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Legislation and Regulation Committee

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Part 1: Legislation for Discussion and Consideration

a. Board Sponsored/Originated Legislation

Attachment 1

This year the board sponsored one measure and was the origin of five additional measures. With one exception, all measures were enacted. Unless otherwise specified, the provisions will take effect January 1, 2019.

1. AB 1751 (Low) (Chapter 478, Statutes of 2018) Controlled substances: CURES database

   Board Position: Support
   Summary: Allows the Department of Justice (DOJ) to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information. This measure also requires DOJ to promulgate regulations no later than July 1, 2020, outlining access to and the use of information within Controlled Substance Utilization, Review and Evaluation System (CURES).

2. AB 1752 (Low) Controlled substances: CURES database

   Board Position: Support
   Summary: This measure sought to expand CURES reporting to also include Schedule V controlled substances and reduce the time frame for reporting to the CURES system to one working day. This measure was held in committee and as such failed passage. It is recommended that the board again seek the changes sought in this measure as reflected elsewhere in this report.

3. AB 2086 (Gallagher) (Chapter 274, Statutes of 2018) Controlled substances: CURES database

   Board Position: Support

Summary: Allows prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

4. AB 2783 (O'Donnell) (Chapter 589, Statutes of 2018) Controlled substances: hydrocodone combination products: schedules

   Board Position: Support
   Summary: Reclassifies specific hydrocodone combination products as Schedule II controlled substances, making California law consistent with federal law.

5. AB 2789 (Wood) (Chapter 438, Statutes of 2018) Health care practitioners: prescriptions: electronic data transmission

   Board Position: Support
   Summary: Requires by January 1, 2022, all written prescriptions issued by licensed prescribers in California be issued as an electronic transmission prescription (e-prescription). By January 1, 2022, all pharmacies, pharmacists or other practitioners authorized to dispense or furnish a prescription must have the capability to receive an e-prescription.

   Exceptions include:
   - any medication listed in Health & Safety Code 11159.2
   - technological/electrical failure
   - prescription that will be filled outside of California
   - hospital pharmacies where
     - patient resides outside of CA, or outside the geographical area of the hospital
     - indigent or homeless patients
     - prescription issued when a patient's pharmacy is closed
   - veterinarians
   - eyeglasses or contact prescriptions
   - prescriber and dispenser are the same entity
   - prescription is not covered by National Council for Prescription Drug Programs' SCRIPT standard

6. SB 1447 (Hernandez) (Chapter 666, Statutes of 2018) Pharmacy: automated drug delivery systems

   Board Position: Support/Sponsor
   Summary: This bill is sponsored by the board. This measure replaces the boards current automated drug delivery system (ADDS) registration requirements with a licensing program that recognizes the different uses for such a device. The measure establishes definitions for the two different functions of ADDS, as automated unit dose system (AUDS), used for administration, and automated patient dispensing system (APDS), used for dispensing directly to the patient, as well as establishes the requirements for each.

Specifically, effective July 1, 2019, this measure prohibits an ADDS from being installed, leased, owned or operated in California unless specified requirements are met. One requirement specifies an ADDS license will only be issued to the holder of a current, valid, and active California pharmacy license. The bill expands the locations for placement and operation of an ADDS to specified locations, including the licensed pharmacy issued the ADDS license, a licensed health facility, a licensed clinic, or a specified medical office. Further, this measure requires the pharmacy issued the ADDS license to own or lease the ADDS machine and own the drugs and devices located within it. The measure requires the pharmacy to supervise the operation of the ADDS. This measure details specific stocking and transfer requirements for the ADDS, requires the pharmacy issued the ADDS license to provide training on the operation and use of that ADDS to specified individuals, and requires the pharmacy to complete periodic self-assessments. The bill requires additional conditions for APDS that are used to dispense medication to patients. The bill authorizes a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS to inspect the location pursuant to these provisions. Lastly, this measure requires the board to report to the legislature regarding the regulations of ADDS machines on or before January 1, 2024.

A copy of each measure is provided in **Attachment 1**.

b. Chaptered Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

Attachments 2 and 3

The Governor signed several measures impacting the board's jurisdiction including some measures where the board had an established position. Below is a summary of those bills. Where applicable, the board's position is noted. Unless otherwise noted, the provisions take effect on January 1, 2019.

1. AB 1753 (Low) (Chapter 479, Statutes of 2018) Controlled substances: CURES database

   Summary: Allows for the reduction of authorized security printers approved by the DOJ to three. Further, this measure requires security prescription forms to contain a unique serialized number that must be reported to CURES and establishes reporting requirements to the DOJ on the delivery of security prescription forms to a prescriber.

2. AB 1953 (Wood) (Chapter 383, Statutes of 2018) Skilled nursing facilities: disclosure of interests in business providing services

   Board Position: Support if Amended
   Summary: Beginning January 1, 2020, requires disclosures by an applicant for licensure as a skilled nursing facility or by a skilled nursing facility licensee to disclose ownership or control interest of 5 percent or more in a corporation, sole proprietorship, or partnership, that provides, or is proposed to provide, any service to the skilled nursing facility.

3. AB 2037 (Bonta) (Chapter 647, Statutes of 2018) Pharmacy: automated patient dispensing systems

   Board Position: Support
   Summary: Allows a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B and Medi-Cal patients through the use of an automated drug delivery system (ADDS). This measure included an urgency provision and took effect immediately upon signature of the governor on September 21, 2018.

4. AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing boards: denial of application: revocation or suspension of licensure: criminal conviction

   Board Position: Oppose
   Summary: Beginning July 1, 2020, the measure places restrictions on the convictions, crimes, or dishonesty, fraud, and deceit or other acts the board may consider in order to deny, revoke or suspend a license. This bill requires reporting on the board's website denial summaries as well as a list of crimes that will be considered for denial and how they substantially relate to the qualifications, functions, or duties of the practice of pharmacy.

5. AB 2256 (Santiago) (Chapter 259, Statutes of 2018) Law enforcement agencies: opioid antagonist

   Board Position: Support
   Summary: Allows law enforcement agencies throughout the state to acquire Naloxone from a pharmacy, wholesaler, or manufacturer without a prescription if it is exclusively for use by employees of the agency who have completed training in administering an opioid antagonist. Further, provisions require that acquisition and disposition records must be maintained by the law enforcement agency for three years

6. AB 2576 (Aguiar-Curry) (Chapter 716, Statutes of 2018) Emergencies: health care

   Board Position: Support
   Summary: Authorizes clinics to furnish dangerous drugs to several entities, authorizes pharmacies to dispense drugs without a prescription, and authorizes the board to waive any requirement in the relevant chapter during a declared state of emergency.

7. AB 2859 (Caballero) (Chapter 240, Statutes of 2018) Pharmacy: safe storage products

   Board Position: Neutral
   Summary: Requires community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products on the premises and close to the pharmacy. Pharmacies, where a licensed pharmacist is the majority owner and manager, of no more than four pharmacies, are exempt from this requirement. These provisions will remain in effect until January 1, 2023.

8. AB 2863 (Nazarian) (Chapter 770, Statutes of 2018) Health care coverage: prescriptions

   Board Position: Support
   Summary: Requires a pharmacy to inform the consumer of the lower price of a covered medication, whether that is the retail price or the cost sharing amount unless the pharmacy automatically charges the lower amount.

9. SB 212 (Jackson) (Chapter 1004, Statutes of 2018) Solid waste: pharmaceutical and sharps waste stewardship

   Summary: Establishes, no later than January 1, 2021, the Pharmaceutical and Sharps Waste Stewardship program in California. This statewide program will be established and funded by the covered entities of covered drugs sold in California, as defined, and will provide convenient receptacles for the return of pharmaceuticals and sharps waste. CalRecycle is required to develop regulations governing this stewardship program no later than January 1, 2021, and the bill's provisions will become effective upon the promulgation of those regulations.

   Under this chapter the board is required to develop and maintain a list of all covered drugs sold in California, as defined in the measure. Further, the board is required to review each stewardship plan for compliance with applicable federal and state law governing drug take back programs. It cannot be known at this time how many stewardship organizations, and resultant stewardship plans will require and approval by staff. Board staff will be required to work in collaboration with CalRecycle for the establishment and enforcement of this program.

10. SB 1021 (Wiener) (Chapter 787, Statutes of 2018) Prescription drugs

    Board Position: Support
    Summary: Eliminates the sunset date on provisions of AB 339 (Gordon, Chapter 619, Statutes of 2015) making permanent provisions, capping monthly copays at $250 total per patient. This measure creates the new prohibition for a health care insurance plan with a drug formulary from having more than four tiers. Further, this measure caps the co-pay amount at the retail price if it is lower than the co-pay.

11. SB 1109 (Bates) (Chapter 693, Statutes of 2018) Controlled substances: Schedule II drugs: opioids

    Board Position: Neutral
    Summary: Requires continuing education for prescribers on the hazards of opioid use. Also requires a specified warning notice to be included on the label or container for an opioid dispensed to a patient for outpatient use.

12. SB 1254 (Stone) (Chapter 697, Statutes of 2018) Hospital pharmacies: medication profiles or lists for high-risk patients

    Board Position: Support
    Summary: Requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge of the patient. The criteria for determining whether a patient is high- risk will be established by each hospital. Additionally, allows for this duty to be performed by a pharmacy technician or intern pharmacist, if they have successfully completed training and proctoring by the pharmacy department and where a quality assurance program is used to monitor competency.

13. SB 1442 (Wiener) (Chapter 569, Statutes of 2018) Community pharmacies: staffing

    Board Position: Support
    Summary: This bill specifies that a community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy unless the pharmacist is assisted at all times by another employee as specified.

    Attachment 2 contains a copy of the chaptered language for each.

    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.

Part 2: Regulations for Discussion and Consideration

c. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Attachment 4

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**.

1. 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.

   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

2. 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 regulation establishes the regulatory framework for 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

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

Summary of Regulation:
This regulation 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.

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 21, 2018

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

Summary of Regulation:
This regulation establishes regulatory requirements for automated 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

5. Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications

Summary of Regulation:
This regulation updates the application abandonment language to include all licensing programs to ensure that all applicants have appropriate notice about the requirements for abandoning an application and reduce the administrative workload associated with the need for frequent amendments when new licensing programs are established.

Timeline:
Approved by Board: February 6, 2018
Submitted to DCA for Pre-Notice Review: July 2, 2018
Formal DCA Pre-Notice Review began: August 3, 2018

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

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

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

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

Summary of Regulation:
This regulation 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.

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

8. Proposed Regulations to Add Title 16 CCR Section 1793.9 Related to Remote Dispensing Technicians

Summary of Regulation:
This proposal establishes regulatory requirements for pharmacy technicians working in a remote dispensing site pharmacy.

Timeline:
Approved by Board: February 6, 2018
Submitted to DCA for Pre-Notice Review: June 11, 2018
Formal DCA Pre-Notice Review began: August 29, 2018

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

Summary of Regulation:
This regulation 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.

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

10. Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

Summary of Regulation:
This proposal amends the board's regulations regarding the duty to provide consultation for mail-order pharmacies.

Timeline:
Approved by Board: May 2, 2018
Submitted to DCA for Pre-Notice Review: July 23, 2018

Returned to the board on: August 23, 2018
Re-submitted to DCA for Pre-Notice Review: September 14, 2018
Formal DCA Pre-Notice Review began: October 1, 2018

Attachment 4 includes the board approved text for each regulation.

d. Board Approved to Initiate Rulemaking – Documents Returned to the Board for Corrections to be Made by Staff

Attachment 5

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**.

1. 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 regulation establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

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

Attachment 5 includes the board approved text for this regulation.

e. Board Approved to Initiate Rulemaking – Documents Being Prepared by Board Staff for Pre-Notice Review

Attachment 6

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**.

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

Summary of Regulation:

This regulation 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.

Timeline:
Approved by Board: November 8, 2017

Board staff anticipates this regulation will be submitted to the department within the next 30 days.

Attachment 6 includes the board approved text for this regulation.

Part 3: General Committee Matters

f. Discussion and Consideration of Legislation/Regulation Committee Strategic Goals for Fiscal Year 2018/19

During the meeting members will have the opportunity to review the committee's goals and the status of each measure. The committee may also wish to determine if any changes would be appropriate to recommend to the board for consideration.

3.1 Education the board on national pharmacy initiatives impacting consumer and the future of pharmacy (e.g., pharmacists, pharmacy, technicians, distributors, etc.) to strategize the board's efforts in alignment with where the profession is going to be in 2020.
Status: The board's Executive Officer provides updates to the board discussions occurring at the national level.

3.2 Support legislative and regulation proposals from board approval to enactment to effectuate the goals of the board.
Status: Last fiscal year 5 regulations took effect. Further, at the end of this legislative year, 1 board sponsored measure signed by the governor. Additional 5 measures were signed where the board was the originator of the measure.

3.3 Advocate for or against legislation that impacts the board's mandate for consumer protection
Status: During the legislative year the board established support positions on 10 measures and oppose positions on 3 measures.

3.4 Establish a systemized, ongoing review process for board regulations to improve and maintain clear and relevant regulations.
Status: Board staff and counsel are working to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary.

g. Review of Pending Legislative Proposals Previously Approved by the Board

Attachment 7

1. Amend Health and Safety Code Section 11165 to Include Schedule V Controlled Substances in CURES Database and Reduce Reporting Requirement Timeframe to One Day

   As indicated previously in this report, Assembly Bill 1752 (Low) failed passage this year. The measure was intended to expand CURES reporting to include Schedule V controlled substances and reduce the time frame for reporting to the CURES system to one working day. AB 1752 can be read here: AB 1752. The board should again advocate for this change.

2. Amend Business & Professions Code Section 4200 Relating to the Examination Score Validity Period for the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

   The board voted at the May 2018 meeting to pursue a statutory change to amend BPC Section 4200 as it relates to the time period that a test score will remain valid for consideration for licensure. Enactment of this legislation would establish that a passing score on NAPLEX or CPJE Pharmacist examinations would be valid for licensure while the occupational analysis that was used to develop that examination is valid or was replaced no more than one year prior. A summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy May 2018 Meeting Minutes.

3. Establish an Advanced Pharmacy Technician (APT) Licensure Program

   At its November 2017 meeting, the board voted to pursue a statutory change to create a new licensing category for Advanced Pharmacy Technicians. This proposal establishes APT as a new category requiring licensure, outlines the requirements for licensure, and details the duties that APTs may perform in different settings. A summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy November 2017 Meeting Minutes.

4. Establish an Advanced Hospital Pharmacy Technician (AHT) Licensure Program

   At the February 2018 meeting the board voted to pursue a statutory change to create a new licensing category for Advanced Hospital Pharmacy Technicians. This proposal establishes the licensing and renewal requirements, proposed duties, and requirements of a hospital choosing to utilize AHT personnel. A summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy February 2018 Meeting Minutes.

5. Amend Business and Professions Code Section 4163 to Allow a Reverse Distributor to Accept Medications for Destruction in Limited Circumstances from a Previously Licensed Source

   During its July 2018 meeting, the board voted to pursue a statutory change that would allow a reverse distributor to accept medications for destruction. Documents pertaining to this discussion may be found in the relevant meeting materials here: Board of Pharmacy July 2018 Meeting Materials.

6. Amend Business and Professions Code Section 4400 Relating to Fees for Government Owned Facilities

   At its November 2017 meeting, the board voted to pursue a statutory change to amend BPC section 4400 to require an application fee from government owned facilities. A summary of the discussion and motion can be found in the board's minutes here: Board of Pharmacy November 2017 Meeting Minutes.

   A copy of each proposal is included in **Attachment 7**.

h. Future Meeting Dates

- January 30, 2019
- May 7, 2019
- July 24, 2019
- November 5, 2019

Attachment 1

Assembly Bill No. 1751
CHAPTER 478

Approved by Governor: September 18, 2018.
Filed with Secretary of State: September 18, 2018.

SECTION 1.

Section 1798.24 of the Civil Code is amended to read:

1798.24.

An agency shall not disclose any personal information in a manner that would link the information disclosed to the individual to whom it pertains unless the information is disclosed, as follows:

(a) To the individual to whom the information pertains.

(b) With the prior written voluntary consent of the individual to whom the ~~record~~ *information* pertains, but only if that consent has been obtained not more than 30 days before the disclosure, or in the time limit agreed to by the individual in the written consent.

(c) To the duly appointed guardian or conservator of the individual or a person representing the individual if it can be proven with reasonable certainty through the possession of agency forms, ~~documents~~ *documents,* or correspondence that this person is the authorized representative of the individual to whom the information pertains.

(d) To those officers, employees, attorneys, agents, or volunteers of the agency that has custody of the information if the disclosure is relevant and necessary in the ordinary course of the performance of their official duties and is related to the purpose for which the information was acquired.

(e) To a person, or to another agency ~~where~~ *if* the transfer is necessary for the transferee agency to perform its constitutional or statutory duties, and the use is compatible with a purpose for which the information was collected and the use or transfer is ~~accounted for~~ in accordance with Section 1798.25. With respect to information transferred from a law enforcement or regulatory agency, or information transferred to another law enforcement or regulatory agency, a use is compatible if the use of the information requested is needed in an investigation of unlawful activity under the jurisdiction of the requesting agency or for licensing, certification, or regulatory purposes by that agency.

(f) To a governmental entity ~~when~~ *if* required by state or federal law.

(g) Pursuant to the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

(h) To a person who has provided the agency with advance, adequate written assurance that the information will be used solely for statistical research or reporting purposes, but only if the information to be disclosed is in a form that will not identify any individual.

(i) Pursuant to a determination by the agency that maintains information that compelling circumstances exist that affect the health or safety of an individual, if upon the disclosure notification is transmitted to the individual to whom the information pertains at his or her last known address. Disclosure shall not be made if it is in conflict with other state or federal laws.

(j) To the State Archives as a record that has sufficient historical or other value to warrant its continued preservation by the California state government, or for evaluation by the Director of General Services or his or her designee to determine whether the record has further administrative, legal, or fiscal value.

(k) To any person pursuant to a subpoena, court order, or other compulsory legal process if, before the disclosure, the agency reasonably attempts to notify the individual to whom the record pertains, and if the notification is not prohibited by law.

(l) To any person pursuant to a search warrant.

(m) Pursuant to Article 3 (commencing with Section 1800) of Chapter 1 of Division 2 of the Vehicle Code.

(n) For the sole purpose of verifying and paying government health care service claims made pursuant to Division 9 (commencing with Section 10000) of the Welfare and Institutions Code.

(o) To a law enforcement or regulatory agency when required for an investigation of unlawful activity or for licensing, certification, or regulatory purposes, unless the disclosure is otherwise prohibited by law.

(p) To another person or governmental organization to the extent necessary to obtain information from the person or governmental organization ~~as necessary~~ for an investigation by the agency of a failure to comply with a specific state law that the agency is responsible for enforcing.

(q) To an adopted person and is limited to general background information pertaining to the adopted person's ~~natural~~ *biological* parents, ~~provided that~~ *if* the information does not include or reveal the identity of the ~~natural~~ *biological* parents.

(r) To a child or a grandchild of an adopted person and disclosure is limited to medically necessary information pertaining to the adopted person's ~~natural~~ *biological* parents. However, the information, or the process for obtaining the information, shall not include or reveal the identity of the ~~natural~~ *biological* parents. The State Department of Social Services shall adopt regulations governing the release of information pursuant to this ~~subdivision by July 1, 1985.~~ *subdivision.* The regulations shall require licensed adoption agencies to provide the same services provided by the department as established by this subdivision.

(s) To a committee of the Legislature or to a Member of the Legislature, or his or her staff ~~when~~ *if* authorized in writing by the member, ~~where~~ *if* the member has permission to obtain the information from the individual to whom it pertains or ~~where~~ *if* the member provides reasonable assurance that he or she is acting on behalf of the individual.

(t) (1) To the University of California, a nonprofit educational institution, or, in the case of education-related data, another nonprofit entity, conducting scientific research, ~~provided~~ *if* the request for information is approved by the Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services Agency (CHHSA) or an institutional review board, as authorized in paragraphs (4) and (5). The approval ~~required under this subdivision~~ shall include a review and determination that all the following criteria have been satisfied:

(A) The researcher has provided a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.

(B) The researcher has provided a sufficient plan to destroy or return all personal information as soon as it is no longer needed for the research project, unless the researcher has demonstrated an ongoing need

for the personal information for the research project and has provided a long-term plan sufficient to protect the confidentiality of that information.

(C) The researcher has provided sufficient written assurances that the personal information will not be reused or disclosed to any other person or entity, or used in any manner, not approved in the research protocol, except as required by law or for authorized oversight of the research project.

(2) The CPHS or institutional review board shall, at a minimum, accomplish all of the following as part of its review and approval of the research project for the purpose of protecting personal information held in agency databases:

(A) Determine whether the requested personal information is needed to conduct the research.

(B) Permit access to personal information only if it is needed for the research project.

(C) Permit access only to the minimum necessary personal information needed for the research project.

(D) Require the assignment of unique subject codes that are not derived from personal information in lieu of social security numbers if the research can still be conducted without social security numbers.

(E) If feasible, and if cost, time, and technical expertise permit, require the agency to conduct a portion of the data processing for the researcher to minimize the release of personal information.

(3) Reasonable costs to the agency associated with the agency's process of protecting personal information under the conditions of CPHS approval may be billed to the researcher, including, but not limited to, the agency's costs for conducting a portion of the data processing for the researcher, removing personal information, encrypting or otherwise securing personal information, or assigning subject codes.

(4) The CPHS may enter into written agreements to enable other institutional review boards to provide the data security approvals required by this subdivision, ~~provided~~ *if* the data security requirements set forth in this subdivision are satisfied.

(5) Pursuant to paragraph (4), the CPHS shall enter into a written agreement with the institutional review board established pursuant to *former* Section ~~49079.5~~ *49079.6* of the Education Code. The agreement shall authorize, commencing July 1, 2010, or the date upon which the written agreement is executed, whichever is later, that board to provide the data security approvals required by this subdivision, ~~provided~~ *if* the data security requirements set forth in this subdivision and the act specified in ~~paragraph (1) of~~ subdivision (a) of Section 49079.5 *of the Education Code* are satisfied.

(u) To an insurer if authorized by Chapter 5 (commencing with Section 10900) of Division 4 of the Vehicle Code.

(v) Pursuant to Section 450, 452, 8009, or 18396 of the Financial Code.

(w) For the sole purpose of participation in interstate data sharing of prescription drug monitoring program information pursuant to the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), if disclosure is limited to prescription drug monitoring program information.

This article ~~shall not be construed to~~ *does not* require the disclosure of personal information to the individual to whom the information pertains ~~when~~ *if* that information may otherwise be withheld as set forth in Section 1798.40.

SEC. 2.

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 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, ~~provided that~~ *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.

~~(3)~~ *(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 ~~is~~ *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, 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, ~~if applicable,~~ 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.~~ *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.

(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 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).

SEC. 2.5.

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 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, ~~provided that~~ *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.

~~(3)~~ *(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 ~~is~~ *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, 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, ~~if applicable,~~ 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.~~ *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 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).

SEC. 3.

Section 2.5 of this bill incorporates amendments to Section 11165 of the Health and Safety Code proposed by both this bill and Assembly Bill 1753. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 11165 of the Health and Safety Code, and (3) this bill is enacted after Assembly Bill 1753, in which case Section 2 of this bill shall not become operative.

Assembly Bill No. 1752
Introduced by Assembly member Low

January 3, 2018

SECTION 1.

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, *Schedule IV,* and Schedule ~~IV~~ *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 ~~IV~~ *V* 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, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in

this subdivision shall not be disclosed, sold, or transferred to any third party, 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) 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 is 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, *Schedule IV,* or Schedule ~~IV~~ *V* controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, *1308.14,* and ~~1308.14,~~ *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 of Justice as soon as reasonably possible, but not more than ~~seven days~~ *one working day* 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, if applicable, 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.

(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) Date of sale of the prescription, 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.

SEC. 2.

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, *Schedule IV,* or Schedule ~~IV~~ *V* 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 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 care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which 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 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 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, *Schedule IV,* or Schedule ~~IV~~ *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 ~~IV~~ *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 ~~1308.14~~ *1308.15* 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.

Assembly Bill No. 2086
CHAPTER 274

Approved by Governor: September 6, 2018.
Filed with Secretary of State: September 6, 2018.

SECTION 1.
Section 11165.6 is added to the Health and Safety Code, to read:

11165.6.
A prescriber shall be allowed to access the CURES database for a list of patients for whom that prescriber is listed as a prescriber in the CURES database.

Assembly Bill No. 2783
CHAPTER 589

Approved by Governor: September 20, 2018.
Filed with Secretary of State: September 20, 2018.

SECTION 1.
Section 11055 of the Health and Safety Code is amended to read:

11055.
(a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Codeine.

(H) Ethylmorphine.

(I) *(i)* Hydrocodone.

(ii) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(iii) Oral liquid preparations of dihydrocodeinone containing the above specified amounts that contain, as its nonnarcotic ingredients, two or more antihistamines in combination with each other.

(iv) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(J) Hydromorphone.

(K) Metopon.

(L) Morphine.

(M) Oxycodone.

(N) Oxymorphone.

(O) Thebaine.

(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(6) Cocaine, except as specified in Section 11054.

(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanyl.

(2) Alphaprodine.

(3) Anileridine.

(4) Bezitramide.

(5) Bulk dextropropoxyphene (nondosage forms).

(6) Dihydrocodeine.

(7) Diphenoxylate.

(8) Fentanyl.

(9) Isomethadone.

(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).

(11) Levomethorphan.

(12) Levorphanol.

(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) Khat, which includes all parts of the plant classified botanically as Catha Edulis, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(8) Cathinone (also known as alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone).

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital.

(2) Pentobarbital.

(3) Phencyclidines, including the following:

(A) 1-(1-phenylcyclohexyl) piperidine (PCP).

(B) 1-(1-phenylcyclohexyl) morpholine (PCM).

(C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph.

The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted, submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the

proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.

(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(A) Phenylacetone. Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

SEC. 2.

Section 11056 of the Health and Safety Code is amended to read:

11056.

(a) The controlled substances listed in this section are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Section 1308.32 of Title 21 of the Code of Federal Regulations, and any other drug of the quantitative composition shown in that list for those drugs or which is the same except that it contains a lesser quantity of controlled substances.

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital or any salt thereof and one or more other active medicinal ingredients which are not listed in any schedule.

(2) Any suppository dosage form containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.

(3) Any substance which contains any quantity of a derivative of barbituric acid or any salt thereof.

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(11) Gamma hydroxybutyric acid, and its salts, isomers and salts of isomers, contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.~~

~~(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts. Additionally, oral liquid preparations of dihydrocodeinone containing the above specified amounts may not contain as its nonnarcotic ingredients two or more antihistamines in combination with each other.~~

~~(5)~~ *(3)* Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~(6)~~ *(4)* Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(7)~~ *(5)* Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(8)~~ *(6)* Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chlormethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.

(11) Formyldienolone.

(12) 4-Hydroxy-19-nortestosterone.

(13) Mesterolone.

(14) Methandriol.

(15) Methandrostenolone.

(16) Methenolone.

(17) 17-Methyltestosterone.

(18) Methyltrienolone.

(19) Nandrolone.

(20) Norbolethone.

(21) Norethandrolone.

(22) Normethandrolone.

(23) Oxandrolone.

(24) Oxymestrone.

(25) Oxymetholone.

(26) Quinbolone.

(27) Stanolone.

(28) Stanozolol.

(29) Stenbolone.

(30) Testosterone.

(31) Trenbolone.

(32) Chorionic Gonadotropin (HGC).

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

SEC. 2.5.

Section 11056 of the Health and Safety Code is amended to read:

11056.

(a) The controlled substances listed in this section are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation ~~which~~ *that* contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical,

position, or geometric), and salts of those isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Section 1308.32 of Title 21 of the Code of Federal Regulations, and any other drug of the quantitative composition shown in that list for those drugs or ~~which~~ *that* is the same except that it contains a lesser quantity of controlled substances.

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation ~~which~~ *that* contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital

or any salt thereof and one or more other active medicinal ingredients ~~which~~ *that* are not listed in any schedule.

(2) Any suppository dosage form containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital

or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.

(3) Any substance ~~which~~ *that* contains any quantity of a derivative of barbituric acid or any salt thereof.

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(11) Gamma hydroxybutyric acid, and its salts, isomers and salts of isomers, contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.~~

~~(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts. Additionally, oral liquid preparations of dihydrocodeinone containing the above specified amounts may not contain as its nonnarcotic ingredients two or more antihistamines in combination with each other.~~

~~(5)~~ *(3)* Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~(6)~~ *(4)* Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(7)~~ *(5)* Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(8)~~ *(6)* Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chlormethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.

(11) Formyldienolone.

(12) 4-Hydroxy-19-nortestosterone.

(13) Mesterolone.

(14) Methandriol.

(15) Methandrostenolone.

(16) Methenolone.

(17) 17-Methyltestosterone.

(18) Methyltrienolone.

(19) Nandrolone.

(20) Norbolethone.

(21) Norethandrolone.

(22) Normethandrolone.

(23) Oxandrolone.

(24) Oxymestrone.

(25) Oxymetholone.

(26) Quinbolone.

(27) Stanolone.

(28) Stanozolol.

(29) Stenbolone.

(30) Testosterone.

(31) Trenbolone.

(32) *Human* ~~Chorionic Gonadotropin (HGC).~~ *clorionic gonadotropin (hCG), except when possessed by, sold to, purchased by, transferred to, or administered by a licensed veterinarian, or a licensed veterinarian's designated agent, exclusively for veterinary use.*

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

SEC. 3.

Section 2.5 of this bill incorporates amendments to Section 11056 of the Health and Safety Code proposed by both this bill and Assembly Bill 2589. That section shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 11056 of the Health and Safety Code, and (3) this bill is enacted after Assembly Bill 2589, in which case Section 2 of this bill shall not become operative.

SEC. 4.

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.

Assembly Bill No. 2789
CHAPTER 438

Approved by Governor: September 17, 2018.
Filed with Secretary of State: September 17, 2018.

SECTION 1.

Section 688 is added to the Business and Professions Code, to read:

688.

(a) On and after January 1, 2022, a health care practitioner authorized to issue a prescription pursuant to Section 4040 shall have the capability to issue an electronic data transmission prescription, as defined under Section 4040, on behalf of a patient and to transmit that electronic data transmission prescription to a pharmacy selected by the patient.

(b) On and after January 1, 2022, a pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 shall have the capability to receive an electronic data transmission prescription on behalf of a patient.

(c) For a prescription for a controlled substance, as defined by Section 4021, generation and transmission of the electronic data transmission prescription shall comply with Parts 1300, 1304, 1306, and 1311 of Title 21 of the Code of Federal Regulations, as amended from time to time.

(d) On and after January 1, 2022, a prescription prescribed by a health care practitioner shall be issued as an electronic data transmission prescription. This subdivision shall not apply to prescriptions issued pursuant to subdivision (e).

(e) Subdivision (d) shall not apply to any of the following:

(1) The prescription is issued pursuant to Section 11159.2 of the Health and Safety Code.

(2) An electronic data transmission prescription is not available due to a temporary technological or electrical failure. For purposes of this paragraph, "temporary technological or electrical failure" means failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption affecting the certified electronic data transmission prescription application used to transmit the prescription.

(3) The prescribing health care practitioner is issuing a prescription to be dispensed by a pharmacy located outside California.

(4) (A) The prescription is issued in a hospital emergency department or urgent care clinic and one or more of the following conditions are present:

(i) The patient resides outside California.

(ii) The patient resides outside the geographic area of the hospital.

(iii) The patient is homeless or indigent and does not have a preferred pharmacy.

(iv) The prescription is issued at a time when a patient's regular or preferred pharmacy is likely to be closed.

(B) Under any of the conditions described in subparagraph (A), a prescription shall be electronically issued but does not require electronic transmission and may be provided directly to the patient.

(5) The prescription is issued by a veterinarian.

(6) The prescription is for eyeglasses or contact lenses.

(7) The prescribing health care practitioner and the dispenser are the same entity.

(8) The prescription is issued by a prescribing health care practitioner under circumstances whereby the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronic data transmission prescription in a timely manner, and the delay would adversely impact the patient's medical condition.

(9) The prescription that is issued includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard, as amended from time to time.

(f) A health care practitioner who issues a prescription for a controlled substance but does not transmit the prescription as an electronic data transmission prescription shall document the reason in the

patient's medical record as soon as practicable and within 72 hours of the end of the technological or electrical failure that prevented the electronic data transmission of the prescription.

(g) A pharmacy that receives an electronic data transmission prescription from a prescribing health care practitioner who has issued the prescription but has not dispensed the medication to the patient shall, at the request of the patient or a person authorized to make a request on behalf of the patient, immediately transfer or forward the electronic data transmission prescription to an alternative pharmacy designated by the requester.

(h) If a pharmacy, or its staff, is aware than an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, the pharmacy shall immediately notify the prescribing health care practitioner.

(i) A pharmacist who receives a written, oral, or faxed prescription shall not be required to verify that the prescription properly falls under one of the exceptions in subdivision (e). Pharmacists may continue to dispense medications from legally valid written, oral, or fax prescriptions pursuant to this division.

(j) A health care practitioner, pharmacist, or pharmacy who fails to meet the applicable requirements of this section shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board. This section does not create a private right 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.

(k) This section shall not apply to a health care practitioner, pharmacist, or pharmacy when providing health care services to an inmate, individual on parole, or youth under the jurisdiction of the Department of Corrections and Rehabilitation.

Senate Bill No. 1447
CHAPTER 666

Approved by Governor: September 21, 2018.
Filed with Secretary of State: September 21, 2018.

SECTION 1.

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

4008.

(a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

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

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person

whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

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

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

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

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

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

(g) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 2.

Section 4008 is added to the Business and Professions Code, to read:

4008.

(a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

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

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

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

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

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

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

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

(g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery system to inspect that automated drug delivery system or proposed location pursuant to Article 25 (commencing with Section 4427).

(h) This section shall become operative on July 1, 2019.

SEC. 3.

Section 4017.3 is added to the Business and Professions Code, to read:

4017.3.

(a) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the 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.

(b) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(d) This section shall become operative on July 1, 2019.

SEC. 4.

Section 4105.5 of the Business and Professions Code is amended to read:

4105.5.

(a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:

(1) Use of the automated drug delivery system is consistent with legal requirements.

(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.

(4) The pharmacy license is unexpired and not subject to disciplinary conditions.

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 5.

Section 4119.1 of the Business and Professions Code is amended to read:

4119.1.

(a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) This section shall not be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 6.

Section 4186 of the Business and Professions Code is amended to read:

4186.

(a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be 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.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an "automated drug delivery system" means 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.

(i) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 7.

Section 4186 is added to the Business and Professions Code, to read:

4186.

(a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be 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.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(h) This section shall become operative on July 1, 2019.

SEC. 8.

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, 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).

SEC. 9.

Article 25 (commencing with Section 4427) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 25. Automated Drug Delivery System

4427.

As used in this article, "drugs" or "dangerous drugs" shall have the same meaning as "dangerous drug" as provided in Section 4022 and "devices" or "dangerous devices" shall have the same meaning as "dangerous device" as provided in Section 4022.

4427.1.

An ADDS shall not be installed or operated in California unless it meets the requirements of this article.

4427.2.

(a) An ADDS installed, leased, owned, or operated in California shall be licensed by the board.

(b) An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

(c) A separate application and license shall be required for each ADDS.

(d) An ADDS license shall only be issued when the following conditions are met:

(1) Use of the ADDS is consistent with legal requirements.

(2) The proposed location for installation of the ADDS meets the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

(3) The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(4) The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

(e) Prior to issuance of the license, the board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of the ADDS shall require a new application for licensure. Replacement of an ADDS shall require notification to the board within 30 days.

(f) The ADDS license shall 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 may be submitted to the board.

(g) The holder of an ADDS license shall advise the board in writing within 30 days if use of the ADDS is discontinued.

(h) The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and 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 subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section 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 this article. 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.

(j) 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.

4427.3.

(a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement 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. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

4427.4.

(a) The ADDS shall be owned or leased by the pharmacy holding the license for the ADDS.

(b) Each ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

(c) An ADDS shall be considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and shall be subject to inspection pursuant to Section 4008.

(d) Drugs and devices stored in an ADDS shall be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and drugs and devices dispensed from the ADDS shall be considered to have been dispensed by that pharmacy.

(e) (1) The stocking and restocking of an ADDS shall be 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 licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

(2) Access to the ADDS shall be controlled and tracked using an identification or password system or biosensor.

(3) The ADDS shall make 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.

(f) If drugs or devices are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs and devices shall be stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

4427.5.

Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to subdivision (b) of Section 4427.3.

4427.6.

In addition to any other requirements imposed by this article, an APDS shall additionally meet the following requirements:

(a) The pharmacy shall develop and implement, and review annually, written policies and procedures pertaining to the APDS, including all of the following:

(1) Maintaining the security of the APDS and the dangerous drugs and dangerous devices within that APDS.

(2) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.

(4) Describing assignment 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.

(5) Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices.

(6) Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

(b) The APDS shall only be 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 pursuant to subdivision (a).

(c) The APDS 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.

(d) A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(e) Drugs shall be dispensed from the APDS only upon authorization by a licensed pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(f) All prescribed drugs and devices dispensed to a patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(g) The APDS shall include a notice, prominently posted on the APDS, providing the name, address, and phone number of the pharmacy that holds the ADDS license for that APDS.

