



## LEGISLATION AND REGULATION COMMITTEE CHAIR REPORT

Greg Lippe, Public Member, Chair  
Lavanza Butler, Licensee Member, Vice Chair  
Ryan Brooks, Public Member  
Shirley Kim, Public Member  
Maria Serpa, Licensee Member

a. **Call to Order and Establishment of a Quorum**

b. **Public Comment for Items Not on the Agenda, Matters for Future Meetings**

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

c. **Discussion and Consideration of Board Sponsored Legislation**

**Attachment 1**

The governor signed all of the board-sponsored measures this year.

1. **AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications**

**Summary:** As amended this measure includes the board's provision that establishes the limited exemption to the license transferability requirements for a pharmacy required to locate because of damage caused by a declared disaster. This measure also includes the requirements for a pharmacy technician working in a remote dispensing site pharmacy.

2. **AB 973 (Irwin, Chapter 184, Statutes of 2019) Pharmacies: Compounding**

**Summary:** Requires the compounding of drug preparations by a pharmacy to be prepared consistent with the relevant compounding chapters of the United States Pharmacopeia-National Formulary.

3. **SB 569 (Stone, Chapter 705, Statutes of 2019) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency**

**Summary:** Authorizes a pharmacist, during a declared local, state, or federal emergency to fill a prescription for a controlled substance on a prescription form that does not conform with security prescription form requirements under specified conditions.

4. SB 655 (Roth, Chapter 213, Statutes of 2019) Pharmacy

**Summary:** Updates several provisions of pharmacy law including alignment of application and renewal requirements and other technical cleanup provisions relating to the following areas:

- Validity period for pharmacy examination scores
- Pharmacy technician trainee provisions
- Advanced practice pharmacist renewal requirements
- Reverse distributor provisions
- Government-owned facility fees

**Attachment 1** includes a copy of each of the measures. They can also be accessed using the following link - - <http://leginfo.legislature.ca.gov>.

d. Chapter Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction or Board Operations

**Attachment 2 and 3**

Several measures were signed this year that impact the board's jurisdiction.

1. AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database

**Board Position:** Support if amended

**Summary:** Requires expanding reporting requirements to also include Schedule V drugs and reduces the reporting period to CURES to within one business day.

2. AB 1076 (Ting, Chapter 578, Statutes of 2019) Criminal Records: Automatic Relief

**Board Position:** Oppose Unless Amended

**Summary:** Requires the DOJ to review summary criminal history information and identify individuals who are eligible for automatic relief by having their arrest and criminal records withheld from disclosure. It also requires the DOJ to provide automatic relief to eligible persons.

3. AB 1264 (Petrie-Norris, Chapter 741, Statutes of 2019) Medical Practice Act: Dangerous Drugs: Appropriate Prior Examination

**Board Position:** None

**Summary:** Specifies that an appropriate prior examination does not require a synchronous interaction between a patient and licensee, provided the licensee complies with the appropriate standard of care.

4. SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure and Postexposure Prophylaxis

**Board Position:** Support

**Summary:** Authorizes a pharmacist to furnish preexposure and postexposure prophylaxis in specified amounts and under specified conditions. Also requires the board to promulgate regulations establishing the training program requirements specified in the bill.

5. SB 601 (Morrell, Chapter 854, Statutes of 2019) State Agencies: Licenses: Fee Waiver

**Board Position:** Support

**Summary:** Requires an individual or business that has been displaced or affected by a declared federal emergency or proclaimed state emergency, to submit an application for reduction or waiver of fees required to renew, activate, or replace a license.

**Attachment 2** includes a copy of each of the measures. They can also be accessed using the following link - - <http://leginfo.legislature.ca.gov>.

**Attachment 3** includes a compilation of changes to relevant sections of the Business and Professions Code, Health and Safety Code, and Civil Code. This information will also be posted to the board's website.

e. Discussion and Consideration of Board Approved Regulations Undergoing Final Review by the Office of Administrative Law

**Attachment 4**

1. Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule

**Summary of Regulation:** This proposal updates the board's fee schedule by increasing the board's fees to address the structural imbalance within the board's budget.

**Status:** Submitted to OAL for Final Review: September 30, 2019. The board requested an April 1, 2020 effective date.

f. **Discussion and Consideration of Board Approved Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency**

**Attachment 5**

1. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

**Summary of Regulation:** This proposal amends the board's regulations regarding the naloxone fact sheet that must be provided to consumers upon furnishing naloxone hydrochloride.

**Status:** Board adopted June 21, 2019. Formal post-adoption review began August 28, 2019.

g. **Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency**

**Attachment 6**

Provided below is a summary of each of the regulations currently undergoing pre-notice review. As there are many steps included in the pre-review process, the status is detailed below. Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30 days are indicated below in **red**. The full timelines for each of the regulation are included in **Attachment 6**.

1. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

**Summary of Regulation:**

This proposal updates the renewal requirement language to include all licensing programs and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

**Status:**

**Returned to Board Staff on July 23, 2019**

2. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

**Summary of Regulation:**

This proposal amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those cited for a records violation to receive a waiver to store records off-site.

**Status:**

**Re-submitted to DCA for Formal Pre-Notice Review: April 9, 2019**

3. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

**Summary of Regulation:**

This proposal establishes regulatory requirements for automated refill programs.

**Status:**

**Formal DCA Pre-Notice Review began: December 5, 2018**

4. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

**Summary of Regulation:**

This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

**Status:**

**Re-submitted to DCA for Pre-Notice Review: October 26, 2018**

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

**Summary of Regulation:**

This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

**Status:**

**Re-submitted to DCA for Pre-Notice Review: December 20, 2018**

6. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

**Summary of Regulation:**

This proposal establishes the regulatory framework for third-party logistics providers.

**Status:**

**Re-submitted to DCA for Pre-Notice Review: December 20, 2018**

7. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

**Summary of Regulation:**

This proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

**Status:**

**Re-submitted to DCA for Pre-Notice Review: December 24, 2018**

*The Board approved self-assessment forms can be found on the Board's website:*

[https://www.pharmacy.ca.gov/licensees/facility/self\\_assess.shtml](https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml)

8. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

**Summary of Regulation:**

This proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

**Status:**

**Submitted to DCA for Pre-Notice Review: December 26, 2018**

*The Board approved self-assessment forms can be found on the Board's website:*

[https://www.pharmacy.ca.gov/licensees/facility/self\\_assess.shtml](https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml)

9. Proposed Regulations to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to ADDS Self-Assessment Form 17M-112

**Summary of Regulation:**

This proposal will require submission of quality assurance records to the board, update the board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form.

**Status:**

**Submitted to DCA for Pre-Notice Review: April 30, 2019**

10. Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria

**Summary of Regulation:**

This proposal will increase transparency and clarity to license applicants with respect to rehabilitation criteria the board considers when evaluating an applicant's eligibility for licensure.

**Status:**

**Submitted to DCA for Pre-Notice Review: May 31, 2019**

11. Proposed Regulations to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing

**Summary of Regulation:**

This proposal will require establish the criteria a pharmacy must meet to identify and ensure a person is assigned to assist the pharmacist as needed when the pharmacist is working as alone in compliance with B&P section 4113.5.

**Status:**

**Submitted to DCA for Pre-Notice Review: August 26, 2019**

12. Proposed Regulations to Amend Title 16 CCR Sections 1735 *et seq.* Related to Pharmaceutical Compounding of Nonsterile Preparations

**Summary of Regulation:**

This proposal will align the board nonsterile compounding regulations with United States Pharmacopeia Chapter 795 Pharmaceutical Compounding-Nonsterile Preparations (USP 795) guidelines, which were revised and published on June 1, 2019 and go into effect on December 1, 2019.

**Status:**

**Submitted to DCA for Pre-Notice Review: September 3, 2019**

**h. Future Committee Meeting Dates**

The committee will meet as part of the January 2020 and May 2020 Board Meetings.

# Attachment 1



## **Assembly Bill No. 690**

### **CHAPTER 679**

Approved by Governor: October 9, 2019.

Filed with Secretary of State: October 9, 2019.

#### **SECTION 1.**

Section 4062 of the Business and Professions Code is amended to read:

#### **4062.**

(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

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

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

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

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

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

*(e) (1) A pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, may be relocated. The relocation shall not be considered a transfer of ownership or location under Section 4110, if no changes are made to the management and control, or ownership, of the pharmacy and all applicable laws and regulations are followed. Notification of the relocation shall be provided to the board immediately upon identification of the new location.*

*(2) For purposes of this section, "severely damaged" means damage that renders the premises unsafe or unfit for entry or occupation.*

## **SEC. 2.**

Section 4132 of the Business and Professions Code is amended to read:

### **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 *satisfy each of the following requirements before* ~~only apply to pharmacy technicians~~ working at *a* remote dispensing sites *pharmacy*.

*(1) Possess a pharmacy technician license that is in good standing.*

*(2) Possess and maintain a certification issued by a board-approved pharmacy technician certification program.*

*(3) Possess one of the following:*

*(A) A minimum of an associate degree in pharmacy technology.*

*(B) A minimum of a bachelor's degree in any subject.*

*(C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.*

*(4) Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.*

(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~~ *their* agent regarding a prescription, either before 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.

### **SEC. 3.**

*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.*

### **SEC. 4.**

*This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:*

*In order to address the public health and safety impact that recent declared federal, state, and local emergencies have had on consumers and pharmacies, especially in medically underserved areas of the state where remote dispensing site pharmacies operate, and in order to be prepared for other declared emergencies that may occur during the upcoming wildfire season which may necessitate the relocation of pharmacies, as soon as possible, it is necessary for this act to go into effect immediately.*

## **Assembly Bill No. 973**

### **CHAPTER 184**

Approved by Governor: August 30, 2019.

Filed with Secretary of State: August 30, 2019.

#### **SECTION 1.**

*Section 4126.8 is added to the Business and Professions Code, to read:*

#### **4126.8.**

*The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.*

#### **SEC. 2.**

*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.*

## **Senate Bill No. 569**

### **CHAPTER 705**

Approved by Governor: October 9, 2019.

Filed with Secretary of State: October 9, 2019.

#### **SECTION 1.**

*Section 11159.3 is added to the Health and Safety Code, to read:*

**11159.3.**

*(a) Notwithstanding any other law, during a declared local, state, or federal emergency, if the California State Board of Pharmacy issues a notice that the board is waiving the application of the provisions of, or regulations adopted pursuant to, the Pharmacy Law, as specified in subdivision (b) of Section 4062 of the Business and Professions Code, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription form meets the requirements of Section 11162.1, if the prescription meets the following requirements:*

*(1) Contains the information specified in subdivision (a) of Section 11164.*

*(2) Indicates that the patient is affected by a declared emergency with the words “11159.3 exemption” or a similar statement.*

*(3) Is written and dispensed within the first two weeks of the notice issued by the board.*

*(b) A pharmacist filling a prescription pursuant to this section shall do all of the following:*

*(1) Exercise appropriate professional judgment, including reviewing the patient’s activity report from the CURES Prescription Drug Monitoring Program before dispensing the medication.*

*(2) If the prescription is for a Schedule II controlled substance, dispense no greater than the amount needed for a seven-day supply.*

*(3) Require the patient to first demonstrate, to the satisfaction of the pharmacist, their inability to access medications. This demonstration may include, but is not limited to, verification of residency within an evacuation area.*

*(c) A pharmacist shall not refill a prescription that has been dispensed pursuant to this section.*

**Senate Bill No. 655**

**CHAPTER 213**

Approved by Governor: August 30, 2019.

Filed with Secretary of State: August 30, 2019.

**SECTION 1.**

Section 4115.5 of the Business and Professions Code is amended to read:

#### **4115.5.**

(a) Notwithstanding any other ~~provision of~~ law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no *fewer than 120 hours and no* more than ~~120~~ *140* hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to ~~320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.~~ *340 hours.*

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates ~~his or her trainee status.~~ *the pharmacy technician trainee's status as a trainee.*

#### **SEC. 2.**

Section 4163 of the Business and Professions Code is amended to read:

**4163.**

(a) A manufacturer, wholesaler, repackager, or pharmacy ~~may~~ *shall* not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) ~~Dangerous- Except as provided in subdivision (c), dangerous~~ drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

*(c) Upon approval of the board, a reverse distributor licensed as a wholesaler may acquire a dangerous drug or dangerous device from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drug or dangerous device.*

**SEC. 3.**

Section 4200 of the Business and Professions Code is amended to read:

**4200.**

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed ~~the North American Pharmacist Licensure Examination and the~~ *a version of the* California Practice Standards and Jurisprudence Examination for Pharmacists ~~on or after January 1, 2004.~~ *that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure and the applicant meets either of the following requirements:*

*(A) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and holds an active pharmacist license in another state or territory of the United States.*

*(B) Has passed the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure.*

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

#### **SEC. 4.**

*Section 4211 is added to the Business and Professions Code, to read:*

#### **4211.**

*(a) An applicant for renewal of an advanced practice pharmacist recognition shall maintain a current and active pharmacist license, and shall submit all of the following as part of the renewal:*

*(1) Application and payment of the renewal fees.*

*(2) (A) Proof satisfactory to the board that the licensee has completed 10 hours of continuing education pursuant to Section 4233.*

*(B) The 10 hours shall be in addition to the continuing education requirements necessary for a pharmacist license renewal pursuant to Section 4231.*

*(C) An advanced practice pharmacist shall retain documentation of completion of continuing education for four years.*

*(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an advanced practice pharmacist recognition.*

*(c) The board may issue an inactive advanced practice pharmacist recognition under any of the following conditions:*

*(1) The pharmacist's license becomes inactive.*

*(2) The advanced practice pharmacist fails to provide documentation of the completion of the required continuing education.*

*(3) As part of an investigation or audit conducted by the board, the advanced practice pharmacist fails to provide documentation substantiating the completion of continuing education.*



*(d) The board shall reactivate an inactive advanced practice pharmacist recognition only if the advanced practice pharmacist pays the required renewal fees pursuant to Section 4210, submits satisfactory proof to the board of completion of the continuing education requirements under Section 4233, and meets all renewal requirements in this section.*

**SEC. 5.**

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

**4400.**

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

(a) 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, 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, designated representative-3PL, or designated 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,~~ *processing an application to change information on a premises license record* 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) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars (\$325) and may be increased to three hundred sixty dollars (\$360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250). The fee for the annual renewal of the license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250).

*(ab) This section shall become inoperative on July 1, 2021, and, as of January 1, 2022, is repealed.*

#### **SEC. 6.**

*Section 4400 is added to the Business and Professions Code, to read:*

#### **4400.**

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

*(a) The fee for a 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*

*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 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 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, 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, designated representative-3PL, or designated 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 processing an application to change information on a premises license record 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 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 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) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars (\$325) and may be increased to three hundred sixty dollars (\$360).*

*(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250). The fee for the annual renewal of the license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250).*

*(ab) This section shall become operative on July 1, 2021.*



# Attachment 2

## Assembly Bill No. 528

### CHAPTER 677

Approved by Governor: October 9, 2019

Filed with Secretary of State: October 9, 2019.

#### **SECTION 1.**

*It is the intent of the Legislature that state laws regarding the operation and use of prescription drug monitoring programs continue to empower health care-oriented technology solutions to the opioid crisis.*

#### **SEC. 2.**

Section 209 of the Business and Professions Code is amended to read:

##### **209.**

The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that ~~he or she is~~ *they are* applying for licensure or renewing ~~his or her~~ *their* license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to ~~order~~ *access* reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

#### **SEC. 3.**

Section 11164.1 of the Health and Safety Code is amended to read:

##### **11164.1.**

(a) (1) Notwithstanding any other ~~provision of~~ law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

*(c) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.*

**SEC. 4.**

*Section 11164.1 is added to the Health and Safety Code, to read:*

**11164.1.**

*(a) (1) Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.*

*(2) A prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.*

*(b) A pharmacy may dispense a prescription for a Schedule III, Schedule IV, or Schedule V controlled substance from an out-of-state prescriber pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.*

*(c) This section shall become operative on January 1, 2021.*

**SEC. 5.**

Section 11165 of the Health and Safety Code is amended to read:

**11165.**

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and ~~Internet~~ *internet* access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, if patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The Department of Justice shall, no later than July 1, 2020, adopt regulations regarding the access and use of the information within CURES. The Department of Justice shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

(4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no

additional CURES data are provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, *and* respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility, if provided.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser

invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The Department of Justice may enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the Department of Justice pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the Department of Justice for interstate data sharing of prescription drug monitoring program information.

(3) Any agreement entered into by the Department of Justice for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if ~~he or she~~ *the authorized user* is registered and in good standing with that state's prescription drug monitoring program.

(5) The Department of Justice shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

*(i) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.*

## **SEC. 6.**

*Section 11165 is added to the Health and Safety Code, to read:*

**11165.**

*(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.*

*(b) The department may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.*

*(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.*

*(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the department, for educational, peer review, statistical, or research purposes, if patient information, including information that may identify the patient, is not compromised. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The department shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.*

*(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.*

*(3) The department shall, no later than January 1, 2021, adopt regulations regarding the access and use of the information within CURES. The department shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:*

*(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.*

*(B) The purposes for which a health care practitioner may access information in CURES.*

*(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.*

*(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.*

*(4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data are provided and the health care practitioner keeps a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.*

*(d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:*

*(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.*

*(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a prescriber using the federal controlled substance registration number of a government-exempt facility.*

*(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.*

*(4) National Drug Code (NDC) number of the controlled substance dispensed.*

*(5) Quantity of the controlled substance dispensed.*

*(6) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, if available.*



*(7) Number of refills ordered.*

*(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.*

*(9) Prescribing date of the prescription.*

*(10) Date of dispensing of the prescription.*

*(11) The serial number for the corresponding prescription form, if applicable.*

*(e) The department may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. A prescriber or dispenser invitee shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.*

*(f) The department shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).*

*(g) The department may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.*

*(h) (1) The department may enter into an agreement with an entity operating an interstate data sharing hub, or an agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.*

*(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the department pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the department for interstate data sharing of prescription drug monitoring program information.*

*(3) An agreement entered into by the department for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.*

*(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if the authorized user is registered and in good standing with that state's prescription drug monitoring program.*

*(5) The department shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).*

*(i) Notwithstanding subdivision (d), a veterinarian shall report the information required by that subdivision to the department as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.*

*(j) If the dispensing pharmacy, clinic, or other dispenser experiences a temporary technological or electrical failure, it shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within its control. The deadline for transmitting prescription information to the department or contracted prescription data processing vendor pursuant to subdivision (d) shall be extended until the failure is corrected. If the dispensing pharmacy, clinic, or other dispenser experiences technological limitations that are not reasonably within its control, or is impacted by a natural or manmade disaster, the deadline for transmitting prescription information to the department or contracted prescription data processing vendor shall be extended until normal operations have resumed.*

*(k) This section shall become operative on January 1, 2021.*

## **SEC. 7.**

Section 11165.1 of the Health and Safety Code is amended to read:

### **11165.1.**

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under ~~his or her~~ *the practitioner's* care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that pharmacist the electronic

history of controlled substances dispensed to an individual under ~~his or her~~ *the pharmacist's* care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons ~~which that~~ include, but are not limited to, the following:

(i) Materially falsifying an application to access information contained in the CURES database.

(ii) Failing to maintain effective controls for access to the patient activity report.

(iii) Having ~~his or her~~ *their* federal DEA registration suspended or revoked.

(iv) Violating a law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Accessing information for a reason other than to diagnose or treat ~~his or her patients, or a patient, or~~ to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a

pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

(g) For purposes of this section, the following terms have the following meanings:

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic

medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(5) "User-initiated basis" means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

*(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.*

**SEC. 8.**

*Section 11165.1 is added to the Health and Safety Code, to read:*

**11165.1.**

*(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, upon receipt of a federal Drug Enforcement Administration (DEA) registration, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).*

*(ii) A pharmacist shall, upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.*

*(iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.*

*(B) The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:*

*(i) Materially falsifying an application to access information contained in the CURES database.*

*(ii) Failing to maintain effective controls for access to the patient activity report.*

*(iii) Having their federal DEA registration suspended or revoked.*

*(iv) Violating a law governing controlled substances or another law for which the possession or use of a controlled substance is an element of the crime.*

*(v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.*

*(C) An authorized subscriber shall notify the department within 30 days of a change to the subscriber account.*

*(D) An approved health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.*

*(E) An approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system certifies all of the following:*

*(i) The entity will not use or disclose data received from the CURES database for a purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.*

*(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:*

*(I) The date of the query.*

*(II) The time of the query.*

*(III) The first and last name of the patient queried.*

*(IV) The date of birth of the patient queried.*

*(V) The identification of the CURES user for whom the system is making the query.*

*(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.*

*(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.*

*(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.*

*(G) The department shall not access patient-identifiable information in an entity's health information technology system.*

*(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.*

*(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).*

*(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.*

*(b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.*

*(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the department may initiate the referral of the*



*history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.*

*(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.*

*(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.*

*(f) A health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for a resulting failure of the CURES database to accurately or timely report that information.*

*(g) For purposes of this section, the following terms have the following meanings:*

*(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.*

*(2) "Department" means the Department of Justice.*

*(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.*

*(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.*

*(h) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.*

## **SEC. 9.**

Section 11165.4 of the Health and Safety Code is amended to read:

**11165.4.**

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time ~~he or she~~ *the health care practitioner* prescribes, orders, administers, or furnishes a controlled substance to a patient, ~~he or she~~ *the health care practitioner* shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in ~~his or her~~ *their* role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before ~~he or she~~ *the health care practitioner* prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason ~~he or she~~ they did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or ~~when it~~ cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within ~~his or her~~ *the health care practitioner's* control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

*(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.*

## **SEC. 10.**

*Section 11165.4 is added to the Health and Safety Code, to read:*

**11165.4.**

*(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.*

*(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.*

*(iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.*

*(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.*

*(2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.*

*(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.*

*(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:*

*(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:*

*(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.*

*(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.*

*(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.*

*(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.*

*(E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.*

*(F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.*

*(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.*

*(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:*

*(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.*

*(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.*

*(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.*

*(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.*

*(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.*

*(F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.*

*(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.*

*(5) (A) If all of the following circumstances are satisfied:*

*(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.*

*(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.*

*(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.*

*(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.*

*(6) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.*

*(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.*

*(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.*

*(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.*

*(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.*

*(e) All applicable state and federal privacy laws govern the duties required by this section.*

*(f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.*

*(g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.*

## **Assembly Bill No. 1076**

### **CHAPTER 578**

Approved by Governor: October 8, 2019

Filed with Secretary of State: October 8, 2019.

#### **SECTION 1.**

Section 480 of the Business and Professions Code, as amended by Section 3 of Chapter 995 of the Statutes of 2018, is amended to read:

#### **480.**

(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

(1) Been convicted of a crime. A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4, 1203.4a, ~~1203.41~~, or ~~1203.41 1203.425~~ of the Penal Code.

(2) Done any act involving dishonesty, fraud, or deceit with the intent to substantially benefit ~~himself~~ ~~themselves~~ or ~~herself or~~ another, or substantially injure another.

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which *the* application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that ~~he or she has~~ *they have* been convicted of a felony if ~~he or she has~~ *they have* obtained a certificate of rehabilitation under Chapter 3.5 (commencing with



Section 4852.01) of Title 6 of Part 3 of the Penal Code or that ~~he or she has~~ *they have* been convicted of a misdemeanor if ~~he or she has~~ *they have* met all applicable requirements of the criteria of rehabilitation developed by the board to evaluate the rehabilitation of a person when considering the denial of a license under subdivision (a) of Section 482.

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, *1203.41*, or ~~1203.41~~ *1203.425* of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

(e) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

## **SEC. 2.**

Section 480 of the Business and Professions Code, as added by Section 4 of Chapter 995 of the Statutes of 2018, is amended to read:

### **480.**

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business

or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

(i) Chapter 1 (commencing with Section 5000) of Division 3.

(ii) Chapter 6 (commencing with Section 6500) of Division 3.

(iii) Chapter 9 (commencing with Section 7000) of Division 3.

(iv) Chapter 11.3 (commencing with Section 7512) of Division 3.

(v) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

(vi) Division 4 (commencing with Section 10000).

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, [1203.42](#), or ~~1203.42~~ [1203.425](#) of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that ~~he or she~~ [the person](#) has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if ~~he or she~~ [that person](#) has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, [1203.42](#), or ~~1203.42~~ [1203.425](#) of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of ~~his or her~~ *the applicant's* complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's ~~Internet Web site~~ *internet website* and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

#### **SEC. 2.5.**

Section 480 of the Business and Professions Code, as added by Section 4 of Chapter 995 of the Statutes of 2018, is amended to read:

**480.**

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

~~(i) Chapter 1 (commencing with Section 5000) of Division 3.~~

~~(ii) (i)~~ Chapter 6 (commencing with Section 6500) of Division 3.

~~(iii) (ii)~~ Chapter 9 (commencing with Section 7000) of Division 3.

~~(iv) (iii)~~ Chapter 11.3 (commencing with Section 7512) of Division 3.

~~(v) (iv)~~ Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

~~(vi) (v)~~ Division 4 (commencing with Section 10000).

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been

dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, [1203.42](#), or ~~1203.42~~ [1203.425](#) of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that ~~he or she~~ [the person](#) has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if ~~he or she~~ [that person](#) has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, [1203.42](#), or ~~1203.42~~ [1203.425](#) of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of ~~his or her~~ *the applicant's* complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's ~~Internet Web site~~ *internet website* and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

### **SEC. 3.**

Section 480.2 of the Business and Professions Code is amended to read:

#### **480.2.**

(a) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license regulated by it on the grounds that the applicant has one of the following:

(1) Been convicted of a crime.

(2) Done any act involving dishonesty, fraud, or deceit with the intent to substantially benefit ~~himself~~ *themselves* or ~~herself or~~ another, or substantially injure another.

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which *the* application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that ~~he or she~~ *the person* has been convicted of a felony if ~~he or she~~ *that person* has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that ~~he or she~~ *the person* has been convicted of a misdemeanor if ~~he or she~~ *the person* has met all applicable requirements of the criteria of rehabilitation developed by the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board to evaluate the rehabilitation of a person when considering the denial of a license under paragraph (1) of subdivision (f).



(c) Notwithstanding any other provisions of this code, a person shall not be denied a license by the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, [1203.41](#), or ~~1203.41~~ [1203.425](#) of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license regulated by it on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

(e) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall develop criteria to aid it, when considering the denial, ~~suspension~~ [suspension](#), or revocation of a license, to determine whether a crime or act is substantially related to the qualifications, functions, or duties of the business or profession it regulates.

(f) (1) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall develop criteria to evaluate the rehabilitation of a person either when:

(A) Considering the denial of a license under this section.

(B) Considering suspension or revocation of a license under Section 490.

(2) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall take into account all competent evidence of rehabilitation furnished by the applicant or licensee.

(g) Except as otherwise provided by law, following a hearing requested by an applicant pursuant to subdivision (b) of Section 485, the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may take any of the following actions:

(1) Grant the license effective upon completion of all licensing requirements by the applicant.

(2) Grant the license effective upon completion of all licensing requirements by the applicant, immediately revoke the license, stay the revocation, and impose probationary conditions on the license, which may include suspension.

(3) Deny the license.

(4) Take other action in relation to denying or granting the license as the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board, in its discretion, may deem proper.

(h) Notwithstanding any other law, in a proceeding conducted by the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.

(i) Notwithstanding Section 7.5, a conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4, 1203.4a, [1203.41](#), or ~~1203.41~~ [1203.425](#) of the Penal Code.

(j) This section shall become operative on July 1, 2020.

#### **SEC. 4.**

Section 11345.2 of the Business and Professions Code, as amended by Section 14 of Chapter 995 of the Statutes of 2018, is amended to read:

#### **11345.2.**

(a) An individual shall not act as a controlling person for a registrant if any of the following apply:

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. Notwithstanding subdivision (c) of Section 480, if the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, [1203.41](#), or ~~1203.41~~ [1203.425](#) of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date ~~he or she~~ *the individual* has knowledge of that fact.

