) 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.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) 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.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license *or a hospital satellite compounding pharmacy* shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the

applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) This section shall become operative on July 1, 2017.

SEC. 3.5. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

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(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

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(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, ~~or~~ as a designated representative-3PL pursuant to Section 4053.1, *or as a designated representative-reverse distributor pursuant to Section 4053.2* shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated ~~representative~~ *representative, designated representative-3PL,* or designated ~~representative-3PL~~ *representative-reverse distributor* shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

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(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) 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.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) 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.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

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(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license *or a hospital satellite compounding pharmacy* shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) This section shall become operative on July 1, 2017.

SEC. 4. Section 3.5 of this bill incorporates amendments to Section 4400 of the Business and Professions Code proposed by both this bill and Senate Bill 752. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4400 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 752, in which case Section 3 of this bill shall not become operative.

SEC. 5. 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,

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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.

SB 443

SECTION 1. *Section 4034.5 is added to the Business and Professions Code, to read:*

4034.5. An "emergency medical services automated drug delivery system" or "EMSADDS" means an automated drug delivery system that stores and distributes drugs for the sole purpose of restocking a secured emergency pharmaceutical supplies container that is used by an emergency medical services agency to provide emergency medical services.

SEC. 2. Section 4119 of the Business and Professions Code is amended to read:

4119. (a) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or dangerous 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 Public Health set forth in Title 22 of the California Code of Regulations and the requirements set forth in Section 1261.5 of the Health and Safety Code. These emergency supplies shall be approved by the facility's patient care policy committee or pharmaceutical service committee and shall be readily available to each nursing station. Section 1261.5 of the Health and Safety Code limits the number of oral dosage form or suppository form drugs in these emergency supplies to ~~24.~~ *48.*

(b) Notwithstanding any other ~~provision of~~ law, a pharmacy may furnish a dangerous drug or a dangerous device to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency, if all of the following are met:

(1) The dangerous drug or dangerous device is furnished exclusively for use in conjunction with services provided in an ambulance, or other approved emergency medical services service provider, that provides prehospital emergency medical services.

(2) The requested dangerous drug or dangerous device is within the licensed or certified emergency medical technician's scope of practice as established by the Emergency Medical Services Authority and set forth in Title 22 of the California Code of Regulations.

(3) The approved service provider within an emergency medical services system provides a written request that specifies the name and quantity of dangerous drugs or dangerous devices.

(4) The approved emergency medical services provider administers dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

(5) The approved emergency medical services provider documents, stores, and restocks dangerous drugs and dangerous devices in accordance with the policies and procedures of the local emergency medical services agency.

Records of each request by, and dangerous drugs or dangerous devices furnished to, an approved service provider within an emergency medical services system, shall be maintained by both the approved service provider and the dispensing pharmacy for a period of at least three years.

The furnishing of controlled substances to an approved emergency medical services provider shall be in accordance with the California Uniform Controlled Substances ~~Act.~~ *Act (Division 10 (commencing with Section 11000) of the Health and Safety Code).*

SEC. 3. *Section 4119.01 is added to the Business and Professions Code, immediately following Section 4119, to read:*

4119.01. (a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

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(1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.

(A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.

(B) The application and initial license fee to operate EMSADDS shall be one hundred dollars ($100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars ($35).

(C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars ($780).

(2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.

(3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

(4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.

(A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

(B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.

(C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.

(5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:

(A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.

(B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.

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(C) A comparison of subparagraphs (A) and (B), and identification of any variances.

(D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.

(E) Identification of possible causes of shortages and overages.

(6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.

(7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

(8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.

(b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.

SEC. 4. *Section 4202.5 is added to the Business and Professions Code, to read:*

4202.5. (a) The board may issue a designated paramedic license to an individual if he or she holds a license as a paramedic in this state and meets the criteria of this section.

(b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.

(c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.

(d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.

(e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars ($140) for a two-year license. The biennial renewal shall be one hundred forty dollars ($140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars ($65).

SEC. 5. 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.

(2) If the board assigns the petition to an administrative law judge, the administrative law judge shall submit a proposed decision, as specified in Section 11517 of the Government Code, to the board for its consideration, which shall include reasons supporting the proposed decision.

(e) The board may grant or deny the petition, or may impose any terms and conditions that it reasonably deems appropriate as a condition of reinstatement or reduction of penalty.

(f) In considering a petition for reinstatement or modification of a penalty, the board or the administrative law judge shall evaluate and consider evidence of rehabilitation submitted by the petitioner using criteria specified in regulations promulgated by the board.

(g) The board may impose, or the administrative law judge may recommend, terms and conditions on the petitioner in reinstating a license, certificate, or permit or in modifying a penalty.

~~(f)~~ *(h)* The petitioner shall provide a current set of fingerprints accompanied by the necessary fingerprinting fee.

