Statutory Changes in Pharmacy Law

Unless otherwise noted, the provisions take effect <u>January 1, 2024</u>.

Underline text is added language, Strikethrough text is deleted language.

Business and Professions Code

115.4.

- (a) Notwithstanding any other law, on and after July 1, 2016, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant has served as an active duty member of the Armed Forces of the United States and was honorably discharged.
- (b) Notwithstanding any other law, on and after July 1, 2024, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that the applicant is an active duty member of a regular component of the Armed Forces of the United States enrolled in the United States Department of Defense SkillBridge program as authorized under Section 1143(e) of Title 10 of the United States Code.
- (b)(c) A board may adopt regulations necessary to administer this section. section in accordance with the provisions of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

115.8.

The Department of Consumer Affairs shall compile information on military, veteran, military and spouse licensure into an annual report for the Legislature, which shall be submitted in conformance with Section 9795 of the Government Code. The report shall include all of the following: following for each license type of each board:

- (a) The number of applications for a temporary license submitted by active duty servicemembers, veterans, or military spouses per calendar fiscal year, pursuant to Section 115.6.
- (b) The number of applications for expedited licenses submitted by veterans and active duty-received from honorably discharged military members and military spouses pursuant to Sections 115.4 and 115.5.
- (c) The number of licenses issued and denied per calendar fiscal year pursuant to Sections 115.4, 115.5, and 115.6.
- (d) The number of licenses issued pursuant to Section 115.6 that were suspended or revoked per calendar <u>fiscal</u> year.
- (e) The number of applications for waived renewal fees received and granted pursuant to Section 114.3 per calendar fiscal year.

(f) The average length of time between application and issuance of licenses pursuant to Sections 115.4, 115.5, and 115.6 per board and occupation. 115.6.

<u>805.9.</u>

- (a) A health facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code shall not deny staff privileges to, remove from medical staff, or restrict the staff privileges of a person licensed by a healing arts board in this state on the basis of a civil judgment, criminal conviction, or disciplinary action imposed by another state if that judgment, conviction, or disciplinary action is based solely on the application of another state's law that interferes with a person's right to receive sensitive services that would be lawful if provided in this state.
- (b) This section does not apply to a civil judgment, criminal conviction, or disciplinary action imposed in another state based upon conduct in another state that would subject a licensee to a similar claim, charge, or action under the laws of this state.
- (c) For purposes of this section:
- (1) "Healing arts board" means any board, division, or examining committee in the Department of Consumer Affairs that licenses or certifies health professionals.
- (2) "Sensitive services" has the same meaning as in Section 56.05 of the Civil Code.

<u>850.1.</u>

- (a) A healing arts board shall not deny an application for licensure or suspend, revoke, or otherwise impose discipline upon a licensee or health practitioner subject to this division on the basis of a civil judgment, criminal conviction, or disciplinary action in another state if that judgment, conviction, or disciplinary action is based solely on the application of another state's law that interferes with a person's right to receive sensitive services that would be lawful if provided in this state, regardless of the patient's location.
- (b) This section does not apply to a civil judgment, criminal conviction, or disciplinary action imposed in another state based upon conduct in another state that would subject an applicant, licensee, or health care practitioner subject to this division to a similar claim, charge, or action under the laws of this state.
- (c) For purposes of this section:
- (1) "Healing arts board" means any board, division, or examining committee in the Department of Consumer Affairs that licenses or certifies health professionals.
- (2) "Sensitive services" has the same meaning as in Section 56.05 of the Civil Code.

<u>852</u>.

The performance, recommendation, or provision of any legally protected health care activity, as defined in Section 1798.300 of the Civil Code, by a licensee or a health care practitioner subject to this division acting within their scope of practice, for a patient who

resides in a state in which the performance, recommendation, or provision of that legally protected health care activity is illegal, shall not, by itself, constitute professional misconduct under this division or any regulation governing the licensure, certification, or authorization of that licensee or practitioner, nor shall any license, certification, or authorization of a licensee or health care practitioner subject to this division be revoked, suspended, or annulled or otherwise subject to any other penalty or discipline provided in this division solely on the basis that the licensee or health care practitioner performed, recommended, or provided any legally protected health care activity for a patient who resides in a state in which the performance, recommendation, or provision of that legally protected health service is illegal.

4052.04.

- (a) In addition to the authority provided in Section 4052, a pharmacist may furnish COVID-19 oral therapeutics following a positive test for SARS-CoV-2, the virus that causes COVID-19.
- (b) Prior to furnishing COVID-19 oral therapeutics pursuant to subdivision (a), a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by the federal Food and Drug Administration in providing these patient care services.
- (c) A pharmacist who furnishes COVID-19 oral therapeutics shall notify the patient's primary care provider, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.
- (d) A pharmacist shall document, to the extent possible, the kind and amounts of COVID-19 oral therapeutics furnished pursuant to subdivision (a), as well as information regarding any testing services provided, in the patient's record in the record system maintained by the pharmacy. The records shall be maintained for three years and shall be available for inspection by all properly authorized personnel of the board.
- (e) For purposes of this section, "COVID-19 oral therapeutics" means drugs that are approved or authorized by the United States Food and Drug Administration for the treatment of COVID-19 and administered orally.
- (f) This section shall remain in effect only until January 1, 2025, and as of that date is repealed.

4071.1.

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's

authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500).

- (b) Nothing in this section shall This section does not reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.
- (c) No A dangerous drug or dangerous device shall <u>not</u> be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.
- (d)(1) A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures.
- (2)(A) A health care facility shall maintain a record of a pharmacist's verification of medication chart orders pursuant to this subdivision.
- (B) A record maintained pursuant to subparagraph (A) shall meet the same requirements as those described in Sections 4081 and 4105.

4110.5.