(c) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

#### **SEC. 5.**

Section 11345.2 of the Business and Professions Code, as added by Section 15 of Chapter 995 of the Statutes of 2018, is amended to read:

#### **11345.2.**

(a) An individual shall not act as a controlling person for a registrant if any of the following apply:

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. If the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, *1203.42*, or ~~1203.42~~ *1203.425* of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date ~~he or she~~ *the individual* has knowledge of that fact.

(c) This section shall become operative on July 1, 2020.

#### **SEC. 6.**

Section 432.7 of the Labor Code is amended to read:

#### **432.7.**

(a) (1) An employer, whether a public agency or private individual or corporation, shall not ask an applicant for employment to disclose, through any written form or verbally, information concerning an arrest or detention that did not result in conviction, or information concerning a referral to, and participation in, any pretrial or posttrial diversion program, or concerning a conviction that has been judicially dismissed or ordered sealed pursuant to law, including, but not limited to, Sections 1203.4, 1203.4a, *1203.425*, 1203.45, and 1210.1 of the Penal Code. An employer also shall not seek from any source whatsoever, or utilize, as a factor in determining

any condition of employment including hiring, promotion, termination, or any apprenticeship training program or any other training program leading to employment, any record of arrest or detention that did not result in conviction, or any record regarding a referral to, and participation in, any pretrial or posttrial diversion program, or concerning a conviction that has been judicially dismissed or ordered sealed pursuant to law, including, but not limited to, Sections 1203.4, 1203.4a, [1203.425](#), 1203.45, and 1210.1 of the Penal Code. This section shall not prevent an employer from asking an employee or applicant for employment about an arrest for which the employee or applicant is out on bail or on ~~his or her~~ *their* own recognizance pending trial.

(2) An employer, whether a public agency or private individual or corporation, shall not ask an applicant for employment to disclose, through any written form or verbally, information concerning or related to an arrest, detention, processing, diversion, supervision, adjudication, or court disposition that occurred while the person was subject to the process and jurisdiction of the juvenile court. An employer also shall not seek from any source whatsoever, or utilize, as a factor in determining any condition of employment including hiring, promotion, termination, or any apprenticeship training program or any other training program leading to employment, any record concerning or related to an arrest, detention, processing, diversion, supervision, adjudication, or court disposition that occurred while a person was subject to the process and jurisdiction of the juvenile court.

(3) For purposes of this section:

(A) "Conviction" includes a plea, verdict, or finding of guilt, regardless of whether a sentence is imposed by the court.

(B) "Conviction" does not include, and shall not be construed to include, any adjudication by a juvenile court or any other court order or action taken with respect to a person who is under the process and jurisdiction of the juvenile court.

(b) This section shall not prohibit the disclosure of the information authorized for release under Sections 13203 and 13300 of the Penal Code, to a government agency employing a peace officer. However, the employer shall not determine any condition of employment other than paid administrative leave based solely on an arrest report. The information contained in an arrest report may be used as the starting point for an independent, internal investigation of a peace officer in accordance with Chapter 9.7 (commencing with Section 3300) of Division 4 of Title 1 of the Government Code.

(c) If a person violates this section, or Article 6 (commencing with Section 11140) of Chapter 1 of Title 1 of Part 4 of the Penal Code, the applicant may bring an action to recover from that person actual damages or two hundred dollars (\$200), whichever is greater, plus costs, and reasonable attorney's fees. An intentional violation of this section shall entitle the applicant to treble actual damages, or five hundred dollars (\$500), whichever is greater, plus costs, and

reasonable attorney's fees. An intentional violation of this section is a misdemeanor punishable by a fine not to exceed five hundred dollars (\$500).

(d) The remedies under this section shall be in addition to and not in derogation of all other rights and remedies that an applicant may have under any other law.

(e) Persons seeking employment or persons already employed as peace officers or persons seeking employment for positions in the Department of Justice or other criminal justice agencies as defined in Section 13101 of the Penal Code are not covered by this section.

(f) (1) Except as provided in paragraph (2), this section does not prohibit an employer at a health facility, as defined in Section 1250 of the Health and Safety Code, from asking an applicant for employment either of the following:

(A) With regard to an applicant for a position with regular access to patients, to disclose an arrest under any section specified in Section 290 of the Penal Code.

(B) With regard to an applicant for a position with access to drugs and medication, to disclose an arrest under any section specified in Section 11590 of the Health and Safety Code.

(2) (A) An employer specified in paragraph (1) shall not inquire into information concerning or related to an applicant's arrest, detention, processing, diversion, supervision, adjudication, or court disposition that occurred while the person was subject to the process and jurisdiction of juvenile court law, unless the information concerns an adjudication by the juvenile court in which the applicant has been found by the court to have committed a felony or misdemeanor offense specified in paragraph (1) that occurred within five years preceding the application for employment.

(B) Notwithstanding any other provision of this subdivision, an employer specified in paragraph (1) shall not inquire into information concerning or related to an applicant's juvenile offense history that has been sealed by the juvenile court.

(3) An employer seeking disclosure of offense history under paragraph (2) shall provide the applicant with a list describing the specific offenses under Section 11590 of the Health and Safety Code or Section 290 of the Penal Code for which disclosure is sought.

(g) (1) A peace officer or employee of a law enforcement agency with access to criminal or juvenile offender record information maintained by a local law enforcement criminal or juvenile justice agency shall not knowingly disclose, with intent to affect a person's employment, any information pertaining to an arrest or detention or proceeding that did not result in a conviction, including information pertaining to a referral to, and participation in, any pretrial or posttrial diversion program, to any person not authorized by law to receive that information.

(2) Any other person authorized by law to receive criminal or juvenile offender record information maintained by a local law enforcement criminal or juvenile justice agency shall not knowingly disclose any information received pertaining to an arrest or detention or proceeding that did not result in a conviction, including information pertaining to a referral to, and participation in, any pretrial or posttrial diversion program, to any person not authorized by law to receive that information.

(3) Except for those specifically referred to in Section 1070 of the Evidence Code, a person who is not authorized by law to receive or possess criminal or juvenile justice records information maintained by a local law enforcement criminal or juvenile justice agency, pertaining to an arrest or other proceeding that did not result in a conviction, including information pertaining to a referral to, and participation in, any pretrial or posttrial diversion program, shall not knowingly receive or possess that information.

(h) "A person authorized by law to receive that information," for purposes of this section, means any person or public agency authorized by a court, statute, or decisional law to receive information contained in criminal or juvenile offender records maintained by a local law enforcement criminal or juvenile justice agency, and includes, but is not limited to, those persons set forth in Section 11105 of the Penal Code, and any person employed by a law enforcement criminal or juvenile justice agency who is required by that employment to receive, analyze, or process criminal or juvenile offender record information.

(i) This section does not require the Department of Justice to remove entries relating to an arrest or detention not resulting in conviction from summary criminal history records forwarded to an employer pursuant to law.

(j) As used in this section, "pretrial or posttrial diversion program" means any program under Chapter 2.5 (commencing with Section 1000) or Chapter 2.7 (commencing with Section 1001) of Title 6 of Part 2 of the Penal Code, Section 13201 or 13352.5 of the Vehicle Code, Sections 626, 626.5, 654, or 725 of, or Article 20.5 (commencing with Section 790) of Chapter 2 of Part 1 of Division 2 of, the Welfare and Institutions Code, or any other program expressly authorized and described by statute as a diversion program.

(k) (1) Subdivision (a) shall not apply to any city, city and county, county, or district, or any officer or official thereof, in screening a prospective concessionaire, or the affiliates and associates of a prospective concessionaire for purposes of consenting to, or approving of, the prospective concessionaire's application for, or acquisition of, any beneficial interest in a concession, lease, or other property interest.

(2) For purposes of this subdivision the following terms apply:

(A) "Screening" means a written request for criminal or juvenile history information made to a local law enforcement agency.

(B) "Prospective concessionaire" means any individual, general or limited partnership, corporation, trust, association, or other entity that is applying for, or seeking to obtain, a public agency's consent to, or approval of, the acquisition by that individual or entity of any beneficial ownership interest in any public agency's concession, lease, or other property right whether directly or indirectly held. However, "prospective concessionaire" does not include any of the following:

(i) A lender acquiring an interest solely as security for a bona fide loan made in the ordinary course of the lender's business and not made for the purpose of acquisition.

(ii) A lender upon foreclosure or assignment in lieu of foreclosure of the lender's security.

(C) "Affiliate" means any individual or entity that controls, or is controlled by, the prospective concessionaire, or who is under common control with the prospective concessionaire.

(D) "Associate" means any individual or entity that shares a common business purpose with the prospective concessionaire with respect to the beneficial ownership interest that is subject to the consent or approval of the city, county, city and county, or district.

(E) "Control" means the possession, direct or indirect, of the power to direct, or cause the direction of, the management or policies of the controlled individual or entity.

(I) (1) Subdivision (a) does not prohibit a public agency, or any officer or official thereof, from denying consent to, or approval of, a prospective concessionaire's application for, or acquisition of, any beneficial interest in a concession, lease, or other property interest based on the criminal history information of the prospective concessionaire or the affiliates or associates of the prospective concessionaire that show any criminal conviction for offenses involving moral turpitude. Criminal history information for purposes of this subdivision includes any criminal history information obtained pursuant to Section 11105 or 13300 of the Penal Code.

(2) In considering criminal history information, a public agency shall consider the crime for which the prospective concessionaire or the affiliates or associates of the prospective concessionaire was convicted only if that crime relates to the specific business that is proposed to be conducted by the prospective concessionaire.

(3) Any prospective concessionaire whose application for consent or approval to acquire a beneficial interest in a concession, lease, or other property interest is denied based on criminal history information shall be provided a written statement of the reason for the denial.

(4) (A) If the prospective concessionaire submits a written request to the public agency within 10 days of the date of the notice of denial, the public agency shall review its decision with regard to any corrected record or other evidence presented by the prospective concessionaire as to the accuracy or incompleteness of the criminal history information utilized by the public agency in making its original decision.

(B) The prospective concessionaire shall submit the copy or the corrected record of any other evidence to the public agency within 90 days of a request for review. The public agency shall render its decision within 20 days of the submission of evidence by the prospective concessionaire.

(m) (1) Paragraph (1) of subdivision (a) does not prohibit an employer, whether a public agency or private individual or corporation, from asking an applicant about, or seeking from any source information regarding, a particular conviction of the applicant if, pursuant to Section 1829 of Title 12 of the United States Code or any other federal law, federal regulation, or state law, any of the following apply:

(A) The employer is required by law to obtain information regarding the particular conviction of the applicant, regardless of whether that conviction has been expunged, judicially ordered sealed, statutorily eradicated, or judicially dismissed following probation.

(B) The applicant would be required to possess or use a firearm in the course of ~~his or her~~ *their* employment.

(C) An individual with that particular conviction is prohibited by law from holding the position sought by the applicant, regardless of whether that conviction has been expunged, judicially ordered sealed, statutorily eradicated, or judicially dismissed following probation.

(D) The employer is prohibited by law from hiring an applicant who has that particular conviction, regardless of whether that conviction has been expunged, judicially ordered sealed, statutorily eradicated, or judicially dismissed following probation.

(2) For purposes of this subdivision, “particular conviction” means a conviction for specific criminal conduct or a category of criminal offenses prescribed by any federal law, federal regulation, or state law that contains requirements, exclusions, or both, expressly based on that specific criminal conduct or category of criminal offenses.

(n) Nothing in this section shall prohibit an employer, whether a public agency or private individual or corporation, required by state, federal, or local law to conduct criminal background checks for employment purposes or to restrict employment based on criminal history from complying with those requirements, or to prohibit the employer from seeking or receiving an applicant’s criminal history report that has been obtained pursuant to procedures otherwise provided for under federal, state, or local law. For purposes of this subdivision, federal law shall include rules or regulations promulgated by a self-regulatory organization, as defined in Section 3(a)(26) of the Securities Exchange Act of 1934, pursuant to the authority in Section 19(b) of the Securities Exchange Act of 1934, as amended by 124 Stat. 1652 (Public Law 11-203).



**SEC. 7.**

*Section 851.93 is added to the Penal Code, to read:*

**851.93.**

*(a) (1) On a monthly basis, the Department of Justice shall review the records in the statewide criminal justice databases, and based on information in the state summary criminal history repository, shall identify persons with records of arrest that meet the criteria set forth in paragraph (2) and are eligible for arrest record relief.*

*(2) A person is eligible for relief pursuant to this section, if the arrest occurred on or after January 1, 2021, and meets any of the following conditions:*

*(A) The arrest was for a misdemeanor offense and the charge was dismissed.*

*(B) The arrest was for a misdemeanor offense, there is no indication that criminal proceedings have been initiated, at least one calendar year has elapsed since the date of the arrest, and no conviction occurred, or the arrestee was acquitted of any charges that arose, from that arrest.*

*(C) The arrest was for an offense that is punishable by imprisonment pursuant to paragraph (1) or (2) of subdivision (h) of Section 1170, there is no indication that criminal proceedings have been initiated, at least three calendar years have elapsed since the date of the arrest, and no conviction occurred, or the arrestee was acquitted of any charges arising, from that arrest.*

*(D) The person successfully completed any of the following, relating to that arrest:*

*(i) A prefiling diversion program, as defined in Section 851.87, administered by a prosecuting attorney in lieu of filing an accusatory pleading.*

*(ii) A drug diversion program administered by a superior court pursuant to Section 1000.5, or a deferred entry of judgment program pursuant to Section 1000 or 1000.8.*

*(iii) A pretrial diversion program, pursuant to Section 1000.4.*

*(iv) A diversion program, pursuant to Section 1001.9.*

*(v) Any diversion program described in Chapter 2.8 (commencing with Section 1001.20), Chapter 2.8A (commencing with Section 1001.35), Chapter 2.81 (commencing with Section 1001.40), Chapter 2.9 (commencing with Section 1001.50), Chapter 2.9A (commencing with Section 1001.60), Chapter 2.9B (commencing with Section 1001.70), Chapter 2.9C (commencing with Section 1001.80), Chapter 2.9D (commencing with Section 1001.81), or Chapter 2.92 (commencing with Section 1001.85), of Title 6.*

*(b) (1) The department shall grant relief to a person identified pursuant to subdivision (a), without requiring a petition or motion by a party for that relief if the relevant information is present in the department's electronic records.*

*(2) The state summary criminal history information shall include, directly next to or below the entry or entries regarding the person's arrest record, a note stating "arrest relief granted," listing the date that the department granted relief, and this section. This note shall be included in all statewide criminal databases with a record of the arrest.*

*(3) Except as otherwise provided in subdivision (d), an arrest for which arrest relief has been granted is deemed not to have occurred, and a person who has been granted arrest relief is released from any penalties and disabilities resulting from the arrest, and may answer any question relating to that arrest accordingly.*

*(c) On a monthly basis, the department shall electronically submit a notice to the superior court having jurisdiction over the criminal case, informing the court of all cases for which a complaint was filed in that jurisdiction and for which relief was granted pursuant to this section. Commencing on February 1, 2021, for any record retained by the court pursuant to Section 68152 of the Government Code, except as provided in subdivision (d), the court shall not disclose information concerning an arrest that is granted relief pursuant to this section to any person or entity, in any format, except to the person whose arrest was granted relief or a criminal justice agency, as defined in Section 851.92.*

*(d) Relief granted pursuant to this section is subject to the following conditions:*

*(1) Arrest relief does not relieve a person of the obligation to disclose an arrest in response to a direct question contained in a questionnaire or application for employment as a peace officer, as defined in Section 830.*

*(2) Relief granted pursuant to this section has no effect on the ability of a criminal justice agency, as defined in Section 851.92, to access and use records that are granted relief to the same extent that would have been permitted for a criminal justice agency had relief not been granted.*

*(3) This section does not limit the ability of a district attorney to prosecute, within the applicable statute of limitations, an offense for which arrest relief has been granted pursuant to this section.*

*(4) Relief granted pursuant to this section does not affect a person's authorization to own, possess, or have in the person's custody or control any firearm, or the person's susceptibility to conviction under Chapter 2 (commencing with Section 29800) of Division 9 of Title 4 of Part 6, if the arrest would otherwise affect this authorization or susceptibility.*

*(5) Relief granted pursuant to this section does not affect any prohibition from holding public office that would otherwise apply under law as a result of the arrest.*

*(6) Relief granted pursuant to this section does not affect the authority to receive, or take adverse action based on, criminal history information, including the authority to receive certified court records received or evaluated pursuant to Section 1522, 1568.09, 1569.17, or 1596.871 of the Health and Safety Code, or pursuant to any statutory or regulatory provisions that incorporate the criteria of those sections.*

*(e) This section shall not limit petitions, motions, or orders for arrest record relief, as required or authorized by any other law, including, but not limited to, Sections 851.87, 851.90, 851.91, 1000.4, and 1001.9.*

*(f) The department shall annually publish statistics for each county regarding the total number of arrests granted relief pursuant to this section and the percentage of arrests for which the state summary criminal history information does not include a disposition, on the OpenJustice Web portal, as defined in Section 13010.*

*(g) This section shall be operative commencing January 1, 2021, subject to an appropriation in the annual Budget Act.*

**SEC. 8.**

*Section 1203.425 is added to the Penal Code, immediately following Section 1203.42, to read:*

**1203.425.**

*(a) (1) On a monthly basis, the Department of Justice shall review the records in the statewide criminal justice databases, and based on information in the state summary criminal history repository and the Supervised Release File, shall identify persons with convictions that meet the criteria set forth in paragraph (2) and are eligible for automatic conviction record relief.*

*(2) A person is eligible for automatic conviction relief pursuant to this section if they meet all of the following conditions:*

*(A) The person is not required to register pursuant to the Sex Offender Registration Act.*

*(B) The person does not have an active record for local, state, or federal supervision in the Supervised Release File.*

*(C) Based upon the information available in the department's record, including disposition dates and sentencing terms, it does not appear that the person is currently serving a sentence for any offense and there is no indication of any pending criminal charges.*

*(D) Except as otherwise provided in clause (iii) of subparagraph (E), there is no indication that the conviction resulted in a sentence of incarceration in the state prison.*

*(E) The conviction occurred on or after January 1, 2021, and meets either of the following criteria:*

*(i) The defendant was sentenced to probation and, based upon the disposition date and the term of probation specified in the department's records, appears to have completed their term of probation without revocation.*

*(ii) The defendant was convicted of an infraction or misdemeanor, was not granted probation, and, based upon the disposition date and the term specified in the department's records, the defendant appears to have completed their sentence, and at least one calendar year has elapsed since the date of judgment.*

*(b) (1) Except as specified in subdivision (h), the department shall grant relief, including dismissal of a conviction, to a person identified pursuant to subdivision (a), without requiring a petition or motion by a party for that relief if the relevant information is present in the department's electronic records.*

*(2) The state summary criminal history information shall include, directly next to or below the entry or entries regarding the person's criminal record, a note stating "relief granted," listing the date that the department granted relief and this section. This note shall be included in all statewide criminal databases with a record of the conviction.*

*(3) Except as otherwise provided in subdivision (d) and in Section 13555 of the Vehicle Code, a person granted conviction relief pursuant to this section shall be released from all penalties and disabilities resulting from the offense of which the person has been convicted.*

*(c) On a monthly basis, the department shall electronically submit a notice to the superior court having jurisdiction over the criminal case, informing the court of all cases for which a complaint was filed in that jurisdiction and for which relief was granted pursuant to this section. Commencing on February 1, 2021, for any record retained by the court pursuant to Section 68152 of the Government Code, except as provided in subdivision (d), the court shall not disclose information concerning a conviction granted relief pursuant to this section or Section 1203.4, 1203.4a, 1203.41, or 1203.42, to any person or entity, in any format, except to the person whose conviction was granted relief or a criminal justice agency, as defined in Section 851.92.*

*(d) Relief granted pursuant to this section is subject to the following conditions:*

*(1) Relief granted pursuant to this section does not relieve a person of the obligation to disclose a criminal conviction in response to a direct question contained in a questionnaire or application for employment as a peace officer, as defined in Section 830.*

*(2) Relief granted pursuant to this section does not relieve a person of the obligation to disclose the conviction in response to any direct question contained in any questionnaire or application for public office, or for contracting with the California State Lottery Commission.*

*(3) Relief granted pursuant to this section has no effect on the ability of a criminal justice agency, as defined in Section 851.92, to access and use records that are granted relief to the same extent that would have been permitted for a criminal justice agency had relief not been granted.*

*(4) Relief granted pursuant to this section does not limit the jurisdiction of the court over any subsequently filed motion to amend the record, petition or motion for postconviction relief, or collateral attack on a conviction for which relief has been granted pursuant to this section.*

*(5) Relief granted pursuant to this section does not affect a person's authorization to own, possess, or have in the person's custody or control any firearm, or the person's susceptibility to conviction under Chapter 2 (commencing with Section 29800) of Division 9 of Title 4 of Part 6, if the criminal conviction would otherwise affect this authorization or susceptibility.*

*(6) Relief granted pursuant to this section does not affect any prohibition from holding public office that would otherwise apply under law as a result of the criminal conviction.*

*(7) Relief granted pursuant to this section does not affect the authority to receive, or take adverse action based on, criminal history information, including the authority to receive certified court records received or evaluated pursuant to Section 1522, 1568.09, 1569.17, or 1596.871 of the Health and Safety Code, or pursuant to any statutory or regulatory provisions that incorporate the criteria of those sections.*

*(8) Relief granted pursuant to this section does not make eligible a person who is otherwise ineligible to provide, or receive payment for providing, in-home supportive services pursuant to Article 7 (commencing with Section 12300) of Chapter 3 of Part 3 of Division 9 of the Welfare and Institutions Code, or pursuant to Section 14132.95, 14132.952, or 14132.956 of the Welfare and Institutions Code.*

*(9) In any subsequent prosecution of the defendant for any other offense, the prior conviction may be pleaded and proved and shall have the same effect as if the relief had not been granted.*

*(e) This section shall not limit petitions, motions, or orders for relief in a criminal case, as required or authorized by any other law, including, but not limited to, Sections 1203.4 and 1204.4a.*

*(f) The department shall annually publish statistics for each county regarding the total number of convictions granted relief pursuant to this section and the total number of convictions prohibited from automatic relief pursuant to subdivision (h), on the OpenJustice Web portal, as defined in Section 13010.*

*(g) Subdivisions (a) to (f), inclusive, shall be operative commencing January 1, 2021, subject to an appropriation in the annual Budget Act.*

*(h) (1) The prosecuting attorney or probation department may, no later than 90 calendar days before the date of a person's eligibility for relief pursuant to this section, file a petition to prohibit the department from granting automatic relief pursuant to this section, based on a showing that granting such relief would pose a substantial threat to the public safety.*

*(2) The court shall give notice to the defendant and conduct a hearing on the petition within 45 days after the petition is filed.*

*(3) At a hearing on the petition pursuant to this subdivision, the defendant, the probation department, the prosecuting attorney, and the arresting agency, through the prosecuting attorney, may present evidence to the court. Notwithstanding Sections 1538.5 and 1539, the hearing may be heard and determined upon declarations, affidavits, police investigative reports, copies of state summary criminal history information and local summary criminal history information, or any other evidence submitted by the parties that is material, reliable, and relevant.*

*(4) The prosecutor or probation department has the initial burden of proof to show that granting conviction relief would pose a substantial threat to the public safety. In determining whether granting such relief would pose a substantial threat to the public safety, the court may consider any relevant factors including, but not limited to, either of the following:*

*(A) Declarations or evidence regarding the offense for which a grant of relief is being contested.*

*(B) The defendant's record of arrests and convictions.*

*(5) If the court finds that the prosecutor or probation department has satisfied the burden of proof, the burden shifts to the defendant to show that the hardship of not obtaining relief outweighs the threat to the public safety of providing such relief. In determining whether the defendant's hardship outweighs the threat to the public safety, the court may consider any relevant factors including, but not limited to, either of the following:*

*(A) The hardship to the defendant that has been caused by the conviction and that would be caused if relief is not granted.*

*(B) Declarations or evidence regarding the defendant's good character.*

*(6) If the court grants a petition pursuant to this subdivision, the court shall furnish a disposition report to the Department of Justice pursuant to Section 13151, stating that relief pursuant to this section was denied, and the department shall not grant relief pursuant to this section.*

*(7) A person denied relief pursuant to this section may continue to be eligible for relief pursuant to Section 1203.4 or 1203.4a. If the court subsequently grants relief pursuant to one of those sections, the court shall furnish a disposition report to the Department of Justice pursuant to Section 13151, stating that relief was granted pursuant to the applicable section, and the department shall grant relief pursuant to that section.*

*(i) At the time of sentencing, the court shall advise a defendant, either orally or in writing, of the provisions of this section and of the defendant's right, if any, to petition for a certificate of rehabilitation and pardon.*

## **SEC. 9.**

Section 11105 of the Penal Code is amended to read:

### **11105.**

(a) (1) The Department of Justice shall maintain state summary criminal history information.

(2) As used in this section:

(A) "State summary criminal history information" means the master record of information compiled by the Attorney General pertaining to the identification and criminal history of a person, such as name, date of birth, physical description, fingerprints, photographs, dates of arrests, arresting agencies and booking numbers, charges, dispositions, sentencing information, and similar data about the person.

(B) "State summary criminal history information" does not refer to records and data compiled by criminal justice agencies other than the Attorney General, nor does it refer to records of complaints to or investigations conducted by, or records of intelligence information or security procedures of, the office of the Attorney General and the Department of Justice.

(b) The Attorney General shall furnish state summary criminal history information to the following, if needed in the course of their duties, provided that when information is furnished to assist an agency, officer, or official of state or local government, a public utility, or any other entity, in fulfilling employment, certification, or licensing duties, Chapter 1321 of the Statutes of 1974 and Section 432.7 of the Labor Code shall apply:

(1) The courts of the state.

(2) Peace officers of the state, as defined in Section 830.1, subdivisions (a) and (e) of Section 830.2, subdivision (a) of Section 830.3, subdivision (a) of Section 830.31, and subdivisions (a) and (b) of Section 830.5.

(3) District attorneys of the state.

(4) Prosecuting city attorneys or city prosecutors of a city within the state.

(5) City attorneys pursuing civil gang injunctions pursuant to Section 186.22a, or drug abatement actions pursuant to Section 3479 or 3480 of the Civil Code, or Section 11571 of the Health and Safety Code.

(6) Probation officers of the state.

(7) Parole officers of the state.

(8) A public defender or attorney of record when representing a person in proceedings upon a petition for a certificate of rehabilitation and pardon pursuant to Section 4852.08.

(9) A public defender or attorney of record when representing a person in a criminal case or a juvenile delinquency proceeding, including all appeals and postconviction motions, or a parole, mandatory supervision pursuant to paragraph (5) of subdivision (h) of Section 1170, or postrelease community supervision revocation or revocation extension proceeding, if the information is requested in the course of representation.

(10) An agency, officer, or official of the state if the state summary criminal history information is required to implement a statute or regulation that expressly refers to specific criminal conduct applicable to the subject person of the state summary criminal history information, and contains requirements or exclusions, or both, expressly based upon that specified criminal conduct. The agency, officer, or official of the state authorized by this paragraph to receive state summary criminal history information may also transmit fingerprint images and related information to the Department of Justice to be transmitted to the Federal Bureau of Investigation.

(11) A city or county, city and county, district, or an officer or official thereof if access is needed in order to assist that agency, officer, or official in fulfilling employment, certification, or licensing duties, and if the access is specifically authorized by the city council, board of supervisors, or governing board of the city, county, or district if the state summary criminal history information is required to implement a statute, ordinance, or regulation that expressly refers to specific criminal conduct applicable to the subject person of the state summary criminal history information, and contains requirements or exclusions, or both, expressly based upon that specified criminal conduct. The city or county, city and county, district, or the officer or official thereof authorized by this paragraph may also transmit fingerprint images and related information to the Department of Justice to be transmitted to the Federal Bureau of Investigation.

(12) The subject of the state summary criminal history information under procedures established under Article 5 (commencing with Section 11120).

(13) A person or entity when access is expressly authorized by statute if the criminal history information is required to implement a statute or regulation that expressly refers to specific



criminal conduct applicable to the subject person of the state summary criminal history information, and contains requirements or exclusions, or both, expressly based upon that specified criminal conduct.