~~(g)~~ *(i)* No petition shall be considered while the petitioner is under sentence for any criminal offense, including any period during which the petitioner is on court-imposed probation or parole, or subject to an order of registration pursuant to Section 290 of the Penal Code. No petition shall be considered while there is an accusation or petition to revoke probation pending against the petitioner.

~~(h)~~ *(j)* Except in those cases where the petitioner has been disciplined pursuant to Section 822, the board may in its discretion deny without hearing or argument any petition that is filed pursuant to this section within a period of two years from the effective date of a prior decision following a hearing under this section.

SEC. 9. Section 2987 of the Business and Professions Code is amended to read:

2987. The amount of the fees prescribed by this chapter shall be determined by the board, and shall be as follows: (a) The application fee for a psychologist shall not be more than fifty dollars ($50).

(b) The examination and reexamination fees for the examinations shall be the actual cost to the board of developing, purchasing, and grading of each examination, plus the actual cost to the board of administering each examination.

(c) The initial license fee is an amount equal to the renewal fee in effect on the last regular renewal date before the date on which the license is issued.

(d) The biennial renewal fee for a psychologist shall be four hundred dollars ($400). The board may increase the renewal fee to an amount not to exceed five hundred dollars ($500).

(e) The application fee for registration ~~and supervision of~~ *as* a psychological assistant ~~by a supervisor under~~ ~~Section 2913, which is payable by that supervisor,~~ *under Section 2913* shall not be more than seventy-five dollars ($75).

(f) The annual renewal fee for registration of a psychological assistant shall not be more than seventy-five dollars ($75).

(g) The duplicate license or registration fee is five dollars ($5).

(h) The delinquency fee is ~~twenty-five dollars ($25).~~ *50 percent of the renewal fee for each license type, not to exceed one hundred fifty dollars ($150).*

(i) The endorsement fee is five dollars ($5).

Notwithstanding any other provision of law, the board may reduce any fee prescribed by this section, when, in its discretion, the board deems it administratively appropriate.

SEC. 10. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ *legal counsel and* inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation,

may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

SEC. 11. Section 4840.5 of the Business and Professions Code is amended to read:

4840.5. Under conditions of an emergency, a registered veterinary technician may render such lifesaving aid and treatment as may be prescribed under regulations adopted by the board pursuant to Section 4836. Such emergency aid and treatment if rendered to an animal patient not in the presence of a licensed veterinarian may only be continued under the direction of a licensed veterinarian. "Emergency" for the purpose of this section, means that the animal has been placed in a life-threatening condition where immediate treatment is ~~necessary to sustain life.~~ *necessary.*

SEC. 12. Section 4887 of the Business and Professions Code is amended to read:

4887. (a) *(1)* A person whose license or registration has been revoked or who has been placed on probation may petition the board for reinstatement or modification of penalty including modification or termination of probation after ~~a period of not less than one year~~ *the period as described below in subparagraphs (A) to (C), inclusive,* has elapsed from the effective date of the decision ordering the disciplinary action. The petition shall state ~~such~~ facts as ~~may be~~ required by the board. *The period shall be as follows:*

(A) At least three years for reinstatement of a surrendered or revoked license.

(B) At least two years for early termination or modification of probation of three years or more.

(C) At least one year for modification of a condition or termination of probation of less than three years.

(2) Notwithstanding paragraph (1), the board may, upon a showing of good cause, specify in a revocation order, a surrender order, or an order imposing probation of more than three years that the person may petition the board for reinstatement or modification or termination of probation after one year.

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SECTION 1. Section 4022.5 of the Business and Professions Code is amended to read:

4022.5. (a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or *designated representative- reverse distributor, or* a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager 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.

SEC. 2. *Section 4022.6 is added to the Business and Professions Code, to read:*

4022.6. "Designated representative-reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

SEC. 3. Section 4040.5 of the Business and Professions Code is amended to read:

4040.5. "Reverse distributor" means every person who acts as an agent for pharmacies, drug wholesalers, third- party logistics providers, manufacturers, and other entities by receiving, inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous ~~drugs.~~ *drugs or dangerous devices.*

SEC. 4. *Section 4053.2 is added to the Business and Professions Code, to read:*

4053.2. (a) Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.

(b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent. (2) He or

she shall meet one of the following requirements:

(A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third- party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.

(B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.

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(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.

(C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.

(c) A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

SEC. 5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ *or in the case of a reverse distributor a designated representative-reverse distributor, that individual* shall 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.

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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.

SEC. 5.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ *or in the case of a reverse distributor a designated representative-reverse distributor, that individual* shall 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) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 6. Section 4100 of the Business and Professions Code is amended to read:

4100. ~~(a)~~ Within 30 days after changing his or her address of record with the board or after changing his or her name according to law, a pharmacist, intern pharmacist, technician, *designated representative, designated representative-3PL,* or designated ~~representative~~ *representative-reverse distributor* shall notify the executive officer of the board of the change of address or change of name.