(h) The labels on all drugs and devices dispensed by the APDS shall comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(i) Any incident involving the APDS where a complaint, error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(j) An APDS may be located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice.

(k) The board shall not issue a pharmacy more than 15 ADDS licenses for APDS units. Consistent with Section 4001.1, the board, by regulation, may reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

(l) The pharmacy holding the ADDS license for an APDS shall maintain the policies and procedures developed pursuant to subdivision (a) for three years after the last date of use of that APDS.

4427.7.

(a) A pharmacy holding an ADDS license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance

with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

4427.8.

(a) This article shall become operative on July 1, 2019.

(b) On or before January 1, 2024, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

(1) The use and dispersion of ADDS throughout the health care system.

(2) The number of ADDS inspections conducted by the board each year and the findings from the inspections.

(3) Public safety concerns relating to the use of ADDS as identified by the board.

SEC. 10.

Section 1261.6 of the Health and Safety Code is amended to read:

1261.6.

(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. 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.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or ~~(k),~~ *(k)* of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) 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.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) 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 drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) 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.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and

mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(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.

(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 automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be 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.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

SEC. 11.

Section 1261.6 is added to the Health and Safety Code, to read:

1261.6.

(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. 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.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) 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.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) 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 drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) 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.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug delivery system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(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.

(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 automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be 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.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become operative on July 1, 2019.

SEC. 12.

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

Attachment 2

Assembly Bill No. 1753
CHAPTER 479

Approved by Governor: September 18, 2018.
Filed with Secretary of State: September 18, 2018.

SECTION 1.
The Legislature finds and declares the following:

(a) The prevailing use of paper prescription pads to prescribe controlled substances leads to significant instances of theft and fraud each year, contributing to the prescription drug abuse crisis and fueling criminal enterprises engaged in drug diversion.

(b) Prescribing controlled substances by means of electronic transmission prescription, or e-prescribing, has long been considered the most effective way to combat prescription pad theft and fraud.

(c) Many states have begun to require that all controlled substances be prescribed electronically as a means of addressing the public health and public safety crises associated with prescription drug abuse and diversion.

(d) Until mandatory e-prescribing is established in California, it is critical that tighter restrictions be placed on the manufacturing and tracking of prescription pads used within the state.

SEC. 2.
Section 11161.5 of the Health and Safety Code is amended to read:

11161.5.
(a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor

of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).

(5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (l) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.

(d) The department may deny a security printer application on any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a 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 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled

substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

(i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or ~~e-mail~~ *email* within 24 hours of the theft or loss.

(l) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(m) The following violations by security printers shall be punishable pursuant to subdivision (n):

(1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.

(2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.

(3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.

(n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):

(1) For a first violation, a fine not to exceed one thousand dollars ($1,000).

(2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars ($2,500) for each violation.

(3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.

(o) In order to facilitate the standardization of all prescription forms and the serialization of prescription forms with unique identifiers, the Department of Justice may cease issuing new approvals of security printers to the extent necessary to achieve these purposes. The department may, pursuant to regulation, reduce the number of currently approved security printers to no

fewer than three vendors. The department shall ensure that any reduction or limitation of approved security printers does not impact the ability of vendors to meet demand for prescription forms.

SEC. 3.
Section 11162.1 of the Health and Safety Code is amended to read:

11162.1.
(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1–24

25–49

50–74

75–100

101–150

151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

(15) A uniquely serialized number, in a manner prescribed by the Department of Justice.

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) ~~This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.~~ *Within the next working day following delivery, a security printer shall submit via Web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:*

(1) Serial numbers of all prescription forms delivered.

(2) All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms.

(3) The delivery shipment recipient names.

(4) The date of delivery.

SEC. 4.
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 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, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, 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) 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 is 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, 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, if applicable, 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.

(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.

SEC. 4.5.
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 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, ~~provided that~~ *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.

~~(3)~~ *(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 ~~is~~ *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, 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, ~~if applicable,~~ 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.~~ *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 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).

SEC. 5.

Section 4.5 of this bill incorporates amendments to Section 11165 of the Health and Safety Code proposed by both this bill and Assembly Bill 1751. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 11165 of the Health and Safety Code, and (3) this bill is enacted after Assembly Bill 1751, in which case Section 4 of this bill shall not become operative.

Assembly Bill No. 1953
CHAPTER 383

Approved by Governor: September 14, 2018.

Filed with Secretary of State: September 14, 2018.

SECTION 1.
Section 128734 is added to the Health and Safety Code, to read:

128734.
(a) Each organization that operates, conducts, owns, or maintains a skilled nursing facility licensed pursuant to subdivision (c) of Section 1250 shall file with the office as part of the information required in subdivisions (a) to (e), inclusive, of Section 128735, whether the licensee, or a general partner, director, or officer of the licensee, has an ownership or control interest of 5 percent or more in a related party that provides any service to the skilled nursing facility. If the licensee, or the general partner, director, or officer of the licensee has such an interest, the licensee shall disclose all services provided to the skilled nursing facility, the number of individuals who provide that service at the skilled nursing facility, and any other information requested by the office. If goods, fees, and services collectively worth ten thousand dollars ($10,000) or more per year are delivered to the skilled nursing facility, the disclosure required pursuant to this subdivision shall include the related party's profit and loss statement, and the Payroll-Based Journal public use data of the previous quarter for the skilled nursing facility's direct caregivers.

(b) For purposes of this section, all of the following definitions shall apply:

(1) "Direct caregiver" shall have the same meaning as that term is defined in Section 1276.65.

(2) "Profit and loss statement" means the most recent annual statement on profits and losses finalized by a related party for the most recent year available.

(3) "Related party" means an organization related to the licensee provider or that is under common ownership or control, as defined in Section 413.17(b) of Title 42 of the Code of Federal Regulations.

(c) Current licensees shall provide the information required by this section to the office in a manner prescribed by the office.

(d) The provisions of this section shall become effective on January 1, 2020.

Assembly Bill No. 2037
CHAPTER 647

Approved by Governor: September 21, 2018.
Filed with Secretary of State: September 21, 2018.

SECTION 1.
Section 4119.11 is added to the Business and Professions Code, to read:

4119.11.

(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated

patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall 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 automated patient dispensing system license may be submitted to the board.

(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

(b) For purposes of this section, the following definitions shall apply:

(1) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the 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.

(2) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) (1) An automated patient dispensing 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.

(2) Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.

(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3) The automated patient dispensing system 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.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.

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.

SEC. 3.

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:

(a) Approximately 115 communities in 47 California counties do not have a pharmacist within 10 miles, creating a barrier to necessary health care. Many of these communities are susceptible to wild fires, enhancing the need for immediate access to medications and to the advice and care of pharmacists.

(b) Rural and isolated communities desperately lack comprehensive pharmacy services. Automated dispensing, remotely performed by a pharmacist, brings a high level of pharmacy care and medication availability to these communities.

(c) Through the use of automated patient dispensing systems, pharmacists can immediately provide medication to underserved patients, and improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes.

(d) In less-isolated communities, the pharmacist is on the front line of health care as the medical professional that the patient sees most often. It is necessary to bring that level of care to millions of people in the state.

(e) Therefore, in order to provide pharmacy services through the use of an automated patient dispensing system as soon as possible, it is necessary that this act take effect immediately.

Assembly Bill No. 2138
CHAPTER 995

Approved by Governor: September 30, 2018.
Filed with Secretary of State: September 30, 2018.

SECTION 1.
Section 7.5 of the Business and Professions Code is amended to read:

7.5.
(a) A conviction within the meaning of this code means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which 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 of the Penal Code. However, a board may not deny a license to an applicant who is otherwise qualified pursuant to subdivision (b) of Section 480.

Nothing in this section shall apply to the licensure of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3.

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

SEC. 2.
Section 7.5 is added to the Business and Professions Code, to read:

7.5.
(a) A conviction within the meaning of this code means a judgment following a plea or verdict of guilty or a plea of nolo contendere or finding of guilt. Any action which 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. However, a board may not deny a license to an applicant who is otherwise qualified pursuant to subdivision (b) or (c) of Section 480.

(b) (1) Nothing in this section shall apply to the licensure of persons pursuant to Chapter 4 (commencing with Section 6000) of Division 3.

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

(A) The State Athletic Commission.

(B) The Bureau for Private Postsecondary Education.

(C) The California Horse Racing Board.

(c) Except as provided in subdivision (b), this section controls over and supersedes the definition of conviction contained within individual practice acts under this code.

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

SEC. 3.
Section 480 of the Business and Professions Code 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, or 1203.41 of the Penal Code.

(2) Done any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself 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 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 been convicted of a felony if he or she 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 has been convicted of a misdemeanor if he or she has 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, or 1203.41 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. 4.

Section 480 is added to the Business and Professions Code, 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, or 1203.42 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 has been convicted of a crime, or on the basis of acts underlying a conviction for a crime, if he or she 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, or 1203.42 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 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 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. 5.
Section 480.2 is added to the Business and Professions Code, 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 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 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 been convicted of a felony if he or she 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 has been convicted of a misdemeanor if he or she 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, or 1203.41 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 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, or 1203.41 of the Penal Code.

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

SEC. 6.
Section 481 of the Business and Professions Code is amended to read:

481.
(a) Each board under the provisions of this code shall develop criteria to aid it, when considering the denial, 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.

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

SEC. 7.
Section 481 is added to the Business and Professions Code, to read:

481.

(a) Each board under this code shall develop criteria to aid it, when considering the denial, suspension, or revocation of a license, to determine whether a crime is substantially related to the qualifications, functions, or duties of the business or profession it regulates.

(b) Criteria for determining whether a crime is substantially related to the qualifications, functions, or duties of the business or profession a board regulates shall include all of the following:

(1) The nature and gravity of the offense.

(2) The number of years elapsed since the date of the offense.

(3) The nature and duties of the profession in which the applicant seeks licensure or in which the licensee is licensed.

(c) A board shall not deny a license based in whole or in part on a conviction without considering evidence of rehabilitation submitted by an applicant pursuant to any process established in the practice act or regulations of the particular board and as directed by Section 482.

(d) Each board shall post on its Internet Web site a summary of the criteria used to consider whether a crime is considered to be substantially related to the qualifications, functions, or duties of the business or profession it regulates consistent with this section.

(e) 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.

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

SEC. 8.
Section 482 of the Business and Professions Code is amended to read:

482.
(a) Each board under the provisions of this code shall develop criteria to evaluate the rehabilitation of a person when:

~~(a)~~ *(1)* Considering the denial of a license by the board under Section 480; or

~~(b)~~ *(2)* Considering suspension or revocation of a license under Section 490.

(b) Each board shall take into account all competent evidence of rehabilitation furnished by the applicant or licensee.

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

SEC. 9.
Section 482 is added to the Business and Professions Code, to read:

482.
(a) Each board under this code shall develop criteria to evaluate the rehabilitation of a person when doing either of the following:

(1) Considering the denial of a license by the board under Section 480.

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

(b) Each board shall consider whether an applicant or licensee has made a showing of rehabilitation if either of the following are met:

(1) The applicant or licensee has completed the criminal sentence at issue without a violation of parole or probation.

(2) The board, applying its criteria for rehabilitation, finds that the applicant is rehabilitated.

(c) 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.

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

SEC. 10.
Section 488 of the Business and Professions Code is amended to read:

488.
(a) Except as otherwise provided by law, following a hearing requested by an applicant pursuant to subdivision (b) of Section 485, the board may take any of the following actions:

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

~~(b)~~ *(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.

~~(c)~~ *(3)* Deny the license.

~~(d)~~ *(4)* Take other action in relation to denying or granting the license as the board in its discretion may deem proper.

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

SEC. 11.
Section 488 is added to the Business and Professions Code, to read:

488.
(a) Except as otherwise provided by law, following a hearing requested by an applicant pursuant to subdivision (b) of Section 485, the 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 board in its discretion may deem proper.

(b) 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.

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

SEC. 12.
Section 493 of the Business and Professions Code is amended to read:

493.
(a) Notwithstanding any other provision of law, in a proceeding conducted by a board within the department pursuant to law 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 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.

(b) As used in this section, "license" includes "certificate," "permit," "authority," and "registration."

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

SEC. 13.

Section 493 is added to the Business and Professions Code, to read:

493.

(a) Notwithstanding any other law, in a proceeding conducted by a board within the department pursuant to law 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.

(b) (1) Criteria for determining whether a crime is substantially related to the qualifications, functions, or duties of the business or profession the board regulates shall include all of the following:

(A) The nature and gravity of the offense.

(B) The number of years elapsed since the date of the offense.

(C) The nature and duties of the profession.

(2) A board shall not categorically bar an applicant based solely on the type of conviction without considering evidence of rehabilitation.

(c) As used in this section, "license" includes "certificate," "permit," "authority," and "registration."

(d) 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.

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

SEC. 14.

Section 11345.2 of the Business and Professions Code 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, or 1203.41 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 has knowledge of that fact.

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

SEC. 15.

Section 11345.2 is added to the Business and Professions Code, 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, or 1203.42 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 has knowledge of that fact.

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

Assembly Bill No. 2256

CHAPTER 259

Approved by Governor: September 05, 2018.
Filed with Secretary of State: September 05, 2018.

SECTION 1.
Section 4119.9 is added to the Business and Professions Code, to read:

4119.9.
Notwithstanding any other law, a pharmacy, wholesaler, or manufacturer may furnish naloxone hydrochloride or other opioid antagonists to a law enforcement agency if both of the following are met:

(a) The naloxone hydrochloride or other opioid antagonist is furnished exclusively for use by employees of the law enforcement agency who have completed training, provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists.

(b) Records regarding the acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished pursuant to this section shall be maintained by the law enforcement agency for a period of three years from the date the records were created. The law enforcement agency shall be responsible for monitoring the supply of naloxone hydrochloride or other opioid antagonists and ensuring the destruction of expired naloxone hydrochloride or other opioid antagonists.

Assembly Bill No. 2576
CHAPTER 716

Approved by Governor: September 23, 2018.
Filed with Secretary of State: September 23, 2018.

SECTION 1.
The Legislature finds and declares all of the following:

(a) The Legislature has previously granted broad authority to the Governor to direct state agencies to take various actions in order to facilitate the immediate provision of emergency necessities and resources to the public throughout disruptions caused by natural disasters and other declared emergencies.

(b) Ensuring that both institutional and individual health care providers can continue to provide care to patients both during and immediately following a declared emergency is essential for protecting the public health and safety.

(c) In the case of a natural disaster or other emergency situations, health care is often provided through innovative or extraordinary means, including providing care telephonically or in

temporary shelters. However, given the complexities of health care regulation and reimbursement, often neither the state nor local jurisdictions are able to readily advise and support health care providers who are trying to help patients under these circumstances.

(d) Community clinics and health centers are crucial to emergency response and recovery efforts by doing all of the following: providing patients with necessary resources, such as how to apply for CalFresh, and information on local assistance centers; information on how to apply for assistance from the Federal Emergency Management Agency (FEMA) and other state and federal resources; information on how to obtain emergency refills for prescription drugs; and information on disaster services from the Employment Development Department for patients who have lost their jobs as a result of the fires. Community clinics and health centers are responsible to the most vulnerable in our state; those individuals who have been hit the hardest by these natural disasters.

(e) The purpose of this legislation is to clarify what state and local agencies can currently do under existing law to ensure continuity of care and access to the broadest array of health care services possible during and immediately following a state of emergency, and to require state agencies to seek any necessary federal approvals that may be required in order to provide care to as many people impacted by the emergency as possible.

SEC. 2.
Section 4062 of the Business and Professions Code is amended to read:

4062.
(a) Notwithstanding Section 4059 or any other ~~provision of~~ 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 ~~provision of~~ law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

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

(c) During a declared federal, state, or local emergency, the board 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~~ *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~~ *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.~~ *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.

SEC. 3.
Section 4064 of the Business and Professions Code is amended to read:

4064.
(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(g) During a proclaimed state of emergency, nothing in either this section or any other provision of this chapter prohibits a pharmacist, a clinic licensed under Section 4180, or a mobile pharmacy or clinic described in subdivision (c) of Section 4062 from refilling a prescription if the prescriber is unavailable, or if after a reasonable effort has been made, the pharmacist, clinic, or mobile pharmacy is unable to contact the prescriber.

SEC. 4.
Section 4126.5 of the Business and Professions Code is amended to read:

4126.5.
(a) A pharmacy may furnish dangerous drugs only to the following:

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

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

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

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

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

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

(7) To another pharmacy under common control. *During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.*

(b) Notwithstanding subdivision (a), or any other law, a clinic licensed under Section 4180 may furnish dangerous drugs to any of the following during a proclaimed state of emergency:

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

(2) A patient pursuant to a prescription or as otherwise authorized by law.

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

(4) To another clinic under common control, including a mobile clinic, as described in subdivision (c) of Section 4062.

~~(b)~~ *(c)* Notwithstanding any other ~~provision of~~ law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

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

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

SEC. 5.

Section 8628.5 is added to the Government Code, to read:

8628.5.

(a) During a state of emergency, the Governor may direct all state agencies to utilize, employ, and direct state personnel, equipment, and facilities for the performance of any and all activities designed to allow community clinics and health centers to provide and receive reimbursement for services provided during or immediately following the emergency, including all of the following:

(1) To issue permits.

(2) To expedite application processing timelines.

(3) To direct, to the extent necessary, the State Department of Health Care Services, or any other state agency, to seek all appropriate federal approvals to allow community clinics and health centers to provide and be reimbursed for Medi-Cal or other services that are provided either telephonically, or to patients at a shelter or other location within the geographical boundaries of the emergency as stated in the proclamation declaring the state of emergency.

(4) To provide guidance, supplemental services, or whatever resources may be necessary to political subdivisions to ensure the provision of services by community clinics and health centers that are necessary to provide for the health and safety of the citizens of the affected area.

(b) Any agency directed by the Governor to perform activities pursuant to subdivision (a) may expend any of the moneys that have been appropriated to it in order to perform those activities, irrespective of the particular purpose for which the moneys were originally appropriated.

Assembly Bill No. 2859
CHAPTER 240

Approved by Governor: August 28, 2018.
Filed with Secretary of State: August 28, 2018.

SECTION 1.

This act shall be known, and may be cited, as the Protecting Our Children and Adolescents from Opioids Act of 2018.

SEC. 2.

(a) The Legislature finds and declares all of the following:

(1) Drug overdoses are now the leading cause of death by injury in the United States, outnumbering both traffic crashes and gun-related deaths.

(2) In 2015, there were 52,404 drug overdose deaths, with 33,091 of those deaths involving the use of opioids.

(3) Every day, 3,000 children 12 to 17 years of age abuse a prescription painkiller for the first time.

(4) The federal Centers for Disease Control and Prevention estimates that the nonmedical use of prescription painkillers costs public and private health insurers $72.8 billion annually.

(5) The National Institute on Drug Abuse has found 90 percent of all teens who abuse pharmaceutical drugs obtain their drugs from their home medicine cabinet or from a friend's medicine cabinet.

(6) Researchers at the Johns Hopkins Bloomberg School of Public Health found that nearly 70 percent of prescription opioid medications kept in homes with children are not stored safely.

(7) Only 18 percent of providers have been estimated to discuss safe storage and disposal of drugs with their patients.

(8) The Partnership for Drug-Free Kids has found that one of the key drivers for abusing prescription painkillers amongst teens is easy access, with more than 3 in 5 teens stating that pain relievers were easy to obtain from their parents' medicine cabinets.

(9) New reports have found that the number of emergency room visits for accidental poisoning amongst toddlers has tripled since 1997.

(b) It is the intent of the Legislature that increasing safe storage practices among parents is an important component to protecting teens and children from the dangers of opioid abuse and that the state must do more to encourage parents to safeguard these medications that are vital to managing certain chronic pain conditions among adults.

SEC. 3.

Section 4106.5 is added to the Business and Professions Code, to read:

4106.5.

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

(1) "Pharmacy" does not include a pharmacy that meets both of the following requirements:

(A) It is owned and operated by a person or persons in which the majority of the beneficial interest, as well as management and control, resides with at least one board-licensed pharmacist, as that term is defined in Section 4036, that exclusively oversees the operations of the pharmacy.

(B) The owner and operator with the beneficial interest, management, and control described in subparagraph (A) owns, operates, and has management and control of no more than four pharmacies.

(2) "Safe storage products" means a device or product made with the purpose of storing prescription medications that includes a locking mechanism that is accessible only by the designated patient with a passcode, alphanumeric code, key, or by another secure mechanism. A safe storage product includes, but is not limited to, medicine lock boxes, locking medicine cabinets, locking medication bags, and prescription locking vials.

(3) "Schedule II, III, or IV controlled substances" means any substance defined as a Schedule II, III, or IV controlled substance in Sections 11055, 11056, and 11057 of the Health and Safety Code.

(b) A pharmacy that dispenses Schedule II, III, or IV controlled substances shall display safe storage products in a place on the building premises that is located close to the pharmacy.

(c) (1) The board shall assess a fine in an amount to be determined by the board for a violation of this section.

(2) Notwithstanding paragraph (1), the board may choose not to take administrative action against a pharmacy if it determines that compliance with this section would create a financial hardship on the pharmacy or that the pharmacy is temporarily out of stock of safe storage products.

(d) Section 4321 shall not apply to a violation of this section.

(e) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

Assembly Bill No. 2863
CHAPTER 770

Approved by Governor: September 26, 2018.
Filed with Secretary of State: September 26, 2018.

SECTION 1.

Section 4079 is added to the Business and Professions Code, immediately following Section 4078, to read:

4079.

(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is inconsistent with this section is void and unenforceable.

(e) 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.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

SEC. 2.

Section 1367.47 is added to the Health and Safety Code, to read:

1367.47.

(a) The maximum amount a health care service plan may require an enrollee to pay at the point of sale for a covered prescription drug is the lesser of the following:

(1) The applicable cost-sharing amount for the prescription drug.

(2) The retail price.

(b) A health care service plan shall not require a pharmacist or pharmacy to charge or collect from an enrollee a cost-sharing amount that exceeds the total retail price for the prescription drug.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

SEC. 3.

Section 10123.65 is added to the Insurance Code, to read:

10123.65.

(a) The maximum amount a health insurer may require an insured to pay at the point of sale for a covered prescription drug is the lesser of the following:

(1) The applicable cost-sharing amount for the prescription drug.

(2) The retail price.

(b) A health insurer shall not require a pharmacist or pharmacy to charge or collect from an insured a cost-sharing amount that exceeds the total retail price for the prescription drug.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the insured had purchased the prescription drug by paying the cost-sharing amount.

SEC. 4.

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. 212
CHAPTER 1004

Approved by Governor: September 30, 2018.
Filed with Secretary of State: September 30, 2018.

SECTION 1.

Chapter 2 (commencing with Section 42030) is added to Part 3 of Division 30 of the Public Resources Code, to read:

CHAPTER 2. Pharmaceutical and Sharps Waste Stewardship

Article 1. Definitions

42030.

For purposes of this chapter, the following terms have the following meanings:

(a) "Authorized collection site" means a location where an authorized collector operates a secure collection receptacle for collecting covered products.

(b) "Authorized collector" means a person or entity that has entered into an agreement with a program operator to collect covered drugs, including, but not limited to, any of the following:

(1) A person or entity that is registered with the United States Drug Enforcement Administration and that qualifies under federal law to modify that registration to collect controlled substances for the purpose of destruction.

(2) A law enforcement agency.

(3) A retail pharmacy that offers drug take-back services in compliance with Article 9.1 (commencing with Section 1776) of Title 16 of the California Code of Regulations.

(c) "Controlled substance" means a substance listed under Sections 11053 to 11058, inclusive, of the Health and Safety Code or Section 812 or 813 of Title 21 of the United States Code, or any successor section.

(d) "Cosmetic" means an article, or a component of an article, intended to be rubbed, poured, sprinkled, sprayed, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance. "Cosmetic" includes articles with or without expiration dates.

(e) (1) "Covered drug" means a drug, including a brand name or generic drug, sold, offered for sale, or dispensed in the State of California in any form, including, but not limited to, any of the following:

(A) Prescription and nonprescription drugs approved by the United States Food and Drug Administration pursuant to Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or Section 351 of the federal Public Health Service Act (42 U.S.C. 262).

(B) A drug marketed pursuant to an over-the-counter drug monograph.

(C) A drug in a medical device, or a combination product containing a drug and a medical device.

(2) "Covered drug" does not include any of the following:

(A) Vitamins or supplements.

(B) Herbal-based remedies and homeopathic drugs, products, or remedies.

(C) Cosmetics, soap, with or without germicidal agents, laundry detergent, bleach, household cleaning products, shampoos, sunscreens, toothpaste, lip balm, antiperspirants, or any other personal care product that is regulated as both a cosmetic and a nonprescription drug under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 301 et seq.).

(D) A drug for which a pharmaceutical product stewardship program or drug takeback program is provided in the state as part of a United States Food and Drug Administration managed risk evaluation and mitigation strategy under 21 U.S.C. Sec. 355-1.

(E) Biological drug products, as defined by 42 U.S.C. 262(i)(1), including those products currently approved in the state under a new drug application that will be deemed to be licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to Section 7002(e) of the federal Biologics Price Competition and Innovation Act of 2009 (Public Law 111-148).

(F) A medical device, or a component part or accessory of a medical device, if it does not contain a covered drug.

(G) Drugs that are used for animal medicines, including, but not limited to, parasiticide products for animals.

(H) Dialysate drugs or other saline solutions required to perform kidney dialysis.

(f) (1) (A) "Covered entity" means the manufacturer of covered products that are sold in or into the state.

(B) If no entity that meets the definition in subparagraph (A) is in the state, "covered entity" means the distributor of covered products that are sold in or into the state that is licensed as a wholesaler, as defined in Section 4043 of the Business and Professions Code, but does not include a warehouse of a retail pharmacy chain that is licensed as a wholesaler if it engages only in intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

(C) If no entity that meets the definition in subparagraph (A) or (B) is in the state, "covered entity" means a repackager, as defined in Section 4044 of the Business and Professions Code, of covered products that are sold in or into the state.

(D) If no entity that meets the definition in subparagraph (A), (B), or (C) is in the state, "covered entity" means the owner or licensee of a trademark or brand under which covered products are sold in or into the state, regardless of whether the trademark is registered.

(E) If no entity that meets the definition in subparagraph (A), (B), (C), or (D) is in the state, "covered entity" means the importer of the covered products that are sold in or into the state.

(2) The department shall adopt regulations on the process for determining what entity is a covered entity following the priority order set forth in paragraph (1).

(g) "Covered product" means a covered drug or home-generated sharps waste.

(h) "Department" means the Department of Resources Recycling and Recovery, and any successor agency.

(i) "Distributor" means a wholesaler, as that term is defined in Section 4043 of the Business and Professions Code.

(j) "Drug" means any of the following:

(1) An article recognized in the official United States pharmacopoeia, the official national formulary, the official homeopathic pharmacopoeia of the United States, or any supplement of the formulary or those pharmacopoeias.

(2) A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals.

(3) A substance, other than food, intended to affect the structure or any function of the body of humans or other animals.

(4) A substance intended for use as a component of any substance specified in this subdivision.

(k) "Generic drug" means a drug that is chemically identical or bioequivalent to a brand name drug in dosage form, safety, strengths, route of administration, quality, performance, characteristics, and intended use, though inactive ingredients may vary.

(l) (1) "Home-generated sharps waste" has the same meaning as defined in Section 117671 of the Health and Safety Code.

(2) "Home-generated sharps waste" does not include either of the following:

(A) Components manufactured for use with external ambulatory insulin pump therapy systems or continuous glucose monitoring systems, including, but not limited to, insulin infusion sets, glucose sensors that are sterile goods indicated for single subcutaneous use, sterile drug delivery channels indicated for single subcutaneous use, and injection ports.

(B) A biological product, as defined in Section 262(i)(1) of Title 42 of the United States Code, including a combination product, as defined in Section 3.2(e) of Title 21 of the Code of Federal Regulations.

(m) "Mail-back program" means a method of collecting covered products from ultimate users by using prepaid, preaddressed mailing envelopes as described in Section 1776.2 of Article 9.1 of Division 17 of Title 16 of the California Code of Regulations.

(n) "Nonprescription drug" means any drug that may be lawfully sold without a prescription.

(o) "Pharmacy" has the same meaning as defined in Section 4037 of the Business and Professions Code.

(p) "Prescription drug" means a drug, including, but not limited to, a controlled substance, that is required under federal or state law to be dispensed with a prescription, or is restricted to use by practitioners only.

(q) "Program operator" means a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program in accordance with this chapter.

(r) "Proprietary information" means information that is all of the following:

(1) Submitted pursuant to this chapter.

(2) A trade secret, or commercial or financial information, that is privileged or confidential, and is identified as such by the entity providing the information to the department.

(3) Not required to be disclosed under any other law or any regulation affecting a covered product or covered entity.

(s) "Retail pharmacy" means an independent pharmacy, a supermarket pharmacy, a chain pharmacy, or a mass merchandiser pharmacy possessing a license from the state board to operate a pharmacy.

(t) "Retail pharmacy chain" means a retail pharmacy with five or more stores in the state.

(u) "Sharps" means hypodermic needles, pen needles, intravenous needles, lancets, and other devices that are used to penetrate the skin for the delivery of medications.

(v) "State board" means the California State Board of Pharmacy.

(w) "Stewardship organization" means an organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)) that is established by a group of covered entities in accordance with this chapter to develop, implement, and administer a stewardship program established pursuant to this chapter.

(x) "Stewardship plan," or "plan" means the plan for collecting and properly managing covered products that is developed by a covered entity or stewardship organization pursuant to this chapter.

(y) "Stewardship program" means a stewardship program for the collection, transportation, and disposal of covered products.

(z) "Ultimate user" means a state resident or other nonbusiness entity and includes a person who has lawfully obtained, and who possesses, a covered product, including a controlled substance, for his or her own use or for the use of a member of his or her household. "Ultimate user" does not include a needle exchange program established under Section 121349 of the Health and Safety Code, or a medical waste generator, as defined in Section 117705 of the Health and Safety Code.

Article 2. Covered Entities and Stewardship Organizations

42031.

(a) (1) No later than 90 days after the effective date of this section, a covered entity shall provide a list of covered products, and a list and description of any drugs or sharps that are not covered products, that it sells or offers for sale in the state to the state board.

(2) A covered entity, or a stewardship organization on behalf of a group of covered entities, shall update the lists described in paragraph (1) and provide the updated lists to the state board on or before January 15 of each year or upon request of the department.

(b) No later than 90 days after the effective date of this section, a retail pharmacy that sells a covered product under its own label shall provide written notification to the state board

identifying the covered entity from which the retail pharmacy obtains a covered product that the retail pharmacy sells under its store label.

(c) The state board shall verify the information received pursuant to subdivisions (a) and (b) and make it available to the department upon request.

(d) The state board may issue a letter of inquiry to any entity listed in subparagraphs (A) to (E), inclusive, of paragraph (1) of subdivision (f) of Section 42030. requesting a list of all drugs and sharps it distributes in California, regardless of whether the drugs or sharps are covered under this chapter, the name of the manufacturer of such products, and any additional information necessary to carry out this chapter. An entity that is issued a letter of inquiry pursuant to this subdivision shall respond in writing no later than 60 days after receipt of the letter. Responses to those inquiries may be shared with the department, but are otherwise deemed proprietary and exempt from disclosure. If the entity does not believe it is a covered entity for purposes of this chapter, it shall submit all of the following to the state board in response to the letter of inquiry:

(1) The basis for the claim that it is not a covered entity.

(2) A list of any drugs and sharps it sells, distributes, repackages, or otherwise offers for sale within the state.

(3) If applicable, the name and contact information of the person or entity from which it obtains a drug or sharp identified pursuant to paragraph (2).

(e) The state board shall obtain and verify and, within 30 days of receipt or upon request by the department, submit to the department a list of drugs and sharps sold or offered for sale in the state excluded from the definition of "covered drugs" pursuant to paragraph (2) of subdivision (e) of Section 42030 or excluded from the definition of "home-generated sharps waste" in subdivision (l) of Section 42030.

(f) Notwithstanding Section 42036.4, information submitted by the state board to the department under this chapter may include proprietary information.

(g) The state board shall notify the department if any covered entity or stewardship organization is in violation of this section for purposes of enforcement by the department.

42031.2.

(a) The department shall adopt regulations for the implementation of this chapter with an effective date of no later than January 1, 2021.

(b) The state board may adopt regulations for the administration of the portions of this chapter for which it has been given responsibilities.

42031.4.

(a) Except as specified in subdivision (d) of Section 42035, a covered entity is not in compliance with this chapter and is subject to penalties pursuant to Article 6 (commencing with Section

42035) if, commencing one year from the adoption of regulations pursuant to Section 42031.2, a covered product sold or offered for sale by the covered entity is not subject to an approved stewardship plan, which is submitted by the covered entity or by a stewardship organization that includes the covered entity, that has been approved by the department pursuant to Section 42032.

(b) In order to comply with the requirements of this chapter, a covered entity may establish and implement a stewardship program independently, or as part of a group of covered entities through membership in a stewardship organization exempt from taxation under Section 501(c)(3) of the federal Internal Revenue Code of 1986 (21 U.S.C. 501(c)(3)).

42031.6.

(a) A program operator shall conduct a comprehensive education and outreach program intended to promote participation in the stewardship program. At a minimum, the education and outreach program shall do all of the following:

(1) Promote its stewardship program to ultimate users by providing signage for hospitals, pharmacies, and other locations, as necessary.

(2) Provide educational and outreach materials for persons authorized to prescribe drugs, pharmacies, pharmacists, ultimate users, and others, as necessary.

(3) Establish an Internet Web site that publicizes the location of authorized collectors and provides other information intended to promote the use of the stewardship program.

(4) Prepare and provide additional outreach materials not specified in this section, as needed to promote the collection and proper management of covered drugs and home-generated sharps waste.

(5) Encourage ultimate users to separate products that are not covered products from covered products, when appropriate, before submitting the covered products to an authorized collection site or mail-back program.

(b) A program operator shall not, as part of the education and outreach program, promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program.

Article 3. Stewardship Plans

42032.

(a) (1) Within six months of the adoption date of regulations by the department pursuant to Section 42031.2, a program operator shall submit to the department for approval a complete stewardship plan that meets the requirements of Section 42032.2 for the establishment and implementation of a stewardship program, in a format determined by the department.

(2) The department shall approve a proposed stewardship program if the program operator submits a completed plan that meets the requirements of this section.

(b) (1) Before submitting a stewardship plan to the department pursuant to this section, a program operator shall submit its proposed stewardship plan to the state board for review, and to any other applicable state agencies with areas of authority relative to the stewardship plan. The duration of time that the state board takes to review a stewardship plan pursuant to this paragraph shall not count toward the time limit specified in paragraph (1) of subdivision (a).

(2) An agency that receives a plan shall review the plan for compliance with state and federal laws and regulations related to the agency's respective authority. The agency shall determine compliance or noncompliance with those laws and regulations, and provide to the program operator that determination and an explanation for any finding of noncompliance, within 90 days of receipt of the plan.

(3) A program operator may submit an updated proposed plan to an agency that issued a determination of noncompliance to attempt to obtain a determination of compliance. A program operator shall submit any determination received from an agency when it submits its stewardship plan to the department.

(4) If, 90 days after submitting a plan to an applicable agency, a program operator has not received a response from the applicable agency, the program operator may submit a certification to the department that the stewardship plan is consistent with all other applicable laws and regulations.

(c) (1) The department shall determine if a stewardship plan is complete, including the determinations required pursuant to subdivision (b), and notify the submitting program operator within 30 days of receipt.

(2) If the department finds that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan set forth in subdivision (d) shall commence upon the original date of receipt.

(3) If the department determines the stewardship plan is incomplete, the department shall identify for the program operator the required additional information, and the program operator shall resubmit the plan within 30 days.

(4) If the department determines upon resubmission that the stewardship plan is complete, the department's 90-day review period for consideration of approval of the plan shall commence upon the date of receipt of the resubmitted plan.

(d) (1) The department shall review a complete submitted stewardship plan and shall approve, disapprove, or conditionally approve the plan within 90 days of receipt of the complete plan.

(2) The department may consult with, or submit a stewardship plan for review to, the state board or another state agency it determines is necessary to determine the completeness of the stewardship plan or for making a determination on the approval of the stewardship plan or an amendment to the stewardship plan. The duration of time that the department takes to review a

stewardship plan pursuant to this paragraph shall not count toward the 90-day time limit specified in paragraph (1).

(e) A program operator shall submit any significant changes to a stewardship plan in writing for approval by the department, and shall not implement the changes prior to that approval.

(f) (1) If the department disapproves a submitted stewardship plan pursuant to subdivision (d), the department shall explain, in writing within 30 days, how the plan does not comply with this chapter, and the program operator shall resubmit a revised plan to the department.

(2) If the department finds that the revised stewardship plan submitted by the program operator does not comply with the requirements of this chapter and disapproves the plan, the covered entity operating its own stewardship program, or the stewardship organization and the covered entities that are members of the stewardship organization, are not in compliance with this chapter until the program operator submits a plan that the department approves.

(g) A program operator shall fully implement operation of an approved stewardship program no later than 270 days after approval by the department of the stewardship plan that establishes the stewardship program.