(14) Health officers of a city, county, city and county, or district when in the performance of their official duties enforcing Section 120175 of the Health and Safety Code.

(15) A managing or supervising correctional officer of a county jail or other county correctional facility.

(16) A humane society, or society for the prevention of cruelty to animals, for the specific purpose of complying with Section 14502 of the Corporations Code for the appointment of humane officers.

(17) Local child support agencies established by Section 17304 of the Family Code. When a local child support agency closes a support enforcement case containing state summary criminal history information, the agency shall delete or purge from the file and destroy any documents or information concerning or arising from offenses for or of which the parent has been arrested, charged, or convicted, other than for offenses related to the parent's having failed to provide support for minor children, consistent with the requirements of Section 17531 of the Family Code.

(18) County child welfare agency personnel who have been delegated the authority of county probation officers to access state summary criminal history information pursuant to Section 272 of the Welfare and Institutions Code for the purposes specified in Section 16504.5 of the Welfare and Institutions Code. Information from criminal history records provided pursuant to this subdivision shall not be used for a purpose other than those specified in this section and Section 16504.5 of the Welfare and Institutions Code. When an agency obtains records both on the basis of name checks and fingerprint checks, final placement decisions shall be based only on the records obtained pursuant to the fingerprint check.

(19) The court of a tribe, or court of a consortium of tribes, that has entered into an agreement with the state pursuant to Section 10553.1 of the Welfare and Institutions Code. This information may be used only for the purposes specified in Section 16504.5 of the Welfare and Institutions Code and for tribal approval or tribal licensing of foster care or adoptive homes. Article 6 (commencing with Section 11140) shall apply to officers, members, and employees of a tribal court receiving state summary criminal history information pursuant to this section.

(20) Child welfare agency personnel of a tribe or consortium of tribes that has entered into an agreement with the state pursuant to Section 10553.1 of the Welfare and Institutions Code and to whom the state has delegated duties under paragraph (2) of subdivision (a) of Section 272 of the Welfare and Institutions Code. The purposes for use of the information shall be for the purposes specified in Section 16504.5 of the Welfare and Institutions Code and for tribal approval or tribal licensing of foster care or adoptive homes. When an agency obtains records

on the basis of name checks and fingerprint checks, final placement decisions shall be based only on the records obtained pursuant to the fingerprint check. Article 6 (commencing with Section 11140) shall apply to child welfare agency personnel receiving criminal record offender information pursuant to this section.

(21) An officer providing conservatorship investigations pursuant to Sections 5351, 5354, and 5356 of the Welfare and Institutions Code.

(22) A court investigator providing investigations or reviews in conservatorships pursuant to Section 1826, 1850, 1851, or 2250.6 of the Probate Code.

(23) A person authorized to conduct a guardianship investigation pursuant to Section 1513 of the Probate Code.

(24) A humane officer pursuant to Section 14502 of the Corporations Code for the purposes of performing ~~his or her~~ *the officer's* duties.

(25) A public agency described in subdivision (b) of Section 15975 of the Government Code, for the purpose of oversight and enforcement policies with respect to its contracted providers.

(26) (A) A state entity, or its designee, that receives federal tax information. A state entity or its designee that is authorized by this paragraph to receive state summary criminal history information also may transmit fingerprint images and related information to the Department of Justice to be transmitted to the Federal Bureau of Investigation for the purpose of the state entity or its designee obtaining federal level criminal offender record information from the Department of Justice. This information shall be used only for the purposes set forth in Section 1044 of the Government Code.

(B) For purposes of this paragraph, "federal tax information," "state entity" and "designee" are as defined in paragraphs (1), (2), and (3), respectively, of subdivision (f) of Section 1044 of the Government Code.

(c) The Attorney General may furnish state summary criminal history information and, when specifically authorized by this subdivision, federal level criminal history information upon a showing of a compelling need to any of the following, provided that when information is furnished to assist an agency, officer, or official of state or local government, a public utility, or any other entity in fulfilling employment, certification, or licensing duties, Chapter 1321 of the Statutes of 1974 and Section 432.7 of the Labor Code shall apply:

(1) A public utility, as defined in Section 216 of the Public Utilities Code, that operates a nuclear energy facility when access is needed in order to assist in employing persons to work at the facility, provided that, if the Attorney General supplies the data, ~~he or she~~ *the Attorney General* shall furnish a copy of the data to the person to whom the data relates.

- (2) To a peace officer of the state other than those included in subdivision (b).
- (3) To an illegal dumping enforcement officer as defined in subdivision (j) of Section 830.7.
- (4) To a peace officer of another country.
- (5) To public officers, other than peace officers, of the United States, other states, or possessions or territories of the United States, provided that access to records similar to state summary criminal history information is expressly authorized by a statute of the United States, other states, or possessions or territories of the United States if the information is needed for the performance of their official duties.
- (6) To a person when disclosure is requested by a probation, parole, or peace officer with the consent of the subject of the state summary criminal history information and for purposes of furthering the rehabilitation of the subject.
- (7) The courts of the United States, other states, or territories or possessions of the United States.
- (8) Peace officers of the United States, other states, or territories or possessions of the United States.
- (9) To an individual who is the subject of the record requested if needed in conjunction with an application to enter the United States or a foreign nation.
- (10) (A) (i) A public utility, as defined in Section 216 of the Public Utilities Code, or a cable corporation as defined in subparagraph (B), if receipt of criminal history information is needed in order to assist in employing current or prospective employees, contract employees, or subcontract employees who, in the course of their employment, may be seeking entrance to private residences or adjacent grounds. The information provided shall be limited to the record of convictions and arrests for which the person is released on bail or on ~~his or her~~ *their* own recognizance pending trial.
- (ii) If the Attorney General supplies the data pursuant to this paragraph, the Attorney General shall furnish a copy of the data to the current or prospective employee to whom the data relates.
- (iii) State summary criminal history information is confidential and the receiving public utility or cable corporation shall not disclose its contents, other than for the purpose for which it was acquired. The state summary criminal history information in the possession of the public utility or cable corporation and all copies made from it shall be destroyed not more than 30 days after employment or promotion or transfer is denied or granted, except for those cases where a current or prospective employee is out on bail or on ~~his or her~~ *their* own recognizance pending

trial, in which case the state summary criminal history information and all copies shall be destroyed not more than 30 days after the case is resolved.

(iv) A violation of this paragraph is a misdemeanor, and shall give the current or prospective employee who is injured by the violation a cause of action against the public utility or cable corporation to recover damages proximately caused by the violations. A public utility's or cable corporation's request for state summary criminal history information for purposes of employing current or prospective employees who may be seeking entrance to private residences or adjacent grounds in the course of their employment shall be deemed a "compelling need" as required to be shown in this subdivision.

(v) This section shall not be construed as imposing a duty upon public utilities or cable corporations to request state summary criminal history information on current or prospective employees.

(B) For purposes of this paragraph, "cable corporation" means a corporation or firm that transmits or provides television, computer, or telephone services by cable, digital, fiber optic, satellite, or comparable technology to subscribers for a fee.

(C) Requests for federal level criminal history information received by the Department of Justice from entities authorized pursuant to subparagraph (A) shall be forwarded to the Federal Bureau of Investigation by the Department of Justice. Federal level criminal history information received or compiled by the Department of Justice may then be disseminated to the entities referenced in subparagraph (A), as authorized by law.

(11) To a campus of the California State University or the University of California, or a four-year college or university accredited by a regional accreditation organization approved by the United States Department of Education, if needed in conjunction with an application for admission by a convicted felon to a special education program for convicted felons, including, but not limited to, university alternatives and halfway houses. Only conviction information shall be furnished. The college or university may require the convicted felon to be fingerprinted, and any inquiry to the department under this section shall include the convicted felon's fingerprints and any other information specified by the department.

(12) To a foreign government, if requested by the individual who is the subject of the record requested, if needed in conjunction with the individual's application to adopt a minor child who is a citizen of that foreign nation. Requests for information pursuant to this paragraph shall be in accordance with the process described in Sections 11122 to 11124, inclusive. The response shall be provided to the foreign government or its designee and to the individual who requested the information.

(d) Whenever an authorized request for state summary criminal history information pertains to a person whose fingerprints are on file with the Department of Justice and the department has no criminal history of that person, and the information is to be used for employment, licensing,

or certification purposes, the fingerprint card accompanying the request for information, if any, may be stamped “no criminal record” and returned to the person or entity making the request.

(e) Whenever state summary criminal history information is furnished as the result of an application and is to be used for employment, licensing, or certification purposes, the Department of Justice may charge the person or entity making the request a fee that it determines to be sufficient to reimburse the department for the cost of furnishing the information. In addition, the Department of Justice may add a surcharge to the fee to fund maintenance and improvements to the systems from which the information is obtained. Notwithstanding any other law, a person or entity required to pay a fee to the department for information received under this section may charge the applicant a fee sufficient to reimburse the person or entity for this expense. All moneys received by the department pursuant to this section, Sections 11105.3 and 26190, and former Section 13588 of the Education Code shall be deposited in a special account in the General Fund to be available for expenditure by the department to offset costs incurred pursuant to those sections and for maintenance and improvements to the systems from which the information is obtained upon appropriation by the Legislature.

(f) Whenever there is a conflict, the processing of criminal fingerprints and fingerprints of applicants for security guard or alarm agent registrations or firearms qualification permits submitted pursuant to Section 7583.9, 7583.23, 7596.3, or 7598.4 of the Business and Professions Code shall take priority over the processing of other applicant fingerprints.

(g) It is not a violation of this section to disseminate statistical or research information obtained from a record, provided that the identity of the subject of the record is not disclosed.

(h) It is not a violation of this section to include information obtained from a record in (1) a transcript or record of a judicial or administrative proceeding or (2) any other public record if the inclusion of the information in the public record is authorized by a court, statute, or decisional law.

(i) Notwithstanding any other law, the Department of Justice or a state or local law enforcement agency may require the submission of fingerprints for the purpose of conducting state summary criminal history information checks that are authorized by law.

(j) The state summary criminal history information shall include any finding of mental incompetence pursuant to Chapter 6 (commencing with Section 1367) of Title 10 of Part 2 arising out of a complaint charging a felony offense specified in Section 290.

(k) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency or organization and the information is to be used for peace officer employment or certification purposes. As used in this subdivision, a peace officer is defined in Chapter 4.5 (commencing with Section 830) of Title 3 of Part 2.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ *their* own recognizance pending trial.

(C) Every arrest or detention, except for an arrest or detention resulting in an exoneration, provided, however, that where the records of the Department of Justice do not contain a disposition for the arrest, the Department of Justice first makes a genuine effort to determine the disposition of the arrest.

(D) Every successful diversion.

(E) Every date and agency name associated with all retained peace officer or nonsworn law enforcement agency employee preemployment criminal offender record information search requests.

(F) Sex offender registration status of the applicant.

(G) Sentencing information, if present in the department's records at the time of the response.

(I) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by a criminal justice agency or organization as defined in Section 13101, and the information is to be used for criminal justice employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ *their* own recognizance pending trial.

(C) Every arrest for an offense for which the records of the Department of Justice do not contain a disposition or which did not result in a conviction, provided that the Department of Justice first makes a genuine effort to determine the disposition of the arrest. However,

information concerning an arrest shall not be disclosed if the records of the Department of Justice indicate or if the genuine effort reveals that the subject was exonerated, successfully completed a diversion or deferred entry of judgment program, or the arrest was deemed a detention, or the subject was granted relief pursuant to Section 851.91.

(D) Every date and agency name associated with all retained peace officer or nonsworn law enforcement agency employee preemployment criminal offender record information search requests.

(E) Sex offender registration status of the applicant.

(F) Sentencing information, if present in the department's records at the time of the response.

(m) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency or organization pursuant to Section 1522, 1568.09, 1569.17, or 1596.871 of the Health and Safety Code, or a statute that incorporates the criteria of any of those sections or this subdivision by reference, and the information is to be used for employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction of an offense rendered against the applicant, except a conviction for which relief has been granted pursuant to Section 1203.49.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ *their* own recognizance pending trial.

(C) Every arrest for an offense for which the Department of Social Services is required by paragraph (1) of subdivision (a) of Section 1522 of the Health and Safety Code to determine if an applicant has been arrested. However, if the records of the Department of Justice do not contain a disposition for an arrest, the Department of Justice shall first make a genuine effort to determine the disposition of the arrest.

(D) Sex offender registration status of the applicant.

(E) Sentencing information, if present in the department's records at the time of the response.

(3) Notwithstanding the requirements of the sections referenced in paragraph (1) of this subdivision, the Department of Justice shall not disseminate information about an arrest

subsequently deemed a detention or an arrest that resulted in the successful completion of a diversion program, exoneration, or a grant of relief pursuant to Section 851.91.

(n) (1) This subdivision shall apply whenever state or federal summary criminal history information, to be used for employment, licensing, or certification purposes, is furnished by the Department of Justice as the result of an application by an authorized agency, organization, or individual pursuant to any of the following:

(A) Paragraph (10) of subdivision (c), when the information is to be used by a cable corporation.

(B) Section 11105.3 or 11105.4.

(C) Section 15660 of the Welfare and Institutions Code.

(D) A statute that incorporates the criteria of any of the statutory provisions listed in subparagraph (A), (B), or (C), or of this subdivision, by reference.

(2) With the exception of applications submitted by transportation companies authorized pursuant to Section 11105.3, and notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction, except a conviction for which relief has been granted pursuant to Section 1203.49, rendered against the applicant for a violation or attempted violation of an offense specified in subdivision (a) of Section 15660 of the Welfare and Institutions Code. However, with the exception of those offenses for which registration is required pursuant to Section 290, the Department of Justice shall not disseminate information pursuant to this subdivision unless the conviction occurred within 10 years of the date of the agency's request for information or the conviction is over 10 years old but the subject of the request was incarcerated within 10 years of the agency's request for information.

(B) Every arrest for a violation or attempted violation of an offense specified in subdivision (a) of Section 15660 of the Welfare and Institutions Code for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ *their* own recognizance pending trial.

(C) Sex offender registration status of the applicant.

(D) Sentencing information, if present in the department's records at the time of the response.

(o) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency or organization pursuant to Section 379 or 550 of the Financial Code, or a



statute that incorporates the criteria of either of those sections or this subdivision by reference, and the information is to be used for employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant for a violation or attempted violation of an offense specified in Section 550 of the Financial Code, except a conviction for which relief has been granted pursuant to Section 1203.49.

(B) Every arrest for a violation or attempted violation of an offense specified in Section 550 of the Financial Code for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ *their* own recognizance pending trial.

(C) Sentencing information, if present in the department's records at the time of the response.

(p) (1) This subdivision shall apply whenever state or federal criminal history information is furnished by the Department of Justice as the result of an application by an agency, organization, or individual not defined in subdivision (k), (l), (m), (n), or (o), or by a transportation company authorized pursuant to Section 11105.3, or a statute that incorporates the criteria of that section or this subdivision by reference, and the information is to be used for employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant, except a conviction for which relief has been granted pursuant to Section *1203.4, 1203.4a, 1203.41, 1203.42, 1203.425, or* 1203.49.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ *their* own recognizance pending trial.

(C) Sex offender registration status of the applicant.

(D) Sentencing information, if present in the department's records at the time of the response.

(q) All agencies, organizations, or individuals defined in subdivisions (k), (l), (m), (n), (o), and (p) may contract with the Department of Justice for subsequent notification pursuant to Section 11105.2. This subdivision shall not supersede sections that mandate an agency, organization, or individual to contract with the Department of Justice for subsequent notification pursuant to Section 11105.2.

(r) This section does not require the Department of Justice to cease compliance with any other statutory notification requirements.

(s) The provisions of Section 50.12 of Title 28 of the Code of Federal Regulations are to be followed in processing federal criminal history information.

(t) Whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency, organization, or individual defined in subdivisions (k) to (p), inclusive, and the information is to be used for employment, licensing, or certification purposes, the authorized agency, organization, or individual shall expeditiously furnish a copy of the information to the person to whom the information relates if the information is a basis for an adverse employment, licensing, or certification decision. When furnished other than in person, the copy shall be delivered to the last contact information provided by the applicant.

**SEC. 10.**

Section 13555 of the Vehicle Code is amended to read:

**13555.**

A termination of probation and dismissal of charges pursuant to Section 1203.4 *of*, or a dismissal of charges pursuant to Section 1203.4a ~~*of*~~ *of, or relief granted pursuant to Section 1203.425 of*, the Penal Code does not affect any revocation or suspension of the privilege of the person convicted to drive a motor vehicle under this chapter. Such person's prior conviction shall be considered a conviction for the purpose of revoking or suspending or otherwise limiting such privilege on the ground of two or more convictions.

**SEC. 11.**

*Section 2.5 of this bill incorporates amendments to Section 480 of the Business and Professions Code, as added by Section 4 of Chapter 995 of the Statutes of 2018, proposed by both this bill and Assembly Bill 1521. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2020, (2) each bill amends Section 480 of the Business and Professions Code, as added by Section 4 of Chapter 995 of the Statutes of 2018, and (3) this bill is enacted after Assembly Bill 1521, in which case Section 2 of this bill shall not become operative.*

## **Assembly Bill No. 1264**

### **CHAPTER 741**

Approved by Governor: October 11, 2019.

Filed with Secretary of State: October 11, 2019.

#### **SECTION 1.**

Section 2242 of the Business and Professions Code is amended to read:

#### **2242.**

(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care.

(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of the patient's practitioner, but in any case no longer than 72 hours.

(2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:

(A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.

(B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be.

(3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refill.

(4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code.

**SEC. 2.**

*This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:*

*In order to ensure patients have access to necessary health care services at the earliest possible time, it is imperative that this bill take effect immediately.*

**Senate Bill No. 159**

**CHAPTER 532**

Approved by Governor: October 7, 2019.

Filed with Secretary of State: October 7, 2019.

**SECTION 1.**

Section 4052 of the Business and Professions Code is amended to read:

**4052.**

(a) Notwithstanding any other law, a pharmacist may:

- (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
- (2) Transmit a valid prescription to another pharmacist.
- (3) Administer drugs and biological products that have been ordered by a prescriber.
- (4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.
- (5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.
- (6) Perform procedures or functions as authorized by Section 4052.6.
- (7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.
- (8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) ~~(i)~~ (i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

~~(ii)~~ (ii) Nicotine replacement products, as authorized by Section 4052.9.

~~(iii)~~ (iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

*(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.*

*(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.*

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

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

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

**SEC. 2.**

*Section 4052.02 is added to the Business and Professions Code, to read:*

**4052.02.**

*(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.*

*(b) For purposes of this section, “preexposure prophylaxis” means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.*

*(c) For purposes of this section, “CDC guidelines” means the “2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.*

*(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.*

*(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:*

*(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist’s satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.*

*(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.*

*(3) The patient does not report taking any contraindicated medications.*

*(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.*

*(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.*

*(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.*

*(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.*

*(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.*

*(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.*

### **SEC. 3.**

*Section 4052.03 is added to the Business and Professions Code, to read:*

#### **4052.03.**

*(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.*

*(b) For purposes of this section, "postexposure prophylaxis" means any of the following:*

*(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.*

*(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.*

*(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.*

*(c) For purposes of this section, “CDC guidelines” means the “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV—United States, 2016,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.*

*(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.*

*(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:*

*(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.*

*(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.*

*(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist*



*shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.*

*(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.*

*(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.*

*(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.*

#### **SEC. 4.**

*Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:*

#### **1342.74.**

*(a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).*

*(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.*

*(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.*

*(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.*

*(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.*

**SEC. 5.**

*Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:*

**10123.1933.**

*(a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).*

*(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.*

*(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.*

*(c) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.*

**SEC. 6.**

Section 14132.968 of the Welfare and Institutions Code is amended to read:

**14132.968.**

(a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel ~~medications~~ *medications*, as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone ~~hydrochloride~~ *hydrochloride*, as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in *subdivision (a) of* Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering ~~immunizations~~ *immunizations*, as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement ~~therapy~~ *therapy*, as authorized in Section 4052.9 of the Business and Professions Code.

*(F) Initiating and furnishing preexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code, limited to no more than a 60-day supply of preexposure prophylaxis to a single patient once every two years.*

*(G) Initiating and furnishing postexposure prophylaxis, as authorized in Section 4052.03 of the Business and Professions Code.*

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section ~~does not restrict or prohibit~~ *neither restricts nor prohibits* any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding 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, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a

status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

**SEC. 7.**

*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.*

**Senate Bill No. 601**

**CHAPTER 854**

Approved by Governor: October 12, 2019.

Filed with Secretary of State: October 12, 2019.

**SECTION 1.**

*Section 11009.5 is added to the Government Code, to read:*

**11009.5.**

*(a) For purposes of this section:*

*(1) "Displaced" means a condition in which the person or business is unable to return to the address of record or other address associated with the license before experiencing economic hardship.*

*(2) "Economic hardship" means the inability to pay living or business expenses, unless otherwise defined by a state agency pursuant to subdivision (c).*

*(3) "Emergency" means an emergency as defined in Section 8558 or a declared federal emergency.*

*(4) "License" includes, but is not limited to, a certificate, registration, or other required document to engage in business.*

*(b) Notwithstanding any other law, a state agency that issues any business license may establish a process for a person or business that has been displaced or is experiencing economic hardship as a result of an emergency to submit an application, that the agency may grant, for a reduction or waiver of any fees required by the agency to obtain a license, renew or activate a license, or replace a physical license for display.*

*(c) A fee or waiver process established pursuant to subdivision (b) shall specify, at a minimum, all of the following:*

*(1) The methodology used by the agency for determining whether a person, as a result of an emergency, has been displaced or is experiencing economic hardship.*

*(2) The procedure for applying for a reduction or fee waiver.*

*(3) That the application shall be made within one year of the date on which the emergency was proclaimed or declared.*

# Attachment 3

## Statutory Changes to Pharmacy Law

Unless otherwise noted, the provisions take effect January 1, 2020

### Business and Professions Code Changes

#### **Section 209 of the Business and Professions Code is amended to read:**

The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that ~~he or she is~~ they are applying for licensure or renewing ~~his or her~~ their license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to ~~order~~ access reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

#### **Section 480 of the Business and Professions Code, as amended by Section 3 of Chapter 995 of the Statutes of 2018, is amended to read:**

(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

(1) Been convicted of a crime. A conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, or the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4, 1203.4a, 1203.41, or ~~1203.41~~ 1203.425 of the Penal Code.

(2) Done any act involving dishonesty, fraud, or deceit with the intent to substantially benefit ~~himself~~ themselves or ~~herself~~ or another, or substantially injure another.

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that ~~he or she has~~ they have been convicted of a felony if ~~he or she has~~ they have obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that ~~he or she has~~ they have been convicted of a misdemeanor if ~~he or she has~~ they have met all applicable requirements of the criteria of rehabilitation developed by the board to evaluate the rehabilitation of a person when considering the denial of a license under subdivision (a) of Section 482.

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.41 1203.425 of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

(e) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

**Section 480 of the Business and Professions Code, as added by Section 4 of Chapter 995 of the Statutes of 2018, is amended to read:**

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.



(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

(i) Chapter 1 (commencing with Section 5000) of Division 3.

(ii) Chapter 6 (commencing with Section 6500) of Division 3.

(iii) Chapter 9 (commencing with Section 7000) of Division 3.

(iv) Chapter 11.3 (commencing with Section 7512) of Division 3.

(v) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.

(vi) Division 4 (commencing with Section 10000).

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or ~~1203.42~~ 1203.425 of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that ~~he or she~~ the person has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if ~~he or she~~ that person has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or ~~1203.42~~ 1203.425 of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of ~~his or her~~ the applicant's complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other

communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's ~~Internet Web site~~ internet website and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

**Section 480 of the Business and Professions Code, as added by Section 4 of Chapter 995 of the Statutes of 2018, is amended to read:**

(a) Notwithstanding any other provision of this code, a board may deny a license regulated by this code on the grounds that the applicant has been convicted of a crime or has been subject to formal discipline only if either of the following conditions are met:

(1) The applicant has been convicted of a crime within the preceding seven years from the date of application that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, regardless of whether the applicant was incarcerated for that crime, or the applicant has been convicted of a crime that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made and for which the applicant is presently incarcerated or for which the applicant was released from incarceration within the preceding seven years from the date of application. However, the preceding seven-year limitation shall not apply in either of the following situations:

(A) The applicant was convicted of a serious felony, as defined in Section 1192.7 of the Penal Code or a crime for which registration is required pursuant to paragraph (2) or (3) of subdivision (d) of Section 290 of the Penal Code.

(B) The applicant was convicted of a financial crime currently classified as a felony that is directly and adversely related to the fiduciary qualifications, functions, or duties of the business or profession for which the application is made, pursuant to regulations adopted by the board, and for which the applicant is seeking licensure under any of the following:

~~(i) Chapter 1 (commencing with Section 5000) of Division 3.~~

~~(ii) (i) Chapter 6 (commencing with Section 6500) of Division 3.~~

~~(iii) (ii) Chapter 9 (commencing with Section 7000) of Division 3.~~

~~(iv) (iii) Chapter 11.3 (commencing with Section 7512) of Division 3.~~

~~(v) (iv) Licensure as a funeral director or cemetery manager under Chapter 12 (commencing with Section 7600) of Division 3.~~

~~(vi) (v) Division 4 (commencing with Section 10000).~~

(2) The applicant has been subjected to formal discipline by a licensing board in or outside California within the preceding seven years from the date of application based on professional misconduct that would have been cause for discipline before the board for which the present application is made and that is substantially related to the qualifications, functions, or duties of the business or profession for which the present application is made. However, prior disciplinary action by a licensing board within the preceding seven years shall not be the basis for denial of a license if the basis for that disciplinary action was a conviction that has been

dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or ~~1203.42~~ 1203.425 of the Penal Code or a comparable dismissal or expungement.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis that ~~he or she~~ the person has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if ~~he or she~~ that person has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code, has been granted clemency or a pardon by a state or federal executive, or has made a showing of rehabilitation pursuant to Section 482.

(c) Notwithstanding any other provision of this code, a person shall not be denied a license on the basis of any conviction, or on the basis of the acts underlying the conviction, that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or ~~1203.42~~ 1203.425 of the Penal Code, or a comparable dismissal or expungement. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or 1203.42 of the Penal Code shall provide proof of the dismissal if it is not reflected on the report furnished by the Department of Justice.

(d) Notwithstanding any other provision of this code, a board shall not deny a license on the basis of an arrest that resulted in a disposition other than a conviction, including an arrest that resulted in an infraction, citation, or a juvenile adjudication.

(e) A board may deny a license regulated by this code on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license. A board shall not deny a license based solely on an applicant's failure to disclose a fact that would not have been cause for denial of the license had it been disclosed.

(f) A board shall follow the following procedures in requesting or acting on an applicant's criminal history information:

(1) A board issuing a license pursuant to Chapter 3 (commencing with Section 5500), Chapter 3.5 (commencing with Section 5615), Chapter 10 (commencing with Section 7301), Chapter 20 (commencing with Section 9800), or Chapter 20.3 (commencing with Section 9880), of Division 3, or Chapter 3 (commencing with Section 19000) or Chapter 3.1 (commencing with Section 19225) of Division 8 may require applicants for licensure under those chapters to disclose criminal conviction history on an application for licensure.

(2) Except as provided in paragraph (1), a board shall not require an applicant for licensure to disclose any information or documentation regarding the applicant's criminal history. However, a board may request mitigating information from an applicant regarding the applicant's criminal history for purposes of determining substantial relation or demonstrating evidence of rehabilitation, provided that the applicant is informed that disclosure is voluntary and that the applicant's decision not to disclose any information shall not be a factor in a board's decision to grant or deny an application for licensure.

(3) If a board decides to deny an application for licensure based solely or in part on the applicant's conviction history, the board shall notify the applicant in writing of all of the following:

(A) The denial or disqualification of licensure.

(B) Any existing procedure the board has for the applicant to challenge the decision or to request reconsideration.

(C) That the applicant has the right to appeal the board's decision.

(D) The processes for the applicant to request a copy of ~~his or her~~ the applicant's complete conviction history and question the accuracy or completeness of the record pursuant to Sections 11122 to 11127 of the Penal Code.