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

SEC. 7. Section 4160 of the Business and Professions Code is amended to read:

4160. (a) A person shall not act as a wholesaler or third-party logistics provider 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) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third- party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. *A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.*

(2) A wholesaler and a third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider. (G)

The wholesaler is not acting as a reverse distributor.

(d) 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. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative- in-charge. *A wholesaler that only acts as a reverse distributor may identify and allow a designated representative- reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.*

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A 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 the designated representative-in-charge, and shall on the same form propose another ~~designated representative or pharmacist~~ *authorized licensee* to take over as the 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.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises 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.

(i) 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 required in an amount established by the board as specified in subdivision (f) of Section 4400. 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~~ *For* purposes of retaining a temporary license, ~~nor~~ *or* for purposes of any disciplinary or license denial proceeding before the board, ~~shall~~ the temporary licenseholder *shall not* be deemed to have a vested property right or interest in the license.

SEC. 8. Section 4200.4 of the Business and Professions Code is amended to read:

4200.4. An applicant who fails ~~the national examination~~ *either the North American Pharmacist Licensure Examination or the California Practice Standards and Jurisprudence Examination for Pharmacists* may not retake ~~the~~ *that* examination for at least ~~90 days or for a period established by regulations adopted by the board~~ *45 days. The board may,* in consultation with the Office of Professional Examination Services of the ~~department.~~ *department, adopt a regulation establishing a different waiting period to retake the examination.*

SEC. 9. Section 4331 of the Business and Professions Code is amended to read:

4331. (a) A person ~~who is not a pharmacist, a designated representative-in-charge, or a designated representative~~ ~~and~~ *not authorized under this chapter* 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) A person who is not a responsible manager or a designated representative-3PL who takes charge of a third- party logistics provider or coordinates the warehousing or distribution of dangerous drugs or dangerous devices within a third-party logistics provider, except as otherwise provided in this chapter, is guilty of a misdemeanor.

(c) A person licensed as a veterinary food-animal drug retailer that fails to place in charge of that veterinary food- animal drug retailer a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the dispensing of prescriptions, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(d) A person licensed as a wholesaler that fails to place in charge of that wholesaler a pharmacist or designated representative, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a pharmacist or designated representative, or as otherwise provided in this chapter, is guilty of a misdemeanor.

(e) A person licensed as a third-party logistics provider that fails to place in charge of a licensed place of business of the third-party logistics provider a responsible manager, or any person who, by himself or herself, or by any other person, permits the furnishing of dangerous drugs or dangerous devices, except by a facility manager, or as otherwise provided in this chapter, is guilty of a misdemeanor.

SEC. 10. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, ~~or~~ as a designated representative-3PL pursuant to Section 4053.1, *or as a designated representative-reverse distributor pursuant to Section 4053.2* shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

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(2) The fee for the annual renewal of a license as a designated ~~representative~~ *representative, designated representative-3PL,* or designated ~~representative 3PL~~ *representative-reverse distributor* shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) 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.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) 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.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

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(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) This section shall become operative on July 1, 2017.

SEC. 10.5. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, 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) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

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(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, ~~or~~ as a designated representative-3PL pursuant to Section 4053.1, *or as a designated representative-reverse distributor pursuant to Section 4053.2* shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated ~~representative~~ *representative, designated representative-3PL,* or designated ~~representative-3PL~~ *representative-reverse distributor* shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) 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.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

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(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) 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.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license *or a hospital satellite compounding pharmacy* shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the

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license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) This section shall become operative on July 1, 2017.

SEC. 11. Section 5.5 of this bill incorporates amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and Assembly Bill 401. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after Assembly Bill 401, in which case Section 5 of this bill shall not become operative.

SEC. 12. Section 10.5 of this bill incorporates amendments to Section 4400 of the Business and Professions Code proposed by both this bill and Senate Bill 351. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4400 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 351, in which case Section 10 of this bill shall not become operative.

SEC. 13. 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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SECTION 1. (a) The Legislature hereby finds and declares all of the following:

(1) Greater access to health care professionals improves patient outcomes. Patients see their pharmacist more often than any other health care professional. Making pharmacists readily available should be a top priority of the state.

(2) Health care delivery and technology are evolving. Utilizing technology to connect patients to pharmacists in areas where there is no access will improve medication adherence and outcomes.

(3) Over 30 percent of patients never fill their prescriptions. According to a study by Kaiser, this number drops to 5 percent when patients have more convenient access to a pharmacy. Lack of convenient access to a pharmacy leads to lower rates of medication adherence and, according to the New England Healthcare Institute, nonadherence leads to over $290 billion in avoidable medial spending each year.