Notwithstanding any other provision of this article, a county, city and county, or special hospital authority described in Chapter 5 (commencing with Section 101850) or Chapter 5.5 (commencing with Section 101852) of Part 4 of Division 101 of the Health and Safety Code may operate a mobile unit one or more mobile units to provide prescription medication within its jurisdiction to those individuals without fixed addresses, individuals living in county-owned or city-and-county-owned or operated housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 9 of the Welfare and Institutions Code. The mobile unit shall be operated as an extension of a pharmacy license held by the county, city and county, or special hospital authority. The mobile pharmacist-in-charge shall determine the number of mobile units that are appropriate for a particular pharmacy license. The mobile unit may dispense prescription medication pursuant to a valid prescription, including a prescription of a physician who practices in the mobile unit, if the county, city and county, or special hospital authority meets all of the following requirements:

- (a) A licensed pharmacist is on the premises and the mobile unit is under the control and management of a pharmacist while prescription medications are being dispensed.
- (b) All activities of the pharmacist, including the furnishing of medication by the pharmacist, are consistent with Article 3 (commencing with Section 4050).

- (c) If a physician is practicing in the mobile unit, all prescribing by the physician meets the requirements of the Medical Practice Act (Chapter 5 (commencing with Section 2000)).
- (d)(1) The mobile unit does not carry or dispense controlled substances.
- (2) Paragraph (1) does not apply to Schedule III, Schedule IV, or Schedule V controlled substances approved by the United States Food and Drug Administration for the treatment of opioid use disorder. Any controlled substance for the treatment of opioid use disorder carried or dispensed in accordance with this paragraph shall be carried in reasonable quantities based on prescription volume and stored securely in the mobile pharmacy unit.
- (e) Dangerous drugs shall not be left in the mobile unit during the hours that the mobile unit is not in operation.
- (f) At least 30 days prior to commencing operation of a mobile unit, a A county, city and county, or special hospital authority shall notify the board of its intention to operate a mobile unit. Notice shall also be given to the board at least 30 days prior to unit as soon as possible, and no later than five business days after commencing operation of a mobile unit. A county, city and county, or special hospital authority shall also notify the board of its intention to discontinue operation of a mobile unit as soon as possible, and at least one business day before discontinuing operation of a mobile unit.

- (a) Every pharmacy shall designate a pharmacist-in-charge and, within 30 days thereof, shall notify the board in writing of the identity and license number of that pharmacist and the date he or she was they were designated.
- (b) The proposed pharmacist-in-charge shall be subject to approval by the board. The board shall not issue or renew a pharmacy license without identification of an approved pharmacist-in-charge for the pharmacy.
- (c)(1) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy.
- (2) The pharmacist-in-charge may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. If the pharmacist-in-charge is not available, a pharmacist on duty may adjust staffing according to workload if needed. This paragraph does not apply to facilities of the Department of Corrections and Rehabilitation.
- (d) (1) The pharmacist-in-charge or pharmacist on duty shall immediately notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. Store management shall take immediate and reasonable steps to address and resolve the conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel,

- or pharmacy staff. If the conditions are not resolved within 24 hours, the pharmacist-in-charge or pharmacist on duty shall ensure the board is timely notified.
- (2) Nothing in this subdivision shall be construed as presenting, limiting, or restraining a pharmacist-in-charge, pharmacy technician, or member of the public from communication with the board, including filing a complaint.
- (3) The conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff may include, but are not limited to, any of the following:
- (A) Workplace safety and health hazards that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- (B) Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
- (C) Vermin infestation that poses a risk to the safety or efficacy of medicine.
- (4) If, after receipt of a notice described in paragraph (1) and an evaluation and assessment of the relevant evidence, the executive officer has a reasonable belief that conditions within a pharmacy exist that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, the executive officer may, in conformance with the processes set forth in subdivisions (b) and (c) of Section 4127.3, issue an order to the pharmacy to immediately cease and desist those pharmacy operations that are affected by the conditions at issue. The cease and desist order shall remain in effect until either the executive officer determines the conditions that presented an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff have been abated or for no more than 30 days, whichever is earlier. Evidence of corrective actions taken shall be submitted by the pharmacy to correct the conditions at issue. Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct pursuant to Section 4156.
- (5) Nothing in this paragraph shall prevent the owner of the licensed premises from closing a pharmacy to mitigate against a perceived immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff.
- (6) Facilities of the Department of Corrections and Rehabilitation shall be exempt from this subdivision.
- (d)(e) Every pharmacy shall notify the board in writing, on a form designed by the board, within 30 days of the date when a pharmacist-in-charge ceases to act as the pharmacist-in-charge, and shall on the same form propose another pharmacist to take over as the pharmacist-in-charge. The proposed replacement pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.
- (e)(f) If a pharmacy is unable, in the exercise of reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer, or administrator of the pharmacy or the entity

that owns the pharmacy and who is actively involved in the management of the pharmacy on a daily basis, to act as the interim pharmacist-in-charge for a period not to exceed 120 days. The pharmacy, or the entity that owns the pharmacy, shall be prepared during normal business hours to provide a representative of the board with the name of the interim pharmacist-in-charge with documentation of the active involvement of the interim pharmacist-in-charge in the daily management of the pharmacy, and with documentation of the pharmacy's good faith efforts prior to naming the interim pharmacist-in-charge to obtain a permanent pharmacist-in-charge. By no later than 120 days following the identification of the interim pharmacist-in-charge, the pharmacy shall propose to the board the name of a pharmacist to serve as the permanent pharmacist-in-charge. The proposed permanent pharmacist-in-charge shall be subject to approval by the board. If disapproved, the pharmacy shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a pharmacist-in-charge is approved by the board.

<u>4113.1.</u>

- (a) Except as specified in subdivision (e), a community pharmacy licensed pursuant to this article shall report, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the board. A community pharmacy shall submit the report no later than 14 days following the date of discovery of the error. These reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code), except that the board may publish deidentified case summary information compiled from the data in the reports so long as deidentification is done in accordance with the requirements set forth in Section 164.514(b)(2) of Title 45 of the Code of Federal Regulations, and includes omitting the name of the reporting pharmacy. The community pharmacy shall maintain records demonstrating compliance with this requirement for three years and shall make these records immediately available at the request of an inspector. A medication error report made pursuant to this section shall not be subject to investigation, discipline, or other enforcement action by the board based solely on a report received pursuant to this section. However, if the board receives other information regarding the medication error independent of the medication error report, that information may serve as basis for discipline or other enforcement by the board.
- (b) Any entity approved by the board shall have experience with the analysis of medication errors that occur in the outpatient setting.
- (c) For purposes of this section, "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, but does not include facilities of the Department of Corrections and Rehabilitation.
- (d) For purposes of this section, "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration. A medication

error does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

(e) An outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event, as specified in subdivision (a), that has been reported to the State Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code. The State Department of Public Health may share a report with the California State Board of Pharmacy.