(h) If a stewardship plan is revoked pursuant to subdivision (a) of Section 42035.4 or terminated by the program operator that submitted the plan, a covered entity no longer subject to that plan may, without being subject to penalties pursuant to Article 6 (commencing with Section 42035), sell or offer for sale covered products in the state for a period of up to one year after the plan terminated or was revoked if the covered entity continues to operate under the most recent approved stewardship plan to which the covered entity was subject.

(i) The department shall make all stewardship plans submitted pursuant to this section available to the public, except proprietary information in the plans protected pursuant to Section 42036.4.

42032.2.

(a) (1) To be complete, a stewardship plan for covered drugs shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered drug sold or offered for sale by each participating covered entity.

(B) Identify and provide contact information for the authorized collectors for the stewardship program, as well as the reasons for excluding any potential authorized collectors from participation in the program.

(C) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(D) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(E) Provide for a handling, transport, and disposal system that complies with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

(F) Provide for a collection system that complies with the requirements of this chapter and meets all of the following requirements for authorized collection sites in each county in which the plan will be implemented:

(i) Provides for a minimum of five authorized collection sites or one authorized collection site per 50,000 people, whichever is greater.

(ii) Provides for a reasonable geographic spread of authorized collection sites and an explanation for the geographic spread.

(iii) Provides for a mail-back program covering any counties where there is not an authorized retail pharmacy operating as an authorized collection site.

(G) Require a program operator to do all of the following:

(i) Permit an ultimate user who is a homeless, homebound, or disabled individual to request prepaid, preaddressed mailing envelopes, or an alternative form of a collection and disposal system, as described in paragraph (2) of subdivision (c), that would render the covered drug inert. A program operator shall accept that request through an Internet Web site and toll-free telephone number that it shall maintain to comply with the requests.

(ii) Provide alternative methods of collection from ultimate users for any covered drugs, other than controlled substances, that cannot be accepted or commingled with other covered drugs in secure collection receptacles or through a mail-back program, to the extent technically feasible and permissible under applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(iii) (I) Provide a service schedule that meets the needs of each authorized collection site to ensure that each secure collection receptacle is serviced as often as necessary to avoid reaching capacity and that collected covered drugs are transported to final disposal in a timely manner. Additionally, a receipt or collection manifest shall be left with the authorized collection site to support verification of the service. The authorized collection site shall maintain and make available to the department this documentation.

(II) An authorized collector shall comply with applicable federal and state laws regarding collection and transportation standards, and the handling of covered drugs, including United States Drug Enforcement Administration regulations.

(H) Provide the policies and procedures for the safe and secure collection, transporting, and disposing of the covered drug, describe how and where records will be maintained and how, at a minimum, instances of security problems that occur will be addressed, and explain the processes that will be taken to change the policies, procedures, and tracking mechanisms to alleviate the problems and to improve safety and security.

(2) Paragraph (1) shall apply only with regard to covered drugs.

(b) (1) At least 120 days before submitting a stewardship plan to the department, the operator of a stewardship program for covered drugs shall notify potential authorized collectors in the county or counties in which it operates of the opportunity to serve as an authorized collector for the proposed stewardship program. If a potential authorized collector expresses interest in participating in a stewardship program, the program operator shall commence good faith negotiations with the potential authorized collector within 30 days.

(2) A retail pharmacy shall make a reasonable effort to serve as an authorized collector as part of a stewardship program in the county in which it is located. If the minimum threshold described in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) is not met in each county in which a retail pharmacy chain has store locations, the retail pharmacy chain shall have at least one location or 15 percent of its store locations, whichever is greater, in that county serve as authorized collectors in a stewardship program.

(3) A program operator shall include as an authorized collector under its stewardship program any entity listed in subdivision (b) of Section 42030 that offers to participate in the stewardship program, in writing and without compensation, even if the minimum convenience standards set in clause (i) of subparagraph (F) of paragraph (1) of subdivision (a) have been achieved. The program operator shall include the offering entity as an authorized collector in the program within 90 days of receiving the written offer to participate. A program operator shall not be required to respond to offers pursuant to this paragraph until the program operator's stewardship plan has been approved by the department.

(c) After a stewardship plan for covered drugs has been approved, the program operator may supplement service, if approved by the department, for a county in which it operates that does not have the minimum number of authorized collection sites due to circumstances beyond the program operator's control, by establishing one or both of the following:

(1) A mail-back program. The mail-back program may include providing information on where and how to receive mail-back materials or providing the locations at which it distributes prepaid, preaddressed mailing envelopes. The program operator shall propose the locations of those envelope distribution locations as part of the stewardship plan. Prepaid mailing envelopes may be mailed to an ultimate user upon request.

(2) An alternative form of collection and disposal of covered drugs that complies with applicable state and federal law, including, but not limited to, United States Drug Enforcement Administration regulations.

(d) (1) To be complete, a stewardship plan for home-generated sharps waste shall do all of the following:

(A) Identify and provide contact information for the stewardship organization, if applicable, and each participating covered entity, and identify each covered product sold or offered for sale by each participating covered entity.

(B) Include any determinations provided by a state agency pursuant to subdivision (b) of Section 42032. Any determination of noncompliance shall be accompanied by a superseding determination of compliance.

(C) Demonstrate adequate funding for all administrative and operational costs of the stewardship program, to be borne by participating covered entities.

(D) Provide for a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws.

(E) Maintain an Internet Web site and toll-free telephone number for purposes of providing information on the program, including disposal options, and to receive requests for sharps waste containers from ultimate users.

(F) Provide that a stewardship program for home-generated sharps waste shall be a mail-back program for home-generated sharps waste that complies with this chapter and that meets all the following requirements:

(i) The program provides or initiates distribution of a sharps waste container and mail-back materials at the point of sale, to the extent allowable by law. Containers and mail-back materials shall be provided at no cost to the ultimate user. The program operator shall select and distribute a container and mail-back materials sufficient to accommodate the volume of sharps purchased by an ultimate user over a selected time period.

(I) For any sharps, the packaging, an insert or instructions, or separate information provided to the ultimate user shall include information on proper sharps waste disposal.

(II) All sharps waste containers shall include on a label affixed to the container or packaging, or on a separate insert included in the container or packaging, the program operator's Internet Web site and toll-free telephone number.

(III) All sharps waste containers shall include prepaid postage affixed to the container or to the mail-back packaging.

(ii) Upon request, the program provides for reimbursement to local agencies for disposal costs related to home-generated sharps waste, unless the program operator provides for the removal of the home-generated sharps waste from the local household hazardous waste facility.

(I) A local agency shall not knowingly request reimbursement for disposal expenses pursuant to this subparagraph for disposal costs resulting from a municipal needle exchange program or a medical waste generator.

(II) Reimbursement costs shall be limited to the actual costs of transportation from the household hazardous waste facility and for the actual costs of disposal.

(III) A request for reimbursement pursuant to this clause shall be submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by this section.

(IV) A cost is eligible for reimbursement pursuant to this clause if the cost is incurred 270 days or more after the approval of a stewardship plan for home-generated sharps waste.

(2) Paragraph (1) shall apply only with regard to home-generated sharps waste.

(e) A stewardship plan shall include provisions to expand into jurisdictions not included in the stewardship plan pursuant to Section 42036.2, in the event a jurisdiction repeals its local stewardship program ordinance.

(f) A stewardship plan shall include educational and outreach provisions to meet the requirements of Section 42031.6.

Article 4. Reports, Budgets, and Records

42033.

With the submission of a stewardship plan, a program operator shall submit to the department an initial stewardship program budget for the first five calendar years of operation of its stewardship program that includes both of the following:

(a) Total anticipated revenues and costs of implementing the stewardship program.

(b) A total recommended funding level sufficient to cover the plan's budgeted costs and to operate the stewardship program over a multiyear period.

42033.2.

(a) On or before March 31, 2022, and each year thereafter, a program operator shall prepare and submit to the department both of the following:

(1) A written report describing the stewardship program activities during the previous reporting period of one year.

(2) A written program budget for stewardship program implementation for the upcoming calendar year.

(b) An annual report submitted pursuant to paragraph (1) of subdivision (a) shall include, at a minimum, all of the following for the prior year:

(1) A list of covered entities participating in the stewardship organization.

(2) The updated and reverified list provided pursuant to paragraph (2) of subdivision (a) of Section 42031 of covered products that each covered entity subject to the stewardship plan sells or offers for sale.

(3) The amount, by weight, of covered products collected from ultimate users at each authorized collection site that is part of the stewardship program.

(4) For a stewardship plan for covered drugs, the name and location of authorized collection sites at which covered drugs were collected.

(5) For a stewardship plan for home-generated sharps waste, information on the mail-back program.

(6) Whether policies and procedures for collecting, transporting, and disposing of covered products, as established in the stewardship plan, were followed during the reporting period and a description of each instance of noncompliance, if any occurred.

(7) Whether any safety or security problems occurred during collection, transportation, or disposal of collected covered products during the reporting period and, if so, what changes have been or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security.

(8) How the program operator complied with all elements in its stewardship plan.

(9) Any other information the department reasonably requires.

(c) An annual program budget submitted pursuant to paragraph (2) of subdivision (a) shall include, at a minimum, both of the following for the upcoming calendar year:

(1) An independent financial audit of the stewardship program, as required by subdivision (b) of Section 42033.4, funded by the stewardship organization from the charge paid from its member covered entities pursuant to Section 42034 or by a covered entity if it operates its own stewardship program.

(2) Anticipated costs and the recommended funding level necessary to implement the stewardship program, including, but not limited to, costs to cover the stewardship plan's budgeted costs and to operate the stewardship program over a multiyear period in a prudent and responsible manner.

(d) (1) The department shall determine if a submitted annual report and program budget are complete and notify the submitting stewardship organization or covered entity within 30 days.

(2) If the department finds that an annual report and program budget are complete, the department's 90-day review period for consideration of approval of the annual report and program budget, set forth in subdivision (e), shall commence upon the original date of receipt.

(3) If the department determines either an annual report or a program budget is incomplete, the department shall identify for the program operator within 30 days the required additional information, and the program operator shall submit a revised annual report or program budget, as applicable, within 30 days.

(4) If the department determines upon resubmission that the annual report or program budget is complete, the department's 90-day review period for consideration of approval of the annual report or program budget shall commence upon the date of receipt of the resubmitted report or program budget.

(e) (1) The department shall review the annual report and program budget required pursuant to this section and within 90 days of receipt shall approve, disapprove, or conditionally approve the annual report and program budget.

(2) (A) If the department conditionally approves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall comply with the conditions of the conditional approval within 60 days of the notice date, unless the Director of Resources Recycling and Recovery determines that additional time is needed.

(B) If the department conditionally approves an annual report or program budget and the conditions are not met within 60 days of the notice date, unless additional time is granted pursuant to subparagraph (A), the department shall disapprove the annual report or program budget.

(3) If the department disapproves an annual report or program budget, the department shall identify the deficiencies in the annual report or program budget and the program operator shall submit a revised annual report or program budget and provide any supplemental information requested within 60 days of the notice date.

42033.4.

(a) A program operator shall keep minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program.

(b) (1) The minutes, books, and records of a program operator shall be audited at the program operator's expense by an independent certified public accountant retained by the program operator at least once each calendar year.

(2) A program operator shall arrange for the independent certified public accountant audit to be delivered to the department, along with the annual report and program budget submitted pursuant to subdivision (a) of Section 42033.2.

(3) The department may conduct its own audit of a program operator. The department shall review the independent certified public accountant audit for compliance with this chapter and consistency with the program operator's stewardship plan, annual report, and program budget submitted pursuant to this chapter. The department shall notify the program operator of any conduct or practice that does not comply with this chapter or of any inconsistencies identified in the department's audit. The program operator may obtain copies of the department's audit, including proprietary information contained in the department's audit, upon request. The department shall not disclose any confidential proprietary information protected pursuant to Section 42036.4 that is included in the department's audit.

42033.5.

For a local jurisdiction that requests removal of home-generated sharps waste or cost recovery or reimbursement for removal pursuant to Section 42032.2, the local jurisdiction shall provide information on home-generated sharps waste to the covered entity or program operator, within a reasonable time upon request by the covered entity or program operator.

42033.6.

As part of the administration of this chapter, within 12 months of a program operator's submission of three consecutive complete annual reports submitted pursuant to Section 42033.2, the department shall develop, and post on its Internet Web site, a report analyzing whether the program operator's stewardship program provides adequate access to safe disposal of home-generated sharps waste or covered drugs, as applicable, to the ultimate user.

Article 5. Financial Provisions

42034.

In order to further the objective that covered entities establish and implement stewardship programs that comply with the requirements of this chapter, each covered entity, either individually or through a stewardship organization, shall pay all administrative and operational costs associated with establishing and implementing the stewardship program in which it participates, including the cost of collecting, transporting, and disposing of covered products.

42034.2.

(a) (1) On or before the end of the 2022–23 fiscal year, and once every three months thereafter, a program operator shall pay to the department an administrative fee. The department shall set the fee at an amount that, when paid by every covered entity, is adequate to cover the department's and any other state agency's full costs of administering and enforcing this chapter. The total amount of fees collected shall not exceed the state's actual and reasonable regulatory costs to implement and enforce this chapter. These costs may include the actual and reasonable costs associated with regulatory activities pursuant to this chapter before submission of stewardship plans pursuant to Section 42032.

(2) For a stewardship organization, the administrative fee paid pursuant to paragraph (1) shall be funded by the covered entities that make up the stewardship organization. This administrative

fee shall be in addition to the charge paid pursuant to Section 42034. A stewardship organization may require its participating covered entities to pay the administrative fee and the charge paid pursuant to Section 42034 at the same time.

(b) The department shall deposit administrative fees paid by a program operator pursuant to subdivision (a) into the Pharmaceutical and Sharps Stewardship Fund, which is hereby established. Upon appropriation by the Legislature, moneys in the fund may be expended by the department, the state board, and any other agency that assists in the regulatory activities of administering and enforcing this chapter. Upon appropriation by the Legislature, moneys in the fund may be used for those regulatory activities and to reimburse any outstanding loans made from other funds used to finance the startup costs of the department's activities pursuant to this chapter. Moneys in the fund shall not be expended for any purpose not enumerated in this chapter.

42034.4.

(a) (1) A stewardship organization may conduct an audit of covered entities that are required to remit a charge or administrative fee to the stewardship organization pursuant to Sections 42034 and 42034.2 to verify that the administrative fees and charges paid are proper and accurate. In addition, a stewardship organization may conduct an audit of authorized collectors to verify the charges submitted are proper and accurate.

(2) The purpose of the audits described in paragraph (1) is to ensure parties required by this chapter to pay or collect an administrative fee or charge are paying or collecting the proper amount to implement the program.

(b) If a stewardship organization conducts an audit pursuant to subdivision (a), it shall do all of the following:

(1) Conduct the audit in accordance with generally accepted auditing practices.

(2) Limit the scope of the audit of covered entities to confirming whether a charge or administrative fee has been properly paid by the covered entities.

(3) Hire an independent third-party auditor to conduct the audit.

(4) Provide a copy of the audit to the department.

Article 6. Enforcement

42035.

(a) (1) On or before June 30, 2022, and at least annually thereafter, the department shall post on its Internet Web site a list of stewardship organizations, including entities with an approved stewardship plan, and covered entities, authorized collection sites, retail pharmacies, and retail pharmacy chains provided in the stewardship plans that are in compliance with this chapter.

(2) The state board shall coordinate with the department to verify that the list posted pursuant to paragraph (1) is consistent with the information submitted to each agency pursuant to Section 42031.

(b) A covered entity or stewardship organization that is not listed on the department's Internet Web site pursuant to subdivision (a), but demonstrates compliance with this chapter before the department is required to post the following year's list pursuant to subdivision (a), may request a certification letter from the department stating that the covered entity or stewardship organization is in compliance with this chapter. A covered entity or stewardship organization that receives a certification letter shall be deemed to be in compliance with this chapter.

(c) A distributor or wholesaler of covered products, and a pharmacy or other retailer that sells or offers for sale a covered product, shall monitor the department's Internet Web site to determine which covered entities and stewardship organizations are in compliance with this chapter. The distributor or wholesaler and the pharmacy or other retailer shall notify the department if it determines that a covered product that it sells or offers for sale is from a covered entity that is not listed on the department's Internet Web site.

(d) The sale, distribution, or offering for sale of any inventory that was in stock before the commencement of a stewardship program is exempt from this chapter and not required to be subject to a stewardship plan.

(e) If the department determines a covered entity or stewardship organization is not in compliance with this chapter, the department shall remove the entity from the list maintained on the department's Internet Web site pursuant to subdivision (a).

42035.2.

(a) (1) The department may impose an administrative penalty on any covered entity, program operator, stewardship organization, or authorized collector that sells, offers for sale, or provides a covered product in violation of this chapter.

(2) The amount of the administrative penalty imposed pursuant to this subdivision shall not exceed ten thousand dollars ($10,000) per day unless the violation is intentional, knowing, or reckless, in which case the administrative penalty shall not exceed fifty thousand dollars ($50,000) per day.

(b) The department shall not impose a penalty on a program operator pursuant to this section for failure to comply with this chapter if the program operator demonstrates it received false or misleading information that contributed to its failure to comply, including, for a stewardship organization, from a participating covered entity.

(c) The department shall deposit all penalties collected pursuant to this section in the Pharmaceutical and Sharps Stewardship Penalty Account, which is hereby created in the Pharmaceutical and Sharps Stewardship Fund established in Section 42034.2. Upon appropriation by the Legislature, moneys in the Pharmaceutical and Sharps Stewardship Penalty Account may

be expended by the department on activities including, but not limited to, the promotion of safe handling and disposal of covered products, grants for related purposes, and the administration and enforcement this chapter.

42035.4.

Upon a written finding that a covered entity, program operator, stewardship organization, or authorized collector has not met a material requirement of this chapter, in addition to any other penalties authorized under this chapter, the department may take one or both of the following actions to ensure compliance with the requirements of this chapter, after affording the covered entity, stewardship organization, or authorized collector a reasonable opportunity to respond to, or rebut, the finding:

(a) Revoke the program operator's stewardship plan approval or require the program operator to resubmit the plan.

(b) Require additional reporting relating to compliance with the material requirement of this chapter that was not met.

42035.6.

(a) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall do both of the following:

(1) Upon request, provide the department with reasonable and timely access, as determined by the department, to its facilities and operations, as necessary to determine compliance with this chapter.

(2) Upon request, provide the department with relevant records necessary to determine compliance with this chapter.

(b) A covered entity, stewardship organization, program operator, retail pharmacy, or retail pharmacy chain shall maintain and keep accessible all records required to be kept or submitted pursuant to this chapter for a minimum of three years.

(c) All reports and records provided to the department pursuant to this chapter shall be provided under penalty of perjury.

(d) The department may take disciplinary action against a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain that fails to provide the department with the access to information required pursuant to this section, including one or both of the following:

(1) Imposing an administrative penalty pursuant to Section 42035.2.

(2) Posting a notice on the department's Internet Web site, in association with the list that the department maintains pursuant to paragraph (1) of subdivision (a) of Section 42035, that the

covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain is no longer in compliance with this chapter.

(e) The department shall not prohibit as a disciplinary action a covered entity, stewardship organization, program operator, pharmacy, retail pharmacy, or retail pharmacy chain from selling a covered product.

42035.8.

All handling, transport, and disposal undertaken as part of a stewardship program under this chapter shall comply with applicable state and federal laws, including, but not limited to, regulations adopted by the United States Drug Enforcement Administration.

Article 7. Miscellaneous Provisions

42036.

(a) Except as provided in subdivision (c), an action specified in subdivision (b) that is taken by a stewardship organization or a covered entity pursuant to this chapter is not a violation of the Cartwright Act (Chapter 2 (commencing with Section 16700) of Part 2 of Division 7 of the Business and Professions Code), the Unfair Practices Act (Chapter 4 (commencing with Section 17000) of Part 2 of Division 7 of the Business and Professions Code), or the Unfair Competition Law (Chapter 5 (commencing with Section 17200) of Part 2 of Division 7 of the Business and Professions Code).

(b) Subdivision (a) shall apply to all of the following actions taken by a stewardship organization or covered entity:

(1) The creation, implementation, or management of a stewardship plan approved by the department pursuant to Article 3 (commencing with Section 42032) and the determination of the types or quantities of covered products collected or otherwise managed pursuant to a stewardship plan.

(2) The determination of the cost and structure of an approved stewardship plan.

(3) The establishment, administration, collection, or disbursement of the charge or administrative fee imposed pursuant to Section 42034 or 42034.2, respectively.

(c) Subdivision (a) shall not apply to an agreement that does any of the following:

(1) Fixes a price of or for covered products, except for an agreement related to costs, charges, or administrative fees associated with participation in a stewardship plan approved by the department and otherwise in accordance with this chapter.

(2) Fixes the output of production of covered products.

(3) Restricts the geographic area in which, or customers to whom, covered products are sold.

42036.2.

(a) This chapter does not apply to a drug or sharp within a jurisdiction that is subject to a local stewardship program pursuant to an ordinance that took effect before April 18, 2018. If that

ordinance is repealed in the jurisdiction or, if more than one ordinance is applicable, those ordinances are repealed in the jurisdiction, the drug or sharp shall be subject to this chapter in that jurisdiction within 270 days after the date on which the ordinance is, or ordinances are, repealed.

(b) This chapter shall preempt a local stewardship program for drugs or sharps enacted by an ordinance or ordinances with an effective date on or after April 18, 2018.

(c) A local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, may continue in operation, but the program and its participants shall not receive or benefit from moneys from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account, including, but not limited to, for administrative or enforcement costs. Participants of a local stewardship program for covered products enacted by an ordinance that has an effective date before April 18, 2018, shall be eligible to participate in a stewardship program under this chapter and thereby become eligible to receive funds from the Pharmaceutical and Sharps Stewardship Fund or the Pharmaceutical and Sharps Stewardship Penalty Account only if the local stewardship program is dissolved.

42036.4.

Proprietary information submitted to the department under this chapter shall be protected by all parties as confidential and shall be exempt from public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code). The department and other parties may only disclose proprietary information in an aggregated form that does not directly or indirectly identify financial, production, or sales data of an individual covered entity or stewardship organization. Proprietary information may be disclosed to the party that submitted the proprietary information.

SEC. 2.

The Legislature finds and declares that Section 1 of this act, which adds Section 42036.4 to the Public Resources Code, imposes a limitation on the public's right of access to the meetings of public bodies or the writings of public officials and agencies within the meaning of Section 3 of Article I of the California Constitution. Pursuant to that constitutional provision, the Legislature makes the following findings to demonstrate the interest protected by this limitation and the need for protecting that interest:

In order to ensure that the competitive market in the state for the manufacture and sale of drugs and sharps is not compromised, it is necessary that proprietary information collected for the purpose of administering a stewardship program be confidential.

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.

Senate Bill No. 1021
CHAPTER 787

Approved by Governor: September 26, 2018.
Filed with Secretary of State: September 26, 2018.

SECTION 1.
Section 1342.71 of the Health and Safety Code, as amended by Section 175 of Chapter 86 of the Statutes of 2016, is amended to read:

1342.71.
(a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on *the* existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the contract that constitute essential health benefits, as defined in Section 1367.005.

(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.

(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

~~(e) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).~~

~~(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).~~

~~(3) For a health care service plan contract that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee's deductible has been satisfied for the year.~~

~~(4) For a nongrandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.~~

~~(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.~~

~~(f) (1) If a health care service plan contract for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:~~

~~(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.~~

~~(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost.~~

~~(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy,~~

~~and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.~~

~~(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars ($600) net of rebates for a one-month supply.~~

~~(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.~~

~~(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers.~~

~~(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.~~

~~(g)~~ *(e)* A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

(f) (1) This section shall not be construed to require a health care service plan to impose cost sharing.

~~(h)~~ *(2)* This section shall not be construed to require ~~a health care service plan to impose cost sharing. This section shall not be construed to require cost~~ *cost* sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

~~(i)~~ *(3)* ~~This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.~~ *A plan's prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment or coinsurance amount, the enrollee shall not be required to pay more than the retail price. The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription medication by paying the cost-sharing amount.*

~~(j)~~ *(g)* In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.

~~(k)~~ *(h)* This section does not apply to a health care service plan ~~that contracts~~ *contract* with the State Department of Health Care Services.

~~(l) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.~~

SEC. 2.

Section 1342.71 of the Health and Safety Code, as added by Section 2 of Chapter 619 of the Statutes of 2015, is repealed.

~~**1342.71.**~~

~~(a) The Legislature hereby finds and declares all of the following:~~

~~(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.~~

~~(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.~~

~~(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.~~

~~(b) A nongrandfathered health care service plan contract that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.~~

~~(c) A health care service plan contract that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this chapter.~~

~~(d) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health care service plan shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for enrollees with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.~~

~~(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a health care service plan contract shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.~~

~~(e) A health care service plan contract shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.~~

~~(f) This section shall not be construed to require a health care service plan to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.~~

~~(g) This section does not require or authorize a health care service plan that contracts with the State Department of Health Care Services to provide services to Medi-Cal beneficiaries to provide coverage for prescription drugs that are not required pursuant to those programs or contracts, or to limit or exclude any prescription drugs that are required by those programs or contracts.~~

~~(h) In the provision of outpatient prescription drug coverage, a health care service plan may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this chapter.~~

~~(i) This section shall not apply to a health care service plan that contracts with the State Department of Health Care Services.~~

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

SEC. 3.
Section 1342.72 is added to the Health and Safety Code, to read:

1342.72.
(a) For combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, a health care service plan shall not have utilization management policies or procedures, including a standard of care, which rely on a multitablet drug regimen instead of a single-tablet drug regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and equally or more likely to result in adherence to a drug regimen.

(b) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(c) This section shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2023, deletes or extends that date.

SEC. 4.
Section 1342.73 is added to the Health and Safety Code, to read:

1342.73.
(a) (1) With respect to an individual or group health care service plan contract subject to Section 1367.006, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient

prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at, or equivalent to, the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).

(3) For a health care service plan contract that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision shall apply only once an enrollee's deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group health care service plan contract, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.

(b) (1) If a health care service plan contract for a nongrandfathered individual or small group product maintains a drug formulary grouped into tiers that includes a fourth tier, a health care service plan contract shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health care service plan's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the Food and Drug Administration of the United States Department of Health and Human Services or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the enrollee to have special training or clinical monitoring for self-administration, or drugs that cost the health plan more than six hundred dollars ($600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the health care service plan shall take into account the other provisions of this section and this chapter.

(3) A health care service plan contract may maintain a drug formulary with fewer than four tiers. A health care service plan contract shall not maintain a drug formulary with more than four tiers.

(4) This section shall not be construed to limit a health care service plan from placing any drug in a lower tier.

(c) This section does not apply to a health care service plan contract with the State Department of Health Care Services.

(d) This section shall remain in effect only until January 1, 2024, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2024, deletes or extends that date.

SEC. 5.
Section 10123.193 of the Insurance Code, as amended by Section 204 of Chapter 86 of the Statutes of 2016, is amended to read:

10123.193.
(a) The Legislature hereby finds and declares all of the following:

(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.

(2) The Legislature intends to build on *the* existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.

(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.

(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section. The cost-sharing limits established by this section apply only to outpatient prescription drugs covered by the policy that constitute essential health benefits, as defined by Section 10112.27.

(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.

(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.

(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds

with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.

(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single-tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.

(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.

~~(f) (1) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).~~

~~(2) With respect to products with actuarial value at or equivalent to the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).~~

~~(3) For a policy of health insurance that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision applies only once an insured's deductible has been satisfied for the year.~~

~~(4) For a nongrandfathered individual or small group policy of health insurance, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.~~

~~(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.~~

~~(g) (1) If a policy of health insurance offered, sold, or renewed in the nongrandfathered individual or small group market maintains a drug formulary grouped into tiers that includes a fourth tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:~~

~~(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.~~

~~(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost.~~

~~(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.~~

~~(D) Tier four shall consist of drugs that are biologics, drugs that the FDA or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the insured to have special training or clinical monitoring for self-administration, or drugs that cost the health insurer more than six hundred dollars ($600) net of rebates for a one-month supply.~~

~~(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the insurer shall take into account the other provisions of this section and this part.~~

~~(3) A policy of health insurance may maintain a drug formulary with fewer than four tiers.~~

~~(4)~~ *(f) (1)* This section shall not be construed to ~~limit~~ *require* a health insurer ~~from placing any drug in a lower tier.~~ *to impose cost sharing.*

~~(h)~~ *(2)* This section shall not be construed to require ~~a health insurer to impose cost sharing. This section shall not be construed to require cost~~ *cost* sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.

(3) A prescription drug benefit shall provide that if the pharmacy's retail price for a prescription drug is less than the applicable copayment or coinsurance amount, the insured shall not be required to pay more than the retail price. The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription medication by paying the cost-sharing amount.

~~(i)~~ *(g)* A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.

~~(j)~~ *(h)* In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.

~~(k) This section shall remain in effect only until January 1, 2020, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2020, deletes or extends that date.~~

SEC. 6.

Section 10123.193 of the Insurance Code, as added by Section 8 of Chapter 619 of the Statutes of 2015, is repealed.

~~**10123.193.**~~

~~(a) The Legislature hereby finds and declares all of the following:~~

~~(1) The federal Patient Protection and Affordable Care Act, its implementing regulations and guidance, and related state law prohibit discrimination based on a person's expected length of life, present or predicted disability, degree of medical dependency, quality of life, or other health conditions, including benefit designs that have the effect of discouraging the enrollment of individuals with significant health needs.~~

~~(2) The Legislature intends to build on existing state and federal law to ensure that health coverage benefit designs do not have an unreasonable discriminatory impact on chronically ill individuals, and to ensure affordability of outpatient prescription drugs.~~

~~(3) Assignment of all or most prescription medications that treat a specific medical condition to the highest cost tiers of a formulary may effectively discourage enrollment by chronically ill individuals, and may result in lower adherence to a prescription drug treatment regimen.~~

~~(b) A nongrandfathered policy of health insurance that is offered, amended, or renewed on or after January 1, 2017, shall comply with this section.~~

~~(c) A policy of health insurance that provides coverage for outpatient prescription drugs shall cover medically necessary prescription drugs, including nonformulary drugs determined to be medically necessary consistent with this part.~~

~~(d) Copayments, coinsurance, and other cost sharing for outpatient prescription drugs shall be reasonable so as to allow access to medically necessary outpatient prescription drugs.~~

~~(e) (1) Consistent with federal law and guidance, the formulary or formularies for outpatient prescription drugs maintained by the health insurer shall not discourage the enrollment of individuals with health conditions and shall not reduce the generosity of the benefit for insureds with a particular condition in a manner that is not based on a clinical indication or reasonable medical management practices. Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section shall be interpreted in a manner that is consistent with this section.~~

~~(2) For combination antiretroviral drug treatments that are medically necessary for the treatment of AIDS/HIV, a policy of health insurance shall cover a single tablet drug regimen that is as effective as a multitablet regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and more likely to result in adherence to a drug regimen.~~

~~(3) Any limitation or utilization management shall be consistent with and based on clinical guidelines and peer-reviewed scientific and medical literature.~~

~~(f) This section shall not be construed to require a health insurer to impose cost sharing. This section shall not be construed to require cost sharing for prescription drugs that state or federal law otherwise requires to be provided without cost sharing.~~

~~(g) A policy of health insurance shall ensure that the placement of prescription drugs on formulary tiers is based on clinically indicated, reasonable medical management practices.~~

~~(h) In the provision of outpatient prescription drug coverage, a health insurer may utilize formulary, prior authorization, step therapy, or other reasonable medical management practices consistent with this part.~~

~~(i) This section shall become operative on January 1, 2020.~~

SEC. 7.

Section 10123.1931 is added to the Insurance Code, immediately following Section 10123.193, to read:

10123.1931.

(a) For combination antiretroviral drug treatments that are medically necessary for the prevention of AIDS/HIV, a health insurer shall not have utilization management policies or procedures, including a standard of care, which rely on a multitablet drug regimen instead of a single-tablet drug regimen unless, consistent with clinical guidelines and peer-reviewed scientific and medical literature, the multitablet regimen is clinically equally or more effective and equally or more likely to result in adherence to a drug regimen.

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2023, deletes or extends that date.

SEC. 8.

Section 10123.1932 is added to the Insurance Code, immediately following Section 10123.1931, to read:

10123.1932.

(a) (1) With respect to an individual or group policy of health insurance subject to Section 10112.28, the copayment, coinsurance, or any other form of cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed two hundred fifty dollars ($250), except as provided in paragraphs (2) and (3).

(2) With respect to products with actuarial value at or equivalent to the bronze level, cost sharing for a covered outpatient prescription drug for an individual prescription for a supply of up to 30 days shall not exceed five hundred dollars ($500), except as provided in paragraph (3).

(3) For a policy of health insurance that is a "high deductible health plan" under the definition set forth in Section 223(c)(2) of Title 26 of the United States Code, paragraphs (1) and (2) of this subdivision applies only once an insured's deductible has been satisfied for the year.

(4) For a nongrandfathered individual or small group policy of health insurance, the annual deductible for outpatient drugs, if any, shall not exceed twice the amount specified in paragraph (1) or (2), respectively.

(5) For purposes of paragraphs (1) and (2), "any other form of cost sharing" shall not include a deductible.

(b) (1) If a policy of health insurance offered, sold, or renewed in the nongrandfathered individual or small group market maintains a drug formulary grouped into tiers that includes a fourth tier, a policy of health insurance shall use the following definitions for each tier of the drug formulary:

(A) Tier one shall consist of most generic drugs and low-cost preferred brand name drugs.

(B) Tier two shall consist of nonpreferred generic drugs, preferred brand name drugs, and any other drugs recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost.

(C) Tier three shall consist of nonpreferred brand name drugs or drugs that are recommended by the health insurer's pharmacy and therapeutics committee based on safety, efficacy, and cost, or that generally have a preferred and often less costly therapeutic alternative at a lower tier.

(D) Tier four shall consist of drugs that are biologics, drugs that the Food and Drug Administration of the United States Department of Health and Human Services or the manufacturer requires to be distributed through a specialty pharmacy, drugs that require the insured to have special training or clinical monitoring for self-administration, or drugs that cost the health insurer more than six hundred dollars ($600) net of rebates for a one-month supply.

(2) In placing specific drugs on specific tiers, or choosing to place a drug on the formulary, the insurer shall take into account the other provisions of this section and this part.

(3) A policy of health insurance may maintain a drug formulary with fewer than four tiers. A policy of health insurance shall not maintain a drug formulary with more than four tiers.

(4) This section shall not be construed to limit a health insurer from placing any drug in a lower tier.

(c) This section shall remain in effect only until January 1, 2024, and as of that date is repealed, unless a later enacted statute that is enacted before January 1, 2024, deletes or extends that date.

SEC. 9.

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. 1109
CHAPTER 693

Approved by Governor: September 22, 2018.
Filed with Secretary of State: September 22, 2018.

SECTION 1.
The Legislature finds and declares all of the following:

(a) Addiction, misuse, and overdose of prescription opioids is a public health crisis affecting both adults and children.

(b) Urgent measures are needed to better inform the public of the risks associated with both the long-term and short-term use of opioids in an effort to address this problem.

(c) Both short-term and long-term prescriptions of opioids to minors fall within situations that require counseling of patients and their parents or guardians by their prescribers.

(d) It is the intent of the Legislature to ensure that health care providers and young athletes receive necessary education on this topic.

SEC. 2.
Section 1645 of the Business and Professions Code is amended to read:

1645.
(a) Effective with the 1974 license renewal period, if the board determines that the public health and safety would be served by requiring all holders of licenses under this chapter to continue their education after receiving a license, it may require, as a condition to the renewal thereof, that they submit assurances satisfactory to the board that they will, during the succeeding two-year period, inform themselves of the developments in the practice of dentistry occurring since the original issuance of their licenses by pursuing one or more courses of study satisfactory to the board or by other means deemed equivalent by the board.

The board shall adopt regulations providing for the suspension of the licenses at the end of the two-year period until compliance with the assurances provided for in this section is accomplished.

(b) The board may also, as a condition of license renewal, require licentiates to successfully complete a portion of the required continuing education hours in specific areas adopted in regulations by the board. The board may prescribe this mandatory coursework within the general areas of patient care, health and safety, ~~and law and ethics.~~ *law and ethics, and the risks of*

addiction associated with the use of Schedule II drugs. The mandatory coursework prescribed by the board shall not exceed ~~fifteen~~ *15* hours per renewal period for dentists, and ~~seven and one-half~~ *7.5* hours per renewal period for dental auxiliaries. Any mandatory coursework required by the board shall be credited toward the continuing education requirements established by the board pursuant to subdivision (a).

(c) For a retired dentist who provides only uncompensated care, the board shall not require more than 60 percent of the hours of continuing education that are required of other licensed dentists. Notwithstanding subdivision (b), all of the hours of continuing education as described in this subdivision shall be gained through courses related to the actual delivery of dental services to the patient or the community, as determined by the board. Nothing in this subdivision shall be construed to reduce any requirements imposed by the board pursuant to subdivision (b).

(d) The board shall report on the outcome of subdivision (c) pursuant to, and at the time of, its regular sunset review process, as provided in Section 1601.1.

SEC. 2.5.

Section 1645 of the Business and Professions Code is amended to read:

1645.