(4) Seventy-seven percent of rural counties are designated as health professional shortage areas. In California there are 115 identified areas located in 47 counties where the closest pharmacy is more than 10 miles away.

(5) In rural communities, the geographic and economic realities make it difficult to maintain a pharmacy. Between 2003 and 2013, there was a 12.1-percent decrease in rural pharmacies. Remote dispensing site pharmacies create an economically feasible way to bring pharmacy access to these underserved areas through the use of technology.

(b) The Legislature further finds and declares both of the following:

(1) Section 4001.1 of the Business and Professions Code establishes public protection as the highest priority of the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. That section further provides that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

(2) Public protection requires the California State Board of Pharmacy to enforce the laws related to a supervising pharmacy, as defined by Section 4044.6 of the Business and Professions Code, and a remote dispensing site pharmacy, as defined in Section 4044.3 of the Business and Professions Code, through licensure.

(c) It is the intent of the Legislature to enact legislation that will promote policies to allow all California patients, regardless of location, to have access to a pharmacist, thereby increasing medication adherence.

SEC. 2. *Section 4044.3 is added to the Business and Professions Code, to read:*

4044.3. (a) "Remote dispensing site pharmacy" means a licensed pharmacy located in this state that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians, as defined in Section 4132, where pharmaceutical care services, including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling, are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

(b) Unless otherwise specified in this chapter, a remote dispensing site pharmacy shall comply with all state and federal laws regulating the practice of pharmacy.

SEC. 3. *Section 4044.6 is added to the Business and Professions Code, to read:*

4044.6. (a) "Supervising pharmacy" means a licensed pharmacy located in this state that is owned and operated by a person or persons where the majority of the beneficial interest in, as well as the management and control, resides with at least one board-licensed pharmacist, as defined in Section 4036, that exclusively oversees the operations of a remote dispensing site pharmacy.

(b) A supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing site pharmacy and its employees pursuant to Section 4131.

SEC. 4. *Section 4044.7 is added to the Business and Professions Code, to read:*

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4044.7. "Telepharmacy" means a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy and provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.

SEC. 5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall 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) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 5.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ *or in the case of a reverse distributor a designated representative-reverse distributor, that individual* shall 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) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

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controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 6. Section 4107 of the Business and Professions Code is amended to read:

4107. (a) The board shall not issue more than one site license to a single premises except as follows: (1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196. (2) To issue a license to compound sterile drugs to a pharmacy pursuant to Section 4127.1 or 4127.2. (3) To issue a centralized hospital packaging license pursuant to Section 4128.

(4) To issue licenses to two independently owned clinics that share a clinic office space pursuant to Section 4180.5.

(b) For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

SEC. 7. *Article 8 (commencing with Section 4130) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:*

Article 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies

4130. (a) A telepharmacy system shall be used for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at a remote dispensing site pharmacy.

(b) If all of the requirements of this article and other relevant provisions of this chapter are met, the board shall issue a remote dispensing site pharmacy license for the purpose of increasing access to dispensing or pharmaceutical care services in the geographic area in which the remote dispensing site pharmacy is to be located.

(c) (1) A remote dispensing site pharmacy shall only be located in a medically underserved area unless otherwise approved by the board. For purposes of this section, a "medically underserved area" means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site.

(2) Notwithstanding paragraph (1), if a pharmacy serving the general public is later established within 10 road miles of a remote dispensing site pharmacy, the remote dispensing site pharmacy may continue to operate.

(d) A remote dispensing site pharmacy shall only be staffed by pharmacists or pharmacy technicians, or both, and shall not employ any unlicensed personnel.

(e) A remote dispensing site pharmacy license shall be issued only to the supervising pharmacy. A supervising pharmacy shall not obtain more than one remote dispensing site pharmacy license.

(f) A remote dispensing site pharmacy shall not be operated by the state and shall not be located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. This section shall not be construed to preclude a pharmacist who is otherwise eligible to operate a remote dispensing site pharmacy pursuant to this section from leasing space in property owned by the state, provided it is not for the purpose of serving individuals otherwise served by pharmacists and pharmacy technicians employed by the state.

(g) A remote dispensing site pharmacy shall not be located or operated for the purpose of displacing state employees.

(h) If a remote dispensing site pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year, it shall cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy.

4131. (a) A supervising pharmacy shall provide telepharmacy services for only one remote dispensing site pharmacy.

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(b) A supervising pharmacy shall not be located greater than 150 road miles from a remote dispensing site pharmacy, unless otherwise approved by the board.

(c) A supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.

(d) Unless staffed by a pharmacist, a remote dispensing site pharmacy shall be staffed by at least one registered pharmacy technician meeting the qualifications of Section 4132. A technician shall remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. For the purposes of this article, direct supervision and control does not require the pharmacist to be physically present at the remote dispensing site pharmacy, but the pharmacist shall use a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy.