4113.6.

- (a) A chain community pharmacy subject to Section 4113.5 shall be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The board shall not take action against a pharmacy for a violation of this subdivision if any of the following conditions apply:
- (1) The pharmacist on duty waives the requirement in writing during specified hours based on workload need.
- (2) The pharmacy is open beyond normal business hours, which is before 8:00 am and after 7:00 pm. During the hours before 8:00 am and after 7:00 pm, the requirement shall not apply.
- (3) The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services such as immunizations, tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), or any other ancillary services provided by law, this paragraph does not apply.
- (b) Where staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on the outgoing telephone message.

- (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her their supervision by a technician.
- (b)(1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

- (A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).
- (B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.
- (C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.
- (D) The pharmacy technician is certified in basic life support.
- (2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).
- (b)(c) This section does not authorize the performance of any tasks specified in subdivision subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.
- (c)(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.
- (d)(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.
- (e)(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.
- (f)(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.
- (2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that

this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

- (3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist pharmacist-in-charge in charge in-writing of his or her their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.
- (g)(h) Notwithstanding subdivisions (a) and (b), to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).(g).
- (h)(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.
- (i)(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:
- (1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.
- (2) Sealing emergency containers for use in the health care facility.
- (3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

4119.01.

(a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs

and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:

- (1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location.
- (A) As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.
- (B) The application and initial license fee to operate EMSADDS shall be one hundred dollars (\$100) per machine. The license shall be renewed annually. The license fee may not be transferred to a different location if the EMSADDS is moved. The penalty fee for failure to renew an EMSADDS license shall be thirty-five dollars (\$35).
- (C) The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be seven hundred eighty dollars (\$780).
- (2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.
- (3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.
- (4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.
- (A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported,

representatives shall not store a dangerous drug or dangerous device at an unlicensed location.

- (B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.
- (C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.
- (5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:
- (A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.
- (B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.
- (C) A comparison of subparagraphs (A) and (B), and identification of any variances.
- (D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.
- (E) Identification of possible causes of shortages and overages.
- (6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.
- (7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.

- (8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.
- (b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.
- (c) This section shall be repealed on January 1, 2025.

4119.01.

- (a) Notwithstanding any other law, a pharmacy, or a licensed wholesaler that is also an emergency medical services provider agency, may restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system (EMSADDS) that is licensed by the board under this section. Dangerous drugs and dangerous devices stored or maintained in an EMSADDS shall be used for the sole purpose of restocking a secured emergency pharmaceutical supplies container as authorized in subdivision (b) of Section 4119. The EMSADDS may be used only if all of the following conditions are met:
- (1) The emergency medical services provider agency obtains a license from the board to operate the EMSADDS. As a requirement for licensure, the EMSADDS shall be located on the premises of a fire department headquarters, a fire station, or at an emergency medical services provider agency's location. A separate license shall be required for each location. As part of its license application, the emergency medical services provider agency shall provide: the address where the EMSADDS will be located; the name of the medical director responsible for overseeing the emergency medical services provider agency; the name of any designated pharmacist or licensed designated paramedic who is responsible for performing the duties as required under this section; the policies and procedures detailing the provisions under which the EMSADDS will operate; and the name and license number of the pharmacy or emergency medical services provider agency wholesaler that will furnish the dangerous drugs and dangerous devices through the EMSADDS.
- (2) Each EMSADDS shall collect, control, and maintain all transaction information necessary to accurately track the movement of drugs into and out of the system for purposes of security, accuracy, and accountability.
- (3) The medical director and designated pharmacist, or the medical director and the licensed designated paramedic, shall develop, adopt, and maintain policies and procedures detailing the provisions under which the EMSADDS will operate. At a minimum, the policies and procedures shall address (A) inventory controls, (B) training, (C) storage and security of the dangerous drugs and dangerous devices, and (D) safeguards to limit access to the EMSADDS to authorized staff only.

- (4) The licensed EMSADDS operator shall limit access to the EMSADDS only to employees of the operator who are licensed by the state and as authorized in this section.
- (A) An EMSADDS may only be restocked by the medical director, a pharmacist, or a licensed designated paramedic, each of whom may possess and transport dangerous drugs or dangerous devices for that purpose. The transport of dangerous drugs or dangerous devices for restocking into an EMSADDS shall be done in a secured manner to prevent theft or unauthorized access, and shall be done under conditions appropriate to meet storage and handling requirements of the dangerous drugs or dangerous devices. While the dangerous drugs or dangerous devices may be transported, representatives shall not store a dangerous drug or dangerous device at an unlicensed location.
- (B) Only a medical director, a pharmacist, or a paramedic may remove dangerous drugs or dangerous devices from an EMSADDS to fill a secured emergency pharmaceutical supplies container. This access shall be observed by a second person who is also a paramedic, a pharmacist, or a medical director. Both the individual who removes dangerous drugs or dangerous devices from the EMSADDS and the observer shall record their participation in the removal of the dangerous drugs or dangerous devices via their signatures or use of biometric identifiers. The restocking of the secured emergency pharmaceutical supplies container from the EMSADDS shall occur at the licensed location of the EMSADDS.
- (C) A medical director, a pharmacist, or a licensed designated paramedic may remove outdated dangerous drugs or dangerous devices from an EMSADDS. Any outdated dangerous drugs or dangerous devices shall be provided to a licensed reverse distributor for destruction.
- (5) Every EMSADDS operator shall perform monthly inventory and inventory reconciliation functions. The medical director, designated pharmacist, or licensed designated paramedic shall perform a reconciliation and prepare a written report based on written policies and procedures developed to maintain the security and quality of the dangerous drugs and dangerous devices. The written inventory reconciliation report shall include all of the following:
- (A) A physical count of all quantities of dangerous drugs and dangerous devices stored in the EMSADDS.
- (B) A review of all dangerous drugs and dangerous devices added into and removed from each EMSADDS since the last monthly inventory.
- (C) A comparison of subparagraphs (A) and (B), and identification of any variances.
- (D) A review of all individuals who accessed the EMSADDS since the last inventory and identification of unauthorized individuals accessing the EMSADDS or suspicious activity.
- (E) Identification of possible causes of shortages and overages.
- (6) The medical director and designated pharmacist, or medical director and licensed designated paramedic, shall be jointly responsible for monthly review of the inventory