(a) ~~Effective~~ *(1)* ~~with the 1974 license renewal period, if the board determines that the public health and safety would be served by requiring all~~ *All* holders of licenses under this chapter ~~to~~ *shall* continue their education after receiving a ~~license, it may require,~~ *license* as a condition to the renewal thereof, ~~that they submit assurances~~ *and shall obtain evidence* satisfactory to the board that they ~~will,~~ *have,* during the ~~succeeding~~ *preceding* two-year period, ~~inform themselves of the~~ *obtained continuing education relevant to* developments in the practice of dentistry ~~occurring since the original issuance of their licenses by pursuing one or more courses of study satisfactory to the board or by other means deemed equivalent by the~~ *and dental assisting consistent with the regulations of the* board.

The board shall adopt regulations providing for the suspension of the licenses at the end of the two-year period until compliance with ~~the assurances provided for in~~ this section is accomplished.

(b) The board may also, as a condition of license renewal, require licentiates to successfully complete a portion of the required continuing education hours in specific areas adopted in regulations by the board. The board may prescribe this mandatory coursework within the general areas of patient care, health and safety, ~~and law and ethics.~~ *law and ethics, and the risks of addiction associated with the use of Schedule II drugs.* The mandatory coursework prescribed by the board shall not exceed ~~fifteen~~ *15* hours per renewal period for dentists, and ~~seven and one-half~~ *7.5* hours per renewal period for dental auxiliaries. Any mandatory coursework required by the board shall be credited toward the continuing education requirements established by the board pursuant to subdivision (a).

(c) For a retired dentist who provides only uncompensated care, the board shall not require more than 60 percent of the hours of continuing education that are required of other licensed dentists. Notwithstanding subdivision (b), all of the hours of continuing education as described in this subdivision shall be gained through courses related to the actual delivery of dental services to the patient or the community, as determined by the board. Nothing in this subdivision shall be construed to reduce any requirements imposed by the board pursuant to subdivision (b).

(d) The board shall report on the outcome of subdivision (c) pursuant to, and at the time of, its regular sunset review process, as provided in Section 1601.1.

SEC. 3.
Section 2190.5 of the Business and Professions Code is amended to read:

2190.5.
(a)*(1)* All physicians and surgeons shall complete a mandatory continuing education course in the subjects of pain management and the treatment of terminally ill and dying patients. For the purposes of this section, this course shall be a one-time requirement of 12 credit hours within the required minimum established by regulation, to be completed by December 31, 2006. All physicians and surgeons licensed on and after January 1, 2002, shall complete this requirement within four years of their initial license or by their second renewal date, whichever occurs first. The board may verify completion of this requirement on the renewal application form.

(2) For physicians and surgeons licensed on or after January 1, 2019, the course described in paragraph (1) shall also include the subject of the risks of addiction associated with the use of Schedule II drugs.

(b) By regulatory action, the board may exempt physicians and surgeons by practice status category from the requirement in subdivision (a) if the physician and surgeon does not engage in direct patient care, does not provide patient consultations, or does not reside in the State of California.

(c) This section shall not apply to physicians and surgeons practicing in pathology or radiology specialty areas.

SEC. 4.
Section 2191 of the Business and Professions Code is amended to read:

2191.
(a) In determining its continuing education requirements, the board shall consider including a course in human sexuality, defined as the study of a human being as a sexual being and how he or she functions with respect thereto, and nutrition to be taken by those licensees whose practices may require knowledge in those areas.

(b) The board shall consider including a course in child abuse detection and treatment to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with abused or neglected children.

(c) The board shall consider including a course in acupuncture to be taken by those licensees whose practices may require knowledge in the area of acupuncture and whose education has not included instruction in acupuncture.

(d) The board shall encourage every physician and surgeon to take nutrition as part of his or her continuing education, particularly a physician and surgeon involved in primary care.

(e) The board shall consider including a course in elder abuse detection and treatment to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with abused or neglected persons 65 years of age and older.

(f) In determining its continuing education requirements, the board shall consider including a course in the early detection and treatment of substance abusing pregnant women to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these women.

(g) In determining its continuing education requirements, the board shall consider including a course in the special care needs of drug addicted infants to be taken by those licensees whose practices are of a nature that there is a likelihood of contact with these infants.

(h) In determining its continuing education requirements, the board shall consider including a course providing training and guidelines on how to routinely screen for signs exhibited by abused women, particularly for physicians and surgeons in emergency, surgical, primary care, pediatric, prenatal, and mental health settings. In the event the board establishes a requirement for continuing education coursework in spousal or partner abuse detection or treatment, that requirement shall be met by each licensee within no more than four years from the date the requirement is imposed.

(i) In determining its continuing education requirements, the board shall consider including a course in the special care needs of individuals and their families facing end-of-life issues, including, but not limited to, all of the following:

(1) Pain and symptom management.

(2) The psycho-social dynamics of death.

(3) Dying and bereavement.

(4) Hospice care.

(j) In determining its continuing education requirements, the board shall give its highest priority to considering a course on pain ~~management.~~ *management and the risks of addiction associated with the use of Schedule II drugs.*

(k) In determining its continuing education requirements, the board shall consider including a course in geriatric care for emergency room physicians and surgeons.

SEC. 5.
Section 2196.2 of the Business and Professions Code is amended to read:

2196.2.
The board shall periodically develop and disseminate information and educational material regarding pain management techniques and ~~procedures~~ *procedures, including the risks of addiction associated with the use of Schedule II drugs,* to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of *Public* Health ~~Services~~ in developing the materials to be distributed pursuant to this section.

SEC. 6.
Section 2454.5 of the Business and Professions Code is amended to read:

2454.5.
In order to ensure the continuing competence of licensed osteopathic physicians and surgeons, the board shall adopt and administer standards for the continuing education of those licensees. The board shall require each licensed osteopathic physician and surgeon to demonstrate satisfaction of the continuing education requirements as a condition for the renewal of a license at intervals of not less than one year nor more than two years. Commencing January 1, 2018, the board shall require each licensed osteopathic physician and surgeon to complete a minimum of 100 hours of American Osteopathic Association continuing education hours during each two-year cycle, of which 40 hours shall be completed in American Osteopathic Association Category 1 continuing education hours and the remaining 60 hours shall be either American Osteopathic Association or American Medical Association accredited as a condition for renewal of an active license. *Licensed osteopathic physicians and surgeons shall complete a course on the risks of addiction associated with the use of Schedule II drugs.*

For purposes of this section, "American Osteopathic Association Category 1" means continuing education activities and programs approved for Category 1 credit by the Committee on Continuing Medical Education of the American Osteopathic Association.

SEC. 7.
Section 2746.51 of the Business and Professions Code is amended to read:

2746.51.

(a) Neither this chapter nor any other provision of law shall be construed to prohibit a certified nurse-midwife from furnishing or ordering drugs or devices, including controlled substances classified in Schedule II, III, IV, or V under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code), when all of the following apply:

(1) The drugs or devices are furnished or ordered incidentally to the provision of any of the following:

(A) Family planning services, as defined in Section 14503 of the Welfare and Institutions Code.

(B) Routine health care or perinatal care, as defined in subdivision (d) of Section 123485 of the Health and Safety Code.

(C) Care rendered, consistent with the certified nurse-midwife's educational preparation or for which clinical competency has been established and maintained, to persons within a facility specified in subdivision (a), (b), (c), (d), (i), or (j) of Section 1206 of the Health and Safety Code, a clinic as specified in Section 1204 of the Health and Safety Code, a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code, a licensed birth center as defined in Section 1204.3 of the Health and Safety Code, or a special hospital specified as a maternity hospital in subdivision (f) of Section 1250 of the Health and Safety Code.

(2) The drugs or devices are furnished or ordered by a certified nurse-midwife in accordance with standardized procedures or protocols. For purposes of this section, standardized procedure means a document, including protocols, developed and approved by the supervising physician and surgeon, the certified nurse-midwife, and the facility administrator or his or her designee. The standardized procedure covering the furnishing or ordering of drugs or devices shall specify all of the following:

(A) Which certified nurse-midwife may furnish or order drugs or devices.

(B) Which drugs or devices may be furnished or ordered and under what circumstances.

(C) The extent of physician and surgeon supervision.

(D) The method of periodic review of the certified nurse-midwife's competence, including peer review, and review of the provisions of the standardized procedure.

(3) If Schedule II or III controlled substances, as defined in Sections 11055 and 11056 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon. For Schedule II controlled substance protocols, the provision for furnishing the Schedule II controlled substance shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(4) The furnishing or ordering of drugs or devices by a certified nurse-midwife occurs under physician and surgeon supervision. For purposes of this section, no physician and surgeon shall supervise more than four certified nurse-midwives at one time. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include all of the following:

(A) Collaboration on the development of the standardized procedure or protocol.

(B) Approval of the standardized procedure or protocol.

(C) Availability by telephonic contact at the time of patient examination by the certified nurse-midwife.

(b) (1) The furnishing or ordering of drugs or devices by a certified nurse-midwife is conditional on the issuance by the board of a number to the applicant who has successfully completed the requirements of paragraph (2). The number shall be included on all transmittals of orders for drugs or devices by the certified nurse-midwife. The board shall maintain a list of the certified nurse-midwives that it has certified pursuant to this paragraph and the number it has issued to each one. The board shall make the list available to the California State Board of Pharmacy upon its request. Every certified nurse-midwife who is authorized pursuant to this section to furnish or issue a drug order for a controlled substance shall register with the United States Drug Enforcement Administration.

(2) The board has certified in accordance with paragraph (1) that the certified nurse-midwife has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this ~~section.~~ *section, including the risks of addiction and neonatal abstinence syndrome associated with the use of opioids.* The board shall establish the requirements for satisfactory completion of this paragraph.

(3) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

(4) A copy of the standardized procedure or protocol relating to the furnishing or ordering of controlled substances by a certified nurse-midwife shall be provided upon request to any licensed pharmacist who is uncertain of the authority of the certified nurse-midwife to perform these functions.

(5) Certified nurse-midwives who are certified by the board and hold an active furnishing number, who are currently authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration shall provide documentation of continuing education specific to the use of Schedule II controlled substances in settings other than a hospital based on standards developed by the board.

(c) Drugs or devices furnished or ordered by a certified nurse-midwife may include Schedule II controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) under the following conditions:

(1) The drugs and devices are furnished or ordered in accordance with requirements referenced in paragraphs (2) to (4), inclusive, of subdivision (a) and in paragraphs (1) to (3), inclusive, of subdivision (b).

(2) When Schedule II controlled substances, as defined in Section 11055 of the Health and Safety Code, are furnished or ordered by a certified nurse-midwife, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician and surgeon.

(d) Furnishing of drugs or devices by a certified nurse-midwife means the act of making a pharmaceutical agent or agents available to the patient in strict accordance with a standardized procedure or protocol. Use of the term "furnishing" in this section shall include the following:

(1) The ordering of a drug or device in accordance with the standardized procedure or protocol.

(2) Transmitting an order of a supervising physician and surgeon.

(e) "Drug order" or "order" for purposes of this section means an order for medication or for a drug or device that is dispensed to or for an ultimate user, issued by a certified nurse-midwife as an individual practitioner, within the meaning of Section 1306.03 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by certified nurse-midwives; and (3) the signature of a certified nurse-midwife on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 8.
Section 2836.1 of the Business and Professions Code is amended to read:

2836.1.
Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c) (1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure.

(2) In addition to the requirements in paragraph (1), for Schedule II controlled substance protocols, the provision for furnishing Schedule II controlled substances shall address the diagnosis of the illness, injury, or condition for which the Schedule II controlled substance is to be furnished.

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician, but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

(e) For purposes of this section, no physician and surgeon shall supervise more than four nurse practitioners at one time.

(f) (1) Drugs or devices furnished or ordered by a nurse practitioner may include Schedule II through Schedule V controlled substances under the California Uniform Controlled Substances Act (Division 10 (commencing with Section 11000) of the Health and Safety Code) and shall be further limited to those drugs agreed upon by the nurse practitioner and physician and surgeon and specified in the standardized procedure.

(2) When Schedule II or III controlled substances, as defined in Sections 11055 and 11056, respectively, of the Health and Safety Code, are furnished or ordered by a nurse practitioner, the controlled substances shall be furnished or ordered in accordance with a patient-specific protocol approved by the treating or supervising physician. A copy of the section of the nurse practitioner's standardized procedure relating to controlled substances shall be provided, upon request, to any licensed pharmacist who dispenses drugs or devices, when there is uncertainty about the nurse practitioner furnishing the order.

(g) (1) The board has certified in accordance with Section 2836.3 that the nurse practitioner has satisfactorily completed a course in pharmacology covering the drugs or devices to be furnished or ordered under this section.

(2) A physician and surgeon may determine the extent of supervision necessary pursuant to this section in the furnishing or ordering of drugs and devices.

(3) Nurse practitioners who are certified by the board and hold an active furnishing number, who are authorized through standardized procedures or protocols to furnish Schedule II controlled substances, and who are registered with the United States Drug Enforcement Administration, shall complete, as part of their continuing education requirements, a course including Schedule II controlled ~~substances~~ *substances, and the risks of addiction associated with their use,* based on the standards developed by the board. The board shall establish the requirements for satisfactory completion of this subdivision.

(h) Use of the term "furnishing" in this section, in health facilities defined in Section 1250 of the Health and Safety Code, shall include (1) the ordering of a drug or device in accordance with the standardized procedure and (2) transmitting an order of a supervising physician and surgeon.

(i) "Drug order" or "order" for purposes of this section means an order for medication which is dispensed to or for an ultimate user, issued by a nurse practitioner as an individual practitioner, within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription of the supervising physician; (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by nurse practitioners; and (3) the signature of a nurse practitioner on a drug order issued in accordance with this section shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

SEC. 9.
Section 3059 of the Business and Professions Code is amended to read:

3059.
(a) It is the intent of the Legislature that the public health and safety would be served by requiring all holders of licenses to practice optometry granted under this chapter to continue their education after receiving their licenses. The board shall adopt regulations that require, as a condition to the renewal thereof, that all holders of licenses submit proof satisfactory to the board that they have informed themselves of the developments in the practice of optometry occurring since the original issuance of their licenses by pursuing one or more courses of study satisfactory to the board or by other means deemed equivalent by the board.

(b) The board may, in accordance with the intent of this section, make exceptions from continuing education requirements for reasons of health, military service, or other good cause.

(c) If for good cause compliance cannot be met for the current year, the board may grant exemption of compliance for that year, provided that a plan of future compliance that includes current requirements as well as makeup of previous requirements is approved by the board.

(d) The board may require that proof of compliance with this section be submitted on an annual or biennial basis as determined by the board.

(e) An optometrist certified to use therapeutic pharmaceutical agents pursuant to Section 3041.3 shall complete a total of 50 hours of continuing education every two years in order to renew his or her certificate. Thirty-five of the required 50 hours of continuing education shall be on the diagnosis, treatment, and management of ocular disease in any combination of the following areas:

(1) Glaucoma.

(2) Ocular infection.

(3) Ocular inflammation.

(4) Topical steroids.

(5) Systemic medication.

(6) Pain ~~medication.~~ *medication, including the risks of addiction associated with the use of Schedule II drugs.*

(f) The board shall encourage every optometrist to take a course or courses in pharmacology and pharmaceuticals as part of his or her continuing education.

(g) The board shall consider requiring courses in child abuse detection to be taken by those licensees whose practices are such that there is a likelihood of contact with abused or neglected children.

(h) The board shall consider requiring courses in elder abuse detection to be taken by those licensees whose practices are such that there is a likelihood of contact with abused or neglected elder persons.

SEC. 10.
Section 3502.1 of the Business and Professions Code is amended to read:

3502.1.
(a) In addition to the services authorized in the regulations adopted by the Medical Board of California, and except as prohibited by Section 3502, while under the supervision of a licensed physician and surgeon or physicians and surgeons authorized by law to supervise a physician assistant, a physician assistant may administer or provide medication to a patient, or transmit orally, or in writing on a patient's record or in a drug order, an order to a person who may lawfully furnish the medication or medical device pursuant to subdivisions (c) and (d).

(1) A supervising physician and surgeon who delegates authority to issue a drug order to a physician assistant may limit this authority by specifying the manner in which the physician assistant may issue delegated prescriptions.

(2) Each supervising physician and surgeon who delegates the authority to issue a drug order to a physician assistant shall first prepare and adopt, or adopt, a written, practice specific, formulary and protocols that specify all criteria for the use of a particular drug or device, and any contraindications for the selection. Protocols for Schedule II controlled substances shall address the diagnosis of illness, injury, or condition for which the Schedule II controlled substance is being administered, provided, or issued. The drugs listed in the protocols shall constitute the formulary and shall include only drugs that are appropriate for use in the type of practice engaged in by the supervising physician and surgeon. When issuing a drug order, the physician assistant is acting on behalf of and as an agent for a supervising physician and surgeon.

(b) "Drug order," for purposes of this section, means an order for medication that is dispensed to or for a patient, issued and signed by a physician assistant acting as an individual practitioner within the meaning of Section 1306.02 of Title 21 of the Code of Federal Regulations. Notwithstanding any other provision of law, (1) a drug order issued pursuant to this section shall be treated in the same manner as a prescription or order of the supervising physician, (2) all references to "prescription" in this code and the Health and Safety Code shall include drug orders issued by physician assistants pursuant to authority granted by their supervising physicians and surgeons, and (3) the signature of a physician assistant on a drug order shall be deemed to be the signature of a prescriber for purposes of this code and the Health and Safety Code.

(c) A drug order for any patient cared for by the physician assistant that is issued by the physician assistant shall either be based on the protocols described in subdivision (a) or shall be approved by the supervising physician and surgeon before it is filled or carried out.

(1) A physician assistant shall not administer or provide a drug or issue a drug order for a drug other than for a drug listed in the formulary without advance approval from a supervising physician and surgeon for the particular patient. At the direction and under the supervision of a physician and surgeon, a physician assistant may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, manufacturer as defined in the Pharmacy Law, or a pharmacist.

(2) A physician assistant shall not administer, provide, or issue a drug order to a patient for Schedule II through Schedule V controlled substances without advance approval by a supervising physician and surgeon for that particular patient unless the physician assistant has completed an education course that covers controlled substances and that meets standards, including pharmacological content, approved by the board. The education course shall be provided either by an accredited continuing education provider or by an approved physician assistant training program. If the physician assistant will administer, provide, or issue a drug order for Schedule II controlled substances, the course shall contain a minimum of three hours exclusively on Schedule II controlled ~~substances.~~ *substances, including the risks of addiction associated with their use.* Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established by the board prior to the physician assistant's use of a registration number issued by the United States Drug Enforcement Administration to the

physician assistant to administer, provide, or issue a drug order to a patient for a controlled substance without advance approval by a supervising physician and surgeon for that particular patient.

(3) Any drug order issued by a physician assistant shall be subject to a reasonable quantitative limitation consistent with customary medical practice in the supervising physician and surgeon's practice.

(d) A written drug order issued pursuant to subdivision (a), except a written drug order in a patient's medical record in a health facility or medical practice, shall contain the printed name, address, and telephone number of the supervising physician and surgeon, the printed or stamped name and license number of the physician assistant, and the signature of the physician assistant. Further, a written drug order for a controlled substance, except a written drug order in a patient's medical record in a health facility or a medical practice, shall include the federal controlled substances registration number of the physician assistant and shall otherwise comply with Section 11162.1 of the Health and Safety Code. Except as otherwise required for written drug orders for controlled substances under Section 11162.1 of the Health and Safety Code, the requirements of this subdivision may be met through stamping or otherwise imprinting on the supervising physician and surgeon's prescription blank to show the name, license number, and if applicable, the federal controlled substances registration number of the physician assistant, and shall be signed by the physician assistant. When using a drug order, the physician assistant is acting on behalf of and as the agent of a supervising physician and surgeon.

(e) The supervising physician and surgeon shall use either of the following mechanisms to ensure adequate supervision of the administration, provision, or issuance by a physician assistant of a drug order to a patient for Schedule II controlled substances:

(1) The medical record of any patient cared for by a physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out shall be reviewed, countersigned, and dated by a supervising physician and surgeon within seven days.

(2) If the physician assistant has documentation evidencing the successful completion of an education course that covers controlled substances, and that controlled substance education course (A) meets the standards, including pharmacological content, established in Sections 1399.610 and 1399.612 of Title 16 of the California Code of Regulations, and (B) is provided either by an accredited continuing education provider or by an approved physician assistant training program, the supervising physician and surgeon shall review, countersign, and date, within seven days, a sample consisting of the medical records of at least 20 percent of the patients cared for by the physician assistant for whom the physician assistant's Schedule II drug order has been issued or carried out. Completion of the requirements set forth in this paragraph shall be verified and documented in the manner established in Section 1399.612 of Title 16 of the California Code of Regulations. Physician assistants who have a certificate of completion of the course described

in paragraph (2) of subdivision (c) shall be deemed to have met the education course requirement of this subdivision.

(f) All physician assistants who are authorized by their supervising physicians to issue drug orders for controlled substances shall register with the United States Drug Enforcement Administration (DEA).

(g) The board shall consult with the Medical Board of California and report during its sunset review required by Article 7.5 (commencing with Section 9147.7) of Chapter 1.5 of Part 1 of Division 2 of Title 2 of the Government Code the impacts of exempting Schedule III and Schedule IV drug orders from the requirement for a physician and surgeon to review and countersign the affected medical record of a patient.

SEC. 11.
Section 4076.7 is added to the Business and Professions Code, to read:

4076.7.
In addition to the requirements of Sections 4076 and 4076.5, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction."

SEC. 12.
Section 49476 is added to the Education Code, to read:

49476.
(a) If a school district, charter school, or private school elects to offer an athletic program, the school district, charter school, or private school shall annually give the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention to each athlete. The athlete and, if the athlete is 17 years of age or younger, the athlete's parent or guardian shall sign a document acknowledging receipt of the Opioid Factsheet for Patients and return that document to the school district, charter school, or private school before the athlete initiates practice or competition. The Opioid Factsheet for Patients may be sent and returned through an electronic medium, including, but not limited to, fax or email.

(b) This section does not apply to an athlete engaging in an athletic activity during the regular schoolday or as part of a physical education course required pursuant to subdivision (d) of Section 51220.

SEC. 13.
Section 11158.1 is added to the Health and Safety Code, to read:

11158.1.

(a) Except when a patient is being treated as set forth in Sections 11159, 11159.2, and 11167.5, and Article 2 (commencing with Section 11215) of Chapter 5, pertaining to the treatment of addicts, or for a diagnosis of chronic intractable pain as used in Section 124960 of this code and Section 2241.5 of the Business and Professions Code, a prescriber shall discuss all of the following with the minor, the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment before directly dispensing or issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid:

(1) The risks of addiction and overdose associated with the use of opioids.

(2) The increased risk of addiction to an opioid to an individual who is suffering from both mental and substance abuse disorders.

(3) The danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

(4) Any other information required by law.

(b) This section does not apply in any of the following circumstances:

(1) If the minor's treatment includes emergency services and care as defined in Section 1317.1.

(2) If the minor's treatment is associated with or incident to an emergency surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

(3) If, in the prescriber's professional judgment, fulfilling the requirements of subdivision (a) would be detrimental to the minor's health or safety, or in violation of the minor's legal rights regarding confidentiality.

(c) Notwithstanding any other law, including Section 11374, failure to comply with this section shall not constitute a criminal offense.

SEC. 14.
Section 124236 is added to the Health and Safety Code, to read:

124236.
(a) A youth sports organization, as defined in paragraph (3) of subdivision (b) of Section 124235, that elects to offer an athletic program shall annually give the Opioid Factsheet for Patients published by the Centers for Disease Control and Prevention to each athlete. The athlete and, if the athlete is 17 years of age or younger, the athlete's parent or guardian shall sign a document acknowledging receipt of the Opioid Factsheet for Patients and return that document to the youth sports organization before the athlete initiates practice or competition. The Opioid Factsheet for Patients may be sent and returned through an electronic medium, including, but not limited to, fax or email.

(b) This section shall apply to all athletes participating in the activities of a youth sports organization, irrespective of their ages. This section shall not be construed to prohibit a youth sports organization, or any other appropriate entity, from adopting and enforcing rules intended to provide a higher standard of safety for athletes than the standard established under this section.

SEC. 15.

Section 2.5 of this bill incorporates amendments to Section 1645 of the Business and Professions Code proposed by both this bill and Senate Bill 1491. That section of this bill shall only become operative if (1) both bills are enacted and become effective on or before January 1, 2019, (2) each bill amends Section 1645 of the Business and Professions Code, and (3) this bill is enacted after Senate Bill 1491, in which case Section 2 of this bill shall not become operative.

SEC. 16.

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. 1254
CHAPTER 697

Approved by Governor: September 22, 2018.
Filed with Secretary of State: September 22, 2018.

SECTION 1.

Section 4118.5 is added to the Business and Professions Code, to read:

4118.5.

(a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patient under the following conditions:

(1) The hospital has more than 100 beds.

(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.

(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:

(1) The hospital pharmacy has a quality assurance program to monitor competency.

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.

(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.

(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.

(e) This section shall not apply to the State Department of State Hospitals.

(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

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. 1442
CHAPTER 569

Approved by Governor: September 19, 2018.
Filed with Secretary of State: September 19, 2018.

SECTION 1.
The Legislature finds and declares as follows:

(a) Licensed pharmacists are health care professionals whose training and experience play a vital role in protecting public health.

(b) Pharmacists are legally and ethically bound to advise their patients, physicians, and other health practitioners on the selection, dosages, interactions, and side effects of medications as well

as monitor the health and progress of those patients to ensure that they are using their medications safely and effectively.

(c) Pursuant to Section 4001.1 of the Business and Professions Code, the highest priority for the regulation of pharmacists is protection of the public.

(d) The duties of a pharmacist include preventing the abuse of prescription opioids. In August 2013, the California State Board of Pharmacy revoked the licenses of both a pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. Four patients died as a result of the pharmacist's actions.

(e) The California State Board of Pharmacy's decision and order in that case identifies "red flags" that pharmacists are legally obligated to watch for before filling such a prescription. These "red flags" include:

(1) Irregularities on the face of the prescription itself.

(2) Nervous patient demeanor.

(3) The age or presentation of patient (e.g., youthful patients seeking chronic pain medications).

(4) Multiple patients all with the same address.

(5) Multiple prescriptions for the same patient for duplicate therapy.

(6) Requests for early refills of prescriptions.

(7) Prescriptions written for an unusually large quantity of drugs.

(8) Prescriptions written for duplicative drug therapy.

(9) Initial prescriptions written for strong opiates.

(10) Long distances traveled from the patient's home to the prescriber's office or to the pharmacy.

(11) Irregularities in the prescriber's qualifications in relation to the type of medications prescribed.

(12) Prescriptions that are written outside of the prescriber's medical specialty.

(13) Prescriptions for medications with no logical connection to an illness or condition.

(f) In 2013, the Governor signed legislation that significantly expanded the scope of practice of pharmacists. Pharmacists are now, without a prescription from a physician, permitted to vaccinate their patients, aid them in the administration of self-administered hormonal contraception, and provide nicotine replacement products. The California State Board of Pharmacy has by regulation promulgated extensive protocols governing each of these new duties.

(g) For self-administered hormonal contraception, the California Code of Regulations requires a pharmacist to complete the following steps:

(1) Ask the patient to use and complete the self-screening tool.

(2) Review the self-screening answers and clarify responses if needed.

(3) Measure and record the patient's seated blood pressure if combined hormonal contraceptives are requested or recommended.

(4) Before furnishing self-administered hormonal contraception, ensure that the patient is appropriately trained in administration of the requested or recommended contraceptive medication.

(5) When a self-administered hormonal contraceptive is furnished, provide the patient with appropriate counseling and information on the product furnished, including:

(A) Dosage.

(B) Effectiveness.

(C) Potential side effects.

(D) Safety.

(E) The importance of receiving recommended preventative health screenings.

(F) That self-administered hormonal contraception does not protect against sexually transmitted infections.

(h) For nicotine replacement products, the California Code of Regulations requires a pharmacist to complete the following steps:

(1) Review the patient's current tobacco use and past quit attempts.

(2) Ask the patient screening questions related to pregnancy, heart attacks, history of heart ailments, chest pain, or nasal allergies.

(3) Review the instructions for use with every patient using a nicotine replacement product.

(i) For vaccines, Section 1746.4 of Title 16 of the California Code of Regulations requires a pharmacist to notify each patient's primary care provider of any vaccine administered to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider.

(j) Notwithstanding the number, complexity, and importance of a pharmacist's duties, including those new obligations described above, the Legislature has heard uncontradicted testimony that licensed pharmacists are left alone for indeterminate periods of time in the pharmacy and are, simultaneously, required by such establishments to perform nonpharmacist functions such as

staffing cash registers and assisting consumers in purchasing prescriptions, groceries, and other nonpharmacy goods. Survey information of pharmacists working in pharmacies reinforces the testimony.

(k) Staffing inadequacies like these interfere with the professional responsibilities of licensed pharmacists, including those requiring time and professional judgment listed above, and pose a risk to the public health because it leaves licensed pharmacists an insufficient amount of time to perform their licensed functions safely and lawfully, exercise their professional discretion, and comply with their legal and ethical obligations to protect the health and well-being of patients.

SEC. 2.

Section 4113.5 is added to the Business and Professions Code, to read:

4113.5.

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Attachment 3

Statutory Changes to Pharmacy Law

Unless otherwise noted, the provisions take effect January 1, 2019

Business and Professions Code Changes

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

(a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

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

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

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

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

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

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

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

(g) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

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

(a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

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

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

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

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

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

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

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

(g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery system to inspect that automated drug delivery system or proposed location pursuant to Article 25 (commencing with Section 4427).

(h) This section shall become operative on July 1, 2019.

Section 4017.3 is added to the Business and Professions Code to read:
(a) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the 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.

(b) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.
(d) This section shall become operative on July 1, 2019.

Section 4021.5 of the Business and Professions Code is amended to read:
(a) "Correctional pharmacy" means a pharmacy, licensed by the board, located within a correctional facility for the purpose of providing drugs to a correctional clinic, as defined in Section 4187, and providing pharmaceutical care to inmates of the correctional facility.

(b) As part of its pharmaceutical care, a correctional pharmacy may dispense or administer medication pursuant to a chart order, as defined in Section 4019, or other valid prescription consistent with this chapter.

Section 4052.2 of the Business and Professions Code is amended to read:
(a) Notwithstanding any other law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, 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, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The

pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.

(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.
(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

Section 4057 of the Business and Professions Code is amended to read:
(a) Except as provided in Section 4006, subdivision (d) of Section 4081, Section 4240, subdivisions (t) and (u) of Section 4301, and Section 4342, this chapter does not apply to the retail sale of nonprescription drugs that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state drug labeling requirements.

(b) This chapter does not apply to specific dangerous drugs and dangerous devices listed in board regulations, where the sale or furnishing is made to any of the following:

(1) A physician, dentist, podiatrist, pharmacist, medical technician, medical technologist, optometrist, or chiropractor holding a currently valid and unrevoked license and acting within the scope of his or her profession.

(2) A clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit under Division 2 (commencing with Section 1200) of the Health and Safety Code, or Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(3) A correctional clinic, as defined in Section 4187, holding a currently valid and unrevoked license or permit under Article 13.5 (commencing with Section 4187).

(c) This chapter shall not apply to a home health agency licensed under Chapter 8 (commencing with Section 1725) of, or a hospice licensed under Chapter 8.5 (commencing with Section 1745) of, Division 2 of, the Health and Safety Code, when it purchases, stores, furnishes, or transports specific dangerous drugs and dangerous devices listed in board regulations in compliance with applicable law and regulations including:

(1) Dangerous devices described in subdivision (b) of Section 4022, as long as these dangerous devices are furnished only upon the prescription or order of a physician, dentist, or podiatrist.

(2) Hypodermic needles and syringes.

(3) Irrigation solutions of 50 cubic centimeters or greater.

(d) This chapter does not apply to the storage of devices in secure central or ward supply areas of a clinic, hospital, institution, or establishment holding a currently valid and unrevoked license or permit pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code, or pursuant to Chapter 2 (commencing with Section 3300) of Division 3 of, or Part 2 (commencing with Section 6250) of Division 6 of, the Welfare and Institutions Code.

(e) This chapter does not apply to the retail sale of vitamins, mineral products, or combinations thereof or to foods, supplements, or nutrients used to fortify the diet of humans or other animals or poultry and labeled as such that are not subject to Section 4022 and that are packaged or bottled in the manufacturer's or distributor's container and labeled in accordance with applicable federal and state labeling requirements.

(f) This chapter does not apply to the furnishing of dangerous drugs and dangerous devices to recognized schools of nursing. These dangerous drugs and dangerous devices shall not include controlled substances. The dangerous drugs and dangerous devices shall be used for training purposes only, and not for the cure, mitigation, or treatment of disease in humans. Recognized schools of nursing for purposes of this subdivision are those schools recognized as training facilities by the California Board of Registered Nursing.

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

(a) Notwithstanding Section 4059 or any other ~~provision of~~ 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 ~~provision of~~ law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

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

(c) During a declared federal, state, or local emergency, the board 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~~ 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~~ 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.~~ 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.

Section 4064 of the Business and Professions Code is amended to read:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(g) During a proclaimed state of emergency, nothing in either this section or any other provision of this chapter prohibits a pharmacist, a clinic licensed under Section 4180, or a mobile pharmacy or clinic described in subdivision (c) of Section 4062 from refilling a prescription if the prescriber is unavailable, or if after a reasonable effort has been made, the pharmacist, clinic, or mobile pharmacy is unable to contact the prescriber.

Section 4076.7 is added to the Business and Professions Code to read:
In addition to the requirements of Sections 4076 and 4076.5, whenever a prescription drug containing an opioid is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug shall prominently display on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states "Caution: Opioid. Risk of overdose and addiction."

Section 4079 is added to the Business and Professions Code to read:
(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is inconsistent with this section is void and unenforceable.

(e) 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.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

Section 4079.5 is added to the Business and Professions Code to read:
(a) A pharmacy shall inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, unless the pharmacy automatically charges the customer the lower price.

(b) If the customer pays the retail price, the pharmacy shall submit the claim to the health care service plan or health insurer in the same manner as if the customer had purchased the prescription drug by paying the cost-sharing amount when submitted by the network pharmacy.

(c) The payment rendered shall constitute the applicable cost sharing and shall apply to the deductible, if any, and also to the maximum out-of-pocket limit in the same manner as if the enrollee had purchased the prescription drug by paying the cost-sharing amount.

(d) A contract provision that is entered into on or after January 1, 2019, that is inconsistent with this section is void and unenforceable.

(e) 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.

(f) A violation of this provision shall not be grounds for disciplinary action or a criminal action.

Section 4081 of the Business and Professions Code is amended to read:
(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

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

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

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three

years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

Section 4105.5 of the Business and Professions Code is amended to read:
(a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:

(1) Use of the automated drug delivery system is consistent with legal requirements.

(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.

(4) The pharmacy license is unexpired and not subject to disciplinary conditions.

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).

<u>(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.</u>

Section 4106.5 is added to the Business and Professions Code to read:
<u>(a) For purposes of this section, the following terms shall have the following meanings:</u>

<u>(1) "Pharmacy" does not include a pharmacy that meets both of the following requirements:</u>

(A) It is owned and operated by a person or persons in which the majority of the beneficial interest, as well as management and control, resides with at least one board-licensed pharmacist, as that term is defined in Section 4036, that exclusively oversees the operations of the pharmacy.

(B) The owner and operator with the beneficial interest, management, and control described in subparagraph (A) owns, operates, and has management and control of no more than four pharmacies.

(2) "Safe storage products" means a device or product made with the purpose of storing prescription medications that includes a locking mechanism that is accessible only by the designated patient with a passcode, alphanumeric code, key, or by another secure mechanism. A safe storage product includes, but is not limited to, medicine lock boxes, locking medicine cabinets, locking medication bags, and prescription locking vials.

(3) "Schedule II, III, or IV controlled substances" means any substance defined as a Schedule II, III, or IV controlled substance in Sections 11055, 11056, and 11057 of the Health and Safety Code.

(b) A pharmacy that dispenses Schedule II, III, or IV controlled substances shall display safe storage products in a place on the building premises that is located close to the pharmacy.

(c) (1) The board shall assess a fine in an amount to be determined by the board for a violation of this section.

(2) Notwithstanding paragraph (1), the board may choose not to take administrative action against a pharmacy if it determines that compliance with this section would create a financial hardship on the pharmacy or that the pharmacy is temporarily out of stock of safe storage products.

(d) Section 4321 shall not apply to a violation of this section.

(e) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

Section 4113.5 is added to the Business and Professions Code to read:
(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

(b) This section shall not apply to any of the following:

(1) A hospital pharmacy, as defined in Section 4029 or 4056.

(2) A pharmacy located in a hospital facility, including, but not limited to, a building where outpatient services are provided in accordance with the hospital's license.

(3) A pharmacy owned or operated by a federal, state, local, or tribal government entity, including, but not limited to, a correctional pharmacy, a University of California pharmacy, or a pharmacy operated by the State Department of State Hospitals.

(4) A pharmacy owned by a person or persons who, collectively, control the majority of the beneficial interest in no more than four pharmacies in California.

(5) A pharmacy entirely owned and operated by a health care service plan that exclusively contracts with no more than two medical groups in the state to provide, or arrange for the provision of, professional medical services to the enrollees of the plan.

(6) A pharmacy that permits patients to receive medications at a drive-through window when both of the following conditions are met:

(A) A pharmacist is working during the times when patients may receive medication only at the drive-through window.