(e) Notwithstanding any other law, a pharmacist may serve as the pharmacist-in-charge for a pharmacy in addition to serving as pharmacist-in-charge of a supervising pharmacy. The designated pharmacist-in-charge of the supervising pharmacy shall also serve as the designated pharmacist-in-charge at the remote dispensing site pharmacy.

(f) Notwithstanding any other law, the pharmacist-in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy shall be responsible for ensuring that both the supervising pharmacy and remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.

4132. (a) In addition to the requirements of Section 4202, a pharmacy technician working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians working at remote dispensing sites.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion. (7)

Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

4133. (a) A telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients.

(b) A telepharmacy system shall facilitate adequate pharmacist supervision and allow the appropriate exchange of visual, verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs.

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(c) Patient counseling shall be provided using audio-visual communication prior to all prescriptions being dispensed from a remote dispensing site pharmacy.

(d) A telepharmacy system shall be able to do all of the following:

(1) Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.

(2) Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription.

(3) Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed.

(4) Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing.

(5) Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery.

(e) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191).

(f) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription.

4134. (a) A pharmacist from the supervising pharmacy shall complete a monthly in-person, self-inspection of each remote dispensing site pharmacy using a form designated by the board and shall retain all inspection reports.

(b) A perpetual inventory shall be kept for all controlled substances stored at a remote dispensing site pharmacy. (c) All controlled substances at a remote dispensing site pharmacy shall be stored in a secure cabinet or safe that is locked.

(d) A pharmacist from the supervising pharmacy shall perform inventory and inventory reconciliation functions at a remote dispensing site pharmacy to detect and prevent the loss of any controlled substance.

(e) The pharmacist-in-charge of a remote dispensing site pharmacy shall review all inventory and inventory reconciliation reports taken and shall establish and maintain secure methods to prevent losses of any controlled substance. The board shall develop written policies and procedures for performing the inventory reconciliation reports required by this section.

(f) A pharmacist from the supervising pharmacy shall compile an inventory reconciliation report of all Schedule II controlled substances at a remote dispensing site pharmacy at least once every three months. This compilation shall require all of the following:

(1) A physical count, not an estimate, of all quantities of Schedule II controlled substances at the remote dispensing site pharmacy. The biennial inventory of controlled substances as required under federal law may serve as one of the mandated inventories under this section in the year that the federal biennial inventory is performed, provided that the biennial inventory was taken no more than three months from the last inventory required by this section.

(2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last inventory reconciliation report.

(3) A comparison of paragraphs (1) and (2) in order to determine if there are any variances.

(4) All records used to compile each inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

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(g) A remote dispensing site pharmacy shall report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss. If the remote dispensing site pharmacy is unable to identify the cause of the loss, the remote dispensing site pharmacy shall undertake further investigation to identify the cause of the loss and security improvements necessary to prevent any additional losses of controlled substances. The pharmacist-in-charge shall be responsible for submitting the report to the board.

(h) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(i) The inventory reconciliation report shall be dated and signed by the individual or individuals performing the inventory and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy. A countersignature shall not be required if the pharmacist-in-charge personally completed the inventory reconciliation report. The inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

4135. (a) While closed, a remote dispensing site pharmacy shall utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(b) Unless a pharmacist is present at the remote dispensing site pharmacy, a remote dispensing site pharmacy shall not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system shall allow for tracking of entries into the remote dispensing site pharmacy and the pharmacist-in- charge shall periodically review the record of entries. Pharmacy services shall not be provided at a remote dispensing site pharmacy if the telepharmacy system is unavailable.

(c) The remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 120 days.

SEC. 8. *Section 4169.1 is added to the Business and Professions Code, immediately following Section 4169, to read:*

4169.1. A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

SEC. 9. *Section 4180.5 is added to the Business and Professions Code, to read:*

4180.5. (a) The board may issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space, provided that the clinics comply with the following:

(1) Each clinic maintains a separate clinic license with the board with its own professional directors, administrators, owners, and officers.

(2) Each clinic maintains physically separate and locked drug stocks.

(3) Each clinic separately maintains all records required by this article, including acquisition and disposition records.

(4) Dangerous drugs and dangerous devices shall not be loaned between the two licensed clinics.

(b) Dangerous drugs and dangerous device losses at the shared clinic office shall be reported to the board as required by law. Each clinic may be jointly and severally responsible for the drug losses.

(c) The applicants shall also provide the board with a copy of the co-location agreement and a one-time application fee of seven hundred fifty dollars ($750) for the licenses.

(d) Any change in ownership in either clinic shall require a new application under this section and fees as required by subdivision (q) of Section 4400 and subdivision (c) of this section.