- reconciliation report, the training, storage, and security of dangerous drugs and dangerous devices, and the restocking of the EMSADDS. Any inventory losses from an EMSADDS shall be reported to the board within seven days from identification of the loss.
- (7) In order for an individual to perform the functions of a licensed designated paramedic described in this section, that individual shall be licensed by the board pursuant to Section 4202.5. A paramedic who only restocks a secured emergency pharmaceutical supplies container from an EMSADDS need not be licensed with the board.
- (8) A record of each access to the EMSADDS, as well as all records used to compile an inventory reconciliation report, shall be maintained at the operator's location for at least three years in a readily retrievable form. The records shall include the identity of every individual who accessed the system or witnessed such access; the date of each access; and the drug, dosage, form, strength, and quantity of dangerous drugs or dangerous devices added or removed.
- (b) A violation of any of the provisions of this section shall constitute unprofessional conduct and provides the board the authority to take action against the EMSADDS operator's license.
- (c) This section shall become operative on January 1, 2025.

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 if 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. A pharmacist shall conduct the review on a monthly basis, which 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 a 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.
- (k) This section shall be repealed on January 1, 2025.

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.

- (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 if 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. A pharmacist shall conduct the review on a monthly basis, which 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 a 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.
- (k) This section shall become operative on January 1, 2025.

4128.2.

- (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.
- (b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.

- (c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.
- (d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.
- (e) A license issued pursuant to this article shall be renewed annually and is not transferrable.
- (f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.
- (g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.
- (h) Until July 1, 2017, the fee for issuance or annual renewal of a centralized hospital packaging pharmacy license shall be six hundred dollars (\$600) and may be increased by the board to eight hundred dollars (\$800).
- (i) This section shall be repealed on January 1, 2025.

4128.2.

- (a) In addition to the pharmacy license requirement described in Section 4110, a centralized hospital packaging pharmacy shall obtain a specialty license from the board prior to engaging in the functions described in Section 4128.
- (b) An applicant seeking a specialty license pursuant to this article shall apply to the board on forms established by the board.
- (c) Before issuing the specialty license, the board shall inspect the pharmacy and ensure that the pharmacy is in compliance with this article and regulations established by the board.
- (d) A license to perform the functions described in Section 4128 may only be issued to a pharmacy that is licensed by the board as a hospital pharmacy.
- (e) A license issued pursuant to this article shall be renewed annually and is not transferrable.
- (f) An applicant seeking renewal of a specialty license shall apply to the board on forms established by the board.
- (g) A license to perform the functions described in Section 4128 shall not be renewed until the pharmacy has been inspected by the board and found to be in compliance with this article and regulations established by the board.
- (h) This section shall become operative on January 1, 2025.

- (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.
- (b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.
- (c) (1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.
- (2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:
- (A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.
- (B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.
- (C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.
- (D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.
- (E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.
- (F) The third-party logistics provider is not a reverse third-party logistics provider.
- (G) The wholesaler is not acting as a reverse distributor.

- (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:
- (1) Its agent for service of process in this state.
- (2) Its principal corporate officers, as specified by the board, if any.
- (3) Its general partners, as specified by the board, if any.
- (4) Its owners if the applicant is not a corporation or partnership.
- (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
- (f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
- (g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred, warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.
- (h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.
- (i) (1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.
- (j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The

responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.

- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be five hundred fifty dollars (\$550) or another amount established by the board not to exceed the annual fee for renewal of a license to compound sterile drug products. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
- (I) The registration fee shall be the fee specified in subdivision (f) of Section 4400.
- (m) This section shall be repealed on January 1, 2025.

- (a) A person located outside this state that (1) ships, sells, mails, warehouses, distributes, or delivers dangerous drugs or dangerous devices into this state or (2) sells, brokers, warehouses, or distributes dangerous drugs or devices within this state shall be considered a nonresident wholesaler or a nonresident third-party logistics provider.
- (b) A nonresident wholesaler or nonresident third-party logistics provider shall be licensed by the board prior to shipping, selling, mailing, warehousing, distributing, or delivering dangerous drugs or dangerous devices to a site located in this state or selling, brokering, warehousing, or distributing dangerous drugs or devices within this state.
- (c)(1) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler or nonresident third-party logistics provider from or through which dangerous drugs or dangerous devices are shipped, sold, mailed, warehoused, distributed, or delivered to a site located in this state or sold, brokered, warehoused, or distributed within this state. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). A license shall be renewed annually and shall not be transferable.

- (2) A nonresident wholesaler and a nonresident third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:
- (A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.
- (B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.
- (C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.
- (D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.
- (E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.
- (F) The third-party logistics provider is not a reverse third-party logistics provider.
- (G) The wholesaler is not acting as a reverse distributor.
- (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler or a nonresident third-party logistics provider, on renewal of a nonresident wholesaler or nonresident third-party logistics provider license, or within 30 days of a change in that information:
- (1) Its agent for service of process in this state.
- (2) Its principal corporate officers, as specified by the board, if any.
- (3) Its general partners, as specified by the board, if any.
- (4) Its owners if the applicant is not a corporation or partnership.
- (e) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
- (f) A nonresident wholesaler or nonresident third-party logistics provider shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
- (g) A nonresident wholesaler or nonresident third-party logistics provider shall maintain records of dangerous drugs and dangerous devices sold, traded, transferred,

warehoused, or distributed to persons in this state or within this state, so that the records are in a readily retrievable form.