(g) (1) For a minimum of three years, each board under this code shall retain application forms and other documents submitted by an applicant, any notice provided to an applicant, all other communications received from and provided to an applicant, and criminal history reports of an applicant.

(2) Each board under this code shall retain the number of applications received for each license and the number of applications requiring inquiries regarding criminal history. In addition, each licensing authority shall retain all of the following information:

(A) The number of applicants with a criminal record who received notice of denial or disqualification of licensure.

(B) The number of applicants with a criminal record who provided evidence of mitigation or rehabilitation.

(C) The number of applicants with a criminal record who appealed any denial or disqualification of licensure.

(D) The final disposition and demographic information, consisting of voluntarily provided information on race or gender, of any applicant described in subparagraph (A), (B), or (C).

(3) (A) Each board under this code shall annually make available to the public through the board's ~~Internet Web site~~ internet website and through a report submitted to the appropriate policy committees of the Legislature deidentified information collected pursuant to this subdivision. Each board shall ensure confidentiality of the individual applicants.

(B) A report pursuant to subparagraph (A) shall be submitted in compliance with Section 9795 of the Government Code.

(h) "Conviction" as used in this section shall have the same meaning as defined in Section 7.5.

(i) This section does not in any way modify or otherwise affect the existing authority of the following entities in regard to licensure:

(1) The State Athletic Commission.

(2) The Bureau for Private Postsecondary Education.

(3) The California Horse Racing Board.

(j) This section shall become operative on July 1, 2020.

**Section 480.2 of the Business and Professions Code is amended to read:**

(a) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license regulated by it on the grounds that the applicant has one of the following:

(1) Been convicted of a crime.

(2) Done any act involving dishonesty, fraud, or deceit with the intent to substantially benefit ~~himself~~ themselves or herself or another, or substantially injure another.

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made.

(b) Notwithstanding any other provision of this code, a person shall not be denied a license solely on the basis that ~~he or she~~ the person has been convicted of a felony if ~~he or she~~ that person has obtained a certificate of rehabilitation under Chapter 3.5 (commencing with Section 4852.01) of Title 6 of Part 3 of the Penal Code or that ~~he or she~~ the person has been convicted of a misdemeanor if ~~he or she~~ the person has met all applicable requirements of the criteria of rehabilitation developed by the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board to evaluate the rehabilitation of a person when considering the denial of a license under paragraph (1) of subdivision (f).

(c) Notwithstanding any other provisions of this code, a person shall not be denied a license by the Bureau for Private Postsecondary Education, the State Athletic Commission, or the

California Horse Racing Board solely on the basis of a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or ~~1203.41~~ 1203.425 of the Penal Code. An applicant who has a conviction that has been dismissed pursuant to Section 1203.4, 1203.4a, or 1203.41 of the Penal Code shall provide proof of the dismissal.

(d) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may deny a license regulated by it on the ground that the applicant knowingly made a false statement of fact that is required to be revealed in the application for the license.

(e) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall develop criteria to aid it, when considering the denial, ~~suspension~~ suspension, or revocation of a license, to determine whether a crime or act is substantially related to the qualifications, functions, or duties of the business or profession it regulates.

(f) (1) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall develop criteria to evaluate the rehabilitation of a person either when:

(A) Considering the denial of a license under this section.

(B) Considering suspension or revocation of a license under Section 490.

(2) The Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board shall take into account all competent evidence of rehabilitation furnished by the applicant or licensee.

(g) Except as otherwise provided by law, following a hearing requested by an applicant pursuant to subdivision (b) of Section 485, the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may take any of the following actions:

(1) Grant the license effective upon completion of all licensing requirements by the applicant.

(2) Grant the license effective upon completion of all licensing requirements by the applicant, immediately revoke the license, stay the revocation, and impose probationary conditions on the license, which may include suspension.

(3) Deny the license.

(4) Take other action in relation to denying or granting the license as the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board, in its discretion, may deem proper.



(h) Notwithstanding any other law, in a proceeding conducted by the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board to deny an application for a license or to suspend or revoke a license or otherwise take disciplinary action against a person who holds a license, upon the ground that the applicant or the licensee has been convicted of a crime substantially related to the qualifications, functions, and duties of the licensee in question, the record of conviction of the crime shall be conclusive evidence of the fact that the conviction occurred, but only of that fact, and the Bureau for Private Postsecondary Education, the State Athletic Commission, and the California Horse Racing Board may inquire into the circumstances surrounding the commission of the crime in order to fix the degree of discipline or to determine if the conviction is substantially related to the qualifications, functions, and duties of the licensee in question.

(i) Notwithstanding Section 7.5, a conviction within the meaning of this section means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action that the Bureau for Private Postsecondary Education, the State Athletic Commission, or the California Horse Racing Board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4, 1203.4a, 1203.41, or ~~1203.41~~ 1203.425 of the Penal Code.

(j) This section shall become operative on July 1, 2020.

**The following section is effective as of October 11, 2019.**

**Section 2242 of the Business and Professions Code is amended to read:**

(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct. An appropriate prior examination does not require a synchronous interaction between the patient and the licensee and can be achieved through the use of telehealth, including, but not limited to, a self-screening tool or a questionnaire, provided that the licensee complies with the appropriate standard of care.

(b) No licensee shall be found to have committed unprofessional conduct within the meaning of this section if, at the time the drugs were prescribed, dispensed, or furnished, any of the following applies:

(1) The licensee was a designated physician and surgeon or podiatrist serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and if the drugs were prescribed, dispensed, or furnished only as necessary to maintain the patient until the return of the patient's practitioner, but in any case no longer than 72 hours.

(2) The licensee transmitted the order for the drugs to a registered nurse or to a licensed vocational nurse in an inpatient facility, and if both of the following conditions exist:

(A) The practitioner had consulted with the registered nurse or licensed vocational nurse who had reviewed the patient's records.

(B) The practitioner was designated as the practitioner to serve in the absence of the patient's physician and surgeon or podiatrist, as the case may be.

(3) The licensee was a designated practitioner serving in the absence of the patient's physician and surgeon or podiatrist, as the case may be, and was in possession of or had utilized the patient's records and ordered the renewal of a medically indicated prescription for an amount not exceeding the original prescription in strength or amount or for more than one refill.

(4) The licensee was acting in accordance with Section 120582 of the Health and Safety Code.

**Section 4052 of the Business and Professions Code is amended to read:**

(a) Notwithstanding any other law, a pharmacist may:

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

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

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

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

(6) Perform procedures or functions as authorized by Section 4052.6.

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

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) ~~(1)~~ (i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

~~(2)~~ (ii) Nicotine replacement products, as authorized by Section 4052.9.

~~(3)~~ (iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

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

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

**Section 4052.02 is added to the Business and Professions Code, to read:**

(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, “preexposure prophylaxis” means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, “CDC guidelines” means the “2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist’s satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.

(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

**Section 4052.03 is added to the Business and Professions Code, to read:**

(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "postexposure prophylaxis" means any of the following:

(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, “CDC guidelines” means the “Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016,” or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:

(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient’s primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient’s primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

**Section 4062 of the Business and Professions Code is amended to read:**

(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

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

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

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

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

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

(e) (1) A pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, may be relocated. The relocation shall not be considered a transfer of ownership or location under Section 4110, if no changes are made to the management and control, or ownership, of the pharmacy and all applicable laws and regulations are followed. Notification of the relocation shall be provided to the board immediately upon identification of the new location.

(2) For purposes of this section, "severely damaged" means damage that renders the premises unsafe or unfit for entry or occupation.

**Section 4115.5 of the Business and Professions Code is amended to read:**

(a) Notwithstanding any other ~~provision of~~ law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.



(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no fewer than 120 hours and no more than ~~120~~ 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to ~~320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.~~ 340 hours.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates ~~his or her trainee status.~~ the pharmacy technician trainee's status as a trainee.

**Section 4126.8 is added to the Business and Professions Code, to read:**

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

**Section 4132 of the Business and Professions Code is amended to read:**

(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~~ satisfy each of the following requirements before only apply to pharmacy technicians working at a remote dispensing sites pharmacy.

(1) Possess a pharmacy technician license that is in good standing.

(2) Possess and maintain a certification issued by a board-approved pharmacy technician certification program.

(3) Possess one of the following:

(A) A minimum of an associate degree in pharmacy technology.

(B) A minimum of a bachelor's degree in any subject.

(C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.

(4) Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

(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~~ their agent regarding a prescription, either before 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.

**Section 4163 of the Business and Professions Code is amended to read:**

(a) A manufacturer, wholesaler, repackager, or pharmacy ~~may~~ shall not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) ~~Dangerous~~ Except as provided in subdivision (c), dangerous drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Upon approval of the board, a reverse distributor licensed as a wholesaler may acquire a dangerous drug or dangerous device from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drug or dangerous device.

**Section 4200 of the Business and Professions Code is amended to read:**

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed ~~the North American Pharmacist Licensure Examination and the~~ a version of the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004. that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure and the applicant meets either of the following requirements:

(A) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and holds an active pharmacist license in another state or territory of the United States.

(B) Has passed the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

**Section 4211 is added to the Business and Professions Code, to read:**

(a) An applicant for renewal of an advanced practice pharmacist recognition shall maintain a current and active pharmacist license, and shall submit all of the following as part of the renewal:

(1) Application and payment of the renewal fees.

(2) (A) Proof satisfactory to the board that the licensee has completed 10 hours of continuing education pursuant to Section 4233.

(B) The 10 hours shall be in addition to the continuing education requirements necessary for a pharmacist license renewal pursuant to Section 4231.

(C) An advanced practice pharmacist shall retain documentation of completion of continuing education for four years.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an advanced practice pharmacist recognition.

(c) The board may issue an inactive advanced practice pharmacist recognition under any of the following conditions:

(1) The pharmacist's license becomes inactive.

(2) The advanced practice pharmacist fails to provide documentation of the completion of the required continuing education.

(3) As part of an investigation or audit conducted by the board, the advanced practice pharmacist fails to provide documentation substantiating the completion of continuing education.

(d) The board shall reactivate an inactive advanced practice pharmacist recognition only if the advanced practice pharmacist pays the required renewal fees pursuant to Section 4210, submits satisfactory proof to the board of completion of the continuing education requirements under Section 4233, and meets all renewal requirements in this section.

**Section 4400 of the Business and Professions Code is amended to read:**

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, 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, designated representative-3PL, or designated 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,~~ processing an application to change information on a premises license record 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) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars (\$325) and may be increased to three hundred sixty dollars (\$360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250). The fee for the annual renewal of the license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250).

(ab) This section shall become inoperative on July 1, 2021, and, as of January 1, 2022, is repealed.

**The following section is effective July 1, 2021.**

**Section 4400 is added to the Business and Professions Code, to read:**

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 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 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 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 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, 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, designated representative-3PL, or designated 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 processing an application to change information on a premises license record 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 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 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) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars (\$325) and may be increased to three hundred sixty dollars (\$360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250). The fee for the annual renewal of the license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250).

(ab) This section shall become operative on July 1, 2021.

**Section 11345.2 of the Business and Professions Code, as amended by Section 14 of Chapter 995 of the Statutes of 2018, is amended to read:**

(a) An individual shall not act as a controlling person for a registrant if any of the following apply:

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. Notwithstanding subdivision (c) of Section 480, if the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, or ~~1203.41~~ 1203.425 of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date ~~he~~ ~~or she~~ the individual has knowledge of that fact.

(c) This section shall become inoperative on July 1, 2020, and, as of January 1, 2021, is repealed.

**Section 11345.2 of the Business and Professions Code, as added by Section 15 of Chapter 995 of the Statutes of 2018, is amended to read:**

(a) An individual shall not act as a controlling person for a registrant if any of the following apply:

(1) The individual has entered a plea of guilty or no contest to, or been convicted of, a felony. If the individual's felony conviction has been dismissed pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, or ~~1203.42~~ 1203.425 of the Penal Code, the bureau may allow the individual to act as a controlling person.

(2) The individual has had a license or certificate to act as an appraiser or to engage in activities related to the transfer of real property refused, denied, canceled, or revoked in this state or any other state.

(b) Any individual who acts as a controlling person of an appraisal management company and who enters a plea of guilty or no contest to, or is convicted of, a felony, or who has a license or certificate as an appraiser refused, denied, canceled, or revoked in any other state shall report that fact or cause that fact to be reported to the office, in writing, within 10 days of the date ~~he~~ or she the individual has knowledge of that fact.

(c) This section shall become operative on July 1, 2020.

## **Health and Safety Code Changes**

**Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:**

(a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

**Section 11159.3 is added to the Health and Safety Code, to read:**

(a) Notwithstanding any other law, during a declared local, state, or federal emergency, if the California State Board of Pharmacy issues a notice that the board is waiving the application of the provisions of, or regulations adopted pursuant to, the Pharmacy Law, as specified in subdivision (b) of Section 4062 of the Business and Professions Code, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription

form meets the requirements of Section 11162.1, if the prescription meets the following requirements:

(1) Contains the information specified in subdivision (a) of Section 11164.

(2) Indicates that the patient is affected by a declared emergency with the words “11159.3 exemption” or a similar statement.

(3) Is written and dispensed within the first two weeks of the notice issued by the board.

(b) A pharmacist filling a prescription pursuant to this section shall do all of the following:

(1) Exercise appropriate professional judgment, including reviewing the patient’s activity report from the CURES Prescription Drug Monitoring Program before dispensing the medication.

(2) If the prescription is for a Schedule II controlled substance, dispense no greater than the amount needed for a seven-day supply.

(3) Require the patient to first demonstrate, to the satisfaction of the pharmacist, their inability to access medications. This demonstration may include, but is not limited to, verification of residency within an evacuation area.

(c) A pharmacist shall not refill a prescription that has been dispensed pursuant to this section.

**Section 11164.1 of the Health and Safety Code is amended to read:**

(a) (1) Notwithstanding any other ~~provision of~~ law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

**This section is effective January 1, 2021.**

**Section 11164.1 is added to the Health and Safety Code, to read:**

(a) (1) Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) A prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) A pharmacy may dispense a prescription for a Schedule III, Schedule IV, or Schedule V controlled substance from an out-of-state prescriber pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2021.

**Section 11165 of the Health and Safety Code is amended to read:**

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and ~~internet internet~~ access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

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

party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The Department of Justice shall, no later than July 1, 2020, adopt regulations regarding the access and use of the information within CURES. The Department of Justice shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

(4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data are provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, and respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.



(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility, if provided.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The Department of Justice may enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a prescription drug monitoring program in

another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the Department of Justice pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the Department of Justice for interstate data sharing of prescription drug monitoring program information.

(3) Any agreement entered into by the Department of Justice for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if ~~he or she~~ the authorized user is registered and in good standing with that state's prescription drug monitoring program.

(5) The Department of Justice shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

(i) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

**This section is effective January 1, 2021.**

**Section 11165 is added to the Health and Safety Code, to read:**

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The department may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the department, for educational, peer review, statistical, or research purposes, if patient information, including information that may identify the patient, is not compromised. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The department shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The department shall, no later than January 1, 2021, adopt regulations regarding the access and use of the information within CURES. The department shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

(4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data are provided and the health care practitioner keeps a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations,

specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Prescribing date of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The department may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. A prescriber or dispenser invitee shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The department shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The department may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The department may enter into an agreement with an entity operating an interstate data sharing hub, or an agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the department pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the department for interstate data sharing of prescription drug monitoring program information.

(3) An agreement entered into by the department for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if the authorized user is registered and in good standing with that state's prescription drug monitoring program.

(5) The department shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

(i) Notwithstanding subdivision (d), a veterinarian shall report the information required by that subdivision to the department as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.

(j) If the dispensing pharmacy, clinic, or other dispenser experiences a temporary technological or electrical failure, it shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within its control. The deadline for transmitting prescription information to the department or contracted prescription data processing vendor pursuant to subdivision (d) shall be extended until the failure is corrected. If

the dispensing pharmacy, clinic, or other dispenser experiences technological limitations that are not reasonably within its control, or is impacted by a natural or manmade disaster, the deadline for transmitting prescription information to the department or contracted prescription data processing vendor shall be extended until normal operations have resumed.

(k) This section shall become operative on January 1, 2021.

**Section 11165.1 of the Health and Safety Code is amended to read:**

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under ~~his or her~~ the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under ~~his or her~~ the pharmacist's care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons ~~which that~~ include, but are not limited to, the following:

(i) Materially falsifying an application to access information contained in the CURES database.

(ii) Failing to maintain effective controls for access to the patient activity report.

(iii) Having ~~his or her~~ their federal DEA registration suspended or revoked.

(iv) Violating a law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Accessing information for a reason other than to diagnose or treat ~~his or her patients, or a patient, or~~ to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional

burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.



(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

(g) For purposes of this section, the following terms have the following meanings:

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(5) "User-initiated basis" means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.

**This section is effective July 1, 2021.**

**Section 11165.1 is added to the Health and Safety Code, to read:**

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, upon receipt of a federal Drug Enforcement Administration (DEA) registration, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the practitioner

or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.

(iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.

(B) The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:

(i) Materially falsifying an application to access information contained in the CURES database.

(ii) Failing to maintain effective controls for access to the patient activity report.

(iii) Having their federal DEA registration suspended or revoked.

(iv) Violating a law governing controlled substances or another law for which the possession or use of a controlled substance is an element of the crime.

(v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of a change to the subscriber account.

(D) An approved health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) An approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system certifies all of the following:

(i) The entity will not use or disclose data received from the CURES database for a purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for a resulting failure of the CURES database to accurately or timely report that information.

(g) For purposes of this section, the following terms have the following meanings:

(1) “Automated basis” means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) “Department” means the Department of Justice.

(3) “Entity” means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) “Health information technology system” means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(h) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

**Section 11165.4 of the Health and Safety Code is amended to read:**

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient’s controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time ~~he or she~~ the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, ~~he or she~~ the health care practitioner shall consult the CURES database to review the patient’s controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, “first time” means the initial occurrence in which a health care practitioner, in ~~his or her~~ their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before ~~he or she~~ the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason ~~he or she~~ they did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or ~~when it~~ cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within ~~his or her~~ the health care practitioner's control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.

**Section 11165.4 is added to the Health and Safety Code, to read:**

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

(iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the



controlled substance prescription that was provided to them by another authorized user of the CURES database.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.

(F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the

temporary technological or electrical failure that is reasonably within the health care practitioner's control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) All applicable state and federal privacy laws govern the duties required by this section.

(f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

## **Government Code Changes**

**Section 11009.5 is added to the Government Code, to read:**

(a) For purposes of this section:

(1) "Displaced" means a condition in which the person or business is unable to return to the address of record or other address associated with the license before experiencing economic hardship.

(2) "Economic hardship" means the inability to pay living or business expenses, unless otherwise defined by a state agency pursuant to subdivision (c).

(3) "Emergency" means an emergency as defined in Section 8558 or a declared federal emergency.

(4) "License" includes, but is not limited to, a certificate, registration, or other required document to engage in business.

(b) Notwithstanding any other law, a state agency that issues any business license may establish a process for a person or business that has been displaced or is experiencing economic hardship as a result of an emergency to submit an application, that the agency may grant, for a reduction or waiver of any fees required by the agency to obtain a license, renew or activate a license, or replace a physical license for display.

(c) A fee or waiver process established pursuant to subdivision (b) shall specify, at a minimum, all of the following:

(1) The methodology used by the agency for determining whether a person, as a result of an emergency, has been displaced or is experiencing economic hardship.

(2) The procedure for applying for a reduction or fee waiver.

(3) That the application shall be made within one year of the date on which the emergency was proclaimed or declared.

## **Labor Code Changes**

### **Section 432.7 of the Labor Code is amended to read:**

(a) (1) An employer, whether a public agency or private individual or corporation, shall not ask an applicant for employment to disclose, through any written form or verbally, information concerning an arrest or detention that did not result in conviction, or information concerning a referral to, and participation in, any pretrial or posttrial diversion program, or concerning a conviction that has been judicially dismissed or ordered sealed pursuant to law, including, but not limited to, Sections 1203.4, 1203.4a, 1203.425, 1203.45, and 1210.1 of the Penal Code. An employer also shall not seek from any source whatsoever, or utilize, as a factor in determining any condition of employment including hiring, promotion, termination, or any apprenticeship training program or any other training program leading to employment, any record of arrest or detention that did not result in conviction, or any record regarding a referral to, and participation in, any pretrial or posttrial diversion program, or concerning a conviction that has been judicially dismissed or ordered sealed pursuant to law, including, but not limited to, Sections 1203.4, 1203.4a, 1203.425, 1203.45, and 1210.1 of the Penal Code. This section shall not prevent an employer from asking an employee or applicant for employment about an arrest for which the employee or applicant is out on bail or on ~~his or her~~ their own recognizance pending trial.

(2) An employer, whether a public agency or private individual or corporation, shall not ask an applicant for employment to disclose, through any written form or verbally, information concerning or related to an arrest, detention, processing, diversion, supervision, adjudication, or court disposition that occurred while the person was subject to the process and jurisdiction of the juvenile court. An employer also shall not seek from any source whatsoever, or utilize, as a factor in determining any condition of employment including hiring, promotion, termination, or any apprenticeship training program or any other training program leading to employment, any record concerning or related to an arrest, detention, processing, diversion, supervision, adjudication, or court disposition that occurred while a person was subject to the process and jurisdiction of the juvenile court.

(3) For purposes of this section:

(A) "Conviction" includes a plea, verdict, or finding of guilt, regardless of whether a sentence is imposed by the court.

(B) "Conviction" does not include, and shall not be construed to include, any adjudication by a juvenile court or any other court order or action taken with respect to a person who is under the process and jurisdiction of the juvenile court.

(b) This section shall not prohibit the disclosure of the information authorized for release under Sections 13203 and 13300 of the Penal Code, to a government agency employing a peace officer. However, the employer shall not determine any condition of employment other than paid administrative leave based solely on an arrest report. The information contained in an arrest report may be used as the starting point for an independent, internal investigation of a peace officer in accordance with Chapter 9.7 (commencing with Section 3300) of Division 4 of Title 1 of the Government Code.

(c) If a person violates this section, or Article 6 (commencing with Section 11140) of Chapter 1 of Title 1 of Part 4 of the Penal Code, the applicant may bring an action to recover from that person actual damages or two hundred dollars (\$200), whichever is greater, plus costs, and reasonable attorney's fees. An intentional violation of this section shall entitle the applicant to treble actual damages, or five hundred dollars (\$500), whichever is greater, plus costs, and reasonable attorney's fees. An intentional violation of this section is a misdemeanor punishable by a fine not to exceed five hundred dollars (\$500).

(d) The remedies under this section shall be in addition to and not in derogation of all other rights and remedies that an applicant may have under any other law.

(e) Persons seeking employment or persons already employed as peace officers or persons seeking employment for positions in the Department of Justice or other criminal justice agencies as defined in Section 13101 of the Penal Code are not covered by this section.

(f) (1) Except as provided in paragraph (2), this section does not prohibit an employer at a health facility, as defined in Section 1250 of the Health and Safety Code, from asking an applicant for employment either of the following:

(A) With regard to an applicant for a position with regular access to patients, to disclose an arrest under any section specified in Section 290 of the Penal Code.

(B) With regard to an applicant for a position with access to drugs and medication, to disclose an arrest under any section specified in Section 11590 of the Health and Safety Code.

(2) (A) An employer specified in paragraph (1) shall not inquire into information concerning or related to an applicant's arrest, detention, processing, diversion, supervision, adjudication, or court disposition that occurred while the person was subject to the process and jurisdiction of juvenile court law, unless the information concerns an adjudication by the juvenile court in which the applicant has been found by the court to have committed a felony or misdemeanor offense specified in paragraph (1) that occurred within five years preceding the application for employment.

(B) Notwithstanding any other provision of this subdivision, an employer specified in paragraph (1) shall not inquire into information concerning or related to an applicant's juvenile offense history that has been sealed by the juvenile court.

(3) An employer seeking disclosure of offense history under paragraph (2) shall provide the applicant with a list describing the specific offenses under Section 11590 of the Health and Safety Code or Section 290 of the Penal Code for which disclosure is sought.

(g) (1) A peace officer or employee of a law enforcement agency with access to criminal or juvenile offender record information maintained by a local law enforcement criminal or juvenile justice agency shall not knowingly disclose, with intent to affect a person's employment, any information pertaining to an arrest or detention or proceeding that did not result in a conviction, including information pertaining to a referral to, and participation in, any pretrial or posttrial diversion program, to any person not authorized by law to receive that information.

(2) Any other person authorized by law to receive criminal or juvenile offender record information maintained by a local law enforcement criminal or juvenile justice agency shall not knowingly disclose any information received pertaining to an arrest or detention or proceeding that did not result in a conviction, including information pertaining to a referral to, and participation in, any pretrial or posttrial diversion program, to any person not authorized by law to receive that information.

(3) Except for those specifically referred to in Section 1070 of the Evidence Code, a person who is not authorized by law to receive or possess criminal or juvenile justice records information maintained by a local law enforcement criminal or juvenile justice agency, pertaining to an arrest or other proceeding that did not result in a conviction, including information pertaining

to a referral to, and participation in, any pretrial or posttrial diversion program, shall not knowingly receive or possess that information.

(h) "A person authorized by law to receive that information," for purposes of this section, means any person or public agency authorized by a court, statute, or decisional law to receive information contained in criminal or juvenile offender records maintained by a local law enforcement criminal or juvenile justice agency, and includes, but is not limited to, those persons set forth in Section 11105 of the Penal Code, and any person employed by a law enforcement criminal or juvenile justice agency who is required by that employment to receive, analyze, or process criminal or juvenile offender record information.

(i) This section does not require the Department of Justice to remove entries relating to an arrest or detention not resulting in conviction from summary criminal history records forwarded to an employer pursuant to law.

(j) As used in this section, "pretrial or posttrial diversion program" means any program under Chapter 2.5 (commencing with Section 1000) or Chapter 2.7 (commencing with Section 1001) of Title 6 of Part 2 of the Penal Code, Section 13201 or 13352.5 of the Vehicle Code, Sections 626, 626.5, 654, or 725 of, or Article 20.5 (commencing with Section 790) of Chapter 2 of Part 1 of Division 2 of, the Welfare and Institutions Code, or any other program expressly authorized and described by statute as a diversion program.

(k) (1) Subdivision (a) shall not apply to any city, city and county, county, or district, or any officer or official thereof, in screening a prospective concessionaire, or the affiliates and associates of a prospective concessionaire for purposes of consenting to, or approving of, the prospective concessionaire's application for, or acquisition of, any beneficial interest in a concession, lease, or other property interest.

(2) For purposes of this subdivision the following terms apply:

(A) "Screening" means a written request for criminal or juvenile history information made to a local law enforcement agency.

(B) "Prospective concessionaire" means any individual, general or limited partnership, corporation, trust, association, or other entity that is applying for, or seeking to obtain, a public agency's consent to, or approval of, the acquisition by that individual or entity of any beneficial ownership interest in any public agency's concession, lease, or other property right whether directly or indirectly held. However, "prospective concessionaire" does not include any of the following:

(i) A lender acquiring an interest solely as security for a bona fide loan made in the ordinary course of the lender's business and not made for the purpose of acquisition.

(ii) A lender upon foreclosure or assignment in lieu of foreclosure of the lender's security.

(C) "Affiliate" means any individual or entity that controls, or is controlled by, the prospective concessionaire, or who is under common control with the prospective concessionaire.

(D) "Associate" means any individual or entity that shares a common business purpose with the prospective concessionaire with respect to the beneficial ownership interest that is subject to the consent or approval of the city, county, city and county, or district.

(E) "Control" means the possession, direct or indirect, of the power to direct, or cause the direction of, the management or policies of the controlled individual or entity.

(I) (1) Subdivision (a) does not prohibit a public agency, or any officer or official thereof, from denying consent to, or approval of, a prospective concessionaire's application for, or acquisition of, any beneficial interest in a concession, lease, or other property interest based on the criminal history information of the prospective concessionaire or the affiliates or associates of the prospective concessionaire that show any criminal conviction for offenses involving moral turpitude. Criminal history information for purposes of this subdivision includes any criminal history information obtained pursuant to Section 11105 or 13300 of the Penal Code.