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SECTION 1. (a) The Legislature hereby finds and declares all of the following:

(1) Greater access to health care professionals improves patient outcomes. Patients see their pharmacist more often than any other health care professional. Making pharmacists readily available should be a top priority of the state.

(2) Health care delivery and technology are evolving. Utilizing technology to connect patients to pharmacists in areas where there is no access will improve medication adherence and outcomes.

(3) Over 30 percent of patients never fill their prescriptions. According to a study by Kaiser, this number drops to 5 percent when patients have more convenient access to a pharmacy. Lack of convenient access to a pharmacy leads to lower rates of medication adherence and, according to the New England Healthcare Institute, nonadherence leads to over $290 billion in avoidable medial spending each year.

(4) Seventy-seven percent of rural counties are designated as health professional shortage areas. In California there are 115 identified areas located in 47 counties where the closest pharmacy is more than 10 miles away.

(5) In rural communities, the geographic and economic realities make it difficult to maintain a pharmacy. Between 2003 and 2013, there was a 12.1-percent decrease in rural pharmacies. Remote dispensing site pharmacies create an economically feasible way to bring pharmacy access to these underserved areas through the use of technology.

(b) The Legislature further finds and declares both of the following:

(1) Section 4001.1 of the Business and Professions Code establishes public protection as the highest priority of the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. That section further provides that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

(2) Public protection requires the California State Board of Pharmacy to enforce the laws related to a supervising pharmacy, as defined by Section 4044.6 of the Business and Professions Code, and a remote dispensing site pharmacy, as defined in Section 4044.3 of the Business and Professions Code, through licensure.

(c) It is the intent of the Legislature to enact legislation that will promote policies to allow all California patients, regardless of location, to have access to a pharmacist, thereby increasing medication adherence.

SEC. 2. *Section 4044.3 is added to the Business and Professions Code, to read:*

4044.3. (a) "Remote dispensing site pharmacy" means a licensed pharmacy located in this state that is exclusively overseen and operated by a supervising pharmacy and staffed by one or more qualified registered pharmacy technicians, as defined in Section 4132, where pharmaceutical care services, including, but not limited to, the storage and dispensing of prescription drugs and controlled substances, drug regimen review, and patient counseling, are remotely monitored or provided, or both, by a licensed pharmacist through the use of telepharmacy technology.

(b) Unless otherwise specified in this chapter, a remote dispensing site pharmacy shall comply with all state and federal laws regulating the practice of pharmacy.

SEC. 3. *Section 4044.6 is added to the Business and Professions Code, to read:*

4044.6. (a) "Supervising pharmacy" means a licensed pharmacy located in this state that is owned and operated by a person or persons where the majority of the beneficial interest in, as well as the management and control, resides with at least one board-licensed pharmacist, as defined in Section 4036, that exclusively oversees the operations of a remote dispensing site pharmacy.

(b) A supervising pharmacy shall be exclusively responsible for the operation of the remote dispensing site pharmacy and its employees pursuant to Section 4131.

SEC. 4. *Section 4044.7 is added to the Business and Professions Code, to read:*

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4044.7. "Telepharmacy" means a system that is used by a supervising pharmacy for the purpose of monitoring the dispensing of prescription drugs by a remote dispensing site pharmacy and provides for related drug regimen review and patient counseling by an electronic method, including, but not limited to, the use of audio, visual, still image capture, and store and forward technology.

SEC. 5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall 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) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 5.5. Section 4059.5 of the Business and Professions Code is amended to read:

4059.5. (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, ~~the designated representative~~ *or in the case of a reverse distributor a designated representative-reverse distributor, that individual* shall 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) Notwithstanding subdivision (a), dangerous drugs and devices and controlled substances may be ordered by a remote dispensing site pharmacy licensed by the board and may be signed for and received by a registered pharmacy technician, who meets the qualifications of Section 4132, at the remote site. A controlled substance signed for by a pharmacy technician under this section shall be stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. Any receipt and storage of a

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controlled substance by a pharmacy technician pursuant to this section shall be captured on video, and that video shall be made accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days.

SEC. 6. Section 4107 of the Business and Professions Code is amended to read:

4107. (a) The board shall not issue more than one site license to a single premises except as follows: (1) To issue a veterinary food-animal drug retailer license to a wholesaler pursuant to Section 4196. (2) To issue a license to compound sterile drugs to a pharmacy pursuant to Section 4127.1 or 4127.2. (3) To issue a centralized hospital packaging license pursuant to Section 4128.

(4) To issue licenses to two independently owned clinics that share a clinic office space pursuant to Section 4180.5.

(b) For the purposes of this subdivision, "premises" means a location with its own address and an independent means of ingress and egress.

SEC. 7. *Article 8 (commencing with Section 4130) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:*

Article 8. Telepharmacy Systems and Remote Dispensing Site Pharmacies

4130. (a) A telepharmacy system shall be used for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at a remote dispensing site pharmacy.