- (h) A nonresident wholesaler or nonresident third-party logistics provider shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler or nonresident third-party logistics provider in compliance with the laws of the state in which it is a resident. An application for a nonresident wholesaler or nonresident third-party logistics provider license in this state shall include a license verification from the licensing authority in the applicant's state of residence. The board may waive the home state licensure requirement for a nonresident third-party logistics provider if the board inspects the location and finds it to be in compliance with this article and any regulations adopted by the board or the applicant provides evidence of its accreditation by the Drug Distributor Accreditation program of the National Association of Boards of Pharmacy. The nonresident third-party logistics provider shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the location, pursuant to subdivision (v) of Section 4400.
- (i)(1) The board shall not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (2) The board shall not issue or renew a nonresident third-party logistics provider license until the nonresident third-party logistics provider identifies a responsible manager and notifies the board in writing of the identity and license number of the designated representative-3PL who will be the responsible manager.
- (j) The designated representative-in-charge shall be responsible for the compliance of the nonresident wholesaler with state and federal laws governing wholesalers. The responsible manager shall be responsible for the compliance of the nonresident third-party logistics provider's place of business with state and federal laws governing third-party logistics providers. A nonresident wholesaler or nonresident third-party logistics provider shall identify and notify the board of a new designated representative-in-charge or responsible manager within 30 days of the date that the prior designated representative-in-charge or responsible manager ceases to be the designated representative-in-charge or responsible manager.
- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's address of record with the board, whichever occurs first. Neither for purposes of retaining a temporary license, nor for purposes of any disciplinary or license denial proceeding before the board, shall the temporary licenseholder be deemed to have a vested property right or interest in the license.
- (I) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

(m) This section shall become operative on January 1, 2025.

- (a) A prescriber shall not dispense drugs or dangerous devices to patients in the prescriber's office or place of practice unless all of the following conditions are met:
- (1) The dangerous drugs or dangerous devices are dispensed to the prescriber's own patient, and the drugs or dangerous devices are not furnished by a nurse or physician attendant.
- (2) The dangerous drugs or dangerous devices are necessary in the treatment of the condition for which the prescriber is attending the patient.
- (3) The prescriber does not keep a pharmacy, open shop, or drugstore, advertised or otherwise, for the retailing of dangerous drugs, dangerous devices, or poisons.
- (4) The prescriber fulfills all of the labeling requirements imposed upon pharmacists by Section 4076, all of the recordkeeping requirements of this chapter, and all of the packaging requirements of good pharmaceutical practice, including the use of childproof containers.
- (5) The prescriber does not use a dispensing device unless the prescriber personally owns the device and the contents of the device, and personally dispenses the dangerous drugs or dangerous devices to the patient packaged, labeled, and recorded in accordance with paragraph (4).
- (6) The prescriber, before dispensing, offers to give a written prescription to the patient that the patient may elect to have filled by the prescriber or by any pharmacy.
- (7) The prescriber provides the patient with written disclosure that the patient has a choice between obtaining the prescription from the dispensing prescriber or obtaining the prescription at a pharmacy of the patient's choice.
- (8)(b) A certified nurse-midwife who functions pursuant to a standardized procedure-mutually agreed-upon policy or protocol described in Section 2746.51, 2746.5, a nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, a physician assistant who functions pursuant to Section 3502.1, or a naturopathic doctor who functions pursuant to Section 3640.5, may hand to a patient of the supervising physician and surgeon a properly labeled prescription drug prepackaged by a physician and surgeon, a manufacturer as defined in this chapter, or a pharmacist.
- (b)(c) The Medical Board of California, the California State Board of Optometry, the Bureau-California Board of Naturopathic Medicine, the Dental Board of California, the Podiatric Medical Board of California, the Osteopathic Medical Board of California, the Board of Registered Nursing, the Veterinary Medical Board, and the Physician Assistant Board shall have authority with the California State Board of Pharmacy to ensure compliance with this section, and those boards are specifically charged with the enforcement of this chapter with respect to their respective licensees.

(c)(d) "Prescriber," as used in this section, means a person, person who holds a physician's and surgeon's certificate, a license to practice optometry, a license to practice naturopathic medicine, a license to practice dentistry, a license to practice veterinary medicine, a certificate to practice podiatry, er a certificate to practice as a nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or a certificate to practice as a nurse-midwife, and who is duly registered by the Medical Board of California, the Osteopathic Medical Board of California, the California State Board of Optometry, the Bureau-California Board of Naturopathic Medicine, the Dental Board of California, the Veterinary Medical Board, the Podiatric Medical Board of California, or the Board of Registered Nursing.

- (a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.
- (b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete a Surgical Clinic Self-Assessment Form as determined by the board as a means to promote compliance through selfexamination and education. The self-assessment shall assess the clinic's compliance with current laws and regulations and include information on compounding practices as specified on the most recent version of the Surgical Clinic Self-Assessment Form approved by the board and posted on its internet website. The professional director of the clinic and consulting pharmacist shall certify on the final page of the Surgical Clinic Self-Assessment Form that they have read, reviewed, and completed self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the board. The completed form shall be signed under penalty of perjury, kept on file in the clinic for three years, and made available to the board or its designee, upon request.
- (c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her their capacity as medical director or a dentist or podiatrist acting in his or her their capacity as a director in a clinic where only dental or podiatric services are provided.
- (d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

4202.

- (a) The board may issue a pharmacy technician license to an individual if the applicant is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:
- (1) Has obtained an associate's degree in pharmacy technology.
- (2) Has completed a course of training specified by the board.
- (3) Has graduated from a school of pharmacy recognized by the board.
- (4) Is certified by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board.
- (b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.
- (c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.
- (d) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.
- (e) Once an individual is licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.
- (f) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

- (a) The board may issue a pharmacy technician license to an individual if the applicant is a high school graduate or possesses a general educational development certificate equivalent, and meets any one of the following requirements:
- (1) Has obtained an associate's degree in pharmacy technology.
- (2) Has completed a course of training specified by the board.
- (3) Has graduated from a school of pharmacy recognized by the board.
- (4) Is certified by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board.