(B) The pharmacist's employer does not require the pharmacist to retrieve items for sale to patients if the items are located outside the pharmacy. These items include, but are not limited to, items for which a prescription is not required.

(7) Any other pharmacy from which controlled substances, dangerous drugs, or dangerous devices are not furnished, sold, or dispensed at retail.

(c) A violation of subdivision (a) is not subject to subdivision (a) of Section 4321.

(d) The board shall not take action against a pharmacy for a violation of this section if both of the following apply:

(1) Another employee is unavailable to assist the pharmacist due to reasonably unanticipated circumstances, including, but not limited to, illness, injury, family emergency, or the employee's termination or resignation.

(2) The pharmacy takes all reasonable action to make another employee available to assist the pharmacist.

(e) This section shall not be construed to permit an employee who is not licensed under this chapter to engage in any act for which a license is required under this chapter.

Section 4118.5 is added to the Business and Professions Code to read:
(a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patient under the following conditions:

(1) The hospital has more than 100 beds.

(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.

(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:

(1) The hospital pharmacy has a quality assurance program to monitor competency.

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.

(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.

(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.

(e) This section shall not apply to the State Department of State Hospitals.

(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

Section 4119.1 of the Business and Professions Code is amended to read:
(a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need

not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) This section shall not be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

(f) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 4119.9 is added to the Business and Professions Code to read:
Notwithstanding any other law, a pharmacy, wholesaler, or manufacturer may furnish naloxone hydrochloride or other opioid antagonists to a law enforcement agency if both of the following are met:

(a) The naloxone hydrochloride or other opioid antagonist is furnished exclusively for use by employees of the law enforcement agency who have completed training, provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists.

(b) Records regarding the acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished pursuant to this section shall be maintained by the law enforcement agency for a period of three years from the date the records were created. The law enforcement agency shall be responsible for monitoring the supply of naloxone hydrochloride or other opioid antagonists and ensuring the destruction of expired naloxone hydrochloride or other opioid antagonists.

The following section is effective as of September 21, 2018.
Section 4119.11 is added to the Business and Professions Code to read:
(a) A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:

(1) The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.

(2) The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3) Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5) The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6) The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7) The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.

(8) Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.

(9) The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.

(10) The automated patient dispensing system license shall 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 automated patient dispensing system license may be submitted to the board.

(11) A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.

(b) For purposes of this section, the following definitions shall apply:

(1) An “automated drug delivery system” (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the 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.

(2) An “automated patient dispensing system” (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(3) An “automated unit dose system” (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) (1) An automated patient dispensing 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.

(2) Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.

(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:

(1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.

(B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.

(C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.

(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

(E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.

(F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.

(2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).

(3) The automated patient dispensing system 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.

(4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.

(8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

(9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.

(11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.

(e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

(f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia,

the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) A pharmacy holding an automated patient dispensing system license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.

(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records.

Section 4126.5 is added to the Business and Professions Code to read:
(a) A pharmacy may furnish dangerous drugs only to the following:

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

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

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

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

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

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

(7) To another pharmacy under common control. During a proclaimed state of emergency, "another pharmacy" as used in this paragraph shall include a mobile pharmacy, as described in subdivision (c) of Section 4062.

(b) Notwithstanding subdivision (a), or any other law, a clinic licensed under Section 4180 may furnish dangerous drugs to any of the following during a proclaimed state of emergency:

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

(2) A patient pursuant to a prescription or as otherwise authorized by law.

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

(4) To another clinic under common control, including a mobile clinic, as described in subdivision (c) of Section 4062.

~~(b)~~ (c) Notwithstanding any other ~~provision of~~ law, a violation of this section may subject the person or persons who committed the violation to a fine not to exceed the amount specified in Section 125.9 for each occurrence pursuant to a citation issued by the board.

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

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

Section 4186 of the Business and Professions Code is amended to read:

(a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be 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.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an "automated drug delivery system" means 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.

(i) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 4186 is added to the Business and Professions Code to read:

(a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be 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.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.
(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(h) This section shall become operative on July 1, 2019.

Section 4187 is added to the Business and Professions Code to read:
For purposes of this article the following terms shall have the following meanings:

(a) "Correctional clinic" means 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 to eligible patients of the Department of Corrections and Rehabilitation.

(b) "Chief executive officer" means the highest ranking health care administrator at a correctional institution.

(c) "Chief medical executive" means a physician and surgeon acting in the capacity of medical director within the correctional institution.

(d) "Chief nurse executive" means the highest ranking nurse within the correctional institution.

(e) "Licensed correctional clinic" means a correctional clinic that is licensed pursuant to this article.

(f) "Supervising dentist" means the highest ranking dentist within the correctional institution.

Section 4187.1 is added to the Business and Professions Code to read:
(a) Notwithstanding any other provision of this chapter, a correctional clinic licensed by the board under this article may obtain 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 under this article 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:

(1) The direction of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.

(2) An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

(b) The dispensing or administering of drugs in a correctional clinic may be performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. The dispensing of drugs in a correctional clinic shall only be performed by a physician and surgeon, a dentist, a pharmacist, or other person lawfully authorized to dispense drugs. Medications dispensed to patients that are to be kept on the patient's person for use shall meet the labeling requirements of Section 4076 and all recordkeeping requirements of this chapter.
(c) A correctional clinic shall keep records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(d) (1) A correctional clinic shall not be entitled to the benefits of this section until it has obtained a license from the board.

(2) A separate license shall be required for each correctional clinic location and shall not be transferrable.

(3) A correctional clinic's location and address shall be identified by correctional institution and building within that correctional institution.

(4) A clinic shall notify the board in advance of any change in the clinic's address on a form furnished by the board.

Section 4187.2 is added to the Business and Professions Code to read:
(a) The policies and procedures to implement the laws and regulations of this article within a correctional clinic shall be developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. Prior to the issuance of a correctional clinic license by the board, an acknowledgment shall be signed by the correctional facility pharmacist-in-charge servicing that 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.

(b) (1) The chief executive officer shall be responsible for the safe, orderly, and lawful provision of pharmacy services. 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 5024.2 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.

(2) A licensed correctional clinic shall notify the board within 30 days of any change in the chief executive officer on a form furnished by the board.

(c) A correctional facility pharmacist shall be required to inspect the clinic at least quarterly.

Section 4187.3 is added to the Business and Professions Code to read:
A Schedule II, III, IV, or V controlled substance 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 this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

Section 4187.4 is added to the Business and Professions Code to read:
The board shall have the authority to inspect a correctional clinic at any time in order to determine whether a correctional clinic is, or is not, operating in compliance with this article.

Section 4187.5 is added to the Business and Professions Code to read:
(a) An automated drug delivery system, as defined in subdivision (h), may be located in a correctional clinic licensed by the board under this article. If an automated drug delivery system is located in a correctional clinic, the correctional clinic shall implement 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. All policies and procedures shall be maintained either in electronic form or paper form at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system 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, in the prescriber's professional judgment, delay in therapy may cause patient harm, a medication may be removed from the automated drug delivery system and administered or furnished to a 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 medication from an automated drug delivery system shall be documented and provided to the correctional pharmacy when it reopens.

(c) Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division who is lawfully authorized to perform that task.

(d) The stocking of an automated drug delivery system shall be performed by either:

(1) A pharmacist.

(2) An intern pharmacist or pharmacy technician, acting under the supervision of a pharmacist.

(e) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the correctional clinic. The review shall be 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.

(f) The automated drug delivery system shall be operated by a licensed correctional pharmacy. Any drugs within an automated drug delivery system are considered owned by the licensed correctional pharmacy until they are dispensed from the automated drug delivery system.

(g) Drugs from the automated drug delivery system in a correctional clinic shall only be removed by a person lawfully authorized to administer or dispense the drugs.

(h) For purposes of this section, an "automated drug delivery system" means 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.

Section 4203.6 is added to the Business and Professions Code to read:
(a) Each application for a license as a correctional clinic under Article 13.5 (commencing with Section 4187) shall be made on a form furnished by the board. The application form shall contain the name and address of the applicant, the name of its chief executive officer, as defined in Section 4187, and the name of the pharmacist-in-charge of the correctional pharmacy that provides drugs to the clinic.

(b) Upon the filing of the application and payment of the fee prescribed in Section 4400, where applicable, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for licensure. The board shall also determine whether this article has been complied with and shall investigate all matters directly related to the issuance of the license. The board shall not, however, investigate any matters connected with the operation of a premises, including, but not limited to, operating hours, parking availability, or operating noise, except those matters relating to the furnishing or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made does not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under this article, the executive officer of the board shall issue a license authorizing the correctional clinic to which it is issued to obtain drugs pursuant to Article 13.5 (commencing with Section 4187). The license shall be renewed annually on or before December 31 of each year upon payment of the renewal fee prescribed in Section 4400, if applicable. A license shall not be transferable.

Section 4301 of the Business and Professions Code is amended to read:
The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct ~~shall include,~~ includes, but is not limited to, any of the following:

(a) Procurement of a license by fraud or misrepresentation.

(b) Incompetence.

(c) Gross negligence.

(d) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153 of the Health and Safety Code.

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

(h) The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous or injurious to oneself, to a person holding a license under this chapter, or to any other person or to the public, or to the extent that the use impairs the ability of the person to conduct with safety to the public the practice authorized by the license.

(i) Except as otherwise authorized by law, knowingly selling, furnishing, giving away, or administering, or offering to sell, furnish, give away, or administer, any controlled substance to an addict.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(k) The conviction of more than one misdemeanor or any felony involving the use, consumption, or self-administration of any dangerous drug or alcoholic beverage, or any combination of those substances.

(l) The conviction of a crime substantially related to the qualifications, functions, and duties of a licensee under this chapter. The record of conviction of a violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of a violation of the statutes of this state regulating controlled substances or dangerous drugs shall be conclusive evidence of unprofessional conduct. In all other cases, the record of conviction shall be conclusive evidence only of the fact that the conviction occurred. The board may inquire into the circumstances surrounding the commission of the crime, in order to fix the degree of discipline or, in the case of a conviction not involving controlled substances or dangerous drugs, to determine if the conviction is of an offense substantially related to the qualifications, functions, and duties of a licensee under this chapter. A plea or verdict of guilty or a conviction following a plea of nolo contendere is deemed to be a conviction within the meaning of this provision. The board may take action 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 Section 1203.4 of the Penal Code allowing the person to withdraw his or her plea of guilty and to enter a plea of not guilty, or setting aside the verdict of guilty, or dismissing the accusation, information, or indictment.

(m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code relating to the Medi-Cal program.

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

(p) Actions or conduct that would have warranted denial of a license.

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board.

(r) The selling, trading, transferring, or furnishing of drugs obtained pursuant to Section 256b of Title 42 of the United States Code to any person a licensee knows or reasonably should have known, not to be a patient of a covered entity, as defined in paragraph (4) of subsection (a) of Section 256b of Title 42 of the United States Code.

(s) The clearly excessive furnishing of dangerous drugs by a wholesaler to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities. Factors to be considered in determining whether the furnishing of dangerous drugs is clearly excessive shall include, but not be limited to, the amount of dangerous drugs furnished to a pharmacy that primarily or solely dispenses prescription drugs to patients of long-term care facilities, the previous ordering pattern of the pharmacy, and the general patient population to whom the pharmacy distributes the dangerous drugs. That a wholesaler has established, and employs, a tracking system that complies with the requirements of subdivision (b) of Section 4164 shall be considered in determining whether there has been a violation of this subdivision. This provision shall not be interpreted to require a wholesaler to obtain personal medical information or be authorized to permit a wholesaler to have access to personal medical information except as otherwise authorized by Section 56 and following of the Civil Code. For purposes of this section, "long-term care facility" ~~shall have~~ has the same meaning given the term in Section 1418 of the Health and Safety Code.

(t) The acquisition of a nonprescription diabetes test device from a person that the licensee knew or should have known was not the nonprescription diabetes test device's manufacturer or the manufacturer's authorized ~~distributors~~ distributor as identified in Section 4160.5.

(u) The submission of a reimbursement claim for a nonprescription diabetes test device to a pharmaceutical benefit manager, health insurer, government agency, or other third-party payor when the licensee knew or reasonably should have known that the diabetes test device was not purchased either directly from the manufacturer or from the nonprescription diabetes test device manufacturer's authorized distributors as identified in Section 4160.5.

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, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

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

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

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

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

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

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

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

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

eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

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

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

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

Article 25 (commencing with section 4427) is added to Chapter 9 of Division 2 of, the Business and Professions Code to read:
Article 25. Automated Drug Delivery System
Section 4427 is added to the Business and Professions Code to read:
As used in this article, "drugs" or "dangerous drugs" shall have the same meaning as "dangerous drug" as provided in Section 4022 and "devices" or "dangerous devices" shall have the same meaning as "dangerous device" as provided in Section 4022.

Section 4427.1 is added to the Business and Professions Code to read:
An ADDS shall not be installed or operated in California unless it meets the requirements of this article.

Section 4427.2 is added to the Business and Professions Code to read:
(a) An ADDS installed, leased, owned, or operated in California shall be licensed by the board.

(b) An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

(c) A separate application and license shall be required for each ADDS.

(d) An ADDS license shall only be issued when the following conditions are met:

(1) Use of the ADDS is consistent with legal requirements.

(2) The proposed location for installation of the ADDS meets the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

(3) The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(4) The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

(e) Prior to issuance of the license, the board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of the ADDS shall require a new application for licensure. Replacement of an ADDS shall require notification to the board within 30 days.

(f) The ADDS license shall 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 may be submitted to the board.

(g) The holder of an ADDS license shall advise the board in writing within 30 days if use of the ADDS is discontinued.

(h) The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and 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 subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section 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 this article. 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.

(j) 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.

Section 4427.3 is added to the Business and Professions Code to read:
(a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4) A correctional clinic licensed pursuant to Section 4187.1.

(5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement 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. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

Section 4427.4 is added to the Business and Professions Code to read:
(a) The ADDS shall be owned or leased by the pharmacy holding the license for the ADDS.

(b) Each ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

(c) An ADDS shall be considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and shall be subject to inspection pursuant to Section 4008.

(d) Drugs and devices stored in an ADDS shall be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and drugs and devices dispensed from the ADDS shall be considered to have been dispensed by that pharmacy.

(e) (1) The stocking and restocking of an ADDS shall be 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 licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

(2) Access to the ADDS shall be controlled and tracked using an identification or password system or biosensor.

(3) The ADDS shall make 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.

(f) If drugs or devices are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs and devices shall be stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

Section 4427.5 is added to the Business and Professions Code to read:
Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to subdivision (b) of Section 4427.3.

Section 4427.6 is added to the Business and Professions Code to read:
In addition to any other requirements imposed by this article, an APDS shall additionally meet the following requirements:

(a) The pharmacy shall develop and implement, and review annually, written policies and procedures pertaining to the APDS, including all of the following:

(1) Maintaining the security of the APDS and the dangerous drugs and dangerous devices within that APDS.

(2) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.

(4) Describing assignment 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.

(5) Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices.

(6) Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

(b) The APDS shall only be 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 pursuant to subdivision (a).

(c) The APDS 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.

(d) A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(e) Drugs shall be dispensed from the APDS only upon authorization by a licensed pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(f) All prescribed drugs and devices dispensed to a patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.

(g) The APDS shall include a notice, prominently posted on the APDS, providing the name, address, and phone number of the pharmacy that holds the ADDS license for that APDS.

(h) The labels on all drugs and devices dispensed by the APDS shall comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(i) Any incident involving the APDS where a complaint, error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(j) An APDS may be located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice.

(k) The board shall not issue a pharmacy more than 15 ADDS licenses for APDS units. Consistent with Section 4001.1, the board, by regulation, may reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

(l) The pharmacy holding the ADDS license for an APDS shall maintain the policies and procedures developed pursuant to subdivision (a) for three years after the last date of use of that APDS.

Section 4427.7 is added to the Business and Professions Code to read:
(a) A pharmacy holding an ADDS license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

Section 4427.8 is added to the Business and Professions Code to read:
(a) This article shall become operative on July 1, 2019.

(b) On or before January 1, 2024, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the

appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

(1) The use and dispersion of ADDS throughout the health care system.

(2) The number of ADDS inspections conducted by the board each year and the findings from the inspections.

(3) Public safety concerns relating to the use of ADDS as identified by the board.

Health and Safety Code Changes

Section 1261.6 of the Health and Safety Code is amended to read:
(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. 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.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or ~~(k),~~ *(k)* of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) 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.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) 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 drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the

prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) 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.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with

system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(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.

(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 automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be 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.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become inoperative on July 1, 2019, and, as of January 1, 2020, is repealed.

Section 1261.6 is added to the Health and Safety Code, to read:

(a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or

administration, relative to the storage, dispensing, or distribution of drugs. 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.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) 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.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) 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 drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) 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.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4017.3 of, and Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of, the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Article 25 (commencing with Section 4427) of Chapter 9 of Division 2 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug delivery system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(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.

(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 automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be 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.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become operative on July 1, 2019.

Section 11055 of the Health and Safety Code is amended to read:
(a) The controlled substances listed in this section are included in Schedule II.

(b) Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

(1) Opium, opiate, and any salt, compound, derivative, or preparation of opium or opiate, with the exception of naloxone hydrochloride (N-allyl-14-hydroxy-nordihydromorphinone hydrochloride), but including the following:

(A) Raw opium.

(B) Opium extracts.

(C) Opium fluid extracts.

(D) Powdered opium.

(E) Granulated opium.

(F) Tincture of opium.

(G) Codeine.

(H) Ethylmorphine.

(I) (i) Hydrocodone.

(ii) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

(iii) Oral liquid preparations of dihydrocodeinone containing the above specified amounts that contain, as its nonnarcotic ingredients, two or more antihistamines in combination with each other.

(iv) Hydrocodone combination products with not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

(J) Hydromorphone.

(K) Metopon.

(L) Morphine.

(M) Oxycodone.

(N) Oxymorphone.

(O) Thebaine.

(2) Any salt, compound, isomer, or derivative, whether natural or synthetic, of the substances referred to in paragraph (1), but not including the isoquinoline alkaloids of opium.

(3) Opium poppy and poppy straw.

(4) Coca leaves and any salt, compound, derivative, or preparation of coca leaves, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine.

(5) Concentrate of poppy straw (the crude extract of poppy straw in either liquid, solid, or powder form which contains the phenanthrene alkaloids of the opium poppy).

(6) Cocaine, except as specified in Section 11054.

(7) Ecgonine, whether natural or synthetic, or any salt, isomer, derivative, or preparation thereof.

(c) Opiates. Unless specifically excepted or unless in another schedule, any of the following opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of those isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan and levopropoxyphene excepted:

(1) Alfentanyl.

(2) Alphaprodine.

(3) Anileridine.

(4) Bezitramide.

(5) Bulk dextropropoxyphene (nondosage forms).

(6) Dihydrocodeine.

(7) Diphenoxylate.

(8) Fentanyl.

(9) Isomethadone.

(10) Levoalphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM. This substance is authorized for the treatment of narcotic addicts under federal law (see Part 291 (commencing with Section 291.501) and Part 1308 (commencing with Section 1308.01) of Title 21 of the Code of Federal Regulations).

(11) Levomethorphan.

(12) Levorphanol.

(13) Metazocine.

(14) Methadone.

(15) Methadone-Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane.

(16) Moramide-Intermediate, 2-methyl-3-morpholino-1, 1-diphenylpropane-carboxylic acid.

(17) Pethidine (meperidine).

(18) Pethidine-Intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine.

(19) Pethidine-Intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate.

(20) Pethidine-Intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid.

(21) Phenazocine.

(22) Piminodine.

(23) Racemethorphan.

(24) Racemorphan.

(25) Sufentanyl.

(d) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system:

(1) Amphetamine, its salts, optical isomers, and salts of its optical isomers.

(2) Methamphetamine, its salts, isomers, and salts of its isomers.

(3) Dimethylamphetamine (N,N-dimethylamphetamine), its salts, isomers, and salts of its isomers.

(4) N-Ethylmethamphetamine (N-ethyl, N-methylamphetamine), its salts, isomers, and salts of its isomers.

(5) Phenmetrazine and its salts.

(6) Methylphenidate.

(7) Khat, which includes all parts of the plant classified botanically as Catha Edulis, whether growing or not, the seeds thereof, any extract from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or extracts.

(8) Cathinone (also known as alpha-aminopropiophenone, 2-aminopropiophenone, and norephedrone).

(e) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Amobarbital.

(2) Pentobarbital.

(3) Phencyclidines, including the following:

(A) 1-(1-phenylcyclohexyl) piperidine (PCP).

(B) 1-(1-phenylcyclohexyl) morpholine (PCM).

(C) Any analog of phencyclidine which is added by the Attorney General by regulation pursuant to this paragraph. The Attorney General, or his or her designee, may, by rule or regulation, add additional analogs of phencyclidine to those enumerated in this paragraph after notice, posting, and hearing pursuant to Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. The Attorney General shall, in the calendar year of the regular session of the Legislature in which the rule or regulation is adopted, submit a draft of a proposed bill to each house of the Legislature which would incorporate the analogs into this code. No rule or regulation shall remain in effect beyond January 1 after the calendar year of the regular session in which the draft of the proposed bill is submitted to each house. However, if the draft of the proposed bill is submitted during a recess of the Legislature exceeding 45 calendar days, the rule or regulation shall be effective until January 1 after the next calendar year.

(4) Secobarbital.

(5) Glutethimide.

(f) Immediate precursors. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances:

(1) Immediate precursor to amphetamine and methamphetamine:

(A) Phenylacetone. Some trade or other names: phenyl-2 propanone; P2P; benzyl methyl ketone; methyl benzyl ketone.

(2) Immediate precursors to phencyclidine (PCP):

(A) 1-phenylcyclohexylamine.

(B) 1-piperidinocyclohexane carbonitrile (PCC).

Section 11056 of the Health and Safety Code is amended to read:
(a) The controlled substances listed in this section are included in Schedule III.

(b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation ~~which~~ that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:

(1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August

25, 1971, as excepted compounds under Section 1308.32 of Title 21 of the Code of Federal Regulations, and any other drug of the quantitative composition shown in that list for those drugs or ~~which~~ that is the same except that it contains a lesser quantity of controlled substances.

(2) Benzphetamine.

(3) Chlorphentermine.

(4) Clortermine.

(5) Mazindol.

(6) Phendimetrazine.

(c) Depressants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation ~~which~~ that contains any quantity of the following substances having a depressant effect on the central nervous system:

(1) Any compound, mixture, or preparation containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital or any salt thereof and one or more other active medicinal ingredients ~~which~~ that are not listed in any schedule.

(2) Any suppository dosage form containing any of the following:

(A) Amobarbital

(B) Secobarbital

(C) Pentobarbital or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.

(3) Any substance ~~which~~ that contains any quantity of a derivative of barbituric acid or any salt thereof.

(4) Chlorhexadol.

(5) Lysergic acid.

(6) Lysergic acid amide.

(7) Methyprylon.

(8) Sulfondiethylmethane.

(9) Sulfonethylmethane.

(10) Sulfonmethane.

(11) Gamma hydroxybutyric acid, and its salts, isomers and salts of isomers, contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).

(d) Nalorphine.

(e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

(1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

(2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(3) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.~~

~~(4) Not more than 300 milligrams of dihydrocodeinone per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts. Additionally, oral liquid preparations of dihydrocodeinone containing the above specified amounts may not contain as its nonnarcotic ingredients two or more antihistamines in combination with each other.~~

~~(5)~~ (3) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.

~~(6)~~ (4) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(7)~~ (5) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

~~(8)~~ (6) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

(f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:

(1) Androisoxazole.

(2) Androstenediol.

(3) Bolandiol.

(4) Bolasterone.

(5) Boldenone.

(6) Chlormethandienone.

(7) Clostebol.

(8) Dihydromesterone.

(9) Ethylestrenol.

(10) Fluoxymesterone.

(11) Formyldienolone.

(12) 4-Hydroxy-19-nortestosterone.

(13) Mesterolone.

(14) Methandriol.

(15) Methandrostenolone.

(16) Methenolone.

(17) 17-Methyltestosterone.

(18) Methyltrienolone.

(19) Nandrolone.

(20) Norbolethone.

(21) Norethandrolone.

(22) Normethandrolone.

(23) Oxandrolone.

(24) Oxymestrone.

(25) Oxymetholone.

(26) Quinbolone.

(27) Stanolone.

(28) Stanozolol.

(29) Stenbolone.

(30) Testosterone.

(31) Trenbolone.

(32) Human ~~Chorionic Gonadotropin (HGC).~~ clorionic gonadotropin (hCG), except when possessed by, sold to, purchased by, transferred to, or administered by a licensed veterinarian, or a licensed veterinarian's designated agent, exclusively for veterinary use.

(g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.

(h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

Section 11018.5 of the Health and Safety Code is amended to read:
(a) "Industrial hemp" means a ~~fiber or oilseed crop, or both,~~ crop that is limited to types of the plant Cannabis sativa L. having no more than three-tenths of 1 percent tetrahydrocannabinol (THC) contained in the dried flowering tops, whether growing or not; the seeds of the plant; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds or resin produced therefrom.

(b) Industrial hemp shall not be subject to the provisions of this division or of Division 10 (commencing with Section 26000) of the Business and Professions Code, but instead shall be regulated by the Department of Food and Agriculture in accordance with the provisions of Division 24 (commencing with Section 81000) of the Food and Agricultural Code, inclusive.

The following section is effective as of July 9, 2018.
Section 11150.2 is added to the Health and Safety Code to read:
(a) Notwithstanding any other law, if cannabidiol is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product

composed of cannabidiol is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within his or her scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.

(b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabidiol may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.

(c) This section does not apply to any product containing cannabidiol that is made or derived from industrial hemp, as defined in Section 11018.5 and regulated pursuant to that section.

Section 11158.1 is added to the Health and Safety Code to read:
(a) Except when a patient is being treated as set forth in Sections 11159, 11159.2, and 11167.5, and Article 2 (commencing with Section 11215) of Chapter 5, pertaining to the treatment of addicts, or for a diagnosis of chronic intractable pain as used in Section 124960 of this code and Section 2241.5 of the Business and Professions Code, a prescriber shall discuss all of the following with the minor, the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment before directly dispensing or issuing for a minor the first prescription in a single course of treatment for a controlled substance containing an opioid:

(1) The risks of addiction and overdose associated with the use of opioids.

(2) The increased risk of addiction to an opioid to an individual who is suffering from both mental and substance abuse disorders.

(3) The danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.

(4) Any other information required by law.

(b) This section does not apply in any of the following circumstances:

(1) If the minor's treatment includes emergency services and care as defined in Section 1317.1.

(2) If the minor's treatment is associated with or incident to an emergency surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

(3) If, in the prescriber's professional judgment, fulfilling the requirements of subdivision (a) would be detrimental to the minor's health or safety, or in violation of the minor's legal rights regarding confidentiality.

(c) Notwithstanding any other law, including Section 11374, failure to comply with this section shall not constitute a criminal offense.

Section 11161.5 of the Health and Safety Code is amended to read:
(a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.

(b) The department may approve security printer applications after the applicant has provided the following information:

(1) Name, address, and telephone number of the applicant.

(2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.

(3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.

(B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).

(5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.

(B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.

(C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (l) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the

department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.

(D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.

(E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.

(c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.

(d) The department may deny a security printer application on any of the following grounds:

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a 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 of the Penal Code.

(2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.

(3) The applicant committed any act that would constitute a violation of this division.

(4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.

(5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.

(6) The department determines that the applicant has submitted an incomplete application.

(7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.

(e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

(f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

(i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.

(j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.

(k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or ~~e-mail~~ email within 24 hours of the theft or loss.

(l) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.

(2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.

(m) The following violations by security printers shall be punishable pursuant to subdivision (n):

(1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.

(2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.

(3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.

(n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):

(1) For a first violation, a fine not to exceed one thousand dollars ($1,000).

(2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars ($2,500) for each violation.

(3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.

(o) In order to facilitate the standardization of all prescription forms and the serialization of prescription forms with unique identifiers, the Department of Justice may cease issuing new approvals of security printers to the extent necessary to achieve these purposes. The department may, pursuant to regulation, reduce the number of currently approved security printers to no fewer than three vendors. The department shall ensure that any reduction or limitation of approved security printers does not impact the ability of vendors to meet demand for prescription forms.

Section 11162.1 of the Health and Safety Code is amended to read:
(a) The prescription forms for controlled substances shall be printed with the following features:

(1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.

(2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."

(3) A chemical void protection that prevents alteration by chemical washing.

(4) A feature printed in thermochromic ink.

(5) An area of opaque writing so that the writing disappears if the prescription is lightened.

(6) A description of the security features included on each prescription form.

(7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:
1–24
25–49
50–74
75–100
101–150
151 and over.

(B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.

(8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."

(9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.

(10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.

(11) The date of origin of the prescription.

(12) A check box indicating the prescriber's order not to substitute.

(13) An identifying number assigned to the approved security printer by the Department of Justice.

(14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.

(B) Each prescriber who signs the prescription form shall identify himself or herself as the prescriber by checking the box by his or her name.

<u>(15) A uniquely serialized number, in a manner prescribed by the Department of Justice.</u>

(b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.

(c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3) of this subdivision.

(2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.

(3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.

(4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

(B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.

(d) ~~This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 2012.~~ Within the next working day following delivery, a security printer shall submit via Web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:

(1) Serial numbers of all prescription forms delivered.

(2) All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms.

(3) The delivery shipment recipient names.

(4) The date of delivery.

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 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, ~~provided that~~ 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.

~~(3)~~ (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 ~~is~~ 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, 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, ~~if applicable,~~ 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.~~ 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 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).

Section 11165.6 is added to the Health and Safety Code to read:
A prescriber shall be allowed to access the CURES database for a list of patients for whom that prescriber is listed as a prescriber in the CURES database.

Section 121349 of the Health and Safety Code is amended to read:
(a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other

potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Authorization shall be made after consultation with the local health officer and local law enforcement leadership, and after a period of public comment, as described in subdivision (e). In making the determination, the department shall balance the concerns of law enforcement with the public health benefits. The authorization shall not be for more than two years. Before the end of the two-year period, the department may reauthorize the program in consultation with the local health officer and local law enforcement leadership.

(d) In order for an entity to be authorized to conduct a project pursuant to this chapter, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:

(1) The entity provides, directly or through referral, all of the following services:

(A) Drug abuse treatment services.

(B) HIV or hepatitis screening.

(C) Hepatitis A and hepatitis B vaccination.

(D) Screening for sexually transmitted infections.

(E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.

(F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.

(3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:

(A) Provide needles and syringe exchange services for all of its participants.

(B) Provide HIV and viral hepatitis prevention education services for all of its participants.

(C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:

(A) The total number of persons served.

(B) The total number of syringes and needles distributed, recovered, and disposed of.

(C) The total numbers and types of referrals to drug treatment and other services.

(e) If the application is provisionally deemed appropriate by the department, the department shall, at least 45 days prior to approval of the application, provide for a period of public comment as follows:

(1) Post on the department's Internet Web site the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.

(2) Send a written and an e-mail notice to the local health officer of the affected jurisdiction.

(3) Send a written and an e-mail notice to the chief of police, the sheriff, or both, as appropriate, of the jurisdictions in which the program will operate.

(f) The department shall establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to this chapter.

(g) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(h) If the department, in its discretion, determines that a state authorized syringe exchange program continues to meet all standards set forth in subdivision (d) and that a public health need exists, it may administratively approve amendments to a program's operations including, but not limited to, modifications to the time, location, and type of services provided, including the designation as a fixed site or a mobile site. The amendment approval shall not be subject to the noticing requirements of subdivision (e).

(i) The department shall have 30 business days to review and respond to the applicant's request for amendment of the authorization. If the department does not respond in writing within 30 business days the request shall be deemed denied.

Section 121349.1 of the Health and Safety Code, as added by Section 2.5 of Chapter 744 of the Statutes of 2011, is repealed.

~~**121349.1.**~~

~~The State Department of Public Health or a city, county, or a city and county with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users. Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes or any materials deemed by a local or state health department to be necessary to prevent the spread of communicable diseases, or to prevent drug overdose, injury,~~

~~or disability during participation in an exchange project. Program participants shall not be subject to criminal prosecution for possession of needles or syringes or any materials deemed by a local or state health department to be necessary to prevent the spread of communicable diseases, or to prevent drug overdose, injury, or disability acquired from an authorized needle and syringe exchange project entity.~~

Section 121349.2 of the Health and Safety Code, as added by Section 3.5 of Chapter 744 of the Statutes of 2011, is repealed
121349.2.
~~Local government, local health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.~~
~~(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed.~~

Section 121349.3 of the Health and Safety Code, as added by Section 5 of Chapter 744 of the Statutes of 2011, is repealed.
~~**121349.3.**~~
~~The health officer of the participating jurisdiction shall present biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this biennial meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local health officer based on the reports to the department from service providers within the jurisdiction of that local health officer.~~

California Civil Code Changes

Section 56.06 of the Civil Code is amended to read:
(a) Any business organized for the purpose of maintaining medical information, as defined in subdivision (j) of Section 56.05, in order to make the information available to an individual or to a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the individual to manage his or her information, or for the diagnosis and treatment of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(b) Any business that offers software or hardware to consumers, including a mobile application or other related device that is designed to maintain medical information, as defined in subdivision (j) of Section 56.05, in order to make the information available to an individual or a provider of health care at the request of the individual or a provider of health care, for purposes of allowing the

individual to manage his or her information, or for the diagnosis, treatment, or management of a medical condition of the individual, shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(c) Any business that is licensed pursuant to Division 10 (commencing with Section 26000) of the Business and Professions Code that is authorized to receive or receives identification cards issued pursuant to Section 11362.71 of the Health and Safety Code or information contained in a physician's recommendation issued in accordance with Article 25 (commencing with Section 2525) of Chapter 5 of Division 2 of the Business and Professions Code shall be deemed to be a provider of health care subject to the requirements of this part. However, this section shall not be construed to make a business specified in this subdivision a provider of health care for purposes of any law other than this part, including laws that specifically incorporate by reference the definitions of this part.

(d) Any business described in this section shall maintain the same standards of confidentiality required of a provider of health care with respect to medical information disclosed to the business.

(e) Any business described in this section is subject to the penalties for improper use and disclosure of medical information prescribed in this part.

Section 56.105 of the Civil Code is amended to read:
Whenever, prior to the service of a complaint upon a defendant in any action arising out of the professional negligence of a person holding a valid physician's and surgeon's certificate issued pursuant to Chapter 5 (commencing with Section 2000) of Division 2 of the Business and Professions Code, ~~or~~ a person holding a valid license as a marriage and family therapist issued pursuant to Chapter 13 (commencing with Section 4980) of Division 2 of the Business and Professions Code, a person holding a valid license as a clinical social worker issued pursuant to Chapter 14 (commencing with Section 4991) of Division 2 of the Business and Professions Code, or a person holding a valid license as a professional clinical counselor issued pursuant to Chapter 16 (commencing with Section 4999.10) of Division 2 of the Business and Professions Code, a demand for settlement or offer to compromise is made on a patient's behalf, the demand or offer shall be accompanied by an authorization to disclose medical information to persons or organizations insuring, responsible for, or defending professional liability that the certificate holder may incur. The authorization shall be in accordance with Section 56.11 and shall authorize disclosure of that information that is necessary to investigate issues of liability and extent of potential damages in evaluating the merits of the demand for settlement or offer to compromise.

Notice of any request for medical information made pursuant to an authorization as provided by this section shall be given to the patient or the patient's legal representative. The notice shall describe the inclusive subject matter and dates of the materials requested and shall also authorize the patient or the patient's legal representative to receive, upon request, copies of the information at his or her expense.

Nothing in this section shall be construed to waive or limit any applicable privileges set forth in the Evidence Code except for the disclosure of medical information subject to the patient's authorization. Nothing in this section shall be construed as authorizing a representative of any

person from whom settlement has been demanded to communicate in violation of the physician-patient privilege with a treating physician, or to communicate in violation of the psychotherapist-patient privilege with a treating licensed marriage and family therapist, licensed clinical social worker, or licensed professional clinical counselor, except for the medical information request.
The requirements of this section are independent of the requirements of Section 364 of the Code of Civil Procedure.

Attachment 4

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~~s~~, ~~and~~ wholesaler~~s~~, 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~~m~~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.

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.

Abandonment of Applications
16 CCR § 1706.2

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 1706.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1706.2. Abandonment of Application Files.

(a) An applicant for a premises license ~~to conduct a pharmacy, non-resident pharmacy, sterile injectable compounding pharmacy, wholesaler, out-of-state distributor, clinic, veterinary food-animal drug retailer, or to furnish hypodermic needles and syringes~~ who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his, her or its file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements in effect at the time of reapplication.

~~(b) An applicant for a pharmacy technician license or a designated representative license who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.~~

(b ~~c~~) An applicant who fails to pay the fee for licensure as a pharmacist required by subdivision (f)(1) of section 1749 of this Division within 12 months after being notified by the board of his or her eligibility shall be deemed to have abandoned the application and must file a new application and be in compliance with the requirements in effect at the time of reapplication.

(c ~~d~~) An applicant to take the pharmacist licensure examinations who fails to take the examinations within 12 months of being deemed eligible, shall be deemed to have abandoned the application and must file a new application in compliance with all of the requirements in effect at the time of reapplication.