(b) If all of the requirements of this article and other relevant provisions of this chapter are met, the board shall issue a remote dispensing site pharmacy license for the purpose of increasing access to dispensing or pharmaceutical care services in the geographic area in which the remote dispensing site pharmacy is to be located.

(c) (1) A remote dispensing site pharmacy shall only be located in a medically underserved area unless otherwise approved by the board. For purposes of this section, a "medically underserved area" means a location that does not have a pharmacy that serves the general public within 10 road miles of the remote dispensing site.

(2) Notwithstanding paragraph (1), if a pharmacy serving the general public is later established within 10 road miles of a remote dispensing site pharmacy, the remote dispensing site pharmacy may continue to operate.

(d) A remote dispensing site pharmacy shall only be staffed by pharmacists or pharmacy technicians, or both, and shall not employ any unlicensed personnel.

(e) A remote dispensing site pharmacy license shall be issued only to the supervising pharmacy. A supervising pharmacy shall not obtain more than one remote dispensing site pharmacy license.

(f) A remote dispensing site pharmacy shall not be operated by the state and shall not be located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. This section shall not be construed to preclude a pharmacist who is otherwise eligible to operate a remote dispensing site pharmacy pursuant to this section from leasing space in property owned by the state, provided it is not for the purpose of serving individuals otherwise served by pharmacists and pharmacy technicians employed by the state.

(g) A remote dispensing site pharmacy shall not be located or operated for the purpose of displacing state employees.

(h) If a remote dispensing site pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year, it shall cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy.

4131. (a) A supervising pharmacy shall provide telepharmacy services for only one remote dispensing site pharmacy.

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(b) A supervising pharmacy shall not be located greater than 150 road miles from a remote dispensing site pharmacy, unless otherwise approved by the board.

(c) A supervising pharmacy and remote dispensing site pharmacy shall be under common ownership.

(d) Unless staffed by a pharmacist, a remote dispensing site pharmacy shall be staffed by at least one registered pharmacy technician meeting the qualifications of Section 4132. A technician shall remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. For the purposes of this article, direct supervision and control does not require the pharmacist to be physically present at the remote dispensing site pharmacy, but the pharmacist shall use a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy.

(e) Notwithstanding any other law, a pharmacist may serve as the pharmacist-in-charge for a pharmacy in addition to serving as pharmacist-in-charge of a supervising pharmacy. The designated pharmacist-in-charge of the supervising pharmacy shall also serve as the designated pharmacist-in-charge at the remote dispensing site pharmacy.

(f) Notwithstanding any other law, the pharmacist-in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy shall be responsible for ensuring that both the supervising pharmacy and remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare.

4132. (a) In addition to the requirements of Section 4202, a pharmacy technician working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians working at remote dispensing sites.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or his or her agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion. (7)

Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

4133. (a) A telepharmacy system shall maintain a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients.

(b) A telepharmacy system shall facilitate adequate pharmacist supervision and allow the appropriate exchange of visual, verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs.

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(c) Patient counseling shall be provided using audio-visual communication prior to all prescriptions being dispensed from a remote dispensing site pharmacy.

(d) A telepharmacy system shall be able to do all of the following:

(1) Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription.

(2) Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription.

(3) Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed.

(4) Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing.

(5) Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery.

(e) The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act (Public Law 104-191).

(f) All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription.

4134. (a) A pharmacist from the supervising pharmacy shall complete a monthly in-person, self-inspection of each remote dispensing site pharmacy using a form designated by the board and shall retain all inspection reports.

(b) A perpetual inventory shall be kept for all controlled substances stored at a remote dispensing site pharmacy. (c) All controlled substances at a remote dispensing site pharmacy shall be stored in a secure cabinet or safe that is locked.

(d) A pharmacist from the supervising pharmacy shall perform inventory and inventory reconciliation functions at a remote dispensing site pharmacy to detect and prevent the loss of any controlled substance.

(e) The pharmacist-in-charge of a remote dispensing site pharmacy shall review all inventory and inventory reconciliation reports taken and shall establish and maintain secure methods to prevent losses of any controlled substance. The board shall develop written policies and procedures for performing the inventory reconciliation reports required by this section.

(f) A pharmacist from the supervising pharmacy shall compile an inventory reconciliation report of all Schedule II controlled substances at a remote dispensing site pharmacy at least once every three months. This compilation shall require all of the following:

(1) A physical count, not an estimate, of all quantities of Schedule II controlled substances at the remote dispensing site pharmacy. The biennial inventory of controlled substances as required under federal law may serve as one of the mandated inventories under this section in the year that the federal biennial inventory is performed, provided that the biennial inventory was taken no more than three months from the last inventory required by this section.

(2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last inventory reconciliation report.