(2) In considering criminal history information, a public agency shall consider the crime for which the prospective concessionaire or the affiliates or associates of the prospective concessionaire was convicted only if that crime relates to the specific business that is proposed to be conducted by the prospective concessionaire.

(3) Any prospective concessionaire whose application for consent or approval to acquire a beneficial interest in a concession, lease, or other property interest is denied based on criminal history information shall be provided a written statement of the reason for the denial.

(4) (A) If the prospective concessionaire submits a written request to the public agency within 10 days of the date of the notice of denial, the public agency shall review its decision with regard to any corrected record or other evidence presented by the prospective concessionaire as to the accuracy or incompleteness of the criminal history information utilized by the public agency in making its original decision.

(B) The prospective concessionaire shall submit the copy or the corrected record of any other evidence to the public agency within 90 days of a request for review. The public agency shall render its decision within 20 days of the submission of evidence by the prospective concessionaire.

(m) (1) Paragraph (1) of subdivision (a) does not prohibit an employer, whether a public agency or private individual or corporation, from asking an applicant about, or seeking from any source information regarding, a particular conviction of the applicant if, pursuant to Section 1829 of Title 12 of the United States Code or any other federal law, federal regulation, or state law, any of the following apply:



(A) The employer is required by law to obtain information regarding the particular conviction of the applicant, regardless of whether that conviction has been expunged, judicially ordered sealed, statutorily eradicated, or judicially dismissed following probation.

(B) The applicant would be required to possess or use a firearm in the course of ~~his or her~~ their employment.

(C) An individual with that particular conviction is prohibited by law from holding the position sought by the applicant, regardless of whether that conviction has been expunged, judicially ordered sealed, statutorily eradicated, or judicially dismissed following probation.

(D) The employer is prohibited by law from hiring an applicant who has that particular conviction, regardless of whether that conviction has been expunged, judicially ordered sealed, statutorily eradicated, or judicially dismissed following probation.

(2) For purposes of this subdivision, “particular conviction” means a conviction for specific criminal conduct or a category of criminal offenses prescribed by any federal law, federal regulation, or state law that contains requirements, exclusions, or both, expressly based on that specific criminal conduct or category of criminal offenses.

(n) Nothing in this section shall prohibit an employer, whether a public agency or private individual or corporation, required by state, federal, or local law to conduct criminal background checks for employment purposes or to restrict employment based on criminal history from complying with those requirements, or to prohibit the employer from seeking or receiving an applicant’s criminal history report that has been obtained pursuant to procedures otherwise provided for under federal, state, or local law. For purposes of this subdivision, federal law shall include rules or regulations promulgated by a self-regulatory organization, as defined in Section 3(a)(26) of the Securities Exchange Act of 1934, pursuant to the authority in Section 19(b) of the Securities Exchange Act of 1934, as amended by 124 Stat. 1652 (Public Law 11-203).

## **Penal Code Changes**

**This section is effective January 1, 2021.**

**Section 851.93 is added to the Penal Code, to read:**

(a) (1) On a monthly basis, the Department of Justice shall review the records in the statewide criminal justice databases, and based on information in the state summary criminal history repository, shall identify persons with records of arrest that meet the criteria set forth in paragraph (2) and are eligible for arrest record relief.

(2) A person is eligible for relief pursuant to this section, if the arrest occurred on or after January 1, 2021, and meets any of the following conditions:

(A) The arrest was for a misdemeanor offense and the charge was dismissed.

(B) The arrest was for a misdemeanor offense, there is no indication that criminal proceedings have been initiated, at least one calendar year has elapsed since the date of the arrest, and no conviction occurred, or the arrestee was acquitted of any charges that arose, from that arrest.

(C) The arrest was for an offense that is punishable by imprisonment pursuant to paragraph (1) or (2) of subdivision (h) of Section 1170, there is no indication that criminal proceedings have been initiated, at least three calendar years have elapsed since the date of the arrest, and no conviction occurred, or the arrestee was acquitted of any charges arising, from that arrest.

(D) The person successfully completed any of the following, relating to that arrest:

(i) A prefiling diversion program, as defined in Section 851.87, administered by a prosecuting attorney in lieu of filing an accusatory pleading.

(ii) A drug diversion program administered by a superior court pursuant to Section 1000.5, or a deferred entry of judgment program pursuant to Section 1000 or 1000.8.

(iii) A pretrial diversion program, pursuant to Section 1000.4.

(iv) A diversion program, pursuant to Section 1001.9.

(v) Any diversion program described in Chapter 2.8 (commencing with Section 1001.20), Chapter 2.8A (commencing with Section 1001.35), Chapter 2.81 (commencing with Section 1001.40), Chapter 2.9 (commencing with Section 1001.50), Chapter 2.9A (commencing with Section 1001.60), Chapter 2.9B (commencing with Section 1001.70), Chapter 2.9C (commencing with Section 1001.80), Chapter 2.9D (commencing with Section 1001.81), or Chapter 2.92 (commencing with Section 1001.85), of Title 6.

(b) (1) The department shall grant relief to a person identified pursuant to subdivision (a), without requiring a petition or motion by a party for that relief if the relevant information is present in the department's electronic records.

(2) The state summary criminal history information shall include, directly next to or below the entry or entries regarding the person's arrest record, a note stating "arrest relief granted," listing the date that the department granted relief, and this section. This note shall be included in all statewide criminal databases with a record of the arrest.

(3) Except as otherwise provided in subdivision (d), an arrest for which arrest relief has been granted is deemed not to have occurred, and a person who has been granted arrest relief is

released from any penalties and disabilities resulting from the arrest, and may answer any question relating to that arrest accordingly.

(c) On a monthly basis, the department shall electronically submit a notice to the superior court having jurisdiction over the criminal case, informing the court of all cases for which a complaint was filed in that jurisdiction and for which relief was granted pursuant to this section. Commencing on February 1, 2021, for any record retained by the court pursuant to Section 68152 of the Government Code, except as provided in subdivision (d), the court shall not disclose information concerning an arrest that is granted relief pursuant to this section to any person or entity, in any format, except to the person whose arrest was granted relief or a criminal justice agency, as defined in Section 851.92.

(d) Relief granted pursuant to this section is subject to the following conditions:

(1) Arrest relief does not relieve a person of the obligation to disclose an arrest in response to a direct question contained in a questionnaire or application for employment as a peace officer, as defined in Section 830.

(2) Relief granted pursuant to this section has no effect on the ability of a criminal justice agency, as defined in Section 851.92, to access and use records that are granted relief to the same extent that would have been permitted for a criminal justice agency had relief not been granted.

(3) This section does not limit the ability of a district attorney to prosecute, within the applicable statute of limitations, an offense for which arrest relief has been granted pursuant to this section.

(4) Relief granted pursuant to this section does not affect a person's authorization to own, possess, or have in the person's custody or control any firearm, or the person's susceptibility to conviction under Chapter 2 (commencing with Section 29800) of Division 9 of Title 4 of Part 6, if the arrest would otherwise affect this authorization or susceptibility.

(5) Relief granted pursuant to this section does not affect any prohibition from holding public office that would otherwise apply under law as a result of the arrest.

(6) Relief granted pursuant to this section does not affect the authority to receive, or take adverse action based on, criminal history information, including the authority to receive certified court records received or evaluated pursuant to Section 1522, 1568.09, 1569.17, or 1596.871 of the Health and Safety Code, or pursuant to any statutory or regulatory provisions that incorporate the criteria of those sections.

(e) This section shall not limit petitions, motions, or orders for arrest record relief, as required or authorized by any other law, including, but not limited to, Sections 851.87, 851.90, 851.91, 1000.4, and 1001.9.

(f) The department shall annually publish statistics for each county regarding the total number of arrests granted relief pursuant to this section and the percentage of arrests for which the state summary criminal history information does not include a disposition, on the OpenJustice Web portal, as defined in Section 13010.

(g) This section shall be operative commencing January 1, 2021, subject to an appropriation in the annual Budget Act.

**Section 1203.425 is added to the Penal Code, immediately following Section 1203.42, to read:**

(a) (1) On a monthly basis, the Department of Justice shall review the records in the statewide criminal justice databases, and based on information in the state summary criminal history repository and the Supervised Release File, shall identify persons with convictions that meet the criteria set forth in paragraph (2) and are eligible for automatic conviction record relief.

(2) A person is eligible for automatic conviction relief pursuant to this section if they meet all of the following conditions:

(A) The person is not required to register pursuant to the Sex Offender Registration Act.

(B) The person does not have an active record for local, state, or federal supervision in the Supervised Release File.

(C) Based upon the information available in the department's record, including disposition dates and sentencing terms, it does not appear that the person is currently serving a sentence for any offense and there is no indication of any pending criminal charges.

(D) Except as otherwise provided in clause (iii) of subparagraph (E), there is no indication that the conviction resulted in a sentence of incarceration in the state prison.

(E) The conviction occurred on or after January 1, 2021, and meets either of the following criteria:

(i) The defendant was sentenced to probation and, based upon the disposition date and the term of probation specified in the department's records, appears to have completed their term of probation without revocation.

(ii) The defendant was convicted of an infraction or misdemeanor, was not granted probation, and, based upon the disposition date and the term specified in the department's records, the defendant appears to have completed their sentence, and at least one calendar year has elapsed since the date of judgment.

(b) (1) Except as specified in subdivision (h), the department shall grant relief, including dismissal of a conviction, to a person identified pursuant to subdivision (a), without requiring a

petition or motion by a party for that relief if the relevant information is present in the department's electronic records.

(2) The state summary criminal history information shall include, directly next to or below the entry or entries regarding the person's criminal record, a note stating "relief granted," listing the date that the department granted relief and this section. This note shall be included in all statewide criminal databases with a record of the conviction.

(3) Except as otherwise provided in subdivision (d) and in Section 13555 of the Vehicle Code, a person granted conviction relief pursuant to this section shall be released from all penalties and disabilities resulting from the offense of which the person has been convicted.

(c) On a monthly basis, the department shall electronically submit a notice to the superior court having jurisdiction over the criminal case, informing the court of all cases for which a complaint was filed in that jurisdiction and for which relief was granted pursuant to this section. Commencing on February 1, 2021, for any record retained by the court pursuant to Section 68152 of the Government Code, except as provided in subdivision (d), the court shall not disclose information concerning a conviction granted relief pursuant to this section or Section 1203.4, 1203.4a, 1203.41, or 1203.42, to any person or entity, in any format, except to the person whose conviction was granted relief or a criminal justice agency, as defined in Section 851.92.

(d) Relief granted pursuant to this section is subject to the following conditions:

(1) Relief granted pursuant to this section does not relieve a person of the obligation to disclose a criminal conviction in response to a direct question contained in a questionnaire or application for employment as a peace officer, as defined in Section 830.

(2) Relief granted pursuant to this section does not relieve a person of the obligation to disclose the conviction in response to any direct question contained in any questionnaire or application for public office, or for contracting with the California State Lottery Commission.

(3) Relief granted pursuant to this section has no effect on the ability of a criminal justice agency, as defined in Section 851.92, to access and use records that are granted relief to the same extent that would have been permitted for a criminal justice agency had relief not been granted.

(4) Relief granted pursuant to this section does not limit the jurisdiction of the court over any subsequently filed motion to amend the record, petition or motion for postconviction relief, or collateral attack on a conviction for which relief has been granted pursuant to this section.

(5) Relief granted pursuant to this section does not affect a person's authorization to own, possess, or have in the person's custody or control any firearm, or the person's susceptibility to

conviction under Chapter 2 (commencing with Section 29800) of Division 9 of Title 4 of Part 6, if the criminal conviction would otherwise affect this authorization or susceptibility.

(6) Relief granted pursuant to this section does not affect any prohibition from holding public office that would otherwise apply under law as a result of the criminal conviction.

(7) Relief granted pursuant to this section does not affect the authority to receive, or take adverse action based on, criminal history information, including the authority to receive certified court records received or evaluated pursuant to Section 1522, 1568.09, 1569.17, or 1596.871 of the Health and Safety Code, or pursuant to any statutory or regulatory provisions that incorporate the criteria of those sections.

(8) Relief granted pursuant to this section does not make eligible a person who is otherwise ineligible to provide, or receive payment for providing, in-home supportive services pursuant to Article 7 (commencing with Section 12300) of Chapter 3 of Part 3 of Division 9 of the Welfare and Institutions Code, or pursuant to Section 14132.95, 14132.952, or 14132.956 of the Welfare and Institutions Code.

(9) In any subsequent prosecution of the defendant for any other offense, the prior conviction may be pleaded and proved and shall have the same effect as if the relief had not been granted.

(e) This section shall not limit petitions, motions, or orders for relief in a criminal case, as required or authorized by any other law, including, but not limited to, Sections 1203.4 and 1204.4a.

(f) The department shall annually publish statistics for each county regarding the total number of convictions granted relief pursuant to this section and the total number of convictions prohibited from automatic relief pursuant to subdivision (h), on the OpenJustice Web portal, as defined in Section 13010.

(g) Subdivisions (a) to (f), inclusive, shall be operative commencing January 1, 2021, subject to an appropriation in the annual Budget Act.

(h) (1) The prosecuting attorney or probation department may, no later than 90 calendar days before the date of a person's eligibility for relief pursuant to this section, file a petition to prohibit the department from granting automatic relief pursuant to this section, based on a showing that granting such relief would pose a substantial threat to the public safety.

(2) The court shall give notice to the defendant and conduct a hearing on the petition within 45 days after the petition is filed.

(3) At a hearing on the petition pursuant to this subdivision, the defendant, the probation department, the prosecuting attorney, and the arresting agency, through the prosecuting

attorney, may present evidence to the court. Notwithstanding Sections 1538.5 and 1539, the hearing may be heard and determined upon declarations, affidavits, police investigative reports, copies of state summary criminal history information and local summary criminal history information, or any other evidence submitted by the parties that is material, reliable, and relevant.

(4) The prosecutor or probation department has the initial burden of proof to show that granting conviction relief would pose a substantial threat to the public safety. In determining whether granting such relief would pose a substantial threat to the public safety, the court may consider any relevant factors including, but not limited to, either of the following:

(A) Declarations or evidence regarding the offense for which a grant of relief is being contested.

(B) The defendant's record of arrests and convictions.

(5) If the court finds that the prosecutor or probation department has satisfied the burden of proof, the burden shifts to the defendant to show that the hardship of not obtaining relief outweighs the threat to the public safety of providing such relief. In determining whether the defendant's hardship outweighs the threat to the public safety, the court may consider any relevant factors including, but not limited to, either of the following:

(A) The hardship to the defendant that has been caused by the conviction and that would be caused if relief is not granted.

(B) Declarations or evidence regarding the defendant's good character.

(6) If the court grants a petition pursuant to this subdivision, the court shall furnish a disposition report to the Department of Justice pursuant to Section 13151, stating that relief pursuant to this section was denied, and the department shall not grant relief pursuant to this section.

(7) A person denied relief pursuant to this section may continue to be eligible for relief pursuant to Section 1203.4 or 1203.4a. If the court subsequently grants relief pursuant to one of those sections, the court shall furnish a disposition report to the Department of Justice pursuant to Section 13151, stating that relief was granted pursuant to the applicable section, and the department shall grant relief pursuant to that section.

(i) At the time of sentencing, the court shall advise a defendant, either orally or in writing, of the provisions of this section and of the defendant's right, if any, to petition for a certificate of rehabilitation and pardon.

**Section 11105 of the Penal Code is amended to read:**

(a) (1) The Department of Justice shall maintain state summary criminal history information.

(2) As used in this section:

(A) "State summary criminal history information" means the master record of information compiled by the Attorney General pertaining to the identification and criminal history of a person, such as name, date of birth, physical description, fingerprints, photographs, dates of arrests, arresting agencies and booking numbers, charges, dispositions, sentencing information, and similar data about the person.

(B) "State summary criminal history information" does not refer to records and data compiled by criminal justice agencies other than the Attorney General, nor does it refer to records of complaints to or investigations conducted by, or records of intelligence information or security procedures of, the office of the Attorney General and the Department of Justice.

(b) The Attorney General shall furnish state summary criminal history information to the following, if needed in the course of their duties, provided that when information is furnished to assist an agency, officer, or official of state or local government, a public utility, or any other entity, in fulfilling employment, certification, or licensing duties, Chapter 1321 of the Statutes of 1974 and Section 432.7 of the Labor Code shall apply:

(1) The courts of the state.

(2) Peace officers of the state, as defined in Section 830.1, subdivisions (a) and (e) of Section 830.2, subdivision (a) of Section 830.3, subdivision (a) of Section 830.31, and subdivisions (a) and (b) of Section 830.5.

(3) District attorneys of the state.

(4) Prosecuting city attorneys or city prosecutors of a city within the state.

(5) City attorneys pursuing civil gang injunctions pursuant to Section 186.22a, or drug abatement actions pursuant to Section 3479 or 3480 of the Civil Code, or Section 11571 of the Health and Safety Code.

(6) Probation officers of the state.

(7) Parole officers of the state.

(8) A public defender or attorney of record when representing a person in proceedings upon a petition for a certificate of rehabilitation and pardon pursuant to Section 4852.08.

(9) A public defender or attorney of record when representing a person in a criminal case or a juvenile delinquency proceeding, including all appeals and postconviction motions, or a parole, mandatory supervision pursuant to paragraph (5) of subdivision (h) of Section 1170, or postrelease community supervision revocation or revocation extension proceeding, if the information is requested in the course of representation.



(10) An agency, officer, or official of the state if the state summary criminal history information is required to implement a statute or regulation that expressly refers to specific criminal conduct applicable to the subject person of the state summary criminal history information, and contains requirements or exclusions, or both, expressly based upon that specified criminal conduct. The agency, officer, or official of the state authorized by this paragraph to receive state summary criminal history information may also transmit fingerprint images and related information to the Department of Justice to be transmitted to the Federal Bureau of Investigation.

(11) A city or county, city and county, district, or an officer or official thereof if access is needed in order to assist that agency, officer, or official in fulfilling employment, certification, or licensing duties, and if the access is specifically authorized by the city council, board of supervisors, or governing board of the city, county, or district if the state summary criminal history information is required to implement a statute, ordinance, or regulation that expressly refers to specific criminal conduct applicable to the subject person of the state summary criminal history information, and contains requirements or exclusions, or both, expressly based upon that specified criminal conduct. The city or county, city and county, district, or the officer or official thereof authorized by this paragraph may also transmit fingerprint images and related information to the Department of Justice to be transmitted to the Federal Bureau of Investigation.

(12) The subject of the state summary criminal history information under procedures established under Article 5 (commencing with Section 11120).

(13) A person or entity when access is expressly authorized by statute if the criminal history information is required to implement a statute or regulation that expressly refers to specific criminal conduct applicable to the subject person of the state summary criminal history information, and contains requirements or exclusions, or both, expressly based upon that specified criminal conduct.

(14) Health officers of a city, county, city and county, or district when in the performance of their official duties enforcing Section 120175 of the Health and Safety Code.

(15) A managing or supervising correctional officer of a county jail or other county correctional facility.

(16) A humane society, or society for the prevention of cruelty to animals, for the specific purpose of complying with Section 14502 of the Corporations Code for the appointment of humane officers.

(17) Local child support agencies established by Section 17304 of the Family Code. When a local child support agency closes a support enforcement case containing state summary criminal history information, the agency shall delete or purge from the file and destroy any documents

or information concerning or arising from offenses for or of which the parent has been arrested, charged, or convicted, other than for offenses related to the parent's having failed to provide support for minor children, consistent with the requirements of Section 17531 of the Family Code.

(18) County child welfare agency personnel who have been delegated the authority of county probation officers to access state summary criminal history information pursuant to Section 272 of the Welfare and Institutions Code for the purposes specified in Section 16504.5 of the Welfare and Institutions Code. Information from criminal history records provided pursuant to this subdivision shall not be used for a purpose other than those specified in this section and Section 16504.5 of the Welfare and Institutions Code. When an agency obtains records both on the basis of name checks and fingerprint checks, final placement decisions shall be based only on the records obtained pursuant to the fingerprint check.

(19) The court of a tribe, or court of a consortium of tribes, that has entered into an agreement with the state pursuant to Section 10553.1 of the Welfare and Institutions Code. This information may be used only for the purposes specified in Section 16504.5 of the Welfare and Institutions Code and for tribal approval or tribal licensing of foster care or adoptive homes. Article 6 (commencing with Section 11140) shall apply to officers, members, and employees of a tribal court receiving state summary criminal history information pursuant to this section.

(20) Child welfare agency personnel of a tribe or consortium of tribes that has entered into an agreement with the state pursuant to Section 10553.1 of the Welfare and Institutions Code and to whom the state has delegated duties under paragraph (2) of subdivision (a) of Section 272 of the Welfare and Institutions Code. The purposes for use of the information shall be for the purposes specified in Section 16504.5 of the Welfare and Institutions Code and for tribal approval or tribal licensing of foster care or adoptive homes. When an agency obtains records on the basis of name checks and fingerprint checks, final placement decisions shall be based only on the records obtained pursuant to the fingerprint check. Article 6 (commencing with Section 11140) shall apply to child welfare agency personnel receiving criminal record offender information pursuant to this section.

(21) An officer providing conservatorship investigations pursuant to Sections 5351, 5354, and 5356 of the Welfare and Institutions Code.

(22) A court investigator providing investigations or reviews in conservatorships pursuant to Section 1826, 1850, 1851, or 2250.6 of the Probate Code.

(23) A person authorized to conduct a guardianship investigation pursuant to Section 1513 of the Probate Code.

(24) A humane officer pursuant to Section 14502 of the Corporations Code for the purposes of performing ~~his or her~~ the officer's duties.

(25) A public agency described in subdivision (b) of Section 15975 of the Government Code, for the purpose of oversight and enforcement policies with respect to its contracted providers.

(26) (A) A state entity, or its designee, that receives federal tax information. A state entity or its designee that is authorized by this paragraph to receive state summary criminal history information also may transmit fingerprint images and related information to the Department of Justice to be transmitted to the Federal Bureau of Investigation for the purpose of the state entity or its designee obtaining federal level criminal offender record information from the Department of Justice. This information shall be used only for the purposes set forth in Section 1044 of the Government Code.

(B) For purposes of this paragraph, “federal tax information,” “state entity” and “designee” are as defined in paragraphs (1), (2), and (3), respectively, of subdivision (f) of Section 1044 of the Government Code.

(c) The Attorney General may furnish state summary criminal history information and, when specifically authorized by this subdivision, federal level criminal history information upon a showing of a compelling need to any of the following, provided that when information is furnished to assist an agency, officer, or official of state or local government, a public utility, or any other entity in fulfilling employment, certification, or licensing duties, Chapter 1321 of the Statutes of 1974 and Section 432.7 of the Labor Code shall apply:

(1) A public utility, as defined in Section 216 of the Public Utilities Code, that operates a nuclear energy facility when access is needed in order to assist in employing persons to work at the facility, provided that, if the Attorney General supplies the data, ~~he or she~~ the Attorney General shall furnish a copy of the data to the person to whom the data relates.

(2) To a peace officer of the state other than those included in subdivision (b).

(3) To an illegal dumping enforcement officer as defined in subdivision (j) of Section 830.7.

(4) To a peace officer of another country.

(5) To public officers, other than peace officers, of the United States, other states, or possessions or territories of the United States, provided that access to records similar to state summary criminal history information is expressly authorized by a statute of the United States, other states, or possessions or territories of the United States if the information is needed for the performance of their official duties.

(6) To a person when disclosure is requested by a probation, parole, or peace officer with the consent of the subject of the state summary criminal history information and for purposes of furthering the rehabilitation of the subject.

(7) The courts of the United States, other states, or territories or possessions of the United States.

(8) Peace officers of the United States, other states, or territories or possessions of the United States.

(9) To an individual who is the subject of the record requested if needed in conjunction with an application to enter the United States or a foreign nation.

(10) (A) (i) A public utility, as defined in Section 216 of the Public Utilities Code, or a cable corporation as defined in subparagraph (B), if receipt of criminal history information is needed in order to assist in employing current or prospective employees, contract employees, or subcontract employees who, in the course of their employment, may be seeking entrance to private residences or adjacent grounds. The information provided shall be limited to the record of convictions and arrests for which the person is released on bail or on ~~his or her~~ their own recognizance pending trial.

(ii) If the Attorney General supplies the data pursuant to this paragraph, the Attorney General shall furnish a copy of the data to the current or prospective employee to whom the data relates.

(iii) State summary criminal history information is confidential and the receiving public utility or cable corporation shall not disclose its contents, other than for the purpose for which it was acquired. The state summary criminal history information in the possession of the public utility or cable corporation and all copies made from it shall be destroyed not more than 30 days after employment or promotion or transfer is denied or granted, except for those cases where a current or prospective employee is out on bail or on ~~his or her~~ their own recognizance pending trial, in which case the state summary criminal history information and all copies shall be destroyed not more than 30 days after the case is resolved.

(iv) A violation of this paragraph is a misdemeanor, and shall give the current or prospective employee who is injured by the violation a cause of action against the public utility or cable corporation to recover damages proximately caused by the violations. A public utility's or cable corporation's request for state summary criminal history information for purposes of employing current or prospective employees who may be seeking entrance to private residences or adjacent grounds in the course of their employment shall be deemed a "compelling need" as required to be shown in this subdivision.

(v) This section shall not be construed as imposing a duty upon public utilities or cable corporations to request state summary criminal history information on current or prospective employees.

(B) For purposes of this paragraph, “cable corporation” means a corporation or firm that transmits or provides television, computer, or telephone services by cable, digital, fiber optic, satellite, or comparable technology to subscribers for a fee.

(C) Requests for federal level criminal history information received by the Department of Justice from entities authorized pursuant to subparagraph (A) shall be forwarded to the Federal Bureau of Investigation by the Department of Justice. Federal level criminal history information received or compiled by the Department of Justice may then be disseminated to the entities referenced in subparagraph (A), as authorized by law.

(11) To a campus of the California State University or the University of California, or a four-year college or university accredited by a regional accreditation organization approved by the United States Department of Education, if needed in conjunction with an application for admission by a convicted felon to a special education program for convicted felons, including, but not limited to, university alternatives and halfway houses. Only conviction information shall be furnished. The college or university may require the convicted felon to be fingerprinted, and any inquiry to the department under this section shall include the convicted felon’s fingerprints and any other information specified by the department.

(12) To a foreign government, if requested by the individual who is the subject of the record requested, if needed in conjunction with the individual’s application to adopt a minor child who is a citizen of that foreign nation. Requests for information pursuant to this paragraph shall be in accordance with the process described in Sections 11122 to 11124, inclusive. The response shall be provided to the foreign government or its designee and to the individual who requested the information.

(d) Whenever an authorized request for state summary criminal history information pertains to a person whose fingerprints are on file with the Department of Justice and the department has no criminal history of that person, and the information is to be used for employment, licensing, or certification purposes, the fingerprint card accompanying the request for information, if any, may be stamped “no criminal record” and returned to the person or entity making the request.

(e) Whenever state summary criminal history information is furnished as the result of an application and is to be used for employment, licensing, or certification purposes, the Department of Justice may charge the person or entity making the request a fee that it determines to be sufficient to reimburse the department for the cost of furnishing the information. In addition, the Department of Justice may add a surcharge to the fee to fund maintenance and improvements to the systems from which the information is obtained. Notwithstanding any other law, a person or entity required to pay a fee to the department for information received under this section may charge the applicant a fee sufficient to reimburse the person or entity for this expense. All moneys received by the department pursuant to this section, Sections 11105.3 and 26190, and former Section 13588 of the Education Code shall be deposited in a special account in the General Fund to be available for expenditure by the department to offset costs incurred pursuant to those sections and for maintenance and

improvements to the systems from which the information is obtained upon appropriation by the Legislature.

(f) Whenever there is a conflict, the processing of criminal fingerprints and fingerprints of applicants for security guard or alarm agent registrations or firearms qualification permits submitted pursuant to Section 7583.9, 7583.23, 7596.3, or 7598.4 of the Business and Professions Code shall take priority over the processing of other applicant fingerprints.

(g) It is not a violation of this section to disseminate statistical or research information obtained from a record, provided that the identity of the subject of the record is not disclosed.