(d ~~e~~) An applicant for an intern pharmacist license who fails to complete all application requirements within one year after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

(e) An applicant for an individual license not included in subdivision (b), (c), or (d), who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file, may be deemed to have abandoned the application and may be required to file a new application and meet all of the requirements which are in effect at the time of reapplication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4029, 4030, 4034, 4034.5, 4037, 4041, 4042, 4043, 4044.3, 4045, 4053, 4110, 4112, 4115, 4120, 4127.1, 4127.15, 4141, 4160, 4161, 4180, 4190, 4200, 4201, 4202, 4202.5, 4203, 4203.5, 4204, 4205, ~~and~~ 4208, and 4210, Business and Professions Code.

Naloxone Fact Sheet

16 CCR § 1746.3

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.

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.

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

COMMUNITY PHARMACY SELF-ASSESSMENT/

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to 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 pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, and readily available ~~and retained~~ in the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~10/14~~ 10/16). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐
Non-Licensed Owner ☐ Other (please specify) ☐

~~Permit~~ License #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding ~~Permit~~ License# _____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. ~~APP~~ APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH# _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   ~~APP~~ APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ TCH # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

_____
PIC Initials

COMMUNITY PHARMACY SELF-ASSESSMENT/

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

1. Facility

Yes No N/A

☐☐☐ 1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)

☐☐☐ 1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, CCR 1714)

☐☐☐ 1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714)

☐☐☐ 1.5. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.6. The pharmacy has a readily accessible restroom. (CCR 1714)

☐☐☐ 1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. A pharmacy may also or instead display the notice on a video screen in lieu of the poster. Additional "Notice to Consumers" in languages other than English may also be posted. (B&PC 4122, CCR ~~1707.2~~ 1707.6)

☐☐☐ 1.8. "Point to Your Language" poster is posted or provided in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6[c])

☐☐☐ ~~1.8~~ 1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ ~~1.9~~ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

PIC Initials

☐☐☐ ~~1.10~~ 1.11. Does the pharmacy compound sterile drugs? (If yes, complete section 27 – "Compounding.")

~~Yes No N/A~~

☐☐☐ ~~1.11~~ 1.12. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

☐☐☐ ~~1.12~~ 1.13. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ ~~1.13~~ 1.14. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ ~~1.14~~ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board: _____

☐☐☐ ~~1.15~~ 1.16. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (B&PC 4059.5[a], H&SC 1120~~(~~[a]~~)~~)

☐☐☐ 2.2. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met: (B&PC 4059.5[f]):

- ☐ 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- ☐ 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- ☐ 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- ☐ 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- ☐ 2.2.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. B&PC 4059.5[f][5])

☐☐☐ 2.3 Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][A][i])

☐☐☐ 2.4 Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][A][ii])

☐☐☐ 2.5 The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][A][iii])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, 22 CCR 70263[q], CCR 1714[b])

☐☐☐ 3.2. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler or pharmacy, or a manufacturer, and provided the dangerous drugs and devices: (B&PC 4169)

- ☐ 3.2.1. Are known or reasonably are known to the pharmacy as not being adulterated.
- ☐ 3.2.2. Are known or reasonably are known to the pharmacy as not being misbranded.
- ☐ 3.2.3. Are not expired.

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Voluntary Drug Repository and Distribution Program (H&SC 150200)

Yes No N/A

☐☐☐ 4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 29 [donate drugs] or Section 30 [operate program] of this Self-Assessment.)

5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (BPC 4113[c], CCR 1709.1[b])

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PIC Initials

☐☐☐ 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new permit is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ 5.4. Is the PIC in charge of another pharmacy?

☐☐☐ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4113)

~~☐☐☐ 5.7. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1[d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

☐☐☐ ~~5.8~~ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (H&SC 1206, 1265)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. ~~The pharmacist furnishes a reasonable quantity of compounded drug products to a prescriber office for office use by the prescriber; transmits a valid prescription to another pharmacist; administers drugs and biological products ordered by the prescriber; manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; provides consultation, training and education to patients about drug therapy disease management and disease prevention; provides professional information and participates in multidiscipline review of patient progress; furnishes medication including emergency contraception drug therapy and self-administered hormonal contraceptives, nicotine replacement products, prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies. (B&PC 4052)~~

Only a pharmacist:

- ☐ transmits a valid prescription to another pharmacist; (B&PC 4052[a][2])
- ☐ administers drugs and biological products ordered by the prescriber; (B&PC 4052[a][3])
- ☐ manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; (B&PC 4052[a][7])
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (B&PC 4052[a][8])
- ☐ provides professional information and participates in multidiscipline review of patient progress; (B&PC 4052[a][9])
- ☐ furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, or prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations pursuant to a protocol; (B&PC 4052 [a][10], B&PC 4052[a][11], B&PC 4052.01, B&PC 4052.3, B&PC 4052.8, B&PC 4052.9)
- ☐ dispenses aid-in-dying drugs; (H&SC 443.5 [b][2]) or
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies (B&PC 4052 [a][12]).

PIC Initials

☐☐☐ 6.2. ~~The pharmacist receives a new prescription order from the prescriber, consults with the patient, identifies, evaluates and interprets a prescription, interprets the clinical data in a patient medication record, consults with any prescriber, nurse, health professional or agent thereof, supervises the packaging of drugs, checks the packaging procedure and product upon completion, is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients, performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (CCR 1707.2, 1793.1, B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, 4070(a))~~

Only a pharmacist:

- ☐ receives a new prescription order from the prescriber; (BP&C 4070 [a]), CCR 1793.1 [a])
- ☐ consults with the patient; (BP&C 4052 [a][8], CCR 1707.2, CCR 1793.1[b])
- ☐ identifies, evaluates and interprets a prescription; (CCR 1793.1 [c])
- ☐ interprets the clinical data in a patient medication record; (CCR 1793.1 [d])
- ☐ consults with any prescriber, nurse, health professional or agent thereof; (CCR 1793.1 [e])
- ☐ supervises the packaging of drugs; (CCR 1793.1 [f])
- ☐ checks the packaging procedure and product upon completion; (CCR 1793.1 [f])
- ☐ is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7 [e]) or
- ☐ performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1 [g])

☐☐☐ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or 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, is performing the following functions, in accordance with policies, procedures~~,~~ or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (B&PC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

☐☐☐ 6.4. Pharmacists ~~are able to~~ have obtained approval to access ~~information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through~~ the CURES Prescription Drug Monitoring Program (PDMP). (H&SC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraceptive pursuant to the statewide protocol found in 16 CCR 1746.

PIC Initials

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (B&PC 1206.6)

~~Yes No N/A~~

☐☐☐ 6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (B&PC 1206.6)

CDPH (CLIA) Registration #:_____ Expiration: _____

☐☐☐ 6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of an Advance Practice Pharmacist

Yes No N/A

☐☐☐ ~~7.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~7.2~~ 7.1. The advance practice pharmacist has received an advance practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~7.2.1~~ 7.1.1Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~7.2.2~~ 7.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ☐ ~~7.2.2~~ 7.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ ~~7.2.2~~ 7.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ☐ ~~7.2.2~~ 7.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

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PIC Initials

8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist may perform all the functions of a pharmacist only under the direct supervision of a pharmacist. A pharmacist may supervise **two interns** at any one time. (B&PC 4114, 4023.5, CCR 1726)

Yes No N/A

☐☐☐ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209[b], [c], [d], CCR 1726)

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. ~~Registered p~~Pharmacy technicians ~~are performing~~ only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (B&PC 4038, 4115, CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies him or ~~her self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

☐☐☐ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7[e])

☐☐☐ 9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee and only for a period of no more than 120 hours. (B&PC 4115.5)

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PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

10. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and—at the direction of a pharmacist—may request and receive refill authorization. (CCR 1793.3)

☐☐☐ 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (~~B&PC 4052[a][7],~~ BPC 4052[a][8], CCR 1707.2)~~:~~

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request; and
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment.
- ☐ 11.1.5. unless a patient or patient's agent declines the consultation directly to the pharmacist.

☐☐☐ 11.2. The pharmacy maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)

☐☐☐ 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ 11.4. Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a])

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ 11.6. If prescription medication is mailed or delivered, written notice about the availability of consultation is provided. (CCR 1707.2[b][2])

CORRECTIVE ACTION OR ACTION PLAN: _____

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12. Prescription Requirements

Yes No N/A

☐☐☐ 12.1. Prescriptions are complete with all the required information. (B&PC 4040, 4070)

☐☐☐ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (B&PC 4070, CCR 1717)

☐☐☐ 12.3. If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (B&PC 4071)

☐☐☐ 12.4. If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717, 1712)

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (B&PC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (B&PC 4040[c])

☐☐☐ 12.7. Internet prescriptions patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (B&PC 4067[a])

☐☐☐ 12.8. With the exception of those prescriptions written under H&SC 11159.2 and H&SC 11167.5, all written controlled substances prescriptions (Schedules II – V) are on California Security Prescription forms. (H&SC 11164[a], H&SC 11167.5)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (H&SC 11164[a][1], 11166)

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (B&PC 4076)

☐☐☐ 13.2. The prescription label is formatted in accordance with CCR 1707.5.

~~☐☐☐ 13.3. If requested by the consumer, the pharmacy provides the consumer with a prescription label that is printed in 12-point typeface. (CCR 1707.5[a])~~

~~**Yes No N/A**~~

~~☐☐☐ 13.4. The label on a drug container dispensed to a patient in California conforms to the following format: (CCR 1707.5[a])~~

~~☐ 13.4.1 The name of the patient, name of the drug and strength of the drug, the directions for use of the drug, the condition or purpose for which the drug was prescribed, if indicated on the prescription, are clustered into one area of the label and comprise at least 50 percent of the label.~~

~~☐ 13.4.2 The label is highlighted in bold typeface or color or uses blank space to set off the items in 13.4.1; (CCR 1707.5[a][2])~~

~~☐ 13.4.3 When applicable, standardized directions for use are utilized. (CCR 1707.5[a][4])~~

~~☐☐☐ 13.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ 13.~~6~~3. The ~~E~~expiration date~~s~~ of a ~~drugs'~~ drug's effectiveness is accurately identified on the label ~~are consistent with those of the manufacturer if the information is required on the original manufacturer's label~~. (B&PC 4076)

☐☐☐ 13.~~7~~4. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717[b][2])

☐☐☐ 13.~~8~~5. Generic substitution is communicated to the patient. (B&PC 4073)

☐☐☐ 13.~~9~~6. If the prescription is filled by a pharmacy technician, before dispensing the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or as otherwise allowed for those filled by a pharmacy technician trainee. (B&PC 4115, 4115.5, CCR 1793.7, CCR 1712)

☐☐☐ 13.~~10~~7. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

PIC Initials

☐☐☐ 13.~~11~~8. 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)

☐☐☐ 13.~~12~~9. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 13.~~13~~10. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.11. Medication guides are provided on required medications. (21 CFR, Part 208, Section 208.24[e])

☐☐☐ 13.~~14~~12. The pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership.

☐☐☐ 13.~~15~~13. The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (B&PC 4076)

Yes No N/A

☐☐☐ 13.~~16~~14. Controlled substance prescriptions are not filled or refilled more than six months from the date written. (H&SC 11200[a])

☐☐☐ 13.15. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and an amount, for all refills of that prescription taken together, exceeding a 120 day supply. (H&SC 11200[b])

☐☐☐ 13.~~17~~ 16. The pharmacy dispenses not more than a 90-day supply of a dangerous drug with the following exceptions ~~(other than controlled substances, or psychotropic medication or drugs)~~: (B&PC 4064.5)

- Controlled substances
- Psychotropic medications
- Self-administered hormonal contraception

PIC Initials

☐ 13.~~17~~16.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (B&PC 4064.5[a])

☐ 13.~~17~~16.1.1 The prescriber has not indicated "no change to quantity" or words of similar meaning; (B&PC 4064.5[d])

☐ 13. ~~17~~16.1.2. The patient has completed an initial 30-day supply; (B&PC 4064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. B&PC 4064.5[b])

☐ 13. ~~17~~16.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (B&PC 4064.5[a][2])

☐ 13. ~~17~~16.1.4. The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (B&PC 4064.5[a][3])

☐ 13. ~~17~~16.1.5. The pharmacist is exercising his or her professional judgment. (B&PC 4064.5[a][4])

☐ 13.~~17~~16.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (B&PC 4064.5[c])

☐☐☐ 13.~~18~~17. The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (B&PC 4074[b], CCR 1744)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (B&PC 4063, 4064)

☐☐☐ 14.2. Refills are documented. (CCR 1717)

☐☐☐ 14.3. Prescriptions for dangerous drugs or devices are filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (B&PC 4064)

☐☐☐ 14.4. Refills for Schedule II controlled substances are prohibited. (H&SC 11200)

~~**Yes No N/A**~~

~~☐☐☐ 14.5. Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120 day supply. (H&SC 11200)~~

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 15.3. The pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐☐☐ 15.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐☐☐ 15.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

- ☐ 15.6.1. Date, location, and participants in the quality assurance review;
- ☐ 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 15.6.3. Findings and determinations; and
- ☐ 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 15.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 15.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 16.1. Before dispensing a prescription that contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐☐☐ 16.2. Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (H&SC 11153)

☐☐☐ 16.3. Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if he or she knows or has objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

~~☐☐☐ 16.4. Internet prescriptions are only dispensed on a prescription issued pursuant to a good faith prior examination. (B&PC 4067[a])~~

☐☐☐ 16.~~5~~ 4. Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 829, 21 USC 802.)

~~☐☐☐ 16.6. All pharmacists have obtained approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained by the California Department of Justice (HSC 11165.1[a][1][A][i])~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Prescription Transfer

Yes No N/A

☐☐☐ 17.1. Only pharmacists may transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])

☐☐☐ 17.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

a. Schedule III, IV and V Controlled Substance Prescription Transfers

☐☐☐ 17.3. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

PIC Initials

~~Yes No N/A~~

☐☐☐ 17.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Confidentiality of Prescriptions

Yes No N/A

☐☐☐ 18.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

☐☐☐ 18.2. All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐☐☐ 18.3. The pharmacy ensures electronically transmitted prescriptions are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

☐☐☐ 18.4. If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the pharmacy maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐☐☐ 18.5. If pharmacy has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure of confidential medical information except as authorized by law. (CCR 1717.1)

☐☐☐ 18.6. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Record Keeping Requirements

Yes No N/A

☐☐☐ 19.1. ~~A~~ All completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ 19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include (B&PC 4081, 4105, 4333):

☐ 19.2.1. Prescription records (B&PC 4081[a])

☐ 19.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])

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PIC Initials

☐ 19.2.3. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)

☐ 19.2.4. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)

☐ 19.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ 19.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 19.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ 19.2.8. Record documenting transfers or sales to other pharmacies, licensees and prescribers (B&PC 4081, 4105, CCR 1718)

~~Yes No N/A~~

☐☐☐ 19.3. Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to: (B&PC 4145.5)

☐ 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;

☐ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.

☐ 19.3.3. The sale of hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (H&S 11364, B&PC 4145.5)

☐ 19.3.4. For industrial use, as determined by the board. (B&PC 4144.5)

☐ 19.3.5. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of ~~30 or fewer~~ hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (B&PC 4145.5)

☐☐☐ 19.4. When hypodermic needles and syringes are furnished by a pharmacy ~~or hypodermic needle and exchange program~~ without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (B&PC 4145.5[e],[f])

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

☐☐☐ 19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, B&PC 4105)

Date Waiver Approved _____ Waiver Number _____

PIC Initials

Address of offsite storage location: _____

☐☐☐ 19.6. The pharmacy ~~dispenses~~ furnishes an epinephrine auto-injector to an authorized entity ~~a prehospital emergency medical care person or lay rescuer~~ for the purpose of rendering emergency care in accordance with H&SC 1797.197a. (B&PC 4119.3, 4119.4)

☐ 19.6.1. An ~~physician/surgeon~~ authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. (B&PC 4119.3[a][1], 4119.4[a][2])

☐ 19.6.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation "Section 1797.197a responder" and "First Aid Purposes Only", the dosage, use and expiration date. (B&PC 4119.3[a][1], 4119.4[b])

☐ 19.6.3. Each dispensed prescription includes the manufacturer's product information sheet for epinephrine auto-injectors. (B&PC 4119.3[a][2], 4119.4[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

☐☐☐ 20.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[b])

☐☐☐ 20.2. Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1], 1304.04[h][2])

☐☐☐ 20.3. All completed inventories are ~~is~~ available for inspection for three years. (CCR 1718)

☐☐☐ 20.4. Indicates on the inventory record whether the inventory was taken at the "open of business" or at the "close of business." (21 CFR 1304.11[a])

☐☐☐ 20.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])

☐☐☐ 20.6. Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the pharmacy uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][2])

☐☐☐ 20.7. Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)

☐☐☐ 20.8. U.S. Official Order Form (DEA Form222) or electronic equivalent (CSOS) is utilized when ordering all schedule II controlled substances. When schedule II controlled substance orders are received by the pharmacy, for each item received, the date and quantity received is indicated on the DEA Form222. (21 CFR 1305.03, 1305.12)

☐☐☐ 20.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

~~Yes No N/A~~

☐☐☐ 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11[b], ~~Prescription Drug Marketing Act of 1987 [Pub. L. 100-293, Apr. 22, 1988] 503.~~ Drug Supply Chain Security Act. B&PC 4160)

☐☐☐ 20.12. When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the pharmacy reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide prescription. (H&SC 11167[d])

☐☐☐ 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ 20.14. Any controlled substances drug loss is reported upon discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ 20.16. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712, 1717[b][1])

☐☐☐ 20.17. All Schedule II through IV controlled substance dispensing data is successfully transmitted to CURES weekly. (H&SC 11165[d])

PIC Initials

☐☐☐ 20.18. When furnishing controlled substances for physician office use, a prescription is not issued in order for an individual practitioner to obtain controlled substances for supplying the practitioner's general dispensing to patients. (21 CFR 1306.04[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 21.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ 21.2. The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

☐☐☐ 21.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65 [c])

- ☐ 21.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 21.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 21.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 21.3.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 21.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

☐☐☐ 21.4. The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

☐☐☐ 21.5. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy

for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])

☐☐☐ 21.6. A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~21~~22. Oral/Electronic Transmission and Fractionation of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 2~~1~~2.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], H&SC 11164)

☐☐☐ 2~~1~~2.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], H&SC 11167.5)

- ☐ 2~~1~~2.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- ☐ 2~~1~~2.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- ☐ 2~~1~~2.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- ☐ 2~~1~~2.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], H&SC 11167.5)

☐☐☐ 2~~1~~2.3. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. (21 CFR 1306.13[a])

PIC Initials _____

☐☐☐ 2~~1~~2.4. The pharmacist maintains records of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill." (21 CFR 1306.13[b], CCR 1745)

☐☐☐ 22.5 The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written when requested by the patient or practitioner. (21 USC 829[f])

☐☐☐ 2~~1~~2.~~5~~6. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of H&SC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], H&SC 11167)

☐☐☐ 2~~1~~2.~~6~~7. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

☐☐☐ 2~~1~~2.~~7~~8. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

☐☐☐ 2~~1~~2.~~8~~9. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

~~Yes No N/A~~

☐☐☐ 2~~1~~2.~~9~~10. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

☐☐☐ 2~~1~~2.~~10~~11. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

☐☐☐ 2~~1~~2.~~11~~12. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (H&SC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 2~~1~~2.~~12~~13. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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2~~2~~3. Automated Dispensing/Delivery Devices

Yes No N/A

☐☐☐ 2~~2~~3.1. Does the pharmacy use an automated dispensing/delivery device and/or prescription drop box? (CCR 1713)

☐☐☐ 23.2. The pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system has registered with the board all automated drug delivery systems that it operates in any location within 30 days of installation, removal, and at the time of renewal. (B~~&~~PC 4105.5[b])

☐☐☐ 23.3. The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. (B~~&~~PC 4105.5[c][2])

☐☐☐ 23.4. The pharmacy reports drugs losses as required by law. (B~~&~~PC 4105.5[c][3])

☐☐☐ 2~~2~~3.~~2~~5. The drugs in an automated dispensing unit are properly labeled and identified with at least the following information: name of drug, strength and dosage form, manufacturer and manufacturer's lot number, and expiration date. (21 CFR Part 210, 211, B~~&~~PC 4342, 21 CFR Part 201.17, HSC 111355)

☐☐☐ 2~~2~~3.~~3~~6. For an "automated drug delivery system" located in a skilled or intermediate care facility licensed by the Department of Public Health, the following is required:

- ☐ 2~~2~~3.~~3~~6.1. Pharmacy and facility have developed policies and procedures to insure safety, accuracy, accountability, security, access, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. (H~~&~~SC 1261.6[d][1])
- ☐ 2~~2~~3.~~3~~6.2. A pharmacist reviews the order and patient's profile prior to the drug being removed. (H~~&~~SC 1261.6[e][2])
- ☐ 2~~2~~3.~~3~~6.3. Stocking of the automated drug delivery system is done by a pharmacist. (H~~&~~SC 1261.6[f])

☐☐☐ 2~~2~~3.~~4~~7. If the automated drug delivery system utilizes removable pockets, drawers, or similar technology, the stocking system is done outside the facility in a pharmacy and delivered to the facility:

- ☐ 2~~2~~3.~~4~~7.1. Drugs are restocked by a pharmacist or by an intern or technician working under the supervision of a pharmacist. (H~~&~~SC 1261.6[f][1])
- ☐ 2~~2~~3.~~4~~7.2. Removable pockets or drawers are transported between the pharmacy and the facility in a secure tamper-evident container. (H~~&~~SC 1261.1[f][2])

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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2~~3~~4. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 2~~3~~4.1. Drugs are repackaged (precounted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], B~~&~~PC 4342, H~~&~~SC 110105, 111430, CCR 1707.5)

☐☐☐ 2~~3~~4.2. A log is maintained for drugs pre-packed for future dispensing. (CCR 1751.1, 21 CFR Parts 210, 211)

☐☐☐ 2~~3~~4.3. Drugs previously dispensed are re-packaged at the patient's request in compliance with B~~&~~PC 4052.7.

CORRECTIVE ACTION OR ACTION PLAN: _____

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24~~5~~. Refill Pharmacy

Yes No N/A

☐☐☐ 24~~5~~.1. Pharmacy processes refills for another California licensed pharmacy (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ 24~~5~~.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 24~~5~~.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is "no" or "not applicable" go to section ~~23~~26.

☐☐☐ 24~~5~~.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ 24~~5~~.5. Refill prescription label meets requirements of B~~&~~PC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ 24~~5~~.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

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PIC Initials

~~Yes No N/A~~

☐☐☐ 24~~5~~.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 24~~5~~.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ 24~~5~~.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

CORRECTIVE ACTION OR ACTION PLAN: _____

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26. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 2~~5~~6.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

- ☐ 2~~5~~6.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])
- ☐ 2~~5~~6.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])
- ☐ 2~~5~~6.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])
- ☐ 2~~5~~6.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ 2~~5~~6.2. The pharmacy meets the following requirements:

- ☐ 2~~5~~6.2.1. Has sufficient knowledge and understanding of bleeding disorders to accurately follow the instructions of the prescribing physician and ensure high-quality service for the patient. (HSC 125286.25[a])
- ☐ 2~~5~~6.2.2. Has access to a provider with sufficient clinical experience that enables the provider to know when patients have an appropriate supply of clotting factor on hand and about proper storage and refrigeration of clotting factors. (HSC 125286.25[b])
- ☐ 2~~5~~6.2.3. Maintains 24-hour on-call service 7 days a week, screens telephone calls for emergencies, acknowledges all telephone calls within one hour or less, and has access to knowledgeable pharmacy staffing on call 24 hours a day. (HSC 125286.25[c])
- ☐ 2~~5~~6.2.4. Has the ability to obtain all brands of blood clotting products approved by the FDA in multiple assay ranges and vial sizes, including products manufactured from human plasma and those manufactured with recombinant biotechnology techniques, provided manufacturer supply exists and payer authorization is obtained. (HSC 125286.25[d])
- ☐ 2~~5~~6.2.5. Supplies all necessary ancillary infusion equipment and supplies with each prescription, as needed. (HSC 125286.25[e])
- ☐ 2~~5~~6.2.6. Stores and ships, or otherwise delivers, all blood clotting products in conformity with all state and federally mandated standards, including those set forth in the product's approved package insert. (HSC 125286.25[f])

PIC Initials

☐ 2~~5~~6.2.7. Upon authorization for a nonemergency prescription, ships the prescribed blood clotting products and ancillary infusion equipment and supplies to the patient within two business days or less. (HSC 125286.25[g])

☐ 2~~5~~6.2.8. Upon approved authorization to dispense a prescription for an emergency situation, provided manufacturer supply exists, delivers prescribed blood products, ancillary infusion equipment and supplies, and medications to the patient within 12 hours for patients living within 100 miles of a major metropolitan airport, and within one day for patients living more than 100 miles from a major metropolitan airport. (HSC 125286.25[h])

☐ 2~~5~~6.2.9. Provides patients who have ordered their products with a designated contact telephone number for reporting problems with a delivery, and responds to calls within a reasonable time period. (HSC 125286.25[i])

☐ 2~~5~~6.2.10. Notifies patients of Class 1 and Class 2 recalls and withdrawals of blood clotting products and ancillary infusion equipment within 24 hours of receiving such notice, and participates in the National Patient Notification System for blood clotting recalls. (HSC 125286.25[j])

☐ 2~~5~~6.2.11. Provides language interpretive services over the telephone or in person, as needed by the patient. (HSC 125286.25[k])

☐ 2~~5~~6.2.12. Has a detailed plan for meeting the requirements of the Standards of Service for Providers of Blood Clotting Products for Home Use Act in the event of a natural or manmade disaster or other disruption of normal business operations. (HSC 125286.25[l])

2~~6~~7. Policies and Procedures

Yes No N/A

☐☐☐ 2~~6~~7.1. There are written policies and procedures in place for:

~~☐ 26.1.1. The pharmacist's administration of immunizations by injection pursuant to a prescriber's order or state protocol for immunizations; (B&PC 4052.1[a][3])~~

☐ 2~~6~~7.1.~~2~~1. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[a],[c])

☐ 2~~6~~7.1.~~3~~2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (B&PC 4104[b],[c])

☐ 2~~6~~7.1.~~4~~3. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (B&PC 4074, CCR 1707.2[b][3])

☐ 2~~6~~7.1.~~5~~4. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 2~~6~~7.1.~~6~~5. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ 2~~6~~7.1.~~7~~6. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (B&PC 4059.5[f][1])

☐ 2~~6~~7.1.~~8~~7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ 2~~6~~7.1.~~9~~8. Reporting requirements to protect the public; (B&PC 4104)

☐ 2~~6~~7.1.~~10~~9. ~~Preventing the dispensing of a prescription drug that is contrary to the law;~~ A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (B&PC 733)

☐ 2~~6~~7.1.~~11~~10. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (B&PC 733)

☐ 2~~6~~7.1.~~12~~11. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

~~Yes No N/A~~

☐☐☐ 2~~6~~7.2. Does your pharmacy employ the use of a common electronic file?

☐ 26.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 2~~6~~7.3. Does your pharmacy furnish emergency contraceptives pursuant to B&PC 4052.3[a][1]? (B&PC 4052, CCR 1746) If yes, does the pharmacy

☐ 2~~6~~7.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)

☐ 2~~6~~7.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ 2~~6~~7.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)

☐ 2~~6~~7.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

PIC Initials

☐ 2~~6~~7.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐ 2~~6~~7.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (B&PC 733[b])

☐ 2~~6~~7.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (B&PC 733[b], B&PC 4052.3)

☐ 2~~6~~7.3.8. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746)

☐☐☐ 2~~6~~7.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.01[a], CCR 1746.3)

☐ 2~~6~~7.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

☐ 2~~6~~7.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

☐☐☐ 27.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.9, CCR 1746.2)

☐☐☐ 27.6. Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (B&PC 4052.3, CCR 1746.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2~~7~~8. Compounding

Yes No N/A

☐☐☐ 2~~7~~8.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. 02/12) (CCR 1735.2~~[j]~~[k]~~)~~

2~~8~~9. Nuclear Pharmacy

Yes No N/A

☐☐☐ 2~~8~~9.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ 2~~8~~9.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ 2~~8~~9.3. The pharmacy possesses a current Sterile Compounding Permit (B&PC 4127) and is compliant with CCR 1751. (Must also complete Compounding Self-Assessment, 17M-39 Rev. 02/12.) (CCR 1735.2 et al.)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

~~29~~30. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ ~~29~~30.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202.5, 150204, B&PC 4169.5)

- ☐ ~~29~~30.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
- ☐ ~~29~~30.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ ~~29~~30.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (B&PC 4169.5)

☐☐☐ ~~29~~30.3. No controlled substances shall be donated. (H&SC 150204[c][1])

PIC Initials

☐☐☐ ~~29~~30.4. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

☐ ~~29~~30.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])

☐ ~~29~~30.4.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

☐ ~~29~~30.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H&C 150202.5[b], 150204[c][3])

☐ ~~29~~30.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ ~~29~~30.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

3~~0~~1. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 3~~0~~1.1. The pharmacy conducts a county-approved drug repository and distribution program. (H&SC 150201, 150204)

☐ 3~~0~~1.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (H&SC 150201[a][1])

☐ 3~~0~~1.1.1.1 Is county owned (H&SC 150201[b][1]) or

☐ 3~~0~~1.1.1.2 Contracts with the county to establish a voluntary drug repository and distribution program. (H&SC 150201[b][1], 150200)

☐ 3~~0~~1.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (H&SC 150201[a][2])

~~**Yes No N/A**~~

☐☐☐ 3~~0~~1.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (H&SC 150204[a][5])

Issued By: _____ Date: _____

☐☐☐ 3~~0~~1.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (H&SC 150204[a][3])

☐☐☐ 3~~0~~1.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (H&SC 150204[a][4][A])

Date last quarterly report was submitted: _____

_____
PIC Initials

☐☐☐ 3~~0~~1.5. The pharmacy complies with the county's established written procedures. (H~~&~~SC 150204[b])

Drugs and Maintenance of Drug Stock

☐☐☐ 3~~0~~1.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (H~~&~~SC 150204[j])

☐☐☐ 3~~0~~1.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (H~~&~~SC 150204[k])

☐☐☐ 3~~0~~1.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H~~&~~SC 150204[n])

☐☐☐ 3~~0~~1.9. Donated medications received are unused, unexpired and meet the following requirements: (H~~&~~SC 150202, 150202.5, 150204[c])

- ☐ 3~~0~~1.9.1. Are received from authorized sources. (H~~&~~SC 150202, 150203)
- ☐ 3~~0~~1.9.2. No controlled substances are received. (H~~&~~SC 150204[c][1])
- ☐ 3~~0~~1.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (H~~&~~SC 150204[c][2])
- ☐ 3~~0~~1.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (H~~&~~SC 150204[c][3])
- ☐ 3~~0~~1.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H~~&~~SC 150204[d])
- ☐ 3~~0~~1.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (H~~&~~SC 150204[i])
- ☐ 3~~0~~1.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (H~~&~~SC 150204[m])

~~Yes No N/A~~

☐☐☐ 3~~0~~1.10. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (H~~&~~SC 150204[d], 150204[h])

PIC Initials

Transferring Donated Drugs From One Participating Entity to Another

☐☐☐ 3~~0~~1.11. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (H~~&~~SC 150204[g][4])

☐☐☐ 3~~0~~1.12. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (H~~&~~SC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ 3~~0~~1.13. Donated medication is not transferred by any participating entity more than once. (H~~&~~SC 150204[g][4][B])

☐☐☐ 3~~0~~1.14. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (H~~&~~SC 150204[g][4][C])

☐☐☐ 3~~0~~1.15. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (H~~&~~SC 150204[g][4][C])

Dispensing to Eligible Patients

☐☐☐ 3~~0~~1.16. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (H~~&~~SC 150204[i])

☐☐☐ 3~~0~~1.17. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (H~~&~~SC 150204[f])

PIC Initials

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy 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 PHARMACY OWNER OR HOSPITAL ADMINISTRATOR:

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 _____

_____
PIC Initials

~~The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.~~

~~California Code of Regulations (CCR), Title 16 and Title 24~~
~~Business and Professions Code (B&PC), Chapter 9, Division 2~~
~~Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act~~
~~California Code of Regulations (CCR), Chapter 1, Division 5, Title 22~~
~~Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)~~

~~**California Board of Pharmacy**~~
~~1625 N. Market Blvd., Suite N219~~
~~Sacramento, CA 95834~~
~~Phone: (916) 574-7900~~
~~Fax: (916) 574-8618~~
~~www.pharmacy.ca.gov~~
~~***Pharmacy Law*** may be obtained by contacting:~~
~~Law Tech Publishing Co.~~
~~1060 Calle Cordillera, Suite 105~~
~~San Clements, CA 92673~~
~~Phone: (800) 498-0911 Ext. 5~~
~~www.lawtechpublishing.com~~
~~**Pharmacist Recovery Program**~~
~~(800) 522-9198 (24 hours a day)~~
~~**Atlantic Associates, Inc.** (CURES)~~
~~Prescription Collection~~
~~8030 S. Willow Street, Bldg 3 Unit 3~~
~~Manchester, NH 03103~~
~~Phone: (888) 492-7341~~
~~Fax: 877-508-6704~~
~~**CURES**~~
~~4949 Broadway~~
~~Sacramento, CA 95820~~
~~Phone: (916) 319-9062~~
~~Fax: (916) 319-9448~~
~~http://www.ag.ca.gov/bne~~
~~**CURES Patient Activity Report Request Forms**:~~
~~http://www.ag.ca.gov/bne/trips.php~~

~~***PRESCRIBER BOARDS:***~~
~~**Medical Board of California**~~
~~2005 Evergreen St., Suite 1200~~
~~Sacramento, CA 95815~~
~~Phone: (800) 633-2322~~
~~Phone: (916) 263-2382~~
~~Fax: (916) 263-2944~~
~~http://www.mbc.ca.gov~~
~~**Dental Board of California**~~
~~2005 Evergreen St., Suite 1550~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2300~~
~~Fax: (916) 263-2140~~
~~http://www.dbc.ca.gov~~
~~**Board of Registered Nursing**~~
~~1625 N. Market Blvd., Suite N217~~
~~Sacramento, CA 95834~~
~~Phone: (916) 322-3350~~
~~Fax: (916) 574-7697~~
~~http://www.rn.ca.gov/~~
~~**Board of Optometry**~~
~~2420 Del Paso Road, Suite 255~~
~~Sacramento, CA 95834~~
~~Phone: (916) 575-7170~~
~~Fax: (916) 575-7292~~
~~http://www.optometry.ca.gov/~~
~~**Osteopathic Medical Board of California**~~
~~1300 National Drive, Suite 150~~
~~Sacramento, CA 95834~~
~~Phone: (916) 928-8390~~
~~Fax: (916) 928-8392~~
~~http://www.ombc.ca.gov~~

PIC Initials

~~**Physician Assistant Committee**~~
~~2500 Evergreen St., Suite 1100~~
~~Sacramento, CA 95815~~
~~Phone: (916) 561-8780~~
~~Fax: (916) 263-2671~~
~~http://www.pac.ca.gov~~
~~**Board of Podiatric Medicine**~~
~~2005 Evergreen St., Suite 1300~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2647~~
~~Fax: (916) 263-2651~~
~~http://www.bpm.ca.gov~~
~~**Veterinary Medical Board**~~
~~2005 Evergreen St., Suite 2250~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2610~~
~~Fax: (916) 263-2621~~
~~http://www.vmb.ca.gov~~
~~***FEDERAL AGENCIES:***~~
~~**Food and Drug Administration**~~
~~**– Industry Compliance**~~
~~http://www.fda.gov/oc/industry/centerlinks.html#drugs~~
~~The **Drug Enforcement Administration** may be contacted at:~~
~~**DEA Website:**~~
~~http://www.deadiversion.usdoj.gov~~
~~**Online Registration – New Applicants:**~~
~~http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm~~
~~**Online Registration – Renewal:**~~
~~www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm~~
~~**Registration Changes (Forms):**~~
~~http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html~~
~~**DEA Registration Support (all of CA):**~~
~~(800) 882-9539~~
~~**Online DEA 106 Theft/Loss Reporting:**~~
~~https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp~~
~~**Online DEA 222 Controlled Substance Ordering System (CSOS):** http://www.deaecom.gov/~~

~~**DEA - Fresno**~~
~~2444 Main Street, Suite 240~~
~~Fresno, CA 93721~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (559) 487-5406~~
~~**DEA - Los Angeles**~~
~~255 East Temple Street, 20th Floor~~
~~Los Angeles, CA 90012~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (213) 621-6942~~
~~**DEA – Oakland**~~
~~1301 Clay Street, Suite 460N~~
~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~
~~**DEA – Redding**~~
~~310 Hensted Drive, Suite 310~~
~~Redding, CA 96002~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (530) 246-5043~~
~~**DEA - Riverside**~~
~~4470 Olivewood Avenue~~
~~Riverside, CA 92501-6210~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (951) 328-6200~~
~~**DEA - Sacramento**~~
~~4328 Watt Avenue~~
~~Sacramento, CA 95821~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~
~~**DEA – San Diego and Imperial Counties**~~
~~4560 Viewridge Avenue~~
~~San Diego, CA 92123-1637~~
~~Registration: (800) 284-1152~~
~~Diversion or Investigation: (858) 616-4100~~
~~**DEA – San Francisco**~~
~~450 Golden Gate Avenue, 14th Floor~~
~~San Francisco, CA 94102~~
~~Registration: (888) 304-3251~~
~~Theft Reports or Diversion: (415) 436-7900~~
~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

PIC Initials _____

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

Business and Professions Code (BPC), Division 1, Chapter 1 – General Provisions
BPC, Division 2, Chapter 1 – General Provisions
BPC, Division 2, Chapter 3 – Clinical Laboratory Technology
BPC, Division 2, Chapter 9 – Pharmacy
California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice Combat Methamphetamine Epidemic Act of 2005. Pub. L. 109-177. 120 Stat. 256.9 Mar. 2006
Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
HSC, Division 10 – Uniform Controlled Substances Act
HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
HSC, Division 106, Part 5, Chapter 2 – Genetic Disease Services
HSC, Division 116 – Surplus Medication Collection and Distribution
United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

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

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to 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 pharmacist-in-charge must also 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. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, and readily available ~~and retained~~ in the pharmacy. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. ~~10/14~~ 10/16) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).~~)

Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

Pharmacy Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐
Non-Licensed Owner ☐ Other (please specify) ☐ _____

~~Permit~~ License #: _____ Exp. Date:_____ Other ~~Permit~~ License #: _____ Exp. Date: _____

Licensed Sterile Compounding ~~Permit~~ License #_____ Expiration: _____

Accredited by (optional): _____ From: _____ To: _____

Centralized Hospital Packaging#: _____ _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.*_____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

_____
PIC
Initials

Pharmacy staff (pharmacists, interns, technicians):
APH~~P~~=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

1. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH# _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

8. _____ RPH # _____ Exp. Date: _____
~~APP~~ APH # _____ Exp. Date: _____
DEA # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ INT # _____ Exp. Date: _____

12. _____ INT # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

16. _____ TCH # _____ Exp. Date: _____

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HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

Please mark the appropriate box for each question. If "NO," enter an explanation on "CORRECTIVE ACTION or ACTION PLAN" lines below. If more space is needed, you may add additional sheets.