- (b) The board shall adopt regulations pursuant to this section for the licensure of pharmacy technicians and for the specification of training courses as set out in paragraph (2) of subdivision (a). Proof of the qualifications of any applicant for licensure as a pharmacy technician shall be made to the satisfaction of the board and shall be substantiated by any evidence required by the board.
- (c) The board shall conduct a criminal background check of the applicant to determine if an applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.
- (d) The board shall not renew a pharmacy technician license unless the applicant submits proof satisfactory to the board that the applicant has successfully completed at least one hour of participation in a cultural competency course, as defined in Section 4231, during the two years preceding the application for renewal.
- (e) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.
- (f) Once an individual is licensed as a pharmacist, the pharmacy technician registration is no longer valid and the pharmacy technician license shall be returned to the board within 15 days.
- (g) This section shall become operative on January 1, 2024.

4202.5.

- (a) The board may issue a designated paramedic license to an individual if he or she holds they hold a license as a paramedic in this state and meets the criteria of this section.
- (b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.
- (c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.
- (d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.
- (e) The fee for application and issuance of an initial license as a designated paramedic shall be one hundred forty dollars (\$140) for a two-year license. The biennial renewal shall be one hundred forty dollars (\$140). The penalty fee for failure to renew an authorized paramedic license shall be sixty-five dollars (\$65).
- (f) This section shall be repealed on January 1, 2025.

4202.5.

- (a) The board may issue a designated paramedic license to an individual if they hold a license as a paramedic in this state and meets the criteria of this section.
- (b) The board shall conduct a criminal background check of the applicant to determine if the applicant has committed acts that would constitute grounds for denial of licensure, pursuant to this chapter or Chapter 2 (commencing with Section 480) of Division 1.5.
- (c) The board may suspend or revoke a license issued pursuant to this section on any ground specified in Section 4301.
- (d) A license issued under this section is dependent on the validity of the holder's paramedic license and shall be automatically suspended if the individual's paramedic license is expired, revoked, or otherwise invalidated by the issuing authority.
- (e) This section shall become operative on January 1, 2025.

- (a) Each application for a license under Section 4190 shall be made on a form furnished by the board. The form of application for a license under this article shall contain the name and address of the applicant, whether the applicant is licensed, the type of services the facility will offer, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.
- (b) Each initial application shall contain a statement from a consulting pharmacist certifying that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of health and safety of the public. Upon the filing of the application and the payment of a fee in subdivision (s) of Section 4400, 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 a license. 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 operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, 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 do 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 Section 4190, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4190. The license shall be renewed annually upon payment of a renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable. As part of the renewal process the consulting pharmacist shall certify compliance with the quarterly inspections as required in Section 4192. Further, as part

of the renewal process of every odd-numbered year, the most recent self-assessment form completed as provided in Section 4192 shall also be provided to the board.

- (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:
- (1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.
- (2) (A) Satisfy any two of the following criteria:
- (i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacytherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
- (ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
- (iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.
- (B) For purposes of this paragraph, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy this paragraph.
- (3) File an application with the board for recognition as an advanced practice pharmacist.
- (4) Pay the applicable fee to the board.
- (b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.
- (c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.
- (d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars (\$300).
- (e) This section shall be repealed on January 1, 2025.

4210.

- (a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:
- (1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.
- (2) (A) Satisfy any two of the following criteria:
- (i) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.
- (ii) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.
- (iii) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.
- (B) For purposes of this paragraph, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy this paragraph.
- (3) File an application with the board for recognition as an advanced practice pharmacist.
- (4) Pay the applicable fee to the board.
- (b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.
- (c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.
- (d) This section shall become operative on January 1, 2025.

- (a) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that the applicant has successfully completed 30 hours of approved courses of continuing pharmacy education during the two years preceding the application for renewal.
- (b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal of a pharmacist license.
- (c) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the

licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

- (d) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (a), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.
- (e) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

<u>42</u>31.

- (a) For purposes of this section, "cultural competency course" means a cultural competency and humility course that meets the following criteria:
- (1) The course focuses on patients who identify as lesbian, gay, bisexual, transgender, gender nonconforming, or queer, or who question their sexual orientation or gender identity and expression.
- (2) The course is approved from an accreditation agency approved by the board.
- (3) The course covers recognized health disparities faced by Black, Indigenous, and people of color.
- (4) The course contains elements demonstrating how sexual identity is directly impacted through intersectionality.
- (b) The board shall not renew a pharmacist license unless the applicant submits proof satisfactory to the board that the applicant has successfully completed 30 hours of approved courses of continuing pharmacy education, including at least one hour of participation in a cultural competency course, during the two years preceding the application for renewal.
- (c) Notwithstanding subdivision (b), the board shall not require completion of continuing education for the first renewal of a pharmacist license.
- (d) If an applicant for renewal of a pharmacist license submits the renewal application and payment of the renewal fee but does not submit proof satisfactory to the board that the licensee has completed 30 hours of continuing pharmacy education, the board shall not renew the license and shall issue the applicant an inactive pharmacist license. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.

- (e) If, as part of an investigation or audit conducted by the board, a pharmacist fails to provide documentation substantiating the completion of continuing education as required in subdivision (b), the board shall cancel the active pharmacist license and issue an inactive pharmacist license in its place. A licensee with an inactive pharmacist license issued pursuant to this section may obtain an active pharmacist license by paying the renewal fees due and submitting satisfactory proof to the board that the licensee has completed 30 hours of continuing pharmacy education.
- (f) This section shall become operative on January 1, 2024.

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 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. a person with substance use disorder.
- (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.
- (I) 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 their 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 256bSection 256b(a)(4) 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" 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 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.
- (v) Actions or conduct that would subvert the efforts of a pharmacist to comply with laws and regulations, or exercise professional judgment, including creating or allowing conditions that may interfere with a pharmacist's ability to practice with competency and safety or creating or allowing an environment that may jeopardize patient care. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.
- (w) Actions or conduct that would subvert the efforts of a pharmacist-in-charge to comply with laws and regulations, exercise professional judgment, or make determinations about adequate staffing levels to safely fill prescriptions of the pharmacy or provide other patient care services in a safe and competent manner. This subdivision does not apply to facilities of the Department of Corrections and Rehabilitation.
- (x) Actions or conduct that would subvert the efforts of a pharmacist intern or a pharmacy technician to comply with laws or regulations.
- (y) Establishing policies and procedures related to time guarantees to fill prescriptions within a specified time unless those guarantees are required by law or to meet

<u>contractual requirements. This subdivision does not apply to facilities of the Department</u> of Corrections and Rehabilitation.