(h) It is not a violation of this section to include information obtained from a record in (1) a transcript or record of a judicial or administrative proceeding or (2) any other public record if the inclusion of the information in the public record is authorized by a court, statute, or decisional law.

(i) Notwithstanding any other law, the Department of Justice or a state or local law enforcement agency may require the submission of fingerprints for the purpose of conducting state summary criminal history information checks that are authorized by law.

(j) The state summary criminal history information shall include any finding of mental incompetence pursuant to Chapter 6 (commencing with Section 1367) of Title 10 of Part 2 arising out of a complaint charging a felony offense specified in Section 290.

(k) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency or organization and the information is to be used for peace officer employment or certification purposes. As used in this subdivision, a peace officer is defined in Chapter 4.5 (commencing with Section 830) of Title 3 of Part 2.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ their own recognizance pending trial.

(C) Every arrest or detention, except for an arrest or detention resulting in an exoneration, provided, however, that where the records of the Department of Justice do not contain a disposition for the arrest, the Department of Justice first makes a genuine effort to determine the disposition of the arrest.

(D) Every successful diversion.

(E) Every date and agency name associated with all retained peace officer or nonsworn law enforcement agency employee preemployment criminal offender record information search requests.

(F) Sex offender registration status of the applicant.

(G) Sentencing information, if present in the department's records at the time of the response.

(I) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by a criminal justice agency or organization as defined in Section 13101, and the information is to be used for criminal justice employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ their own recognizance pending trial.

(C) Every arrest for an offense for which the records of the Department of Justice do not contain a disposition or which did not result in a conviction, provided that the Department of Justice first makes a genuine effort to determine the disposition of the arrest. However, information concerning an arrest shall not be disclosed if the records of the Department of Justice indicate or if the genuine effort reveals that the subject was exonerated, successfully completed a diversion or deferred entry of judgment program, or the arrest was deemed a detention, or the subject was granted relief pursuant to Section 851.91.

(D) Every date and agency name associated with all retained peace officer or nonsworn law enforcement agency employee preemployment criminal offender record information search requests.

(E) Sex offender registration status of the applicant.

(F) Sentencing information, if present in the department's records at the time of the response.

(m) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an

authorized agency or organization pursuant to Section 1522, 1568.09, 1569.17, or 1596.871 of the Health and Safety Code, or a statute that incorporates the criteria of any of those sections or this subdivision by reference, and the information is to be used for employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction of an offense rendered against the applicant, except a conviction for which relief has been granted pursuant to Section 1203.49.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ their own recognizance pending trial.

(C) Every arrest for an offense for which the Department of Social Services is required by paragraph (1) of subdivision (a) of Section 1522 of the Health and Safety Code to determine if an applicant has been arrested. However, if the records of the Department of Justice do not contain a disposition for an arrest, the Department of Justice shall first make a genuine effort to determine the disposition of the arrest.

(D) Sex offender registration status of the applicant.

(E) Sentencing information, if present in the department's records at the time of the response.

(3) Notwithstanding the requirements of the sections referenced in paragraph (1) of this subdivision, the Department of Justice shall not disseminate information about an arrest subsequently deemed a detention or an arrest that resulted in the successful completion of a diversion program, exoneration, or a grant of relief pursuant to Section 851.91.

(n) (1) This subdivision shall apply whenever state or federal summary criminal history information, to be used for employment, licensing, or certification purposes, is furnished by the Department of Justice as the result of an application by an authorized agency, organization, or individual pursuant to any of the following:

(A) Paragraph (10) of subdivision (c), when the information is to be used by a cable corporation.

(B) Section 11105.3 or 11105.4.

(C) Section 15660 of the Welfare and Institutions Code.

(D) A statute that incorporates the criteria of any of the statutory provisions listed in subparagraph (A), (B), or (C), or of this subdivision, by reference.



(2) With the exception of applications submitted by transportation companies authorized pursuant to Section 11105.3, and notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction, except a conviction for which relief has been granted pursuant to Section 1203.49, rendered against the applicant for a violation or attempted violation of an offense specified in subdivision (a) of Section 15660 of the Welfare and Institutions Code. However, with the exception of those offenses for which registration is required pursuant to Section 290, the Department of Justice shall not disseminate information pursuant to this subdivision unless the conviction occurred within 10 years of the date of the agency's request for information or the conviction is over 10 years old but the subject of the request was incarcerated within 10 years of the agency's request for information.

(B) Every arrest for a violation or attempted violation of an offense specified in subdivision (a) of Section 15660 of the Welfare and Institutions Code for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ their own recognizance pending trial.

(C) Sex offender registration status of the applicant.

(D) Sentencing information, if present in the department's records at the time of the response.

(o) (1) This subdivision shall apply whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency or organization pursuant to Section 379 or 550 of the Financial Code, or a statute that incorporates the criteria of either of those sections or this subdivision by reference, and the information is to be used for employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant for a violation or attempted violation of an offense specified in Section 550 of the Financial Code, except a conviction for which relief has been granted pursuant to Section 1203.49.

(B) Every arrest for a violation or attempted violation of an offense specified in Section 550 of the Financial Code for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ their own recognizance pending trial.

(C) Sentencing information, if present in the department's records at the time of the response.

(p) (1) This subdivision shall apply whenever state or federal criminal history information is furnished by the Department of Justice as the result of an application by an agency, organization, or individual not defined in subdivision (k), (l), (m), (n), or (o), or by a transportation company authorized pursuant to Section 11105.3, or a statute that incorporates the criteria of that section or this subdivision by reference, and the information is to be used for employment, licensing, or certification purposes.

(2) Notwithstanding any other law, whenever state summary criminal history information is initially furnished pursuant to paragraph (1), the Department of Justice shall disseminate the following information:

(A) Every conviction rendered against the applicant, except a conviction for which relief has been granted pursuant to Section 1203.4, 1203.4a, 1203.41, 1203.42, 1203.425, or 1203.49.

(B) Every arrest for an offense for which the applicant is presently awaiting trial, whether the applicant is incarcerated or has been released on bail or on ~~his or her~~ their own recognizance pending trial.

(C) Sex offender registration status of the applicant.

(D) Sentencing information, if present in the department's records at the time of the response.

(q) All agencies, organizations, or individuals defined in subdivisions (k), (l), (m), (n), (o), and (p) may contract with the Department of Justice for subsequent notification pursuant to Section 11105.2. This subdivision shall not supersede sections that mandate an agency, organization, or individual to contract with the Department of Justice for subsequent notification pursuant to Section 11105.2.

(r) This section does not require the Department of Justice to cease compliance with any other statutory notification requirements.

(s) The provisions of Section 50.12 of Title 28 of the Code of Federal Regulations are to be followed in processing federal criminal history information.

(t) Whenever state or federal summary criminal history information is furnished by the Department of Justice as the result of an application by an authorized agency, organization, or individual defined in subdivisions (k) to (p), inclusive, and the information is to be used for employment, licensing, or certification purposes, the authorized agency, organization, or individual shall expeditiously furnish a copy of the information to the person to whom the information relates if the information is a basis for an adverse employment, licensing, or certification decision. When furnished other than in person, the copy shall be delivered to the last contact information provided by the applicant.

## Insurance Code Changes

**Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:**

(a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

## Vehicle Code Changes

**Section 13555 of the Vehicle Code is amended to read:**

A termination of probation and dismissal of charges pursuant to Section 1203.4 of, or a dismissal of charges pursuant to Section 1203.4a ~~of~~ of, or relief granted pursuant to Section 1203.425 of, the Penal Code does not affect any revocation or suspension of the privilege of the person convicted to drive a motor vehicle under this chapter. Such person's prior conviction shall be considered a conviction for the purpose of revoking or suspending or otherwise limiting such privilege on the ground of two or more convictions.

## Welfare and Institutions Code Changes

**Section 14132.968 of the Welfare and Institutions Code is amended to read:**

(a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel ~~medications~~ medications, as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone ~~hydrochloride~~ hydrochloride, as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in subdivision (a) of Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering ~~immunizations~~ immunizations, as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement ~~therapy~~ therapy, as authorized in Section 4052.9 of the Business and Professions Code.

(F) Initiating and furnishing preexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code, limited to no more than a 60-day supply of preexposure prophylaxis to a single patient once every two years.

(G) Initiating and furnishing postexposure prophylaxis, as authorized in Section 4052.03 of the Business and Professions Code.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section ~~does not restrict or prohibit~~ neither restricts nor prohibits any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding 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, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

# **Attachment 4**

## Regulation Timeline

### e. Discussion and Consideration of Board Approved Regulations Undergoing Final Review by the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 CCR Section 1749 Related to the Board's Fee Schedule

**Timeline:**

Approved by Board: December 14, 2018

Submitted to DCA for Pre-Notice Review: December 17, 2018

45-Day Comment Period began: April 26, 2019 and Closed June 10, 2019

Adopted by Board: June 21, 2019

Submitted to DCA for Formal Review: June 24, 2019

Submitted to OAL for Final review: September 30, 2019

**Fee Schedule**  
**16 CCR § 1749**



## Title 16. Board of Pharmacy Proposed Text

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

### Proposal to Amend section 1749 in Article 6 of Division 17 of Title 16 California Code of Regulations to read as follows:

#### 1749. Fee Schedule.

The ~~application, renewal, penalties, and other fees, unless otherwise specified, for the issuance and renewal of licenses, certificates, and permits, and the penalties to be assessed for failure to renew in accordance with section 163.5 of the Business and Professions Code and Pharmacy Law~~ are hereby fixed as follows:

- (a) The fee for the issuance of any pharmacy license, including a remote dispensing site pharmacy license, is ~~five hundred twenty dollars (\$520)~~ five hundred seventy dollars (\$570). The fee for the annual renewal of any pharmacy license, including a remote dispensing site pharmacy license, is ~~six hundred sixty five dollars (\$665)~~ nine hundred and thirty dollars (\$930). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (b) The fee for the issuance of any temporary pharmacy license is three hundred twenty-five dollars (\$325).
- (c) The fee for the issuance of a pharmacy technician license ~~is shall be one hundred and forty dollars (\$140)~~ one hundred ninety-five dollars (\$195). The fee for the biennial renewal of a pharmacy technician license ~~is shall be one hundred forty dollars (\$140)~~ one hundred ninety-five dollars (\$195). The penalty for failure to renew a ~~pharmacy technician license~~ is ~~seventy dollars (\$70)~~ ninety-seven dollars and fifty cents (\$97.50).
- (d) The application fee for ~~application and~~ examination as a pharmacist is ~~two hundred sixty dollars (\$260)~~ two hundred eighty-five dollars (\$285).
- (e) The fee for regrading an examination is one hundred fifteen dollars (\$115).
- (f)(1) The fee for the issuance of an original pharmacist license is ~~one hundred ninety-five dollars (\$195)~~ two hundred and fifteen dollars (\$215).
- (2) The application fee for ~~application of~~ an advanced practice pharmacist license is three hundred dollars (\$300). If granted, there is no fee for the initial license issued, which will expire at the same time the pharmacist's license expires.
- (g)(1) The fee for the biennial renewal of a pharmacist's license is ~~three hundred sixty dollars (\$360)~~ five hundred five dollars (\$505). The penalty fee for failure to renew is one hundred fifty dollars (\$150).
- (2) The fee for the biennial renewal of an advanced practice pharmacist license is three hundred dollars (\$300). The penalty fee for failure to renew is one hundred fifty dollars (\$150). The fees in this paragraph are in addition to the fees required to renew the pharmacist's license as specified in paragraph 1.

- (h) ~~The fee for the issuance or renewal of a wholesaler or third-party logistics provider license is seven hundred eighty dollars (\$780)~~ eight hundred twenty dollars (\$820). The fee for the annual renewal of a wholesaler or third-party logistics provider license is eight hundred twenty dollars (\$820). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a temporary wholesaler or third-party logistics provider license is seven hundred fifteen dollars (\$715).
- (i) The fee for the issuance of a hypodermic license is ~~one hundred seventy dollars (\$170)~~ two hundred forty dollars (\$240). The fee for the annual renewal of a hypodermic needle license is two hundred eighty dollars ~~(\$200)~~ (\$280). The penalty for failure to renew is one hundred forty dollars ~~(\$100)~~ (\$140).
- (j) The fee for the issuance of a ~~license as a designated representative license~~ pursuant to Section 4053 of the Business and Professions Code, ~~or a designated representative-3PL license pursuant to Section 4053.1 of the Business and Professions Code, or a designated representative-reverse distributor license pursuant to Section 4053.2 of the Business and Professions Code,~~ is ~~one hundred fifty dollars (\$150)~~ two hundred ten dollars (\$210). The fee for the annual renewal of a license as a designated representative, ~~or designated representative-3PL, or a designated representative-reverse distributor~~ is shall be two hundred and fifteen dollars (\$215) ~~three hundred dollars (\$300)~~. The penalty for failure to renew is ~~one hundred seven dollars and fifty cents (\$107.50)~~ one hundred fifty dollars (\$150).
- (k) The application fee for the application or renewal of a license as a nonresident wholesaler or nonresident third-party logistics provider is ~~seven hundred eighty dollars (\$780)~~ eight hundred twenty dollars (\$820). The fee for the annual renewal of a nonresident wholesaler or nonresident third-party logistics provider is eight hundred twenty dollars (\$820). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a nonresident wholesaler or nonresident third-party logistics provider temporary license is seven hundred fifteen dollars (\$715).
- (l) The fee for an intern pharmacist license is ~~one hundred sixty five dollars (\$165)~~ two hundred thirty dollars (\$230). The fee for transfer of intern hours or verification of licensure to another state is thirty dollars (\$30).
- (m) The fee for the reissuance of any ~~permit, license, or certificate,~~ or renewal thereof, which must be reissued because of change in the information, other than name change, is one hundred thirty dollars ~~(\$100)~~ (\$130).
- (n) The fee for the reissuance of any license that has been lost or destroyed or reissued due to a name change is forty-five dollars (\$45).
- (o) The fee for evaluation of continuing education courses for accreditation is forty dollars (\$40) for each hour of accreditation requested.
- (p) The fee for the issuance of a clinic license is ~~five hundred twenty dollars (\$520)~~ five hundred seventy dollars (\$570). The fee for the annual renewal of a clinic license is ~~three hundred twenty five dollars (\$325)~~ three hundred sixty dollars (\$360). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (q) The fee for the issuance of a nongovernmental license to compound sterile drug ~~products preparations or a hospital satellite compounding pharmacy license~~ is ~~one thousand six hundred forty five dollars (\$1,645)~~ two thousand three hundred five dollars (\$2,305). The fee for the annual renewal of a nongovernmental license to

compound sterile drug products/preparations or a hospital satellite compounding pharmacy license is ~~one thousand three hundred twenty-five dollars (\$1,325)~~ one thousand eight hundred fifty-five dollars (\$1,855). The penalty for failure to renew a nongovernmental license to compound sterile drug preparations or a hospital satellite compounding pharmacy license is one hundred fifty dollars (\$150). The fee for a nongovernmental temporary license to compound sterile drug preparations or a hospital satellite compounding pharmacy temporary license is ~~five hundred fifty dollars (\$550)~~ seven hundred fifteen dollars (\$715).

- (r) The fee for the issuance of a nonresident sterile compounding pharmacy is ~~two thousand three hundred eighty dollars (\$2,380)~~ three thousand three hundred thirty-five dollars (\$3,335). The fee for the annual renewal of nonresident sterile compounding pharmacy license is ~~two thousand two hundred seventy dollars (\$2,270)~~ three thousand one hundred eighty dollars (\$3,180). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a temporary nonresident sterile compounding pharmacy license is ~~five hundred fifty dollars (\$550)~~ seven hundred fifteen dollars (\$715).
- (s) The fee for the issuance of a license as a designated representative for a veterinary food-animal drug retailer is ~~one hundred fifty dollars (\$150)~~ two hundred ten dollars (\$210). The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer is ~~two hundred fifteen dollars (\$215)~~ three hundred dollars (\$300). The penalty for failure to renew is ~~one hundred seven dollars and fifty cents (\$107.50)~~ one hundred fifty dollars (\$150).
- (t) The fee for a veterinary food-animal drug retailer license is ~~four hundred and thirty-five dollars (\$435)~~ six hundred ten dollars (\$610). The application fee for the annual renewal for a veterinary food-animal drug retailer is ~~three hundred thirty dollars (\$330)~~ four hundred sixty dollars (\$460). The fee for the issuance of a veterinary food-animal drug retailer temporary license is two hundred and fifty dollars (\$250). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (u) The fee for the issuance of a retired pharmacist license shall be forty-five dollars (\$45).
- (v) The fee for the issuance of a centralized hospital packaging pharmacy license is ~~eight hundred twenty dollars (\$820)~~ one thousand one hundred fifty dollars (\$1,150). The fee for the annual renewal fee for of a centralized hospital packaging pharmacy license is ~~eight hundred five dollars (\$805)~~ one thousand one hundred twenty five dollars (\$1,125). The penalty for failure to renew is one hundred fifty dollars (\$150).
- (w) The fee for the issuance of an outsourcing facility license is ~~two thousand two hundred seventy dollars (\$2,270)~~ three thousand one hundred eighty dollars (\$3,180). The annual renewal fee for the annual renewal of an outsourcing facility is ~~one thousand three hundred twenty-five dollars (\$1,325)~~ one thousand eight hundred fifty-five dollars (\$1,855). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for an temporary outsourcing facility temporary license is seven hundred fifteen dollars (\$715).
- (x) The fee for the issuance of a nonresident outsourcing facility license is ~~two thousand three hundred eighty dollars (\$2,380)~~ three thousand three hundred thirty-five dollars (\$3,335). The fee for the annual renewal fee for of a nonresident outsourcing facility

is ~~two thousand two hundred seventy dollars (\$2,270)~~ three thousand one hundred eighty dollars (\$3,180). The penalty for failure to renew is one hundred fifty dollars (\$150). The fee for a nonresident outsourcing facility temporary license is seven hundred fifteen dollars (\$715).

(y) The fee for the issuance of a correctional clinic license that is not owned by the state is five hundred seventy dollars (\$570). The annual renewal application fee for a correctional clinic license is three hundred sixty dollars (\$360). The penalty for failure to renew is one hundred fifty dollars (\$150).

(z) The application and initial license fee for operation of an EMSADDS is one hundred dollars (\$100). The application fee for the annual renewal of an EMSADDS is one hundred dollars (\$100). The penalty for failure to renew is thirty-five dollars (\$35).

(aa) The application fee of a co-location clinic license is seven hundred fifty dollars (\$750).

(ab) The application and initial license fee for a designated paramedic license is one hundred and forty dollars (\$140). The application fee for the biennial renewal of a designated paramedic license is one hundred forty dollars (\$140). The penalty for failure to renew a designated paramedic license is sixty-five dollars (\$65).

Note: Authority cited: Sections 4005 and 4400, Business and Professions Code.

Reference: Sections 163.5, 4005, 4044.3, 4053, 4053.1, 4110, 4112, 4119.01, 4120, 4127.1, 4127.15, 4127.2, 4128.2, 4129.1, 4129.2, 4129.8, 4130, 4160, 4161, 4180, 4180.5, 4187, 4190, 4196, 4200, 4202, 4202.5, 4203, 4208, 4210, 4304, 4400, 4401 and 4403, Business and Professions Code.

# **Attachment 5**

## Regulation Timeline

### **f. Discussion and Consideration of Board Approved Regulations Undergoing Formal Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency**

1. Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet

**Timeline:**

Approved by Board: May 4, 2017

Submitted to DCA for Pre-Notice Review: May 31, 2017

Returned to the board: January 18, 2018

Modified language approved by board: March 27, 2018

Re-submitted to DCA for Pre-Notice Review: June 13, 2018

Returned to the board on: July 2, 2018

Re-submitted to DCA for Pre-Notice Review: July 2, 2018

Formal DCA Pre-Notice Review began: July 2, 2018

45-Day Comment Period began: April 26, 2019 and Closed on June 17, 2019

Adopted by Board: June 21, 2019

Submitted to DCA for Formal Review: August 28, 2019

# **Naloxone Fact Sheet**

**16 CCR § 1746.3**

## BOARD OF PHARMACY

**Proposal to amend** § 1746.3 in Article 5 of Division 17 of Title 16 of the California Code of Regulations to read:

### **§ 1746.3. Protocol for Pharmacists Furnishing Naloxone Hydrochloride.**

A pharmacist furnishing naloxone hydrochloride pursuant to section 4052.01 of the Business and Professions Code shall satisfy the requirements of this section.

(a) As used in this section:

(1) "Opioid" means naturally derived opiates as well as synthetic and semi-synthetic opioids.

(2) "Recipient" means the person to whom naloxone hydrochloride is furnished.

(b) Training. Prior to furnishing naloxone hydrochloride, pharmacists who use this protocol must have successfully completed a minimum of one hour of an approved continuing education program specific to the use of naloxone hydrochloride in all routes of administration recognized in subsection (c)(4) of this protocol, or an equivalent curriculum-based training program completed in a board recognized school of pharmacy.

(c) Protocol for Pharmacists Furnishing Naloxone Hydrochloride.

Before providing naloxone hydrochloride, the pharmacist shall:

(1) Screen the potential recipient by asking the following questions:

(A) Whether the potential recipient currently uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may skip screening question B.);

(B) Whether the potential recipient is in contact with anyone who uses or has a history of using illicit or prescription opioids. (If the recipient answers yes, the pharmacist may continue.);

(C) Whether the person to whom the naloxone hydrochloride would be administered has a known hypersensitivity to naloxone. (If the recipient answers yes, the pharmacist may not provide naloxone. If the recipient responds no, the pharmacist may continue.)



The screening questions shall be made available on the Board of Pharmacy's website in alternate languages for patients whose primary language is not English.

(2) Provide the recipient training in opioid overdose prevention, recognition, response, and administration of the antidote naloxone.

(3) When naloxone hydrochloride is furnished:

(A) The pharmacist shall provide the recipient with appropriate counseling and information on the product furnished, including dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. The recipient is not permitted to waive the required consultation.

(B) The pharmacist shall provide the recipient with any informational resources on hand and/or referrals to appropriate resources if the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time.

(C) The pharmacist shall answer any questions the recipient may have regarding naloxone hydrochloride.

(4) Product Selection: A pharmacist shall advise the recipient on how to choose the route of administration based on the formulation available, how well it can likely be administered, the setting, and local context. A pharmacist may supply naloxone hydrochloride as an intramuscular injection, intranasal spray, auto-injector or in another FDA-approved product form. A pharmacist may also recommend optional items when appropriate, including alcohol pads, rescue breathing masks, and rubber gloves.

(5) Labeling: A pharmacist shall label the naloxone hydrochloride consistent with law and regulations. Labels shall include an expiration date for the naloxone hydrochloride furnished. An example of appropriate labeling is available on the Board of Pharmacy's website.

(6) Fact Sheet: The pharmacist shall provide the recipient a copy of the current naloxone fact sheet approved by the Board of Pharmacy or a fact sheet approved by the executive officer. The executive officer may only approve a fact sheet that has all the elements and information that are contained in the current board-approved fact sheet. ~~This~~ The board-approved fact sheet shall be made available on the Board of Pharmacy's website in alternate languages for patients

whose primary language is not English. Fact sheets in alternate languages must be the current naloxone fact sheet approved by the Board of Pharmacy.

(7) Notifications: If the recipient of the naloxone hydrochloride is also the person to whom the naloxone hydrochloride would be administered, then the naloxone recipient is considered a patient for purposes of this protocol and notification may be required under this section.

If the patient gives verbal or written consent, then the pharmacist shall notify the patient's primary care provider of any drug(s) and/or device(s) furnished, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the patient and that primary care provider.

If the patient does not have a primary care provider, or chooses not to give notification consent, then the pharmacist shall provide a written record of the drug(s) and/or device(s) furnished and advise the patient to consult an appropriate health care provider of the patient's choice.

(8) Documentation: Each naloxone hydrochloride product furnished by a pharmacist pursuant to this protocol shall be documented in a medication record for the naloxone recipient, and securely stored within the originating pharmacy or health care facility for a period of at least three years from the date of dispense. The medication record shall be maintained in an automated data or manual record mode such that the required information under title 16, sections 1707.1 and 1717 of the California Code of Regulations is readily retrievable during the pharmacy or facility's normal operating hours.

(9) Privacy: All pharmacists furnishing naloxone hydrochloride in a pharmacy or health care facility shall operate under the pharmacy or facility's policies and procedures to ensure that recipient confidentiality and privacy are maintained.

Note: Authority cited: Section 4052.01, Business and Professions Code.

Reference: Section 4052.01, Business and Professions Code.

# **Attachment 6**

## Regulation Timelines

### **g. Discussion and Consideration of Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency**

#### **Regulations under Pre-Notice review by DCA Legal Affairs**

1. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

**Timeline:**

Approved by Board: May 2, 2018

Submitted to DCA for Pre-Notice Review: July 12, 2018

Returned to the board: September 6, 2018

Re-submitted to DCA for Pre-Notice Review: September 18, 2018

Returned to the board: September 28, 2018

Re-submitted to DCA for Pre-Notice Review: October 4, 2018

Formal DCA Pre-Notice Review began: October 16, 2018

**Returned to the Board on: July 23, 2019**

2. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

**Timeline:**

Approved by Board: January 24, 2017

Submitted to DCA for Pre-Notice Review: April 27, 2017

Returned to the board: January 18, 2018

Re-submitted to DCA for Pre-Notice Review: June 25, 2018

Returned to the board: July 3, 2018

Re-submitted to DCA for Pre-Notice Review: July 13, 2018

Formal DCA Pre-Notice Review began: August 20, 2018

Returned to the board: March 19, 2019

**Re-submitted to DCA for Formal Pre-Notice Review: April 9, 2019**

3. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

**Timeline:**

Approved by Board: May 3, 2017

Submitted to DCA for Pre-Notice Review: November 7, 2017

Returned to the Board on: March 26, 2018

Re-submitted to DCA for Pre-Notice Review: June 29, 2018

Returned to the Board on: August 20, 2018

**Re-submitted to DCA for Pre-Notice Review: September 20, 2018**

## **Regulations under Pre-Notice review by DCA Legal Counsel**

4. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

### **Timeline:**

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 23, 2017

Returned to the board: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: August 21, 2017

Returned to the board: February 24, 2018

Modified language approved by board: March 27, 2018

Re-submitted to DCA for Pre-Notice Review: July 11, 2018

Returned to the board: August 20, 2018

**Re-submitted to DCA for Pre-Notice Review: October 26, 2018**

5. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

### **Timeline:**

Approved by Board: October 26, 2016

Submitted to DCA for Pre-Notice Review: January 26, 2017

Returned to the Board on: March 28, 2017

Re-submitted to DCA for Pre-Notice Review: May 24, 2018

Returned to the board: August 6, 2018

Re-submitted to DCA for Pre-Notice Review: August 16, 2018

Returned to the board: November 2, 2018

**Re-submitted to DCA for Pre-Notice Review: December 20, 2018**

6. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

### **Timeline:**

Approved by board: October 26, 2016

Submitted to DCA for Pre-Notice Review: February 9, 2017

Returned to the board on: February 28, 2017

Re-submitted to DCA for Pre-Notice Review: October 25, 2017

Returned to the board on: March 26, 2018

Re-submitted to DCA for Pre-Notice Review: June 28, 2018

Returned to the board on: August 28, 2018

Re-submitted to DCA for Pre-Notice Review: September 6, 2018

Returned to the board on: October 30, 2018

**Re-submitted to DCA for Pre-Notice Review: December 20, 2018**

7. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

**Timeline:**

Approved by Board: November 8, 2017

Submitted to DCA for Pre-Notice Review: February 2, 2018

Returned to the Board on: April 17, 2018

Re-submitted to DCA for Pre-Notice Review: July 23, 2018

Returned to the Board on: November 13, 2018

**Re-submitted to DCA for Pre-Notice Review: December 24, 2018**

8. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

**Timeline:**

Approved by Board: November 8, 2017

**Submitted to DCA for Pre-Notice Review: December 26, 2018**

9. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

**Timeline:**

Approved by Board: January 30, 2019

**Submitted to DCA for Pre-Notice Review: April 30, 2019**

10. Proposed Regulations to Amend Title 16 CCR Sections 1769 and 1770 Related to Criminal Conviction Substantial Relationship and Rehabilitation Criteria

**Timeline:**

Approved by Board: May 6, 2019

**Submitted to DCA for Pre-Notice Review: May 31, 2019**

11. Proposed Regulations to Add Title 16 CCR Section 1714.3 Related to Community Pharmacy Staffing

**Timeline:**

Approved by Board: July 25, 2019

**Submitted to DCA for Pre-Notice Review: August 26, 2019**

12. Proposed Regulations to Amend Title 16 CCR Sections 1735 et seq. Related to Pharmaceutical Compounding of Nonsterile Preparations

**Timeline:**

Approved by Board: July 25, 2019

**Submitted to DCA for Pre-Notice Review: September 3, 2019**

**Renewal  
Requirements  
16 CCR §§ 1702,  
1702.1, 1702.2, 1702.5**



**Title 16. Board of Pharmacy  
Proposed Text**

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

**Amend section 1702 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1702. Pharmacist Renewal Requirements.**

- (a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.
- (1) A pharmacist ~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.
- (2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
- (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
- (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
- (b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
- (c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproof.
- (d) As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with any continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.2.
- (e) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

**Amend section 1702.1 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1702.1. Pharmacy Technician Renewal Requirements for Individual Licensees Other Than Pharmacists.**

This section applies to the renewal of any license held by an individual other than a license as a pharmacist or an advanced practice pharmacist.