1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (B&PC 4116, 4117, CCR 1714)

☐☐☐ 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (B&PC 4104[a])

☐☐☐ 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (B&PC 4104[b])

☐☐☐ 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (B&PC 4104[c])

☐☐☐ 1.5. The pharmacy maintains "night stock" medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.7. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐☐☐ 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

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PIC Initials

Yes No N/A

☐☐☐ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (B&PC 4032, 4058)

☐☐☐ 1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[c])

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?
(~~If yes, complete section 27 – "Compounding"~~) (If yes, complete Compounding Self-Assessment Form 17M-39, Rev. 10/12)

☐☐☐ 1.13. The pharmacy is subscribed to the board's e-mail notifications. (B&PC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Nursing Stations

Yes No N/A

☐☐☐ 2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ 2.2. The pharmacist, intern, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (B&PC 4119.7[c], 4115[j], 22 CCR 70263[q][10])

☐ 2.2.1. An intern shall report any irregularities to the pharmacist. (B&PC 4119.7[c]);

☐ 2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (B&PC 4115[i][3]);

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

3. Delivery of Drugs

Yes No N/A

☐☐☐ 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (B&PC 4059.5[a])

☐☐☐ 3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (B&PC 4059.5[c])

☐☐☐ 3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (B&PC 4059.5[f]):

- ☐ 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (B&PC 4059.5[f][1]);
- ☐ 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][2]);
- ☐ 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (B&PC 4059.5[f][3]);
- ☐ 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (B&PC 4059.5[f][4]); and
- ☐ 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (B&PC 4059.5[f][5])

☐☐☐ 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][A][i])

☐☐☐ 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][A][ii])

☐☐☐ 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][A][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

4. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (B&PC 4342, H&SC 111255, CCR 1714 (b), 22 CCR 70263[q])

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, or on an emergency basis for a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales). (B&PC 4380, CCR 1710[a])

~~**Yes No N/A**~~

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (B&PC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (B&PC 4119.7[b]

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (H&SC 150202, 150202.5, 150204)

- ☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (H&SC 150202.5)
- ☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (H&SC 150202.5)

☐☐☐ 5.2. No controlled substances shall be donated. (H&SC 150204[c][1])

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150202.5, 150204[c])

- ☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- ☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (H&SC 150202.5[a])

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PIC Initials

☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (H&SC 150202.5[b], 150204[c][3])

☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])

☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (H&SC 150204[n])

6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (B&PC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.1[b])

☐☐☐ 6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (B&PC 4101, 4330)

~~☐☐☐ 6.5. Is the PIC serving concurrently as the designated representative-in-charge for a wholesaler or veterinary food-animal retailer? (CCR 1709.1 [d])~~

~~If yes, name the wholesaler or veterinary food-animal retailer. _____~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. ~~Within the scope of the inpatient pharmacy service, the pharmacist receives a chart order for an inpatient; identifies, evaluates and interprets the chart order; reviews patient's drug regimen and interprets the clinical data in the patient's medication record; consults with any prescriber, nurse or health care professional; calculates drug doses; supervises the packaging of drugs and checks the packaging procedures and products upon completion; is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such~~

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PIC Initials

~~activities are performed completely, safely and without risk of harm to patients; performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (B&PC 4052, 4052.2, CCR 1793.1)~~ Only a pharmacist: (BPC 4019, BPC 4052, BPC 4051, BPC 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)

- The pharmacist rReceives a chart order for an inpatient; (BPC 4019, BPC 4051 [b], BPC 4052, BPC 4052.2, CCR 1717, CCR 1793.1[a])
- Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], BPC 4052.2[a][4], CCR 1793.1[d])
- Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- Calculates drug doses; (BPC 4052 [a][3], BPC 4052.2 [a][3], BPC 4052.2 [a][4])
- Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e])
- Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (BPC 4052, BPC 4052.2, CCR 1793.1[g])

☐☐☐ 7.2 ~~Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator; ordering or performing routine drug therapy-related patient assessment procedures; ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; initiating or adjusting the drug regimen of a patient, and/or performing moderate or waived laboratory tests. Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in B&PC section 4052.2.~~

Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (B&PC 4027, 4051, 4052, 4052.2)

- Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052.1[a][2], [3]; 4052.2[a][2], [3])
- Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])

☐ Performing moderate or waived laboratory tests. (Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency training, or (2) demonstrated clinical experience in direct patient care delivery as specified in ~~B&PC~~ BPC section 4052.2[d]. (BPC 4052.4)

☐☐☐ 7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Advanced Practice Pharmacist

Yes No N/A

~~☐☐☐ 8.1. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (B&PC 4052[b])~~

☐☐☐ ~~8.2~~.8.1 The advance practice pharmacist has received an advance practice pharmacist ~~recognition~~ license ~~by~~ from the board and may do the following: (B&PC 4016.5, 4210)

- ☐ ~~8.2.1~~ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (B&PC 4052.6[a])
- ☐ ~~8.2.1~~ 8.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (B&PC 4052.6[b])
- ☐ ~~8.2.1~~ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (B&PC 4052.6[b])
- ☐ ~~8.2.1~~ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (B&PC 4052.6[d])
- ☐ ~~8.2.1~~ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (B&PC 4052.6[e])

9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (B&PC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (B&PC 4119.6)

☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (B&PC 4119.7[c])

~~Yes No N/A~~

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned, when applicable. (B&PC 4209[b], [c], [d], CCR 1726)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. (B&PC 4023.5, 4038, 4115, CCR 1793.2, CCR 1793.7)

☐☐☐ 10.2. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[f], CCR 1793.7[f])

☐☐☐ ~~10.2~~ 10.3. ~~The ratio for technicians performing the tasks above, related to the furnishing of drugs to inpatients, does not exceed one pharmacist on duty for two technicians on duty. However, w~~When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in B&PC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (B&PC 4038, 4115[f], CCR 1793.7[f])

☐☐☐ ~~10.2~~ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

☐☐☐ ~~10.2~~ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies him or her ~~self~~ herself as a pharmacy technician or pharmacy technician trainee. (B&PC 680, B&PC 4115.5[e], CCR 1793.7[d])

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PIC Initials

☐☐☐ ~~10.2~~ 10.6. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

~~☐☐☐ 10.6. The ratio is no less than one pharmacist to two technicians. (B&PC 4115[g], CCR 1793.7)~~

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (B&PC 4115[g], CCR 1714.1[c])

~~Yes No N/A~~

☐☐☐ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- ☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (B&PC 4119, 4115[i])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (B&PC 4115[i])
- ☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (B&PC 4115[i])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (B&PC 4007, CCR 1793.3)

☐☐☐ 11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

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PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- ☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ☐ 12.1.2. Repackaging and compounding records;
- ☐ 12.1.3. Physician orders;
- ☐ 12.1.4. Wards, nursing stations and night stock medications;
- ☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ☐ 12.1.6. Bedside medications;
- ☐ 12.1.7. Emergency drug supply;
- ☐ 12.1.8. Pass medications;
- ☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ☐ 12.1.10. Routine distribution of inpatient medications;
- ☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ☐ 12.1.12. Handling of medication when pharmacist not on duty; and
- ☐ 12.1.13. Use of electronic image and data order transmissions.

~~Yes No N/A~~

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ☐ 12.2.1. Destruction of controlled substances; and
- ☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, CCR 1751, CCR 1751.8)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (B&PC 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by B&PC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (B&PC 4019, 4040, 22 CCR 70263[g])

~~**Yes No N/A**~~

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. (B&PC 4081, 4105, 4333)

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (B&PC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication ~~and parenteral admixtures~~ are properly labeled and include the information as required by B&PC 4076, or the information is otherwise readily available at the time of drug administration. (B&PC 4076[b]~~, CCR 1751.2~~)

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with B&PC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (B&PC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

15. Duration of Drug Therapy

Yes No N/A

☐☐☐ 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

☐☐☐ 16.1. Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (B&PC 4040, CCR 1764, Civil Code 56 et seq.)

☐☐☐ 16.3. Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

☐☐☐ 16.5. Records regarding dangerous drugs and dangerous devices stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within three business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (BPC 4105, CCR 1707)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

17. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (B&PC 4125, CCR 1711)

☐☐☐ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 17.3. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates with the patient or patient's agent that a medication error has occurred and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711 [c][3])

~~**Yes No N/A**~~

☐☐☐ 17.4. When a medication error has occurred (drug was administered to or by the patient, or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711 [c][3])

☐☐☐ 17.5. Investigation of pharmacy medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

☐☐☐ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

- ☐ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 17.6.3. Findings and determinations;
- ☐ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

☐☐☐ 17.7. The record of the quality assurance review is immediately retrievable in the pharmacy and is maintained in the pharmacy for at least one year from the date it was created. (CCR 1711[f])

☐☐☐ 17.8. Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with B&PC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. ~~A~~ All completed ~~biennial~~ pharmacy self -assessments ~~is~~ are on file in the pharmacy and ~~is~~ are maintained for three years. (CCR 1715)

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. These records include:

- ☐ 18.2.1. Prescription records (B&PC 4081[a])
- ☐ 18.2.2. Purchase Invoices for all prescription drugs (B&PC 4081[b])

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PIC Initials

☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)

☐ 18.2.4. U.S. Official Order Forms (DEA Form- 222) (21 CFR 1305.13)

☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.07)

☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (B&PC 4081)

☐ 18.2.8. Record documenting transfers or sales to other pharmacies and prescribers (B&PC 4059, 4081, 4105, 4332, CCR 1718)

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (H&SC 150200, 150202[a][1]), 150204~~(~~[k]~~)~~, B&PC 4105~~(~~[c]~~)~~.

~~Yes No N/A~~

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, ~~Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503~~ Drug Supply Chain Security Act (DSCSA), B&PC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, ~~PDMA 503~~ DSCSA, B&PC 4160)

☐☐☐ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

☐☐☐ ~~18.6~~ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ ~~18.7~~ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ ~~18.8~~ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ ~~18.9~~ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

☐☐☐ ~~18.10~~ 18.11. Any controlled substances drug loss is reported upon discovery to the DEA and to the Board of Pharmacy within 30 days. (21 CFR 1301.74[c], CCR 1715.6)

☐☐☐ ~~18.11~~ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days.

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Initials

Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

☐☐☐ ~~18.12~~ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR

☐☐☐ ~~18.13~~ 18.14. Does the pharmacy comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the pharmacy. (CCR 1712)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 19.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ 19.2 The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

☐☐☐ 19.3 A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65 [c])

- ☐ 19.3.1 A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 19.3.2 A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 19.3.3 A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 19.3.4 All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 19.3.5 Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

☐☐☐ 19.4 The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

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PIC Initials

☐☐☐ 19.5 The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])

☐☐☐ 19.6 A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

☐☐☐ 19.7 A separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. (CCR 1715.65 [g])

☐☐☐ 19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

- ☐ 19.8.1 All controlled substances added to an automated drug delivery system are accounted for;
- ☐ 19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel;
- ☐ 19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
- ☐ 19.8.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~19~~20. After-Hours Supply of Medication

Yes No N/A

☐☐☐ ~~19~~20.1. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~20~~21. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ ~~20~~21.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

☐☐☐ ~~20~~21.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1])

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PIC Initials

☐☐☐ ~~20~~21.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ ~~20~~21.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. (22 CCR 70263[f][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~21~~22. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ ~~21~~22.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (B&PC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~22~~23. Emergency Room Dispensing

Yes No N/A

☐☐☐ ~~22~~23.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (B&PC 4068[a])

- ☐ ~~22~~23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ ~~22~~23.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ ~~22~~23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ ~~22~~23.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III or IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code;
- ☐ ~~22~~23.1.5.The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and
- ☐ ~~22~~23.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when

pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

☐☐☐ ~~22~~23.2. The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (B&PC 4068[a][7])

☐☐☐ ~~22~~23.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (B&PC 4068[b])

☐☐☐ ~~22~~23.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ ~~22~~23.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ ~~22~~23.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 section 4[b], 16 CFR 1700.15., CCR 1717)

☐☐☐ ~~22~~23.7. Patient package inserts are dispensed with all estrogen medications (21 CFR 310.515)

☐☐☐ 23.8. The pharmacy provides patients with required Black Box Warning Information. (21 CFR 201.57[c])

☐☐☐ 23.9. Medication guides are provided on required medications. (21 CFR Part 208)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~23~~24. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ ~~23~~24.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved by the medical staff that ensures that each patient receives the medication consultation. (B&PC 4074, CCR 1707.2)

☐☐☐ ~~23~~24.2. Prescriptions are transmitted to another pharmacy as required by law. (B&PC 4072, CCR 1717[f], 1717.4)

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PIC Initials

☐☐☐ ~~23~~24.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5. (B&PC 4076, CCR 1707.5)

~~☐☐☐ 23.4. If requested by the patient, the prescription label is printed in 12-point typeface. (CCR 1707.5[a])~~

~~☐☐☐ 23.5. The pharmacy is exempt from the prescription label requirements in CCR 1707.5.~~

~~Exemption approved by board from: _____ to _____~~

☐☐☐ ~~23~~24.~~6~~4. Appropriate drug warnings are provided orally or in writing. (B&PC 4074, CCR 1744)

☐☐☐ ~~23~~24.~~7~~5. The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (B&PC 4076, CCR 1717)

☐☐☐ ~~23~~24.~~8~~6. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (B&PC 4073)

☐☐☐ ~~23~~24.~~9~~7. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product. (B&PC 4115[f], CCR 1793.7)

☐☐☐ ~~23~~24.~~10~~8. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ ~~23~~24.~~11~~9. 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. (~~25~~ 15 USC 1473 ~~section 4[b]~~, 16 CFR 1700.15, CCR 1717)

☐☐☐ ~~23~~24.~~12~~10. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 24.11. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])

☐☐☐ 24.12. Medication guides are provided on required medications. (21 CFR Part 208)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~24~~25. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ ~~24~~25.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

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PIC Initials

☐☐☐ ~~24~~25.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy:

If the answer to this and the previous question is "no" or "not applicable" go to Section ~~23.~~ 26.

☐☐☐ ~~24~~25.3. Prescription information is electronically transferred between the two pharmacies. (CCR 1710[b][6])

☐☐☐ ~~24~~25.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ ~~24~~25.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ ~~24~~25.6. Each cassette or container meets the requirements of Business and Professions Code section 4076. (CCR 1710[b][3])

☐☐☐ ~~24~~25.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

~~25~~26. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ ~~25~~26.1. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located ~~packages unit dose medication for inpatients of one or more hospitals under common ownership~~ within a 75-mile radius: (B&PC 4128)

Hospitals to which central packaged unit dose medications are provided:

☐ ~~25~~26.1.1. _____ Distance (miles): _____

☐ ~~25~~26.1.2. _____ Distance (miles): _____

☐ ~~25~~26.1.3. _____ Distance (miles): _____

☐ ~~25~~26.1.4. _____ Distance (miles): _____

☐ 26.1.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to BPC 4128.4.

☐ 26.1.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to BPC 4128.4.

☐ 26.1.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

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PIC Initials

☐☐☐ ~~25~~26.2. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (B&PC 4128.3)

☐☐☐ ~~25~~26.3. ~~All~~ Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded ~~and readable~~ to be machine readable at the inpatient's bedside using barcode medication administrative software. ~~The barcode information contains~~: (B&PC 4128.4)

☐ ~~25.3.1. The date the medication was prepared.~~ The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration.

☐ ~~25.3.2. The components used in the drug product.~~ The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.

~~☐ 25.3.3. The lot number or control number.~~

~~☐ 25.3.4. The expiration date.~~

~~☐ 25.3.5. The National Drug Code Directory number.~~

~~☐ 25.3.6. The name of the centralized hospital packaging pharmacy.~~

~~Yes No N/A~~

☐☐☐ ~~25~~26.4. ~~The~~ Any label for each unit dose medication produced by a centralized hospital packaging pharmacy ~~contains the expiration date, the established name of the drug, the quantity of the active ingredient, and special storage or handling requirements~~ displays a human-readable label that contains the following: (B&PC 4128.5[a])

☐ 26.4.1 The date the medication was prepared.

☐ 26.4.2 The beyond-use date

☐ 26.4.3 The established name of the drug.

☐ 26.4.4 The quantity of each active ingredient.

☐ 26.4.5 The lot number or control number assigned by the centralized hospital packaging pharmacy.

☐ 26.4.6 Special storage or handling requirements.

☐ 26.4.7 The name of the centralized hospital packaging pharmacy.

☐☐☐ 26.5 The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])

☐ 26.5.1 The components used in the drug product.

☐ 26.5.2 The expiration date of each of the drug's components.

☐ 26.5.3 The National Drug Code Directory number.

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PIC Initials

☐☐☐ ~~25~~26.~~5~~6. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (B&PC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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~~26~~27. Policies and Procedures

Yes No N/A

☐☐☐ ~~26~~27.1. There are written policies and procedures in place for:

- ☐ ~~26~~27.1.1. The assurance that each patient received information regarding each medication given at the time of discharge.
- ☐ ~~26~~27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (B&PC 4104[a])
- ☐ ~~26~~27.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (B&PC 4104[b])
- ☐ ~~26~~27.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (B&PC 4104[b])
- ☐ ~~26~~27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in B&PC 4104[c][1-6].
- ☐ ~~26~~27.1.6. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to H&SC 1250, or to an inmate of an adult correctional facility or juvenile detention facility. (B&PC 4074, CCR 1707.2[b][3])
- ☐ ~~26~~27.1.7. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])
- ☐ ~~26~~27.1.8. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])
- ☐ ~~26~~27.1.9. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

~~27~~28. Compounding

Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the "Compounding Self-Assessment" Form 17M-39 (Rev. 02/12). (CCR 1735.2[i])

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy 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 HOSPITAL ADMINISTRATOR:

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 _____

_____
PIC Initials

~~The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations),* at the California State Law Library, or at other libraries or Internet web sites.~~

~~California Code of Regulations (CCR), Title 16 and Title 24~~
~~Business and Professions Code (B&PC), Chapter 9, Division 2~~
~~Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act~~
~~California Code of Regulations (CCR), Chapter 1, Division 5, Title 22~~
~~Code of Federal Regulations (CFR), Title 21, Chapter II, Drug Enforcement Administration (www.dea.gov)~~

~~**California Board of Pharmacy**~~
~~1625 N. Market Blvd., Suite N219~~
~~Sacramento, CA 95834~~
~~Phone: (916) 574-7900~~
~~Fax: (916) 574-8618~~
~~www.pharmacy.ca.gov~~

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~~Phone: (800) 498-0911 Ext. 5~~
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~~**Pharmacist Recovery Program**~~
~~(800) 522-9198 (24 hours a day)~~

~~**Atlantic Associates, Inc.** (CURES)~~
~~Prescription Collection~~
~~8030 S. Willow Street, Bldg 3 Unit 3~~
~~Manchester, NH 03103~~
~~Phone: (888) 492-7341~~
~~Fax: 877-508-6704~~

~~**CURES**~~
~~4949 Broadway~~
~~Sacramento, CA 95820~~
~~Phone: (916) 319-9062~~
~~Fax: (916) 319-9448~~
~~http://www.ag.ca.gov/bne~~

~~**CURES Patient Activity Report Request Forms**:~~
~~http://www.ag.ca.gov/bne/trips.php~~

~~***PRESCRIBER BOARDS:***~~
~~**Medical Board of California**~~
~~2005 Evergreen St., Suite 1200~~
~~Sacramento, CA 95815~~
~~Phone: (800) 633-2322~~
~~Phone: (916) 263-2382~~
~~Fax: (916) 263-2944~~
~~http://www.mbc.ca.gov~~
~~**Dental Board of California**~~
~~2005 Evergreen St., Suite 1550~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2300~~
~~Fax: (916) 263-2140~~
~~http://www.dbc.ca.gov~~
~~**Board of Registered Nursing**~~
~~1625 N. Market Blvd., Suite N217~~
~~Sacramento, CA 95834~~
~~Phone: (916) 322-3350~~
~~Fax: (916) 574-7697~~
~~http://www.rn.ca.gov/~~
~~**Board of Optometry**~~
~~2420 Del Paso Road, Suite 255~~
~~Sacramento, CA 95834~~
~~Phone: (916) 575-7170~~
~~Fax: (916) 575-7292~~
~~http://www.optometry.ca.gov/~~
~~**Osteopathic Medical Board of California**~~
~~1300 National Drive, Suite 150~~
~~Sacramento, CA 95834~~
~~Phone: (916) 928-8390~~
~~Fax: (916) 928-8392~~
~~http://www.ombc.ca.gov~~

~~**Physician Assistant Committee**~~
~~2500 Evergreen St., Suite 1100~~
~~Sacramento, CA 95815~~
~~Phone: (916) 561-8780~~
~~Fax: (916) 263-2671~~
~~http://www.pac.ca.gov~~
~~**Board of Podiatric Medicine**~~
~~2005 Evergreen St., Suite 1300~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2647~~
~~Fax: (916) 263-2651~~
~~http://www.bpm.ca.gov~~
~~**Veterinary Medical Board**~~
~~2005 Evergreen St., Suite 2250~~
~~Sacramento, CA 95815~~
~~Phone: (916) 263-2610~~
~~Fax: (916) 263-2621~~
~~http://www.vmb.ca.gov~~
~~***FEDERAL AGENCIES:***~~
~~**Food and Drug Administration**~~
~~**– Industry Compliance**~~
~~http://www.fda.gov/oc/industry/centerlinks.html#drugs~~
~~The **Drug Enforcement Administration** may be contacted at:~~
~~**DEA Website:**~~
~~http://www.deadiversion.usdoj.gov~~
~~**Online Registration – New Applicants:**~~
~~http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm~~
~~**Online Registration - Renewal:**~~
~~www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm~~
~~**Registration Changes (Forms):**~~
~~http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html~~
~~**DEA Registration Support (all of CA):**~~
~~(800) 882-9539~~
~~**Online DEA 106 Theft/Loss Reporting:**~~
~~https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp~~
~~**Online DEA 222 Controlled Substance Ordering System (CSOS):** http://www.deaecom.gov/~~

~~**DEA - Fresno**~~
~~2444 Main Street, Suite 240~~
~~Fresno, CA 93721~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (559) 487-5406~~
~~**DEA - Los Angeles**~~
~~255 East Temple Street, 20th Floor~~
~~Los Angeles, CA 90012~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (213) 621-6942~~
~~**DEA – Oakland**~~
~~1301 Clay Street, Suite 460N~~
~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~
~~**DEA – Redding**~~
~~310 Hensted Drive, Suite 310~~
~~Redding, CA 96002~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (530) 246-5043~~
~~**DEA - Riverside**~~
~~4470 Olivewood Avenue~~
~~Riverside, CA 92501-6210~~
~~Registration: (888) 415-9822 or (213) 621-6960~~
~~Diversion or Investigation: (951) 328-6200~~
~~**DEA - Sacramento**~~
~~4328 Watt Avenue~~
~~Sacramento, CA 95821~~
~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~
~~**DEA – San Diego and Imperial Counties**~~
~~4560 Viewridge Avenue~~
~~San Diego, CA 92123-1637~~
~~Registration: (800) 284-1152~~
~~Diversion or Investigation: (858) 616-4100~~
~~**DEA – San Francisco**~~
~~450 Golden Gate Avenue, 14th Floor~~
~~San Francisco, CA 94102~~
~~Registration: (888) 304-3251~~
~~Theft Reports or Diversion: (415) 436-7900~~
~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (408) 291-2631~~

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions
BPC, Division 2, Chapter 9 – Pharmacy
California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
CCR, Title 22, Division 5, Chapter 1 – General Acute Care Hospitals
Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
CFR, Title 21, Chapter I, Subchapter C, Part 290 – Controlled Drugs
CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice
Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act
HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
HSC, Division 116 – Surplus Medication Collection and Distribution
United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

Remote Dispensing Technicians
16 CCR § 1793.9

Title 16. Board of Pharmacy
Proposed Text

Add section 1793.9 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1793.9 Pharmacy Technician in a Remote Dispensing Site Pharmacy

A pharmacy technician must satisfy each of the following requirements before working in a remote dispensing site pharmacy:

(a) Possess a pharmacy technician license that is in good standing.
(b) Possess and maintain a certification issued by an approved pharmacy technician certifying program.
(c) (1) Possess a minimum of an associate degree in pharmacy technology;
(2) Possess a minimum of a bachelor's degree in any subject; or
(3) Complete a course of training specified by the board as provided in section 1793.6.
(d) Complete 1,000 hours of experience working as a pharmacy technician within the three years prior to first working in the remote dispensing site pharmacy.

Authority: Sections 4005 and 4132, Business and Professions Code
Reference: Sections 4005, 4026.5, 4044.3, 4052, 4115, 4132 and 4202, Business and Professions Code

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 reproval.

(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~~ applying ~~icant~~ 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 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, 4022.7, 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.

Mail-Order Pharmacy Consultation
16 CCR § 1707.2

Title 16. Board of Pharmacy

Amend section 1707.2 in Article 2 of Division 17 of Title 16 California Code of Regulations to read as follows:

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;.

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:~~

(3~~A~~) whenever the prescription drug has not previously been dispensed to a patient; or

(4~~B~~) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.

(b)(1~~2~~) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail, or delivery), a pharmacy shall ensure that ~~the patient receives written notice~~:

(A) the patient receives written notice of his or her right to request consultation; ~~and~~

(B) the patient receives written notice of ~~a~~ the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record~~.~~; and

(C)A pharmacist shall be available (i) to speak to the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one business hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(2~~3~~) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

(1) directions for use and storage and the importance of compliance with directions; and

(2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

(1) the name and description of the medication;

(2) the route of administration, dosage form, dosage, and duration of drug therapy;

(3) any special directions for use and storage;

(4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;

(5) prescription refill information;

(6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code. Reference: Sections 4005, 4076, 4112 and 4122, Business and Professions Code.

Attachment 5

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:
(~~1~~ 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.

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

PHARMACY TECHNICIAN APPLICATION

~~**All items of information requested in this application are mandatory.**~~ Please read the application instructions before you complete the application. Failure to provide any of the requested information will result in the application being considered incomplete ~~an incomplete application and a deficiency letter being mailed to you~~. An applicant for a pharmacy technician license, who fails to complete all the application requirements within 60 days after being notified by the board of deficiencies, may be deemed to have abandoned the application and may be required to file a new application, fee, and meet all the requirements which are in effect at the time of reapplication. ~~Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.**~~ All questions on this application must be answered. ~~If not applicable indicate N/A. Attach additional sheets on paper if necessary.~~

Military Expedite ☐ **MILITARY** (Are you serving in the United States military?)
☐ **VETERAN** (Have you ever served in the United States military?)
☐ **ACTIVE DUTY MILITARY-Spouse or Partner (**~~Check here if you meet the requirements for expediting your application.)~~

Applicant Information - Please Type or Print

Full Legal Name: Last Name: First Name: Middle Name:

Previous Names (AKA, Maiden Name, Alias, etc):

*Official Mailing/Public Address of Record (Street Address, PO Box #, etc):

City: State: Zip Code:

Residence Address (if different from above):

City: State: Zip Code:

Home#: ( ) Cell#: ( ) Work#: ( ) Email Address:

Date of Birth (Month/Day/Year): **US Social Security # or ~~Individual Tax ID~~ ITIN #: Driver's License No: State:

Mandatory Education (check one box)

Please indicate how you satisfy the ~~mandatory~~ education requirement in Business and Professions Code section 4202(a).

☐ High school graduate or foreign equivalent.
Attach an official embossed transcript or notarized copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

☐ Completed a general education development certificate equivalent.
Attach an official transcript of your test results or certificate of proficiency.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION
NO POLAROID OR SCANNED IMAGES
PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to section 4202(a)(1)(2)(3)(4) of the Business and Professions Code.

☐ Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

☐ Attached is a ~~certified~~ copy of PTCB certificate or ExCPT certificate – Date certified:_____

☐ Attached is a ~~certified~~ copy of ~~your~~ military training DD214

List all state(s) where you hold or held a license as a pharmacy technician, pharmacist, intern pharmacist, and/or ~~pharmacy technician and or~~ another health care professional ~~license~~, including California. Attach an additional sheet, if necessary.

State	Registration Number	Active or Inactive	Issued Date	Expiration Date

Self-Query Report by the National Practitioner Data Bank (NPDB)

☐ Attached is the original sealed envelope containing my Self-Query Report from NPDB. (This must be submitted with your application.)

Photo ☐ Enf 1st Check ☐ Enf 2nd Check ☐ Qualify Code _____ Self-Query ☐	FP Cards/Live Scan ☐ FP Cards Sent _____ FP Fees ☐ DOJ Clear Date: _____ FBI Clear Date: _____	**FOR BOARD USE ONLY** License no. _____ Date issued _____ Date expires _____	App fee no. _____ Amount _____ Date cashiered _____

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

1. Do you have a mental illness or physical illness that in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? **If "yes," attach a statement of explanation. If "no," proceed to #2.** Are the limitations caused by your mental illness or physical illness reduced or improved because you receive ongoing treatment or participate in a monitoring program? Yes ☐ No ☐ **If "yes," attach a statement of explanation.** If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing mental illness or physical illness to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.	Yes ☐ No ☐
2. Have you previously engaged in the illegal use of controlled substances? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
3. Do you currently participate in a substance abuse program or have previously participated in a substance abuse program in the past five years? If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you to ensure you are maintaining sobriety? Yes ☐ No ☐ **Attach a statement of explanation.**	Yes ☐ No ☐
4. Has disciplinary action ever been taken against your designated representative, pharmacist, intern pharmacist and/or pharmacy technician license in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
5. Have you ever had an application for a designated representative, pharmacist, intern pharmacist and/or pharmacy technician license denied in this state or any other state? **If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.**	Yes ☐ No ☐
6. Have you ever had a pharmacy license, or any professional or vocational license or registration denied, suspended, revoked, placed on probation or had other disciplinary action taken by this or any other government authority in California or any other state? **If "yes," provide the name of company, type of permit, type of action, year of action and state.** _____	Yes ☐ No ☐

7. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? **If "yes," provide company name, type of permit, permit number and state where licensed.**	Yes ☐ No ☐
8. Have you ever been convicted of, or pleaded guilty or nolo contender/no contest to, any crime, in any state, the United States or its territories, a military court, or any foreign country? Include any felony or misdemeanor offense, and any infraction involving drugs or alcohol with a fine of $500 or more. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 et seq., or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210 et seq., or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction. Failure to answer truthfully and completely may result in the denial of your application. NOTE: You may answer "NO" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions more than two years old on the date you submit your application for violations of California Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or California Health and Safety Code section 11360, subdivision (b); and (4) infractions or traffic violations with a fine of less than $500 that do not involve drugs or alcohol. You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident). If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. You may wish to provide the following information in order to assist in the processing of your application: 1) certified copies of the arresting agency report; 2) certified copies of the court documents; 3) and a descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required. **Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.**	Yes ☐ No ☐

Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)

APPLICANTS MUST ANSWER THE FOLLOWING QUESTIONS.

Ownership Information - For any affirmative answer, attach a statement of explanation including company name, type of license, license number, and identify the state, territory, foreign country, or other jurisdiction where licensed. 1. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator, or medical director on a license to conduct a pharmacy, wholesaler, third-party logistics provider, or any other entity licensed in any state, territory, foreign country, or other jurisdiction?	1. Yes ☐ No ☐
Disciplinary History - The following questions pertain to a license sought or held in any state, territory, foreign country, or other jurisdiction. For any affirmative answer, attach a statement of explanation including type of license, license number, type of action, date of action, and identify the state, territory, foreign country, or other jurisdiction. 2. Have you ever had an application for pharmacy technician, intern pharmacist, pharmacist, any type of designated representative, and/or any other professional or vocational license or registration denied? 3. Have you ever had a pharmacy technician, intern pharmacist, pharmacist, any type of designated representative, and/or any other professional or vocational license or registration suspended, revoked, placed on probation, or had other disciplinary action taken against it? 4. Have you ever had a pharmacy, wholesaler, third-party logistics provider, and/or any other entity license denied, suspended, revoked, placed on probation, or had other disciplinary action taken?	2. Yes ☐ No ☐ 3. Yes ☐ No ☐ 4. Yes ☐ No ☐
Practice Impairment or Limitation The board will make an individualized assessment of the nature, the severity, and the duration of the risks associated with any identified condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether the applicant is not qualified for licensure. If the board is unable to make a determination based on the information provided, the board may require an applicant to be examined by one or more physicians or psychologists, at the board's cost, to obtain an independent evaluation of whether the applicant is able to safely practice despite the mental illness or physical illness affecting competency. A copy of any independent evaluation would be provided to the applicant. **For any affirmative answer, attach a statement of explanation.** 5. Have you ever been diagnosed with an emotional, mental, or behavioral disorder that may impair your ability to practice safely? 6. Have you ever been diagnosed with a physical condition that may impair your ability to practice safely? 7. Do you have any other condition that may in any way impair or limit your ability to practice safely? 8. Have you ever participated in, been enrolled in, or required to enter into any drug, alcohol, or substance abuse recovery program? 9. If you answered "Yes" to questions 5 through 8 above, have you ever received treatment or participated in any program that improves your ability to practice safely?	5. Yes ☐ No ☐ 6. Yes ☐ No ☐ 7. Yes ☐ No ☐ 8. Yes ☐ No ☐ 9. Yes ☐ No ☐ N/A ☐

Criminal Record History

Applicants who answer "**No"** to the questions below, but have a previous conviction or plea, may have their application denied for knowingly falsifying the application. If in doubt as to whether a conviction should be disclosed, it is best to disclose the conviction on the application.

For each conviction, you must submit with the application: 1) certified copies of the arresting agency records, 2) certified copies of the court documents (court docket), 3) a signed and dated descriptive explanation of the circumstances surrounding the conviction (i.e., dates and location of the incident and all circumstances surrounding the incident), and 4) proof of compliance with probation or parole. If the documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is recommended. In addition, you may submit evidence of rehabilitation or any information you deem appropriate.

10. Have you EVER been convicted of, or pleaded guilty or nolo contendere/no contest to, ANY crime, in any state, the United States or its territories, a military court, or any foreign country? 10. Yes ☐ No ☐

This includes any felony or misdemeanor offense and any infraction. You must disclose a conviction even if it was: (1) later dismissed or expunged pursuant to Penal Code section 1203.4 or an equivalent release from penalties and disabilities provision from a non-California jurisdiction, or (2) later dismissed or expunged pursuant to Penal Code section 1210.1 or an equivalent post-conviction drug treatment diversion dismissal provision from a non-California jurisdiction.

NOTE: You may answer "No" regarding, and need not disclose, any of the following: (1) criminal matters adjudicated in juvenile court; (2) criminal charges dismissed or expunged pursuant to Penal Code section 1000.4 or an equivalent deferred entry of judgment provision from a non-California jurisdiction; (3) convictions for violations of Health and Safety Code section 11357, subdivisions (b), (c), (d), or (e), or Health and Safety Code section 11360, subdivision (b), that are more than two years old on the date you sign your application; and (4) traffic violations that do not involve drugs or alcohol.