<u>4316.5.</u>

Notwithstanding any other law, the board may assess administrative fines and issue orders of abatement to any unlicensed entity who engages in any action that requires licensure under the jurisdiction of the board, not to exceed five thousand dollars (\$5,000) for each occurrence pursuant to a citation issued by the board.

4400.

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

- (a) The fee for a pharmacy license shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The fee for the issuance of a temporary pharmacy permit shall be two hundred fifty dollars (\$250) and may be increased to three hundred twenty-five dollars (\$325).
- (b) The fee for a pharmacy license annual renewal shall be six hundred sixty-five dollars (\$665) and may be increased to nine hundred thirty dollars (\$930).
- (c) The fee for the pharmacist application and examination shall be two hundred sixty dollars (\$260) and may be increased to two hundred eighty-five dollars (\$285).
- (d) The fee for regrading an examination shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.
- (e) The fee for a pharmacist license shall be one hundred ninety-five dollars (\$195) and may be increased to two hundred fifteen dollars (\$215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars (\$360) and may be increased to five hundred five dollars (\$505).
- (f) The fee for a wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).
- (g) The fee for a hypodermic license shall be one hundred seventy dollars (\$170) and may be increased to two hundred forty dollars (\$240). The fee for a hypodermic license renewal shall be two hundred dollars (\$200) and may be increased to two hundred eighty dollars (\$280).
- (h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant

- to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).
- (2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).
- (i)(1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars (\$150) and may be increased to two hundred ten dollars (\$210).
- (2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars (\$215) and may be increased to three hundred dollars (\$300).
- (j)(1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820).
- (2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars (\$300) and may be decreased to no less than two hundred twenty-five dollars (\$225). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be decreased to no less than five hundred fifty dollars (\$550).
- (3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars (\$780) and may be increased to eight hundred twenty dollars (\$820).
- (k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.
- (I) The fee for an intern pharmacist license shall be one hundred sixty-five dollars (\$165) and may be increased to two hundred thirty dollars (\$230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).
- (m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.
- (n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

- (o) The fee for processing an application to change information on a premises license record shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).
- (p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (q) The fee for any applicant for a clinic license shall be five hundred twenty dollars (\$520) for each license and may be increased to five hundred seventy dollars (\$570). The annual fee for renewal of the license shall be three hundred twenty-five dollars (\$325) for each license and may be increased to three hundred sixty dollars (\$360).
- (r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars (\$140) and may be increased to one hundred ninety-five dollars (\$195).
- (s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars (\$435) and may be increased to six hundred ten dollars (\$610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars (\$330) and may be increased to four hundred sixty dollars (\$460).
- (t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).
- (u) The fee for issuance of a sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars (\$1,645) and may be increased to two thousand three hundred five dollars (\$2,305). The fee for a temporary license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to one thousand eight hundred fifty-five dollars (\$1,855).
- (v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to three thousand three hundred thirty-five dollars (\$3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to three thousand one hundred eighty dollars (\$3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

- (w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars (\$1,325) and may be increased to up to one thousand eight hundred fifty-five dollars (\$1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars (\$715).
- (x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars (\$2,380) and may be increased to up to three thousand three hundred thirty-five dollars (\$3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars (\$2,270) and may be increased to up to three thousand one hundred eighty dollars (\$3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.
- (y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars (\$820) and may be increased to one thousand one hundred fifty dollars (\$1,150). The annual renewal of the license shall be eight hundred five dollars (\$805) and may be increased to one thousand one hundred twenty-five dollars (\$1,125).
- (z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars (\$520) and may be increased to five hundred seventy dollars (\$570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars (\$325) and may be increased to three hundred sixty dollars (\$360).
- (aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250). The fee for the annual renewal of the license shall be two hundred dollars (\$200) and may be increased to two hundred fifty dollars (\$250).
- (ab) This section shall become operative on July 1, 2021.
- (ac) This section shall be repealed on January 1, 2025.