- (a) An individual licensee ~~pharmacy technician applicant~~ for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.
- (1) The individual ~~A pharmacy technician~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.
- (2) The individual ~~A pharmacy technician~~ applicant for renewal shall pay the actual cost of compliance with subdivision (a).
- (3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).
- (4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
- (b) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
- (c) As a condition of renewal, ~~a pharmacy technician applicant~~ the individual shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.
- (d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4038, 4115, 4202, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

**Repeal section 1702.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations.**

**~~1702.2. Designated Representative Renewal Requirements.~~**

- ~~(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.~~
- ~~(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.~~
- ~~(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).~~
- ~~(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).~~
- ~~(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).~~
- ~~(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.~~
- ~~(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproof.~~
- ~~(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.~~

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

**Amend section 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1702.5. Renewal Requirements for Premises or Facilities ~~Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy.~~**

This section applies to a renewal application submitted by a licensed premises or facility.

- (a) As a condition of renewal, an applicant seeking renewal of a premises or facility license ~~as a nonresident wholesaler or as a nonresident pharmacy~~ shall report to the board any disciplinary action taken by any government agency since the issuance or last renewal of the license. ~~An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license.~~ Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.
- (b) For purposes of this section, “disciplinary action” means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation, or public reprimand or reproval.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.

# **Offsite Storage**

**16 CCR § 1707**

**Title 16. Board of Pharmacy  
Proposed Text**

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

**§ 1707. Waiver Requirements for Off-Site Storage of Records**

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code.~~

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:

- (1) maintain the storage area so that the records are secure, including from unauthorized access; and
- (2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:

- (1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.
- (2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

# **Automatic Refill Programs**

**16 CCR § 1717.5**

**Title 16. BOARD OF PHARMACY**  
**Proposed Text**

**Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1717.5. Automatic Refill Programs.**

- (a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.
- (1) Written notice regarding the program shall be given to the patient or patient's agent. Such notice shall include instructions about how to withdraw a prescription medication from the program.
  - (2) The patient or patient's agent shall enroll by written, online or electronic consent to participate in the program.
  - (3) The pharmacy shall keep a copy of the written consent to enroll on file for one year from date of dispensing.
  - (4) The pharmacy shall have written policies and procedures in place that outline specifics of the program. The policies and procedures shall specify the medications that may be refilled through the program.
  - (5) The patient or patient's agent shall have the option to withdraw from the program at any time.
  - (6) The pharmacy shall complete a drug regimen review for each prescription refilled through the program.
  - (7) Each time a prescription is refilled through the program, the pharmacy shall provide a written notification to the patient or patient's agent confirming that the prescription medication is enrolled in the program.
  - (8) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication in the program reported as unneeded or unnecessary, if the pharmacy had been notified of withdrawal or disenrollment from the program.
  - (9) A pharmacy shall make available any written notification required by this section in alternate languages as required by state or federal law.
- (b) A health care facility licensed pursuant to Health and Safety Code section 1250 that automatically refills prescription medications for its patients need not comply with the provisions of this section.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.



# **Pharmacy Technician**

**16 CCR § 1793.5,  
1793.6, and 1793.65**

**Title 16. Board of Pharmacy  
Proposed Regulation Text**

**Proposal to amend** §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§ 1793.5. Pharmacy Technician Application.**

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~10/15~~ 7/2018)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5, 4005, 4007, 4038, 4115, and 4202, 4207 and 4400~~, Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

**Proposal to amend** §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**§ 1793.6. Training Courses Specified by the Board.**

A course of training that meets the requirements of Business and Professions Code section 4202

(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health--System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c) (1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(± A) Knowledge and understanding of different pharmacy practice settings.

(2 B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(3 C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4 D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(5 E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(6 F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(7 G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to admission to the course of training, an administrator or instructor must conduct a criminal background check and counsel applicants to the program about the negative impact to securing licensure if the background check reveals criminal history.

(B) Administer at least one drug screening to each student to evaluate use of illicit drugs or use of drugs without a prescription. The results of any screen shall be considered as part of the evaluation criteria to determine (1) acceptance into the course of training, or (2) appropriateness for continuation in the course of training. An administrator or instructor shall counsel students about the negative impact of a positive drug screen on eligibility for licensure.

(C) Require students to be at least 18 years of age prior to the beginning of instruction.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subsection (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115~~, and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

**Proposal to add §1793.65 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**1793.65 Pharmacy Technician Certification Programs Approved by the Board.**

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and

(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, 2021.

Note: Authority cited: Business and Professions Code Sections 4005 and 4202. Reference: Business and Professions Code Sections 4038 and 4202.

**Attachment 6:** Board Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

A hardcopy of the proposed pharmacy technician application will be made available at the meeting or upon request. Requests may be emailed to [Debbie.Damoth@dca.ca.gov](mailto:Debbie.Damoth@dca.ca.gov).

**Pharmacy Ownership,  
Management, and  
Control, Including  
Through Trusts  
16 CCR § 1709**

**Title 16. Board of Pharmacy  
Proposed Text**

**To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

§1709. Names of Owners and Pharmacist In Charge Disclosure and Notification Requirements

- (a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership (~~individual, partnership or corporation~~) and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.
- (b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.
- (c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership transfer of permit and shall require a new application for a change of ownership licensure:
- (1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.
- (d) If any beneficial interest of the pharmacy is held in trust, the applicant, licensee, or any person with management or control of the pharmacy, shall do the following:
- (1) In addition to the requirements in subdivision (a), as part of their application and annual renewal, report the name of any other person in any position with management or control of the pharmacy.
- (2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the annual renewal, the name, address and contact information for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and annual renewal shall also include the name, address, and contact information for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the pharmacy.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4110, 4111, 4112, 4113, 4120, 4124, 4130, 4133, 4141, 4149, 4160, 4161, 4196, 4201, 4302, 4304, 4305, 4307, 4308, and 4330, Business and Professions Code.

**Third-Party Logistics  
Providers and  
Dangerous Drug  
Distributors  
16 CCR §§ 1780-1783**



## Title 16. Board of Pharmacy

### Proposed Language

**To Amend** Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

#### **Article 10. ~~Wholesalers~~ Dangerous Drug Distributors**

**To Amend** Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

##### **1780. Minimum Standards for Wholesalers and Third-Party Logistics Providers.**

The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

- (a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.
- (b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the standards set forth in the latest edition of the United States Pharmacopeia-Standards (1990, 22nd Revision).
- (c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
  - (1) All facilities shall be equipped with an alarm system to detect entry after hours.
  - (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
  - (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.
- (d) All materials must be examined upon receipt and ~~or~~ before shipment.
  - (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  - (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
- (e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
  - (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
  - (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.

- (3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets the standards set forth in the latest edition of the appropriate United States Pharmacopeia-Standards (1990, 22nd Revision).
- (f) Policies and procedures must be written and made available upon request by the board.
- (1) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.
  - (2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.
  - (3) Each ~~W~~ wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.
  - (4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.
- (g) The board shall require an applicant for a licensed premise or for renewal of that license to certify that it meets the requirements of this section at the time of licensure or renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161, 4161.5 and 4304, and 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

**To Amend** Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1781. ~~Exemption Certificate~~ Pharmacist or Designated Representative on Premises and In Control.**

- (a) A registered pharmacist, or a designated representative certified in accordance with Section 4053 ~~or 4054~~ of the Business and Professions Code, shall be present and in control of a manufacturer's, or wholesaler's licensed premises during the conduct of business.
- (b) A designated representative – 3PL certified in accordance with Section 4053.1 of the Business and Professions Code, shall be present and in control of a third-party logistics provider's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4053, 4053.1, 4160, and 4161 ~~4054~~, Business and Professions Code.

**To Amend** Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1782. Reporting Sales of Drugs Subject to Abuse.**

~~All~~ Each manufacturer, and wholesaler, and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Note: Authority cited: Section 4005, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~ Reference: Sections 4053.1, 4081, 4164, 4165, and 4332, Business and Professions Code; ~~and Section 26692, Health and Safety Code.~~

**To Amend** Section 1786 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

**1783. Manufacturer, ~~or Wholesaler,~~ or Third-Party Logistics Provider Furnishing Drugs and Devices.**

- (a) A manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.
- (b) “Authorized person” means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. “Authorized person” also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or wholesaler,~~ or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
- (c) Dangerous drugs or devices furnished by a manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or wholesaler,~~ or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or wholesaler,~~ or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or wholesaler,~~ or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.
- (d) A manufacturer, ~~or wholesaler,~~ or third-party logistics provider shall not accept payment for or allow the use of an entity’s credit to establish an account for the purchase of dangerous

drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the ~~p~~ermit for the authorized person; and (2) on an account bearing the name of the permittee.

- (e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4053.1, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4163, 4165 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

# **Self-Assessment Forms**

**16 CCR § 1715**

**17M – 13**

**17M – 14**

**Title 16. Board of Pharmacy  
Proposed Regulation**

**Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.**

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new pharmacy permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.
- (3) There is a change in the licensed location of a pharmacy to a new address.

(c) A pharmacist-in-charge of a community pharmacy shall use the the components of this assessment shall be on Form 17M-13 (Rev. 10/14 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment and on Form 17M-14 (Rev. 10/14 16) entitled "Hospital Pharmacy Self-Assessment." ~~which are Both forms are~~ hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations.~~

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name and license number of the pharmacy

- (B) Address, phone number, and website address, if applicable, of the pharmacy
- (C) DEA registration number, expiration date and date of most recent DEA inventory
- (D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the certification.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference:  
Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070,  
4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333,  
Business and Professions Code.



# **Self-Assessment Form**

**16 CCR § 1784  
17M – 26**

## Proposal to Amend 16 CCR Amend § 1784

§ 1784. Self-Assessment of a Wholesaler/Third Party Logistics Provider by the Designated Representative-In- Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of~~ Each wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, before July 1 of every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued, ~~or~~

(2) There is a change in the designated representative-in-charge or responsible manager.

The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations.~~ Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) DEA registration number and expiration date and date of most recent DEA;  
inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date,  
if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of  
each Board-licensed staff person currently employed by the licensee in the facility at the  
time the self-assessment is completed, the person's license type and number, and the  
expiration date for each license.

(3) The designated representative-in-charge or responsible manager shall respond "yes",  
"no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the  
self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated representative-in-charge or responsible  
manager shall provide a corrective action or action plan to come into compliance with the  
law.

(5) The designated representative-in-charge or responsible manager shall initial each page  
of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under  
penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he  
or she is responsible;

(B) Any deficiency identified within the self-assessment will be corrected and the  
timeframe for correction;

(C) He or she understands that all responses are subject to verification by the Board of  
Pharmacy; and

(D) The information provided in the self-assessment form is true and correct.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page  
of the self-assessment that he or she has read and reviewed the completed self-assessment  
and understands that failure to correct any deficiency identified in the self-assessment

could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

**Automated Drug  
Delivery Systems  
(ADDS)**

**16 CCR §§ 1711, 1713,  
and 1715.1**

**Title 16. Board of Pharmacy  
Proposed DRAFT Regulation**

**Proposal to amend §17## of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**§ 17##. Self-Assessment of an Automated Drug Delivery System by Pharmacist-in-Charge.**

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

- (1) A new automated drug delivery system permit has been issued, or
- (2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system, or
- (3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form ##X-## (Rev 12/18) entitled "Automated Drug Delivery System Self-Assessment". Form ##X-## shall be used for all automated drug delivery systems and is hereby incorporated by reference.

(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:

- (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
- (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;

(C) DEA registration number, expiration date and date of most recent DEA inventory;

(D) Hours of operation of the pharmacy; and

(3) The pharmacist-in-charge shall respond “yes”, “no” or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(4) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink on the self-assessment form.

(6) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink on the self-assessment form.

(7) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system’s license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment. An automated drug delivery system shall correct any non-compliance as specified in the assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.1, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, and 4333, 4400, 4427, 4427.1, 4427.2 4427.3, 4427.4, and 4427.5 Business and Professions Code.





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Business, Consumer Services and Housing Agency  
 Department of Consumer Affairs  
 Gavin Newsom, Governor



**AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT**

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 1715.1 of Title 16 of the California Code of Regulations, evaluating the pharmacy’s compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If “NO”, enter an explanation and timeframe when the deficiency will be completed on the “CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE” lines at the end of the section. If more space is needed, you may add additional sheets.

**Pharmacy Name:** \_\_\_\_\_  
**Address:** \_\_\_\_\_  
**City:** \_\_\_\_\_  
**Phone:** \_\_\_\_\_  
**Fax number:** \_\_\_\_\_  
**Website:** \_\_\_\_\_  
**Pharmacy License #:** \_\_\_\_\_  
**Expiration Date:** \_\_\_\_\_  
**DEA Registration #:** \_\_\_\_\_  
**DEA Expiration Date:** \_\_\_\_\_  
**DEA Inventory Date:** \_\_\_\_\_  
**Last C2 Inventory Reconciliation Date (CCR 1715.65(c)):** \_\_\_\_\_  
**Pharmacy Hours: M-F:** \_\_\_\_\_ **Saturday** \_\_\_\_\_ **Sunday** \_\_\_\_\_

PIC: \_\_\_\_\_ RPH# \_\_\_\_\_  
 ADDS License #: \_\_\_\_\_  
 ADDS Expiration Date: \_\_\_\_\_  
 ADDS Address: \_\_\_\_\_  
 City: \_\_\_\_\_  
 ADDS Hours: M-F: \_\_\_\_\_ Saturday \_\_\_\_\_ Sunday \_\_\_\_\_  
 Please explain if the ADDS hours are different than the pharmacy:  
 \_\_\_\_\_

**FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3**

**SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED**

An **ADDS** – “**Automated drug delivery system**,” a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

**IDENTIFY THE TYPE OF ADDS DEVICE USED**

Yes No N/A

1.1. The pharmacy uses an **APDS** – “**Automated PATIENT dispensing system**,” an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

1.2 The pharmacy uses an **AUDS** – “**Automated UNIT DOSE system**,” an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

**SECTION 2: LOCATION OF DEVICES**

Yes No N/A

2.1 Provides pharmacy services to the patient of **covered entities**, as defined, that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. “Covered entity” as defined by Section 256b of Title 42 of United States Code. [BPC 4119.11(a)-(a)(11)]

2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to Section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with Section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

Yes No N/A

- 2.4 Provides pharmacy services through a **clinic** licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3]
- 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]
- 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]
- 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in Section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy**, used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

**SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS**

(Answer N/A if licensure not required)

Yes No N/A

- 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]
- 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]
- 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]
- 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]
- Use of the ADDS is consistent with legal requirements.
  - The proposed location for installation of the ADDS met the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
  - The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
  - The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

3.5 A precicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]  
List date(s) of pre-license inspection(s):  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

Yes No N/A

- 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]
  
- 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]
  
- 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]
  
- 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]
  
- 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]
  
- 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]
  
- 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.**

**Please Note: The Pharmacist-in-Charge of the pharmacy and the owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.**

- SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- SECTION 5 – ADDS adjacent to the secured pharmacy area and Medical Offices.
- SECTION 6 – ADDS in a health facility pursuant to HSC 1250 (LTC).
- SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- SECTION 8 – ADDS operated by a correctional clinic.

**SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY**

**A. GENERAL REQUIREMENTS**

Yes No N/A

- 4.1 Covered Entity May Contract with Pharmacy to Provide Services- The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC Section 4126 to provide those pharmacy services through the use of the APDS. [BPC 4119.11(a)(2)]
- 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by the Health Resources and Services Administration and are available for inspection by Board during normal business hours. [BPC 4126(a)]
- 4.3 Drugs purchased and received pursuant to Section 256b of Title 42 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]
- 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]
- 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]
- 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**B. UNDERLYING OPERATING PHARMACY**

Yes No N/A

4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

4.9 A preclosure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: \_\_\_\_\_

4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10)] List of current APDS licenses:

1. \_\_\_\_\_ 2. \_\_\_\_\_

3. \_\_\_\_\_ 4. \_\_\_\_\_

5. \_\_\_\_\_ 6. \_\_\_\_\_

7. \_\_\_\_\_ 8. \_\_\_\_\_

9. \_\_\_\_\_ 10. \_\_\_\_\_

11. \_\_\_\_\_ 12. \_\_\_\_\_

13. \_\_\_\_\_ 14. \_\_\_\_\_

15. \_\_\_\_\_

**Yes No N/A**

4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11)]

4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy’s compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: \_\_\_\_\_

4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy’s drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]

4.18 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. [BPC 4119.11(a)(5)]
- The operation of the APDS. [BPC 4119.11(a)(5)]
- The maintenance of the APDS. [BPC 4119.11(a)(5)]
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**C. PHARMACIST RESPONSIBILITIES**

Yes No N/A

- 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.
  
- 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]
  - 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]
  - 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2)]
  - 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]
  
- 4.21 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: \_\_\_\_\_

- 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]
  - All controlled substances added to the ADDS/APDS are accounted for;
  - Access to ADDS/APDS is limited to authorized facility personnel;
  - An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
  - Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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#### D. DEVICE REQUIREMENTS

Yes No N/A

4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]

4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: \_\_\_\_\_

4.27.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2)]

Yes No N/A

- 4.27.3 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3)]
- 4.27.4 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]
- 4.27.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]
- 4.27.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6)]
- 4.27.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]
- 4.27.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]
- 4.27.9 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9)]
- 4.28 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 4.29 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
- 4.30 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 4.31 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**E. RECORD KEEPING REQUIREMENTS**

Yes No N/A

4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

4.35 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**F. POLICIES AND PROCEDURES**

Yes No N/A

- 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:
- Maintaining the security of the APDS and dangerous drug and devices within the APDS
  - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
  - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
  - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
  - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
  - Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: \_\_\_\_\_

Yes No N/A

4.37 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4105.5(c)(2)]

4.38 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA AND IN MEDICAL OFFICES.**

**A. GENERAL REQUIREMENTS**

Yes No N/A

5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l)]

- 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]
- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
  - Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
  - Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
  - Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.
  - Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
  - Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

- 1. \_\_\_\_\_ 2. \_\_\_\_\_
- 3. \_\_\_\_\_ 4. \_\_\_\_\_
- 5. \_\_\_\_\_ 6. \_\_\_\_\_
- 7. \_\_\_\_\_ 8. \_\_\_\_\_
- 9. \_\_\_\_\_ 10. \_\_\_\_\_
- 11. \_\_\_\_\_ 12. \_\_\_\_\_
- 13. \_\_\_\_\_ 14. \_\_\_\_\_
- 15. \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**B. PHARMACIST RESPONSIBILITIES:**

Yes No N/A

5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

5.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f)]

Yes No N/A

5.7 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following:  
[CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy’s compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]

Date of Last Self-Assessment: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**C. DEVICE REQUIREMENTS:**

Yes No N/A

5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

Yes No N/A

5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

5.15 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

5.16 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

5.17 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

5.18 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

5.19 The labels on all drugs and devices dispensed by the APDS comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

5.20 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

5.21 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473[b], 16 CFR 1700.15, CCR 1717]

5.22 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

5.23 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

5.24 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**D. RECORD KEEPING REQUIREMENTS**

Yes No N/A

- 5.25 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]
  
- 5.26 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]
  
- 5.27 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**E. POLICIES AND PROCEDURES**

Yes No N/A

- 5.28 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]
  - Maintaining the security of the APDS and dangerous drug and devices within the APDS
  - Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
  - Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
  - Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
  - Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
  - Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: \_\_\_\_\_

Yes No N/A

5.29 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES**

**A. GENERAL REQUIREMENTS**

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6 (a)(3)]

Yes No N/A

6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]

6.2 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6 (d)(1)]

6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

6.4 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**B. PHARMACIST RESPONSIBILITIES:**

Yes No N/A

- 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]
- 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]
- 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]
- 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]
- 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]
- 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]
- 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: \_\_\_\_\_

- 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]
- All controlled substances added to the ADDS are accounted for;
  - Access to ADDS is limited to authorized facility personnel;
  - An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
  - Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

6.10 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy’s compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**C. DEVICE REQUIREMENTS:**

Yes No N/A

6.11 The stocking and restocking of the ADDS is performed in compliance with Section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1)]

6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

6.13 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

6.14 The information required by BPC Section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

**When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:**

Yes No N/A

6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

6.17 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the

ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

**When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6 (f)]:**

Yes No N/A

- 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]
- 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]
- 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]
- 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]
- 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]
- 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]
- 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]
- 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**D. RECORD KEEPING REQUIREMENTS**

Yes No N/A

- 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7 (b)]
  
- 6.27 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**E. POLICIES AND PROCEDURES**

Yes No N/A

- 6.28 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]
  
- 6.29 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]
  
- 6.30 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]
  
- 6.31 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]
  
- 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]
  
- 6.33 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190**

**A. GENERAL REQUIREMENTS**

Yes No N/A

- 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: \_\_\_\_\_ Expiration Date: \_\_\_\_\_

- 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

- 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

- 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

- 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

- 7.6 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

- 7.7 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

- 7.8 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

Yes No N/A

- 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule II controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:
- A physical count (not estimate) of all quantities of all **federal Schedule II controlled substances**.
  - A review of all acquisition and disposition records of **federal Schedule II controlled substances** since that last inventory reconciliation report:  
Date of last inventory \_\_\_\_\_
  - A comparison of (1) and (2) to determine if there are any variances.
  - All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
  - Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.
- 7.10 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]
- 7.11 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]
- 7.12 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]
- 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]
- 7.14 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]
- 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]
- 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).
- 7.17 Medication guides are provided on required medications. [21 CFR 208.1]



Yes No N/A

7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j]

7.19 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]

List of current APDS licenses:

1. \_\_\_\_\_ 2. \_\_\_\_\_

3. \_\_\_\_\_ 4. \_\_\_\_\_

5. \_\_\_\_\_ 6. \_\_\_\_\_

7. \_\_\_\_\_ 8. \_\_\_\_\_

9. \_\_\_\_\_ 10. \_\_\_\_\_

11. \_\_\_\_\_ 12. \_\_\_\_\_

13. \_\_\_\_\_ 14. \_\_\_\_\_

15. \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**B. PHARMACIST RESPONSIBILITY**

Yes No N/A

7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

7.21 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

7.22 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: \_\_\_\_\_

Yes No N/A

- 7.23 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]
- 7.24 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]
- 7.25 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]
- 7.26 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]
- 7.27 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. [BPC 4186(e)]
- 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]
- 7.29 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**C. POLICIES AND PROCEDURES**

Yes No N/A

- 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]
  - Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
  - Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
  - Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
  - Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to

subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: \_\_\_\_\_

Yes No N/A

7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]

7.34 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]

7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]

7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

## **SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC**

### **A. GENERAL REQUIREMENTS**

Yes No N/A

8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of Section 1206 of the Health and Safety Code, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

Yes No N/A

8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation’s Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

8.5 Medications dispensed to patients that are kept on the patient’s person for use shall meet the labeling requirements of Section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

8.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

8.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

8.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

8.9 The correctional clinic’s location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

8.10 The correctional clinic will notify the board in advance of any change in the clinic’s address on a form furnished by the board. [BPC 4187.1(d)(4)]

8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**B. POLICIES AND PROCEDURES**

Yes No N/A

8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. [BPC 4187.2(a)]

8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation’s Central Fill Pharmacy, and the correctional clinic’s chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]

8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee’s policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**C. PHARMACIST RESPONSIBILITIES**

Yes No N/A

8.20 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

8.21 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber’s professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

8.22 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: \_\_\_\_\_

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_  
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**D. DEVICE REQUIREMENT**

Yes No N/A

8.23 Drugs removed from the ADDS is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

8.24 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

8.25 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

8.26 Drugs from the ADDS in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**E. RECORD KEEPING REQUIREMENTS**

Yes No N/A

8.27 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE \_\_\_\_\_

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**CERTIFICATION ACKNOWLEDGMENT**

**PHARMACIST-IN-CHARGE CERTIFICATION:**

I, (please print) \_\_\_\_\_, RPH # \_\_\_\_\_ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Pharmacist-in-Charge)

**ACKNOWLEDGEMENT BY OWNER OF ADDS:**

I, (please print) \_\_\_\_\_, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature \_\_\_\_\_ Date \_\_\_\_\_

**CERTIFICATION OF COMPLETED ACTION PLAN**

**PHARMACIST-IN-CHARGE CERTIFICATION:**

I, (please print) \_\_\_\_\_, RPH # \_\_\_\_\_ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature \_\_\_\_\_ Date \_\_\_\_\_  
(Pharmacist-in-Charge)

**ACKNOWLEDGEMENT BY OWNER OF ADDS:**

I, (please print) \_\_\_\_\_, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature \_\_\_\_\_ Date \_\_\_\_\_



**Criminal Conviction  
Substantial  
Relationship and  
Rehabilitation Criteria  
16 CCR §§  
1769 and 1770**

**Title 16. Board of Pharmacy  
Proposed Regulation**

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

**Amend section 1769 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

(a) In addition to any other requirements for licensure, when considering the approval of an application, the board or its designee may require an applicant to be examined by one or more physicians and surgeons or psychologists designated by the board if it appears that the applicant may be unable to safely practice due to mental illness or physical illness affecting competency. An applicant's failure to comply with the examination requirement shall render his or her application incomplete. The board shall pay the full cost of such examination. The board shall seek that the evaluation be conducted within 60 days of the date the applicant is advised that an examination is required. The board shall receive the examiner's evaluation within 60 days of the date the examination is completed. The report of the examiner shall be made available to the applicant.

If after receiving the report of the evaluation, the board determines that the applicant is unable to safely practice, the board may deny the application.

(b) When considering the denial of a facility or personal license under Section 480 of the Business and Professions Code on the grounds that the applicant was convicted of a crime, the board shall consider whether the applicant made a showing of rehabilitation and is presently eligible for a license, if the applicant completed the criminal sentence at issue without a violation of parole or probation. In making this determination, the board shall consider the following criteria:~~the board, in evaluating the rehabilitation of the applicant and his present eligibility for licensing or registration, will consider the following criteria:~~

(1) The nature and gravity of the crime(s).

(2) The length(s) of the applicable parole or probation period(s).

(3) The extent to which the applicable parole or probation period was shortened or lengthened, and the reason(s) the period was modified.

(4) The terms or conditions of parole or probation and the extent to which they bear on the applicant's rehabilitation.

(5) The extent to which the terms or conditions of parole or probation were modified, and the reason(s) for modification.

(c) If subdivision (b) is inapplicable, or the board determines that the applicant did not make the showing of rehabilitation based on the criteria in subdivision (b), the board shall apply the following criteria in evaluating an applicant's rehabilitation. The board shall find that the

applicant made a showing of rehabilitation and is presently eligible for a license if, after considering the following criteria, the board finds that the applicant is rehabilitated:

- (1) The nature and severity of the act(s) or ~~offense(s)~~crimes(s) under consideration as grounds for denial.
- (2) Evidence of any act(s) or crime(s) committed subsequent to the act(s) or crime(s) under consideration as grounds for denial under Section 480 of the Business and Professions Code.
- (3) The time that has elapsed since commission of the act(s) or crime(s) referred to in subdivision (1) or (2).
- (4) Whether the applicant has complied with any terms of parole, probation, restitution or any other sanctions lawfully imposed against the applicant.