Arrest Date	Conviction Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)

11. Is any criminal action pending against you, or are you currently awaiting judgement and sentencing following entry of a plea or jury verdict? 11. Yes ☐ No ☐

Arrest Date	Violation(s)	Case #	Court of Jurisdiction (Full Name and Address)

APPLICANT AFFIDAVIT

You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete. Falsification of the information on this application may constitute grounds for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being deemed ~~rejected as~~ incomplete, including failing to provide a statement of explanation for any affirmative answers. The board must receive your application within 60 days of your signature below.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form pursuant to Business and Professions Code sections 30 and 4000 and following and California Code of Regulations title 16, division 17. ~~The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code sections 4200 and 4202 and Title 16 California Code of Regulations section 1793.5 and 1793.6.~~ The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

~~**Mandatory Submission.** Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.~~

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by law ~~Civil Code Section 1798.40~~.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Records Act request (Government Code section 6250 and following), as allowed by the Information Practices Act (Civil Code section 1798 and following);
- To another government agency as required or permitted by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

***Address of Record**: Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 and following ~~et seq.~~) and the Public Records Act (Government Code section 6250 and following ~~et seq.~~) and will be ~~placed~~ available on the Internet. This is where the board will mail all official correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

****Disclosure of your U.S. social security ~~account~~ number or individual taxpayer identification number (ITIN) is mandatory.** Section 30 of the Business and Professions Code, section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security ~~account~~ number or individual taxpayer identification number. Your social security ~~account~~ number or individual taxpayer identification number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security ~~account~~ number or individual taxpayer identification number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

NOTICE: The State Board of Equalization and the Franchise Tax Board may share taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if your state tax obligation is not paid.

MANDATORY REPORTER

Under California law, each person licensed by the California State Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect ~~purposes~~ laws. California Penal Code section 11166 and Welfare and Institutions Code section 15630 require that all mandated reporters make a report to an agency specified in Penal Code section 11165.9 and Welfare and Institutions Code section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder, and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of ~~Section 11166 and Section 15630~~ the laws above is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars ($1,000), or by both that imprisonment and fine. For further details about these requirements, ~~consult~~ refer to Penal Code section 11164 and Welfare and Institutions Code section 15630, and ~~subsequent~~ following sections.

APPLICANT AFFIDAVIT

~~(must be signed and dated by the applicant)~~ Must be signed and dated by the applicant. Must be received by the board within 60 days.

I, _____ , hereby attest to the fact that I am the applicant whose signature appears
(Print Full Legal Name)

below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers, and representations made in this application, including all supplementary statements. I understand that my application may be denied, or any license disciplined, for fraud or misrepresentation.

_____ _____
Original Signature of Applicant Date

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

Instructions: ~~This form must be completed by the university, college, school, or pharmacist.~~ The Director, Registrar, or Pharmacist must complete and sign this form certifying the identified individual has met the specified requirements in section 4202 of the Business and Professions Code and, if applicable, board regulations. ~~(The person who must complete this form will depend on how the applicant is qualifying).~~ All dates must include the month, day, and year ~~in order~~ for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

☐ Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists (ASHP) as specified in Title 16, California Code of Regulations section 1793.6(a) on _____/_____/_____
(completion date must be included)

☐ Completed a training course that provided at least 240 hours of instruction as specified in Title 16, California Code of Regulations section 1793.6(c) on _____/_____/_____
(completion date must be included)

☐ Completed an Associate Degree in Pharmacy Technology and was conferred on ~~her/him on~~ _____/_____/_____
(graduation date must be included)

☐ Graduated from a school of pharmacy accredited or granted candidate status by the ~~American Council on Pharmaceutical Education~~ Accreditation Council for Pharmacy Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on ~~her/him on~~ _____/_____/_____
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: _____/_____/_____

Affix school seal here.

OR

Attach a business card of the pharmacist who provided the training pursuant to section 1793.6(c) of Title 16, ~~of the~~ California Code of Regulations here. The pharmacist's license number shall be listed.

Name of Pharmacy Technician Training Program ~~University, College,~~ or School of Pharmacy ~~Name~~: _____

Address: _____

_____

Print Name of Director, Registrar, or Pharmacist: _____

Phone Number: _____

Email: _____

Attachment 6

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~~ E~~e~~ach 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.

California State Board of Pharmacy
1625 N. Market Blvd., Suite N219
Sacramento, California 95834
(916) 574-7900 FAX (916) 574-8618

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER ~~DANGEROUS DRUGS & DANGEROUS DEVICES~~ SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 21.

All references to "drugs" throughout this self-assessment refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (B&PC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS= Wholesaler
- 3PL= Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR includes Designated Representative, Designated Representative-3PL and Designated Representative Reverse Distributor

~~Wholesaler~~ Licensed Premises Name: _____

Address: _____

Phone: _____

~~Wholesaler~~ Licensed Premises E-mail address: _____

Ownership: Please mark one

sole owner partnership corporation LLC

non- licensed owner Other (please specify) _____

CA ~~Wholesaler Permit~~ License#_____ Expiration Date_____

Other ~~Permit~~ License #_____ Expiration Date_____
(Use additional sheets if needed.)

DEA Registration #_____ Expiration Date_____

VAWD Accreditation # _____ Expiration Date_____

Date of most recent DEA Inventory _____

Hours: Weekdays _____Sat_____ Sun_____ 24 Hours

~~Designated representative-in-charge (~~DRIC~~)~~ / RM ~~pharmacist (RPH)~~ _____

DR~~IC~~ License # / RPH License #_____ Expiration Date_____

Website Address (optional):_____

Licensed ~~Wholesaler~~ Staff (~~designated representative (~~DR~~)~~, pharmacist):

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

Please mark the appropriate box for each question. If "NO," enter an explanation on the "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, add additional sheets.

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current ~~wholesaler~~ ~~permit~~ license for this business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (B~~&~~PC 4160[a][c][f]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Have you established and do you maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees and a brief statement of the capacity in which they are employed. (B~~&~~PC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly

☐ ☐ ☐ 2.1.2. Are well ventilated

☐ ☐ ☐ 2.1.3. Are free from rodents and insects

☐ ☐ ☐ 2.1.4. Are adequately lit

☐ ☐ ☐ 2.1.5. Have plumbing in good repair

☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards. (The standards for various drugs may differ, see USP 1990 22nd Edition) (CCR 1780[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, or any drug returned under conditions that cast doubt on the drugs safety, identity, strength, quality or purity? (CCR 1780[e])

Yes No N/A

☐ ☐ ☐ 2.3. Are dangerous drugs and dangerous devices stored in a secured and locked area? (CCR 1780[a])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs are stored limited to authorized personnel? (CCR 1780[c])

List personnel with keys to the area(s) where drugs are stored (list by name or job title):

_____

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.5. Does this business operate only when a ~~designated representative~~ DR or pharmacist is on the premises? (CCR 1781)

2.6. The ~~wholesaler~~ licensed premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry. (CCR 1780[c][1]).

☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit (CCR 1780[c][3]).

☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c][2]).

Explain how your security system complies with these requirements.

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for pharmacies, drug wholesalers, third-party logistics provider, manufacturers and others, by receiving, inventorying and managing the disposition of outdated or nonsalable drugs? (B&PC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.8. The facility is subscribed to the board's email ~~e-mail~~ notifications. (B&PC 4013)

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~Yes No N/A~~

☐ ☐ ☐ 2.9. The facility receives the board's email ~~e-mail~~ notifications through the owner's electronic notice system. (B&PC 4013[c])

Date Last Notification Received: _____

Email ~~E-mail~~ address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the ~~designated representative-in-charge~~ DRIC/RM are both equally responsible for maintenance of the records and inventory. (B&PC 4081[b])

☐ ☐ ☐ 3.2. Is the ~~designated representative-in-charge~~ DRIC/RM at least 18 years of age and is responsible for the ~~wholesaler's~~ compliance with all state and federal laws for the wholesale distribution of drugs? The ~~designated representative-in-charge~~ DRIC/RM may be a pharmacist. (B&PC 4160[d], 4053.1~~(~~[b]~~)~~)

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the ~~designated representative-in-charge~~ DRIC/RM ~~or pharmacist~~. (B&PC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must identify and notify the board of the appointment of a new ~~designated representative-in-charge~~ DRIC/RM within 30 days of the termination of the former ~~designated representative-in-charge~~ DRIC/RM. (B&PC 4160[d], 4160 [e], 4331[c]) The appropriate form for this notification is ~~a "Change of Designated Representative-in-Charge," which is~~ available on the board's website.

~~Yes No N/A~~

☐ ☐ ☐ 3.5. The ~~designated representative-in-charge~~ DRIC/RM who ends his or her employment at a ~~wholesaler~~ licensed premises, must notify the board within 30 days. (B&PC 4305.5[c], 4101[b]). This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

~~4. Designated Representative/Pharmacist~~

~~Yes No N/A~~

~~☐ ☐ ☐ If a designated representative or pharmacist changes his/her name or personal address of record, he/she must notify the board in writing within 30 days. (B&PC 4100, CCR 1704)~~

~~CORRECTIVE ACTION OR ACTION PLAN _____~~

~~_____~~

5. Ordering Drugs by this Business for Future Sale/Transfer or Trade

Yes No N/A

☐ ☐ ☐ 5.1. Are drugs ordered only from a business licensed by this board or from a licensed manufacturer? (B&PC 4163[b], 4169)

☐ ☐ ☐ 5.2. If drugs are returned to your premises by a business that originally purchased the drugs from you, do you document the return with an acquisition record for your business and a disposition record for the business returning the drugs? (B&PC 4081, 4332)

☐ ☐ ☐ 5.3. For license verification, the ~~wholesaler~~ licensed premises may use the licensing information displayed on the board's Internet web site. (B&PC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

6. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 6.1. When drugs are received by your business, are they delivered to the licensed ~~wholesale~~ premises, and received by and signed for only by a ~~designated representative~~ DR or a pharmacist? (~~B & P~~ BPC 4059.5[a])

☐ ☐ ☐ 6.2. When drugs are received by your business, are the outside containers visibly inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1])

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section ~~11~~ 12 of this document.

7. Drug Stock

Yes No N/A

☐ ☐ ☐ 7.1. Is all drug stock open for inspection during regular business hours? (B&PC 4081[a])

☐ ☐ ☐ 7.2. Are all drugs you order maintained in a secure manner at your licensed ~~wholesale~~ premises? You cannot order, obtain or purchase drugs that you are not able to store on your licensed premises. (B&PC 4167)

☐ ☐ ☐ 7.3. Do all drugs you sell conform to the standards and tests for quality and strength provided in the latest edition of United States Pharmacopoeia or Sherman Food Drug and Cosmetic Act? (B&PC 4342[a])

☐ ☐ ☐ 7.4. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired and may not be distributed. (CCR 1718.1)

☐ ☐ ☐ 7.5. Are outdated, damaged, deteriorated or misbranded drugs held in a quarantine area physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

☐ ☐ ☐ 7.6. Are drugs with the outer or secondary seal broken, or partially used or returned drugs held in a quarantine area and physically separated from other drugs until returned to the supplier or sent for destruction? (CCR 1780[e], CFR 1307.21)

Yes No N/A

☐ ☐ ☐ 7.7. When the conditions under which drugs were returned to your premises cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and either returned to your supplier or destroyed? If testing or investigation proves the drugs meet USP standards, the drugs may be returned to normal stock. (CCR 1780[e], CFR 1307.21)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

8. Sale or Transfer of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 8.1. Are drugs sold only to businesses or persons licensed by this board, licensed by a prescriber board, licensed as a manufacturer, or to a licensed health care entity authorized to receive drugs?

8.2. Describe how you verify a business or person is appropriately licensed. (B&PC 4059.5[a], [b],[d], B&PC 4169)

_____

_____

8.3. List any businesses or individuals that order drugs from you that are not licensed according to the list above:

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 8.4. Are drugs only furnished by your business to an authorized person? (B&PC 4163[a]) Note: An authorized person can be a business or natural person.

8.5. Does your business only receive drugs from a pharmacy if:

☐ ☐ ☐ 8.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 8.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 8.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (B&PC 4126.5[a])

~~Yes No N/A~~

☐ ☐ ☐ 8.6 Are all drugs that are purchased from another business or that are sold, traded or transferred by your business:

☐ ☐ ☐ 8.6.1. transacted with a business licensed with this board as a ~~wholesaler~~ WLS/3PL or pharmacy?

☐ ☐ ☐ 8.6.2. free of adulteration as defined by the CA Health & Safety Code section 111250?

☐ ☐ ☐ 8.6.3. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 8.6.4. **confirmed** to not be beyond their use date (expired drugs)? (B&PC 4169)

8.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, traded or transferred by this business in the past 2 years.

_____

_____

8.8. If your business sells, transfers, or delivers dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 8.8.1. comply with all CA pharmacy laws related to the distribution of drugs?

☐ ☐ ☐ 8.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 8.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of drugs?

☐ ☐ ☐ 8.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs?

8.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or dangerous devices. (B&PC 4059.5[e])

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ ~~8.10. When you are not an authorized distributor for a drug, a pedigree must accompany the product when sold, traded, or transferred (Prescription Drug Marketing Act of 1987).~~

~~Yes No N/A~~

☐ ☐ ☐ 8.10. For products included in the Drug Supply Chain Security Act, transaction histories, transaction information, and transaction statements are provided to authorized trading partners when the products are sold, traded, or transferred. (21 USC 360eee-1[c])

☐ ☐ ☐ 8.11. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (B&PC 4380)

~~Yes No N/A~~

☐ ☐ ☐ 8.12. Does your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (B&PC 4341, B&PC 651, CCR 1766)

☐ ☐ ☐ 8.13. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (B&PC 650)

_____

_____

☐ ☐ ☐ 8.14. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (B&PC 4066, CFR 1301.25)

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

9. Donations of Medication to Voluntary Drug Repository and Distribution Programs (H&SC 150200, 150203, 150204)

Yes No N/A

☐☐☐ 9.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (H&SC 150203, 150204)

☐☐☐ 9.2. No controlled substances shall be donated. (H&SC 150204[c][1])

~~**Yes No N/A**~~

☐☐☐ 9.3. Drugs that are donated are unused, unexpired and meet the following requirements: (H&SC 150204[c])

- ☐ 9.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (H&SC 150204[c][2])
- ☐ 9.3.2. Have never been in the possession of a patient or individual member of the public. (H&SC 150204[c][3])
- ☐ 9.3.3. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (H&SC 105204[d])
- ☐ 9.3.4. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (H&SC 150204[m])

10. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Before you ship drugs to a purchaser, do you inspect the shipment to assure the drugs were not damaged while stored by your business? (CCR 1780[d][2])

☐ ☐ ☐ 10.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (B&PC 4166[a])

10.3. List the common carriers (shipping or delivery companies) you use.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

11. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 11.1. Are all drugs ordered by a pharmacy or another wholesaler are delivered to the address of the buyer's licensed premises and signed for and received by a pharmacist or designated representative where allowed? (B&PC 4059.5[a])

~~Yes No N/A~~

☐ ☐ ☐ 11.2. Are all drugs ordered by a manufacturer or prescriber delivered to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (B&PC 4059.5[d])

☐ ☐ ☐ 11.3. All drugs delivered to a hospital are delivered either to the pharmacy premises or to a central receiving area within the hospital. (B&PC 4059.5[c])

☐ ☐ ☐ 11.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility, indicating the name and amount of each dangerous drug delivered. (B&PC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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12. **Controlled Substances**

Yes No N/A

☐ ☐ ☐ 12.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 12.2. Are DEA requirements for storage of Schedule II controlled substances being met? (specific requirements are listed in CFR 1301.72[a])

☐ ☐ ☐ 12.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (specific requirements are listed in CFR 1301.72[b])

☐ ☐ ☐ 12.4. Is a DEA inventory completed by your business every two years for all schedules (II - V) of controlled substances? (CFR 1304.11[a],[c],[e])

☐ ☐ ☐ 12.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780(f)[2])

☐ ☐ ☐ 12.6. Does the biennial inventory record document that the inventory was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 12.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

12.7.1. List the individuals at this location authorized by power of attorney to order controlled substances.

_____

_____

~~Yes No N/A~~

☐ ☐ ☐ 12.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.90)

☐ ☐ ☐ 12.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 12.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (~~H & S~~ HSC 11153.5[a],[b],[c])

☐ ☐ ☐ 12.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances (CFR 1301.74[f])

☐ ☐ ☐ 12.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74 [a])

12.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances

_____

_____

☐ ☐ ☐ 12.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (CFR 1301.74[f])

☐ ☐ ☐ 12.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

☐ ☐ ☐ 12.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

~~Yes No N/A~~

☐ ☐ ☐ 12.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 from? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13 [b])

☐ ☐ ☐ 12.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 12.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☐ 12.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 12.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 12.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 12.23. Are all records of purchase and sale for all schedules of controlled substances for your business kept on your licensed business premises for 3 years from the making? (B&PC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a] [b], and H&SC 11252, 11253~~, 1304.03~~)

☐ ☐ ☐ 12.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04 [f][1])

☐ ☐ ☐ 12.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04 [f][2])

☐ ☐ ☐ 12.26. Before your business distributes carfentanil etorphine HCL and or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.75[g], 1305.16[b])

☐ ☐ ☐ 12.27. Do you separate records for the sale of carfentanil etorphine hydrochloride and or diprenorphine from all other records? (CFR 1305.17[d])

~~Yes No N/A~~

☐ ☐ ☐ 12.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 12.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

13. Policies and Procedures

13.1. Does this business maintain and adhere to policies and procedures for the following: (CCR 1780[f])

Yes No N/A

☐ ☐ ☐ 13.1.1. Receipt of drugs

☐ ☐ ☐ 13.1.2. Security of drugs

☐ ☐ ☐ 13.1.3. Storage of drugs-(including maintaining records to document proper storage)

☐ ☐ ☐ 13.1.4. Inventory of drug-(including correcting inaccuracies in inventories)

☐ ☐ ☐ 13.1.5. Distributing drugs

☐ ☐ ☐ 13.1.6. Identifying, recording and reporting theft or losses

☐ ☐ ☐ 13.1.7. Correcting errors and inaccuracies in inventories

Physically quarantining and separating:

☐ ☐ ☐ 13.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs

☐ ☐ ☐ 13.1.9. drugs that have been partially used~~?~~

☐ ☐ ☐ 13.1.10. drugs where the outer or secondary seals on the container have been broken

☐ ☐ ☐ 13.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

☐ ☐ ☐ 13.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity (CCR 1780[e],[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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14. Training

Yes No N/A

☐ ☐ ☐ 14.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

_____

CORRECTIVE ACTION OR ACTION PLAN _____

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15. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 15.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (B~~&~~PC 4054, ~~)(~~4059[c]) If so, please complete the next 4 questions, if not proceed to Section ~~15.~~ 16.

☐ ☐ ☐ 15.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (B&PC 4059[d])

☐ ☐ ☐ 15.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a designated representative or a pharmacist? Note: refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☐ 15.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the designated representative or pharmacist responsible for distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of

drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

☐ ☐ ☐ 15.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

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16. Record Keeping Requirements

Yes No N/A

☐ ☐ ☐ 16.1. Does your business' sales record for drugs include date of sale, your business name and address, the business name and address of the buyer, and the names and quantities of the drugs sold? (B&PC 4059[b])

☐ ☐ ☐ 16.2.~~1.~~ Does your business maintain transaction histories, transaction information, and transaction statements for products included in the Drug Supply Chain Security Act? (21 USC 360eee-1[c])

☐ ☐ ☐ 16.3.~~2.~~ Are purchase and sales records for all transactions retained on your licensed premises for 3 years from the date of making? (B&PC 4059.5 [a], 4081~~[a]~~, 4105[c], ~~4081,~~ 4332~~, 4059.5[a]~~) ~~Note: A drug pedigree is considered to be a part of the records of purchase and sale and must be retained for three years from the making.~~

☐ ☐ ☐ 16.4.~~3.~~ Are all purchase and sales records retained in a readily retrievable form? (B&PC 4105[a])

☐ ☐ ☐ 16.5.~~4.~~ Is a current accurate inventory maintained for all dangerous drugs? (B&PC 4081, 4332, CCR 1718)

☐ ☐ ☐ 16.6.~~5.~~ If you temporarily remove purchase or sales records from your business, does your business retain on your licensed premises at all times, a photocopy of each record temporarily removed? (B&PC 4105[b])

☐ ☐ ☐ 16.7.~~6.~~ Are required records stored off-site only if a board issued written waiver has been granted?

16.8.~~7.~~ If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below. (CCR 1707[a])

Date _____ Address_____

☐ ☐ ☐ 16.9.~~8.~~ Is an off-site written waiver in place and is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 16.10.~~9.~~ If an off-site written waiver is in place, are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2])

☐ ☐ ☐ 16.11.~~10.~~ Can the records that are retained electronically be produced immediately in hard copy form by any designated representative, if the designated representative-in-charge is not present? (B & P 4105[d])

☐ ☐ ☐ 16.12.~~11.~~ Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][4])

~~Yes No N/A~~

☐ ☐ ☐ 16.13.~~12.~~ Has this licensed premises, or the designated representative-in-charge/responsible manager ~~or pharmacist~~, been cited, fined or disciplined by this board or any other state or federal agency within the last 3 years? If so list each incident with a brief explanation (B&PC 4162[a][4]):

_____

_____

☐ ☐ ☐ 16.14.~~13.~~ Has the licensed premises received any orders of correction from this board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (B&PC 4083)

☐ ☐ ☐ 16.15.~~14.~~ Has this ~~business~~ licensed premises received a letter of admonishment from this board? A copy must be retained on the premises for 3 years from the date of issue. (B&PC 4315[e])

☐ ☐ ☐ 16.16.~~15.~~ If this ~~business~~ licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling controlled substances – these additional requirements are in Section 12 of this document.

17. Reporting Requirements to the Board

Yes No N/A

☐ ☐ ☐ 17.1. A designated representative-in-charge/responsible manager who terminates employment at this business, must notify the board within 30 days of the termination (B&PC 4101[b], 4305.5[c].

☐ ☐ ☐ 17.2. The owner must report to the board within 30 days the termination of the designated representative-in-charge or responsible manager ~~or pharmacist~~ (B&PC 4305.5[a])

☐ ☐ ☐ 17.3. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 17.4. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

~~Yes No N/A~~

☐ ☐ ☐ 17.5. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 17.6. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (B&PC 4201[i], CCR 1709[b])

☐ ☐ ☐ 17.7. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (B&PC 4164[a])

☐ ☐ ☐ 17.8. ~~Effective January 1, 2006 your~~ The wholesaler ~~business will develop and~~ maintains a tracking system for individual sales of dangerous drugs at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long term care facilities
2. identify purchases of any dangerous drugs at preferential or contract prices
3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (B&PC 4164[b])

☐ ☐ ☐ 17.9. I understand that this ~~wholesaler~~ license is not transferable to a new owner. A change of ownership must be reported to this board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (B&PC 4201[g])

☐ ☐ ☐ 17.10. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 17.11. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

☐ ☐ ☐ 17.12. Upon discovery, the business notifies the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler as required by B&PC 4169.1

CORRECTIVE ACTION OR ACTION PLAN _____

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18. Additional Licenses/Permits Required

18.1. List all licenses and permits required to conduct this business, including local business licenses, ~~wholesale~~ licenses held in other states, permits or licenses required by foreign countries or other entities (B&PC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER ~~PHARMACIST~~ CERTIFICATION:

I, (please print) _____, ~~DRIC# / RPH #~~ _____ hereby certify that I have completed the self-assessment of this ~~wholesale business~~ licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager ~~pharmacist (RPH)~~. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager~~Pharmacist (RPH)~~

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE OFFICER:

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~~ premises license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov ~~(see *Laws and Regulations*)~~, at the California State Law Library, or at other libraries or Internet Web sites:

California Code of Regulations (CCR), Title 16, unless otherwise noted

Business and Professions Code (B&PC), Chapter 9, Division 2, unless otherwise noted

Health and Safety Code (H&SC), Division 10, Uniform Controlled Substances Act

Health and Safety Code (H&SC), Division 104, Part 5, Sherman Food, Drug and Cosmetic Laws

United States Code of Federal Regulations (CFR), Title 21, Chapter II, Part 1300, Drug Enforcement Administration, Food and Drugs and Codified Controlled Substances Act (CSA)

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~~Phone: (916) 263-2610~~
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~~http://www.vmb.ca.gov~~

~~Theft Reports or Diversion: (415) 436-7900~~

~~***Federal Agencies:***~~

~~**Food and Drug Administration – Industry Compliance**~~
~~http://www.fda.gov/oc/industry/centerlinks.html#drugs~~

~~The **Drug Enforcement Administration** may be contacted at:~~

~~**DEA Website:**~~
~~http://www.deadiversion.usdoj.gov~~
~~**Online Registration – New Applicants:**~~
~~http://www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms_new.htm~~
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~~www.deadiversion.usdoj.gov/drugreg/reg_apps/onlineforms.htm~~
~~**Registration Changes (Forms):**~~
~~http://www.deadiversion.usdoj.gov/drugreg/change_requests/index.html~~
~~**Online DEA 106 Theft/Loss Reporting:**~~
~~https://www.deadiversion.usdoj.gov/webforms/app106Login.jsp~~
~~**Controlled Substance Ordering System (CSOS):**~~
~~http://www.deaecom.gov/~~

~~**DEA Registration Support (all of CA):**~~
~~(800) 882-9539~~

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~~255 East Temple Street, 20th Floor~~
~~Los Angeles, CA 90012~~
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~~Diversion or Investigation: (213) 621-6942~~

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~~San Francisco, CA 94102~~
~~Registration: (888) 304-3251~~

~~**DEA – Sacramento**~~
~~4328 Watt Avenue~~
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~~Registration: (888) 304-3251 or (415) 436-7900~~
~~Diversion or Investigation: (916) 480-7250~~

~~**DEA – Riverside**~~
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~~Oakland, CA 94612~~
~~Registration: (888) 304-3251~~
~~Diversion or Investigation: (510) 637-5600~~

~~**DEA – San Jose**~~
~~One North First Street, Suite 405~~
~~San Jose, CA 95113~~
~~Registration: (888) 304-3251~~
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~~**DEA – Redding**~~
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~~Redding, CA 96002~~
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Attachment 7

AMENDED IN SENATE JUNE 20, 2018

AMENDED IN ASSEMBLY APRIL 5, 2018

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL No. 1752

Introduced by Assembly Member Low

January 3, 2018

An act to amend Sections 11165 and 11165.1 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

AB 1752, as amended, Low. Controlled substances: CURES database.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the Department of Justice as soon as reasonably possible, but not more than 7 days after the date a controlled substance is dispensed.

This bill would add Schedule V controlled substances to the CURES database. The bill would require a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed. The bill would ~~change what information is required to be reported by deleting references to classification codes and adding the date of sale~~

~~of the prescription.~~ *additionally require the date of sale of the prescription, if applicable, to be reported.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. 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, 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 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, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, 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) 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 is 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, 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 of Justice as soon as reasonably possible, but not more than one working day 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, if applicable, 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.

(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.

~~(6)~~

(7) Number of refills ordered.

~~(7)~~

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

~~(8)~~

(9) Date of origin of the prescription.

~~(9)~~

(10) Date of dispensing of the prescription.

~~(10)~~

(11) Date of sale of the ~~prescription.~~ *prescription, 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.

SEC. 2. 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, Schedule IV, or Schedule V 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 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 care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which 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 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 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, 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, 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.

O

Amend Business & Professions Code Section 4200 Relating to the Examination Score Validity Period for the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(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 California Practice Standards and Jurisprudence Examination for ~~Pharmacists on or after January 1, 2004.~~ and satisfies one of the following:

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

(B) Has passed a version of the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.

(7) Has passed a version of the California Practice Standards and Jurisprudence Examination for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.

(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.

Establish an Advanced Pharmacy Technician (APT) Licensure Program

Proposed BPC 4038.5 (Definition)

"Advanced Pharmacy Technician" means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.6. Such an individual may also perform nondiscretionary tasks as specified in Section 4115.

Proposed 4115.6

(a) In a pharmacy as defined in Business and Professions Code Section 4037, a licensed advanced pharmacy technician may perform these technical tasks:

(1) Verify the accuracy of the typed prescription label and verify the filling of a prescription container by confirming that the medication and quantity reflected on the label accurately reflects the container's contents for drug orders that previously have been reviewed and approved by a pharmacist. A pharmacist is responsible for performing all reviews and verification requiring professional judgement including drug utilization review.

(2) Except for controlled substances, accept new or seek clarification about a prescription from a prescriber's office unless the prescription requires the professional judgment of a pharmacist.

(3) Inquire about the intended purpose or indication for prescribed medication on verbal orders received from a prescriber's office.

(4) Except for controlled substances, transfer a prescription to another pharmacy.

(5) Receive the transfer of a prescription from another pharmacy.

(6) Provide the technical task of administration of an immunization under the supervision of a pharmacist trained in immunizations.

(7) Compile a medication list by interviewing patient.

(8) Perform other technical tasks including taking patient's blood pressure or temperature.

(b) A pharmacy as used in subdivision (a) may use the services of an advanced pharmacy technician if all the following conditions are met:

(1) The duties authorized in subdivision (a) are performed under the supervision of a pharmacist and are specified in the pharmacy's policies and procedures.

(2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).

(3) A pharmacist shall personally provide all new prescription medications directly to the patient or patient's agent, and must provide patient information consistent with the provisions of Section 4052 (a) (8) or other clinical services.

(4) A pharmacist shall provide other clinical services beyond required consultation.

(5) A record is created identifying the personnel responsible for the preparing and dispensing of the prescription medication.

Proposed BCP 4211 (Licensing Requirement)

(a) The board may issue an advanced pharmacy technician license to an individual who meets all the following requirements:

(1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,

(2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).

(3) Has obtained a minimum of an associate's degree in pharmacy technology, obtained a bachelor's degree, or higher or completed a board approved training program.

(4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a pharmacy.

(5) Has passed an advanced pharmacy technician examination.

(b) As an alternative to the requirements in subdivision (a), has graduated from a school of pharmacy recognized by the board.

(c) A license issued pursuant to this section shall be valid for two years.

Establish an Advanced Hospital Pharmacy Technician (AHT) Licensure Program

Proposed BPC 4038.6

"Advanced Hospital Pharmacy Technician" means an individual licensed by the board who is authorized to perform technical pharmacy tasks as authorized in Section 4115.7.

Proposed 4115.7

(a) In a hospital pharmacy, licensed advanced hospital pharmacy technician may perform the nondiscretionary tasks authorized in Section 4115 in addition to the following technical tasks under the general direction of a pharmacist:

(1) Package emergency supplies for use in the health care facility.

(2) Seal emergency containers for use in health care facility.

(3) Prepare and seal drug kits for use in the health care facility.

(4) Perform unit inspections of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in-charge and the director or chief executive officer of the health facility in accordance with the health care facility's policies and procedures;

(5) Verify the accuracy of a pharmacy technician's filling of floor and ward stock and unit dose distribution systems for hospital patient orders that have been previously reviewed and approved by a licensed pharmacist.

(6) Other technical tasks deemed appropriate by the board.

(b) A hospital pharmacy may use the services of an advanced hospital pharmacy technician if all of the following conditions are met:

(1) The duties authorized in (a) are performed under general direction of a pharmacist and are specified in the hospital pharmacy's policies and procedures

(2) The pharmacist-in-charge is responsible for ongoing evaluation of the performance of personnel as authorized in subdivision (a).

(3) Pharmacists are deployed to the inpatient care setting to provide clinical services.

Proposed BCP 4211.1

(a) The board may issue an advanced hospital pharmacy technician license to an individual who meets all the following requirements:

(1) Holds an active pharmacy technician license issued pursuant to this chapter that is in good standing,

(2) Possesses a certification issued by a pharmacy technician certifying program as defined in Section 4202(a)(4).

(3) Has obtained a minimum of an associate's degree in pharmacy technology, obtained a bachelor's degree, or higher or completed a board-approved training program.

(4) Has obtained 3,000 hours of experience performing the duties of a licensed pharmacy technician in a hospital pharmacy.

(5) Has passed an advanced pharmacy technician examination.

(b) As an alternative to the requirements in subdivision (a), the applicant has graduated from a school of pharmacy recognized by the board.

(c) A license issued pursuant to this section shall be valid for two years.

(d) Each person, upon application for licensure, 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.

Proposed BPC 4234.5

An advanced hospital pharmacy technician shall complete 20 hours of continuing education each renewal cycle. A licensee must also maintain certification as specified in Section 4211.1 (a)(2).

Proposal to Amend BPC 4400

[…]

(z) ~~This section shall become operative on July 1, 2017.~~ The fee for the advanced hospital pharmacy technician application and examination shall be $260 dollars and may be increased to $285. The fee for initial licensure and biennial renewal of as an advanced hospital pharmacy technician shall be $140 and may be increased to $195.

California State Board of Pharmacy
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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
DRAFT MINUTES

DATE:	July 24-25, 2018
LOCATION:	Department of Consumer Affairs – 1st Floor Hearing Room 1625 N. Market Blvd. Sacramento, CA 95834
BOARD MEMBERS PRESENT:	Victor Law, Licensee Member, President Gregory Lippe, Public Member, Vice President Allen Schaad, Licensee Member, Treasurer Maria Serpa, Licensee Member Deborah Veale, Licensee Member Ricardo Sanchez, Public Member Albert Wong, Licensee Member Stanley Weisser, Licensee Member Lavanza Butler, Licensee Member Shirley Kim, Public Member
BOARD MEMBERS NOT PRESENT:	Amjad Khan, Public Member Valerie Muñoz, Public Member Ryan Brooks, Public Member
STAFF PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Laura Hendricks, Staff Analyst Joshua Room, Supervising Deputy Attorney General

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Tuesday, July 24, 2018

I. Call to Order, Establishment of Quorum and General Announcements

President Law called the meeting to order at 12:40 p.m.

Board members present: Victor Law, Maria Serpa, Ricardo Sanchez, Deborah Veale, Allen Schaad, Gregory Lippe, Stanley Weisser, Shirley Kim, Lavanza Butler and Albert Wong. New board members Maria Serpa and Shirley Kim were sworn in by Chief Deputy Director Christopher Shultz.

Board member Weisser expressed his concern that a pharmacist may not have the time to study and pass the CPJE within a one-year timeframe. Board member Veale also expressed concern with creating additional requirements where none are needed.

Ms. Sodergren explained that there are approximately 30 cases where the board granted reinstatement with conditions that must be met before the license is reinstated (such as passing the CPJE). The challenge for staff is that the law does not currently specify how long someone has to complete the provisions for reinstatement, so the license reinstatement order remains open in perpetuity.

Ms. Sodergren also explained that when the board makes the decision to grant reinstatement they are relying on specific facts, such as completion of continuing education, letters of recommendation, sobriety, etc. As years pass the individual's circumstances many change (for example they may relapse) and the board may want to re-assess the situation before they allow the person to reinstate their license.

After further discussion the board decided not to vote on the committee's motion and instead refer the matter back to the Enforcement Committee for further discussion of the petition process and refinement of the proposal to create a timeframe to complete the provisions of reinstatement.

Pharmacist Steve Gray spoke in support of returning the item to the Enforcement Committee for further discussion.

c. Discussion and Consideration of Potential Statutory or Regulatory Amendments to Allow a Reverse Distributor to Accept Medications for Destruction in Limited Circumstances from a Previously Licensed Source

Chairperson Schaad explained that BPC section 4040.5 provides the definition of a reverse distributor as an entity that among other functions manages the disposition of outdated or nonsalable dangerous drugs or devices. (Note: A reverse distributor is licensed as a wholesaler and must comply with wholesaler. requirements unless a specific exemption is provided in the law.)

Chairperson Schaad also explained that BPC section 4163 specifies that a wholesaler can only acquire dangerous drugs and devices from a *licensed* source.

Chairperson Schaad reported that during the meeting the committee considered a request from staff to pursue a change in the law that would create a limited exception to allow for a reverse distributor to remove and arrange for the destruction of the drug products for a limited period of time after a license is cancelled, surrendered or terminated.

Chairperson Schaad stated that the committee made a motion to direct board staff to develop a proposal to allow for a reverse distributor to take back some medications.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Direct board staff to develop a proposal to allow for a reverse distributor to take back some medications.

Support: 9 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Khan				x
Kim			x	
Law	x			
Lippe	x			
Munoz				x
Sanchez	x			
Schaad	x			
Serpa	x			
Veale	x			
Weisser	x			
Wong	x			

d. Discussion and Consideration of Current Board Investigation Timeframes and Performance Measures

Chairperson Schaad stated that one of the committee's strategic goals is to implement processes to shorten the cycle times from the initial investigation to the resolution of cases. Below are benchmarks that are currently measured by board staff.

1. Assignment – Measures the time from the date the complaint is received or initiated.
2. Investigation – Measures the duration from the date the matter is assigned to the date the investigation report is submitted.
3. Review Times – Measures the time from the date the investigation is reviewed until review by the supervisor and second level review is completed.
4. Closure times – Measures the duration from the time the investigation report is reviewed until the case is closed.

Chairperson Schaad reported that the committee discussed the average time frames for the benchmarks provided as part of the meeting materials and discussed different way to report the data.

Chairperson Schaad stated that the committee did not take action on this item but will continue reviewing workload including investigation times.

There were no comments from the board or from the public.

e. Discussion of the Presentation of the Administrative Case Process and Case Resolution

23. Revenue and Renewal [4400 - 4409]

(Article 23 added by Stats. 1996, Ch. 890, Sec. 3.)

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). There shall be no annual renewal fee for a pharmacy owned by the California Department of Veterans Affairs.

(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). There shall be no annual renewal fee for a pharmacy owned by the California Department of Veterans Affairs.

(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, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

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

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

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

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

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

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

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

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

five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

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

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

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

(Amended (as added by Stats. 2016, Ch. 799, Sec. 26) by Stats. 2017, Ch. 623, Sec. 3.5. (SB 351) Effective January 1, 2018.)