(3) A comparison of paragraphs (1) and (2) in order to determine if there are any variances.

(4) All records used to compile each inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

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(g) A remote dispensing site pharmacy shall report to the board, in writing, any identified losses of controlled substances and possible causes of the loss within 30 days of discovering the loss unless the cause of loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovering the loss. If the remote dispensing site pharmacy is unable to identify the cause of the loss, the remote dispensing site pharmacy shall undertake further investigation to identify the cause of the loss and security improvements necessary to prevent any additional losses of controlled substances. The pharmacist-in-charge shall be responsible for submitting the report to the board.

(h) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(i) The inventory reconciliation report shall be dated and signed by the individual or individuals performing the inventory and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy. A countersignature shall not be required if the pharmacist-in-charge personally completed the inventory reconciliation report. The inventory reconciliation report shall be maintained in the remote dispensing site pharmacy for at least three years in a readily retrievable form.

4135. (a) While closed, a remote dispensing site pharmacy shall utilize an alarm or other comparable monitoring system to protect its equipment, records, and supply of drugs, devices, and other restricted sale items from unauthorized access, acquisition, or use.

(b) Unless a pharmacist is present at the remote dispensing site pharmacy, a remote dispensing site pharmacy shall not be open or its employees allowed access to it during times the supervising pharmacy is closed. The security system shall allow for tracking of entries into the remote dispensing site pharmacy and the pharmacist-in- charge shall periodically review the record of entries. Pharmacy services shall not be provided at a remote dispensing site pharmacy if the telepharmacy system is unavailable.

(c) The remote dispensing site pharmacy shall retain a recording of facility surveillance, excluding patient communications, for a minimum of 120 days.

SEC. 8. *Section 4169.1 is added to the Business and Professions Code, immediately following Section 4169, to read:*

4169.1. A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

SEC. 9. *Section 4180.5 is added to the Business and Professions Code, to read:*

4180.5. (a) The board may issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space, provided that the clinics comply with the following:

(1) Each clinic maintains a separate clinic license with the board with its own professional directors, administrators, owners, and officers.

(2) Each clinic maintains physically separate and locked drug stocks.

(3) Each clinic separately maintains all records required by this article, including acquisition and disposition records.

(4) Dangerous drugs and dangerous devices shall not be loaned between the two licensed clinics.

(b) Dangerous drugs and dangerous device losses at the shared clinic office shall be reported to the board as required by law. Each clinic may be jointly and severally responsible for the drug losses.

(c) The applicants shall also provide the board with a copy of the co-location agreement and a one-time application fee of seven hundred fifty dollars ($750) for the licenses.

(d) Any change in ownership in either clinic shall require a new application under this section and fees as required by subdivision (q) of Section 4400 and subdivision (c) of this section.

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(e) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to this section until the board is provided with documentation from the Director of the Department of Health Care Services that any Medi-Cal financing issues, including the ability to claim associated federal financial participation or 340(b) program participation, have been sufficiently addressed to the director's satisfaction. The Department of Health Care Services may seek any federal approvals it deems necessary to implement this section.

(f) The board shall not issue licenses authorized under Section 4180 to two independently owned clinics that share a clinic office space pursuant to the section until the board is provided with documentation from the Director of the Department of Public Health that any licensing and regulatory issues have been sufficiently addressed to the director's satisfaction.

(g) This section shall become inoperative on January 1, 2021, and as of that date is repealed.

SEC. 10. *Section 1211 is added to the Health and Safety Code, to read:*

1211. (a) Notwithstanding any other law, a clinic licensed pursuant to Section 1204 may operate in shared clinic space with a clinic exempt from licensure pursuant to subdivision (b) of Section 1206 under the following conditions:

(1) Each clinic uses signage that clearly identifies which clinic is operating during the hours of operation. (2) The

licensed clinic reports the operating hours of both clinics.

(3) Each clinic maintains separate medical records. (4)

Each clinic maintains separate drug storage.

(5) Both clinics are licensed by the California State Board of Pharmacy pursuant to Section 4180.5 of the Business and Professions Code.

(b) The department may enter and inspect the shared space at any time pursuant to Section 1227 of the Health and Safety Code, including accessing records. The exempt clinic shall allow the department to access and inspect its records.

(c) The licensed clinic shall be responsible for any statutory or regulatory violations occurring on the premises.

(d) Notwithstanding the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code), the department may implement, interpret, or make specific this section by means of all-facility letters, or similar instructions, without taking regulatory action.

(e) This section shall become inoperative on January 1, 2021, and as of that date is repealed.

SEC. 11. Section 5.5 of this bill incorporates amendments to Section 4059.5 of the Business and Professions Code proposed by both this bill and Senate Bill 752. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2018, (2) each bill amends Section 4059.5 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 752, in which case Section 5 of this bill shall not become operative.

SEC. 12. 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.