(5) The criteria in subdivision (b)(1)-(5), as applicable.

~~(5)~~(6) Evidence, if any, of rehabilitation submitted by the applicant.

~~(e)~~(d) When considering the suspension or revocation of a facility or a personal license on the ground that the licensee or the registrant has been convicted of a crime, the board, in evaluating the rehabilitation of such person and his present eligibility for a license will consider the following criteria:

- (1) Nature and severity of the act(s) or offense(s).
- (2) Total criminal record.
- (3) The time that has elapsed since commission of the act(s) or offense(s).
- (4) Whether the licensee has complied with all terms of parole, probation, restitution or any other sanctions lawfully imposed against the licensee.
- (5) Evidence, if any, of rehabilitation submitted by the licensee.

Note: Authority cited: Sections 482 and 4005, Business and Professions Code. Reference: Sections 480, 481, 482, 488, 493, 4030, 4200 and 4400, Business and Professions Code.

**Amend section 1770 of Article 8 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

- (a) For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Section 141 or Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime, professional misconduct, or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by ~~his~~the license or registration in a manner consistent with the public health, safety, or welfare.
- (b) In making the substantial relationship determination required under subdivision (a) for a crime, the board shall consider the following criteria:
- (1) The nature and gravity of the offense;
  - (2) The number of years elapsed since the date of the offense; and
  - (3) The nature and duties of the profession or occupation the person may perform with the license type sought or held.
- (c) For purposes of subdivision (a), substantially related crimes, professional misconduct, or acts shall include, but are not limited to, those which:
- (1) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, governing the practice of pharmacy.
  - (2) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of any law of this state, or any other jurisdiction, relating to controlled substances or dangerous drugs.
  - (3) Violate or attempt to violate, directly or indirectly, or to aid, abet or conspire to violate, any provision of law of this state, or any other jurisdiction, relating to government provided or government supported healthcare.
  - (4) Involve dishonesty, fraud, deceit, or corruption related to money, items, documents, or personal information.
  - (5) Involve a conviction for driving under the influence of drugs or alcohol.

Note: Authority cited: Sections 481, 493, and 4005, Business and Professions Code. Reference: Sections 141, 480, 481, 490, 493, 4300, 4301, 4301.5, and 4309, Business and Professions Code.

**Community Pharmacy  
Staffing  
16 CCR § 1714.3**

**Title 16. Board of Pharmacy  
Proposed Regulation**

**Add section 1714.3 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

**Section 1714.3. Community Pharmacy Staffing**

This section applies to a community pharmacy that is required to comply with Business and Professions Code section 4113.5.

- (a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee, the pharmacy must make another person available to assist a pharmacist. The pharmacy must:
- (1) Designate the names of one or more persons who will be available to assist the pharmacist;
  - (2) Determine that each designated person is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3;
  - (3) Determine that each designated person qualifies to access to controlled substances by conducting a background check on each person that is consistent with federal requirements for pharmacy employees with such access;
  - (4) Ensure that a designated person responds and is able to assist the pharmacist within five minutes after the pharmacist's request.
- (b) A pharmacy must have and maintain policies and procedures that addresses the following:
- (1) The required criteria and training for a designated person, which shall be consistent with subdivision (a).
  - (2) The process for the pharmacist to request assistance and to document the response time between the request and arrival of the designated person at the pharmacy.
  - (3) All impacted pharmacy employees and designated persons must read and sign a copy of the policies and procedures required by this section.
- (c) The pharmacy must maintain the policies and procedures in the pharmacy premises in a readily retrievable format.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4005, 4007, 4029, 4036, 4037, 4056, 4110, and 4113.5, Business and Professions Code.

**Pharmaceutical  
Compounding of  
Nonsterile  
Preparations  
16 CCR §§ 1735 et  
seq.**

## Title 16. Board of Pharmacy

### Proposed Regulation

Proposed changes to the current regulation language are shown by strikethrough for deleted language and underline for added language.

**Repeal section 1735 of Article 4.5 of Division 17 of Title 16 of the California Code of Regulations and replace as follows:**

#### **Article 4.5 Compounding**

##### **1735. Compounding in Licensed Pharmacies**

~~(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:~~

- ~~(1) Altering the dosage form or delivery system of a drug~~
- ~~(2) Altering the strength of a drug~~
- ~~(3) Combining components or active ingredients~~
- ~~(4) Preparing a compounded drug preparation from chemicals or bulk drug substances~~

~~(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.~~

~~(c) The parameters and requirements stated by Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile compounding are stated by Article 7 (Section 1751 et seq.).~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

##### **1735.1. Compounding Definitions**

~~(a) "Ante-area" means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room.~~

~~(b) "Beyond use date" means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes).~~

~~(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-~~



filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building exhausting. This external exhaust should be dedicated to one BSC or CACI.

d) ~~“Bulk drug substance” means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.~~

e) ~~“Cleanroom or clean area or buffer area” means a room or area with HEPA-filtered air that provides ISO-Class 7 or better air quality where the primary engineering control (PEC) is physically located.~~

1) ~~For nonhazardous compounding a positive pressure differential of 0.02 to 0.05 inch water column relative to all adjacent spaces is required.~~

2) ~~For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.~~

~~(f) “Compounding Aseptic Containment Isolator (CACI)” means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building exhaust. This external exhaust should be dedicated to one BSC or CACI. Air within the CACI shall not be recirculated nor turbulent.~~

~~(g) “Compounding Aseptic Isolator (CAI)” means a form of isolator specifically designed for nonhazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent.~~

~~h) “Controlled cold temperature” means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).~~

~~(i) “Controlled freezer temperature” means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.~~

~~(j) “Controlled room temperature” means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).~~

~~(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.~~

~~(l) "Daily" means occurring every day the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.~~

~~m) "Displacement airflow method" means a concept which utilizes a low pressure differential high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds.~~

~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient.~~

~~(o) "Equipment" means items that must be calibrated, maintained or periodically certified.~~

~~p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.~~

~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.~~

~~r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist in-charge.~~

~~(s) "Integrity" means retention of potency until the beyond use date provided on the label, so long as the preparation is stored and handled according to the label directions.~~

~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).~~

~~(u) "Media fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the~~

resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

~~(v) "Non-sterile to sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.~~

~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. It does not (x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves.~~

~~y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range shall be calculated and defined in the master formula.~~

~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.~~

~~aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.~~

~~ab) "Primary Engineering Control (PEC)" means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.~~

~~ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.~~

~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.~~

~~(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.~~

~~(af) "Segregated sterile compounding area" means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye washing station, located within three feet of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations. include topical, sublingual, rectal or buccal routes of administration.~~

~~(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).~~

~~(2) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).~~

~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug preparation Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

## **1735.2. Compounding Limitations and Requirements; Self Assessment**

~~(a) Except as specified in (b) and (c), no drug preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.~~

~~(b) A pharmacy may prepare and store a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.~~

~~(c) A "reasonable quantity" that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug preparation that:~~

~~(1) Is ordered by the prescriber or the prescriber's agent using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for office administration; and~~

~~(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and~~

~~(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the~~

~~prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and~~

~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded medication and the nature of the prescriber's practice; and~~

~~(5) With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to all prescribers to whom the pharmacy furnishes, is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; and~~

~~(6) Does not exceed an amount the pharmacy can reasonably and safely compound.~~

~~(d) No pharmacy or pharmacist shall compound a drug preparation that:~~

~~(1) Is classified by the FDA as demonstrably difficult to compound;~~

~~(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or~~

~~(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.~~

~~(e) A drug preparation shall not be compounded until the pharmacy has first prepared a written master formula document that includes at least the following elements:~~

~~(1) Active ingredients to be used.~~

~~(2) Equipment to be used.~~

~~(3) The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.~~

~~(4) Inactive ingredients to be used.~~

~~(5) Specific and essential compounding steps used to prepare the drug.~~

~~(6) Quality reviews required at each step in preparation of the drug.~~

~~(7) Post-compounding process or procedures required, if any.~~

~~(8) Instructions for storage and handling of the compounded drug preparation.~~

~~(f) Where a pharmacy does not routinely compound a particular drug preparation, the master formula record for that preparation may be recorded on the prescription document itself.~~

~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated~~

on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.~~

~~(i) Every compounded drug preparation shall be given beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and determined based on the professional judgment of the pharmacist performing or supervising the compounding.~~

~~(1) For non-sterile compounded drug preparation(s), the beyond use date shall not exceed any of the following:~~

~~(A) the shortest expiration date or beyond use date of any ingredient in the compounded drug preparation;~~

~~(B) the chemical stability of any one ingredient in the compounded drug preparation;~~

~~(C) the chemical stability of the combination of all ingredients in the compounded drug preparation;~~

~~(D) for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation;~~

~~(E) for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation; and~~

~~(F) for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.~~

~~(G) A pharmacist, using his or her professional judgment may establish an extended date as provided in (D), (E), and (F), if the pharmacist researches by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors the pharmacist must analyze include:~~

~~(i) the nature of the drug and its degradation mechanism,~~

~~(ii) the dosage form and its components,~~

~~(iii) the potential for microbial proliferation in the preparation,~~

~~(iv) the container in which it is packaged,~~

~~(v) the expected storage conditions, and~~

~~(vi) the intended duration of therapy.~~

~~Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.~~

~~(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:~~

- ~~(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,~~
- ~~(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,~~
- ~~(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and~~
- ~~(D) The beyond use date assigned for sterility in section 1751.8.~~

~~(3) For sterile compounded drug preparations, extension of a beyond use date is only allowable when supported by the following:~~

- ~~(A) Method Suitability Test,~~
- ~~(B) Container Closure Integrity Test, and~~
- ~~(C) Stability Studies~~

~~(4) In addition to the requirements of paragraph three (3), the drugs or compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.~~

~~(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.~~

~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.~~

~~(k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist in charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist in charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist in charge before any sterile compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist in charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.~~

~~(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:~~

- ~~(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.~~
- ~~(2) such ingredients cannot be used for any sterile compounded drug preparation more than~~
- ~~(1) year after the date of receipt by the pharmacy.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

### **1735.3. Recordkeeping of Compounded Drug Preparations**

(a) For each compounded drug preparation, pharmacy records shall include:

~~(1) The master formula document.~~

~~(2) A compounding log consisting of a single document containing all of the following:~~

~~(A) Name and Strength of the compounded drug preparation.~~

~~(B) The date the drug preparation was compounded.~~

~~(C) The identity of any pharmacy personnel engaged in compounding the drug preparation.~~

~~(D) The identity of the pharmacist reviewing the final drug preparation.~~

~~(E) The quantity of each ingredient used in compounding the drug preparation.~~

~~(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (I) shall apply.~~

~~(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(F)) are sterile— in a single lot for administration within seventy-two (72) hours to a patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for “Redispensed CSPs” found in Chapter 797 of the United States Pharmacopeia— National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference.~~

~~(G) A pharmacy assigned unique reference or lot number for the compounded drug product preparation.~~

~~(H) The beyond use date or beyond use date and time of the final compounded drug, expressed in the compounding document in a standard date and time format.~~

~~(I) The final quantity or amount of drug preparation compounded for dispensing.~~

~~(J) Documentation of quality reviews and required post-compounding process and procedures.~~

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug products used to compound drug preparations shall be obtained, whenever possible, from FDA registered suppliers. The pharmacy shall acquire and retain certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of



~~purity or analysis acquired by the pharmacy shall be matched to the corresponding chemical, bulk drug substance, or drug products received.~~

~~(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).~~

~~Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.~~

#### **1735.4. Labeling of Compounded Drug Preparations**

~~(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:~~

- ~~(1) Name of the compounding pharmacy and dispensing pharmacy (if different);~~
- ~~2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;~~
- ~~(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;~~
- ~~(4) The beyond use date for the drug preparation;~~
- ~~(5) The date compounded; and~~
- ~~6) The lot number or pharmacy reference number.~~

~~(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.~~

~~(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.~~

~~(d) Prior to dispensing drug preparations compounded into unit dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) — (c).~~

~~(e) All hazardous agents shall bear a special label which states “Chemotherapy — Dispose of Properly” or “Hazardous — Dispose of Properly.”~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.~~

### **1735.5. Compounding Policies and Procedures**

~~(a) Any pharmacy engaged in compounding shall maintain written policies and procedures for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action.~~

~~(b) The policies and procedures shall be reviewed and such review shall be documented on an annual basis by the pharmacist in charge. The policies and procedures shall be updated whenever changes in policies and procedures are implemented.~~

~~(c) The policies and procedures shall include at least the following:~~

~~1) Procedures for notifying staff assigned to compounding duties of any changes in policies.~~

~~2) A written plan for recall of a dispensed compounded drug preparation where subsequent demonstrates the potential for adverse effects with continued use. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).~~

~~3) Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in , and for training on these procedures as part of the staff training and competency evaluation process.~~

~~(4) Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.~~

~~(5) Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.~~

~~(6) Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.~~

~~(7) Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist in charge.~~

~~8) Dates and signatures accompanying any revisions to the policies and procedures approved by pharmacist in charge.~~

~~9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.~~

~~10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.~~

~~(11) Policies and procedures for proper garbing when compounding with hazardous products. shall include when to utilize double shoe covers.~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4127, and 4301, Business and Professions Code~~

### **1735.6. Compounding Facilities and Equipment**

~~(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.~~

~~(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.~~

~~(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.~~

~~(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.~~

~~(e) Hazardous drug compounding shall be completed in an externally exhausted physically separate room with the following requirements:~~

~~(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hours or less or when non-sterile products are compounded; and~~

~~2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and~~

~~(3) A) For sterile compounding, each BSC or CACI shall also be externally exhausted.~~

~~(B) For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant HEPA filter in series or be externally exhausted.; For purposes of this paragraph, a containment ventilated enclosure means a full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.~~

~~Each PEC in the room shall also be externally vented; and~~

~~4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.~~

~~(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.~~

### **1735.7. Training of Compounding Staff**

~~(a) A pharmacy engaged in compounding shall maintain documentation demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating that all personnel involved in compounding are trained in all aspects of policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the compounding process.~~

~~(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.~~

~~(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation.~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code~~

### **1735.8. Compounding Quality Assurance**

~~(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug preparations.~~

~~(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.~~

~~(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled strength, including the frequency of testing. All qualitative and quantitative analysis reports for compounded drug preparations shall be retained by the pharmacy and maintained along with the compounding log and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.~~

~~(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug preparation is ever discovered to be outside minimum standards for integrity, potency, quality, or labeled strength.~~

~~(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.~~

~~Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.~~

### **1735. Nonsterile Compounding in Licensed Pharmacies**

This article applies to nonsterile compounding performed in a pharmacy. A pharmacy performing nonsterile compounding shall comply with the standards established by United States Pharmacopeia (USP) General Chapter 795 (Chapter 795), titled *Pharmaceutical Compounding – Nonsterile Preparations*, unless additional or different standards are established by this article.

(a) For purposes of this article, compounding occurs in a pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a patient specific prescription.

(b) Repackaging of a compounded nonsterile preparation (CNSP) shall be considered compounding and this article shall apply.

(c) Reconstitution in accordance with directions that have not been Food and Drug Administration (FDA) approved is considered compounding and this article applies.

(d) Consistent with the provisions of 503A of the Federal Food, Drug and Cosmetic Act, no compounded nonsterile preparations (CNSPs) shall be compounded prior to receipt by a pharmacy for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescriber, on the prescription that a compounded preparation is necessary for the identified patient.

(1) Notwithstanding subdivision (d), a pharmacy may prepare and store a limited quantity of CNSP in advance of receipt of a patient specific prescription document where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(e) No pharmacy or pharmacist shall compound a CNSP that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drug preparations have been found to be unsafe or not effective; or

3) Is a copy or essentially a copy of one or more commercially available drug products, unless

(A) the drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, or (B) the compounding of that CNSP is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of

the shortage or the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

(4) Is made with any component not intended for use in a CNSP for the intended patient population.

(f) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment as required by section 1715

(g) In addition to section 1707.2 of the board's regulations, consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of a CNSP and CNSP related supplies furnished by the pharmacy.

(h) Compounding with blood or blood components shall be done in compliance with Health and Safety Code section 1602.5.

(i) Storing, weighing, measuring, compounding, and/or performing other manipulation of an active pharmaceutical ingredient (API) or added substance deemed hazardous by Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, [Hazardous Drugs – Handling in Healthcare Settings], and any board regulations.

(j) Storing, weighing, measuring, compounding, and/or performing other manipulation of an antineoplastic under Occupational Safety and Health (NIOSH) shall be done in compliance with USP Chapter 800, [Hazardous Drugs – [Handling in Healthcare Settings], and any board regulations.

#### **1735.1. INTRODUCTION AND SCOPE AND COMPOUNDING DEFINITIONS.**

The definitions in this section supplement the definitions provided in USP Chapter 795.

(a) "Approved labeling" means the Food and Drug Administration's (FDA) approved labeling that contains FDA approved information for the diluent, the resultant strength, the container closure system, and storage time.

(b) "Copy or essentially a copy" of a commercially available drug product means all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

(c) "Diluent" means a liquid with no pharmacological activity used in reconstitution, such as water or sterile water for injection.

(d) "Integrity" means retention of potency until the beyond use date provided on the label when the preparation is stored and handled according to the label directions.

(e) "Repackaging" means the act of removing a product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation, when the act is not done pursuant to a prescription.

(f) "Preparation" means a drug or nutrient compounded in a pharmacy, which may or may not be sterile.

(g) "Product" means a commercially or conventionally manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

(h) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula document.

(i) "Strength" means amount of active ingredient per unit of a compounded drug preparation.

(j) "Potency" means an active ingredient strength.

### **1735.2 PERSONNEL TRAINING AND EVALUATION**

The requirements of this section apply in addition to the requirements in USP Chapter 795.

(a) Training, evaluation, and requalification procedures for personnel preparing, verifying, and/or handling a CNSP shall also address the following topics:

- (1) Quality assurance and quality control procedures,
- (2) Container closure and equipment selection, and
- (3) Component selection and handling.

(b) A pharmacist responsible for or directly supervising compounding of CNSPs, shall demonstrate proficiency in skills necessary to ensure the integrity, potency, quality, and labeled strength of a CNSP.

(c) Personnel who fails any aspect of training or demonstrated competency, shall not be involved in the compounding process until after successfully passing reevaluations in the deficient area(s) as detailed in the SOPs.

(d) The pharmacy must document that any person assigned to provide training has obtained training and demonstrated competency in any subject in which the person will provide training or observe and measure competency.

### **1735.3 PERSONAL HYGIENE AND GARBING**

This section supplements the requirements established by USP Chapter 795.

(a) The supervising pharmacist shall evaluate compounding personnel experiencing any of the following: rashes, recent tattoos or oozing sores, conjunctivitis, active respiratory infection or and other conditions to determine if such condition could contaminate a CNSP or the environment. The supervising pharmacist shall not allow personnel with potentially contaminating conditions to enter the compounding area.

(b) Prior to entry into the compounding area all hand, wrist, and other exposed jewelry or piercing shall be removed.

(c) A gown and face mask shall be used whenever a closed system processing device is required.

(d) Disposable garb shall not be shared by staff and shall be discarded after each shift and when soiled. Garb removed during a shift must be maintained in the compounding area.

(e) Non-disposable garb shall be cleaned with a germicidal detergent and sanitized with 70% isopropyl alcohol before re-use.

(f) Eye glasses shall be cleaned as part of hand hygiene and garbing, the standards for which the pharmacy shall specify in its standard operating procedures (SOPs).

(g) Before any hand hygiene or garbing accommodation is granted pursuant to USP 795 Section 3.1, the designated person shall determine that the quality of the environment and any CNSPs is not affected. Documentation of the determination shall be done prior to the accommodation being allowed.

#### **1735.4 BUILDING AND FACILITIES**

This section supplements the requirements established by USP Chapter 795.

(a) A sink used for compounding or hand hygiene shall not be part of a restroom or water closet.

(b) Compounding personnel must monitor temperatures in storage area(s) and compounding areas to determine whether the temperature remains within the appropriate range for the CNSPs or components. Monitoring shall be done either (1) manually at least once daily on days that the facility is open or (2) by a continuous temperature recording device. This shall be documented.

(c) Purified water, distilled water, or reverse osmosis water shall be used for rinsing equipment and utensils.



(d) No CNSP shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in USP Chapter 795 or the pharmacy's written SOPs

### **1735.5 CLEANING AND SANITIZING**

This section supplements the requirements established by USP Chapter 795.

(a) Documentation of the cleaning and sanitizing of the compounding area shall reflect the name of the person completing the cleaning and sanitizing as well as the cleaning and sanitizing agents used.

(b) Any cleaning or sanitizing agents shall be used in accordance with manufacturers' specifications.

### **1735.6 EQUIPMENT AND COMPONENTS**

This section supplements the requirements established by USP Chapter 795.

(a) Any equipment used to compound CNSP shall be used in accordance with the manufacturer's specifications.

(b) Any component used to compound a CNSP shall be used and stored, , in accordance with all industry standards including the following:

- (1) United States Pharmacopeia (USP) - National Formulary (NF),
- (2) Food Drug and Cosmetic Act (FD&CA) and federal regulations adopted to implement that act,
- 3) Food Drug Administration (FDA) requirements and considering issued Guidance Documents and Alerts, and
- (4) Manufacturers' specifications and requirements.

(c) Any active pharmaceutical ingredient (API) or added substance used to compound a CNSP shall be obtained from an FDA-registered facility and shall be accompanied by a valid certificate of analysis (COA). This COA shall be, at minimum in English and should all the requirements of USP Chapter 1080, Bulk Pharmaceutical Excipient- Certificate of Analysis. All COAs shall be readily retrievable for at least 3 years from last use in CNSP.

### **1735.7. MASTER FORMULATION AND COMPOUNDING RECORDS**

This section supplements the requirements established by USP Chapter 795.

(a) A CNSP shall not be compounded until the pharmacy has first prepared a written master formulation document in compliance with USP Chapter 795 and identified in that document the following additional elements:

- (1) Active pharmaceutical ingredient (API) or added substance(s) and their amounts, which shall include, at a minimum, salt form and purity grade, when available,
- (2) Container–closure systems to be used, which shall include, container and closure types.
- (3) The source referenced to assign the BUD; each source referenced shall be readily retrievable the time of compounding and shall be maintained for three years from the date each CNSP is dispensed.
- (4) Instructions for storage and handling of the compounded drug preparation.

(b) Where a pharmacy does not routinely compound a particular drug preparation, the master formulation record for that preparation may be recorded on the prescription document itself. This record shall comply with USP Chapter 795 and this section.

(c) A compounding record shall be a single document. The document shall satisfy the requirements of USP Chapters 795, as well as the following:

- (1) The date and time of preparation. The time of preparation is the time when compounding the CNSP started, which also determines when the assigned BUD starts.
- (2) The assigned internal identification number shall be unique for each compounded drug preparation.
- (3) The total quantity compounded shall include the number of units made and volume or weight of each unit.
- (4) The identity of each person performing the compounding and pharmacist verifying the final drug preparation.

### **1735.8 RELEASE INSPECTIONS**

This section supplements the requirements established by USP Chapter 795.

(a) A pharmacist performing, or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, when label instructions for storage and handling are followed after the preparation is dispensed.

### **1735.9 LABELING**

This section supplements the requirements established by USP Chapter 795.

(a) A CNSP shall also include the following:

- (1) Route of intended administration, and
- (2) Name of compounding pharmacy and dispensing pharmacy (if different).

(b) Labeling shall also include:

- (1) Any special handling instructions,

(2) Any applicable warning statements, and

(3) Name, address, and phone number of the compounding facility if the CNSP is to be sent outside of the facility or healthcare system in which it was compounded.

(c) Any CNSP dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required by Business and Professions Code section 4076 and section 1707.5.

### **1735.10 ESTABLISHING BEYOND-USE DATES**

This section supplements the requirements established by USP Chapter 795.

(a) Beyond use dates (BUDs) assigned with only a date shall expire at midnight at the end of date.

(b) A CNSPs BUDs shall not exceed:

(1) The chemical and physical stability data of the API and any added substances in the preparation,

(2) The compatibility of the container–closure system with the finished preparation (e.g. possible leaching, interactions, and storage conditions), or

(43) Shortest remaining expiration date or BUD of any of the starting components.

(c) (1) If the BUD of the CNSP is extended beyond the BUDs in USP Chapter 795, an aqueous CNSP, as defined by USP Chapter 795, shall be tested in compliance with USP Chapter 51, Antimicrobial Effectiveness Testing.

(2) If a pharmacy chooses to use antimicrobial effectiveness testing results provided by an FDA-registered facility or published in peer-reviewed literature sources the full reference, including the raw data and testing method suitability, and shall be fully available at the time of compounding and three years from each dispense.

### **1735.11 Standard Operating Procedures (SOPs)**

This section supplements the requirements established by USP Chapter 795.

(a) Standard operating procedures (SOPs) shall:

(1) Comply with USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding,

(2) In addition to the SOPs listed in USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding, include:

(A) Methods by which the supervising pharmacist will ensure the quality of compounded drug preparations.

(B) Procedures for handling, compounding, and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdictional standards.

(C) The methods a pharmacist will use to determine and approve the ingredients and the compounding process for each preparation before compounding begins

(b) Any pharmacy engaged in compounding nonsterile drug preparations shall maintain and follow written SOPs for compounding.

(c) The SOPs shall be reviewed on an annual basis by the pharmacist-in-charge. Such review shall be documented by the pharmacist-in-charge. The policies and procedures shall be updated whenever changes are implemented. Such changes shall be disseminated to the affected staff prior to implementation.

### **1735.12 QUALITY ASSURANCE AND QUALITY CONTROL**

This section supplements the requirements established by USP Chapter 795.

(a) The quality assurance program shall comply with section 1711 and USP Chapter 1163, Quality Assurance in Pharmaceutical Compounding. In addition, the program shall include the following:

(1) A written procedure for scheduled action, such as a recall, in the event any compounded drug preparation is discovered to be outside the expected standards for integrity, potency, quality, or labeled strength.

(2) A written procedure for responding to out-of-range temperature variations within the medication storage areas where a furnished drug may be returned for furnishing to another patient.

(3) A written procedure addressing each of the USP Chapter 1163's integrated components and standard operating procedures.

### **1735.13 PACKAGING AND TRANSPORTING**

This section supplements the requirements established by USP Chapter 795.

(a) There shall be a defined process and documented procedure to ensure temperature sensitive products will arrive at their desired destinations after transporting within the expected quality standards for integrity, potency, quality and labeled strength.

(b) Packaging materials shall protect CNSPs from damage, leakage, contamination, degradation, and adsorption while preventing inadvertent exposure to transportation personnel.

(c) A pharmacist supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation.

### **1735.14 COMPLAINT HANDLING AND ADVERSE EVENT REPORTING**

This section supplements the requirements established by USP Chapter 795.

(a) The pharmacy shall process recalls and adverse event reporting in compliance with Business and Professions Code section 4126.9.

(b) All complaints related to a potential quality problem with a compounded drug preparation and all adverse events shall be reviewed by the pharmacist-in-charge. Such review shall be documented and dated.

### **1735.15 DOCUMENTATION**

This section supplements the requirements established by USP Chapter 795.

(a) Pharmacies shall maintain each record required by USP Chapter 795 or this article in the pharmacy, in a readily retrievable form, for at least three years from the date the record was last used. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070.

(b) Records created shall be maintained in a manner to allow for all versions of the document to be viewed. When a change to a record must be made, the record's original text must be maintained, and the record must reflect each change, the person who made the change, and the date and time the change was made.

Note: Authority cited: Sections 4001.1, 4005, , 4057, 4127 of Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, 4057, 4076, 4081, 4127, 4127.7 and 4169, 4301 and 4332 of the Business and Profession Code.