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

- (a) (1) The fee for a pharmacy license shall be seven hundred fifty dollars (\$750) and may be increased to two thousand dollars (\$2,000). The fee for the issuance of a temporary pharmacy permit shall be one thousand six hundred dollars (\$1,600) and may be increased to two thousand seven hundred forty dollars (\$2,740).
- (2) The fee for a nonresident pharmacy license shall be two thousand four hundred twenty-seven dollars (\$2,427) and may be increased to three thousand four hundred twenty-four dollars (\$3,424). The fee for the issuance of a temporary nonresident pharmacy permit shall be two thousand dollars (\$2,000) and may be increased to two thousand four hundred sixty-nine dollars (\$2,469).
- (b) (1) The fee for a pharmacy license annual renewal shall be one thousand twenty-five dollars (\$1,025) and may be increased to two thousand dollars (\$2,000).
- (2) The fee for a nonresident pharmacy license annual renewal shall be one thousand twenty-five dollars (\$1,025) and may be increased to two thousand dollars (\$2,000).
- (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 one hundred fifteen dollars (\$115) and may be increased to two hundred dollars (\$200). 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 four hundred fifty dollars (\$450) and may be reduced to three hundred sixty dollars (\$360).
- (f) The fee for a wholesaler or third-party logistics provider license and annual renewal shall be one thousand dollars (\$1,000) and may be increased to one thousand four hundred eleven dollars (\$1,411). A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be increased to one thousand nine dollars (\$1,009).
- (g) The fee for a hypodermic license shall be five hundred fifty dollars (\$550) and may be increased to seven hundred seventy-five dollars (\$775). The fee for a hypodermic license renewal shall be four hundred dollars (\$400) and may be increased to five hundred sixty-one dollars (\$561).
- (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 three hundred forty-five dollars (\$345) and may be increased to four hundred eighty-five dollars (\$485).
- (2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be three hundred eighty-eight dollars (\$388) and may be increased to five hundred forty-seven dollars (\$547).
- (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 three hundred forty-five dollars (\$345) and may be increased to four hundred eighty-five dollars (\$485).
- (2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be three hundred eighty-eight dollars (\$388) and may be increased to five hundred forty-seven dollars (\$547).
- (j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be one thousand dollars (\$1,000) and may be increased to one thousand four hundred eleven dollars (\$1,411).
- (2) A temporary license fee shall be seven hundred fifteen dollars (\$715) and may be increased to one thousand nine dollars (\$1,009).
- (3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be one thousand dollars (\$1,000) and may be increased to one thousand four hundred eleven dollars (\$1,411).
- (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.
- (1) The fee for an intern pharmacist license shall be one hundred seventy-five dollars (\$175) and may be increased to two hundred forty-five dollars (\$245). The fee for transfer of intern hours or verification of licensure to another state shall be one hundred twenty dollars (\$120) and may be increased to one hundred sixty-eight dollars (\$168).
- (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 seventy-five dollars (\$75) and may be increased to one hundred dollars (\$100).
- (o) (1) The fee for processing an application to change information on a premises license record shall be three hundred ninety-five dollars (\$395) and may be increased to five hundred fifty-seven dollars (\$557).
- (2) The fee for processing an application to change a name or correct an address on a premises license record shall be two hundred six dollars (\$206) and may be increased to two hundred eighty-two dollars (\$282).
- (3) The fee for processing an application to change a pharmacist-in-charge, designated representative-in-charge, or responsible manager on a premises license record shall be two hundred fifty dollars (\$250) and may be increased to three hundred fifty-three dollars (\$353).
- (p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.
- (q) The fee for any applicant for a clinic license shall be six hundred twenty dollars (\$620) and may be increased to eight hundred seventy-three dollars (\$873). The annual

fee for renewal of the license shall be four hundred dollars (\$400) and may be increased to five hundred sixty-one dollars (\$561).

- (r) The fee for the issuance of a pharmacy technician license shall be one hundred twenty dollars (\$120) and may be increased to one hundred sixty-five dollars (\$165). The fee for renewal of a pharmacy technician license shall be one hundred eighty dollars (\$180) and may be reduced to one hundred twenty-five dollars (\$125).
- (\$) The fee for a veterinary food-animal drug retailer license shall be six hundred ten dollars (\$610) and may be increased to eight hundred twenty-five dollars (\$825). The annual renewal fee for a veterinary food-animal drug retailer license shall be four hundred sixty dollars (\$460) and may be increased to five hundred sixty-one dollars (\$561). The fee for the temporary license shall be five hundred twenty dollars (\$520) and may be increased to seven hundred thirty-two dollars (\$732).
- (t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be fifty dollars (\$50) and may be increased to one hundred dollars (\$100).
- (u) The fee for issuance of a sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be three thousand eight hundred seventy-five dollars (\$3,875) and may be increased to five thousand four hundred sixty-six dollars (\$5,466). The fee for a temporary license shall be one thousand sixty-five dollars (\$1,065) and may be increased to one thousand five hundred three dollars (\$1,503). The annual renewal fee of the license shall be four thousand eighty-five dollars (\$4,085) and may be increased to five thousand seven hundred sixty-two dollars (\$5,762).
- (v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be eight thousand five hundred dollars (\$8,500) and may be increased to sixteen thousand five hundred two dollars (\$16,502). The annual renewal of the license shall be eight thousand five hundred dollars (\$8,500) and may be increased to seventeen thousand forty dollars (\$17,040). 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. The fee for a temporary license shall be one thousand five hundred dollars (\$1,500) and may be increased to two thousand dollars (\$2,000).
- (w) The fee for the issuance of an outsourcing facility license shall be twenty-five thousand dollars (\$25,000) and may be increased to thirty-five thousand two hundred fifty-six dollars (\$35,256). The fee for the renewal of an outsourcing facility license shall be twenty-five thousand dollars (\$25,000) and may be increased to forty-one thousand three hundred sixty-six dollars (\$41,366). The fee for a temporary outsourcing facility license shall be four thousand dollars (\$4,000) and may be increased to five thousand six hundred forty-two dollars (\$5,642).

- (x) The fee for the issuance of a nonresident outsourcing facility license shall be twentyeight thousand five hundred dollars (\$28,500) and may be increased to forty-two thousand three hundred eighteen dollars (\$42,318). The fee for the renewal of a nonresident outsourcing facility license shall be twenty-eight thousand five hundred dollars (\$28,500) and may be increased to forty-six thousand three hundred fifty-three dollars (\$46,353). 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. The fee for a temporary nonresident outsourcing license shall be four thousand dollars (\$4,000) and may be increased to five thousand six hundred forty-two dollars (\$5,642).
- (y) The fee for the issuance of a centralized hospital packaging license shall be three thousand eight hundred fifteen dollars (\$3,815) and may be increased to five thousand three hundred eighteen dollars (\$5,318). The annual renewal of the license shall be two thousand nine hundred twelve dollars (\$2,912) and may be increased to four thousand one hundred seven dollars (\$4,107).
- (z)(1) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) shall be six hundred twenty dollars (\$620) and may be increased to eight hundred seventy-three dollars (\$873). The annual renewal fee for that correctional clinic license shall be four hundred dollars (\$400) and may be increased to five hundred sixty-one dollars (\$561).
- (2) The fee for the issuance of an ADDS license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) shall be five hundred dollars (\$500) and may be increased to seven hundred five dollars (\$705). The annual renewal fee for the correctional clinic ADDS shall be four hundred dollars (\$400) and may be increased to five hundred sixty-one dollars (\$561).
- (aa) The fee for an ADDS license shall be five hundred twenty-five dollars (\$525) and may be increased to seven hundred forty-one dollars (\$741). The fee for the annual renewal of the license shall be four hundred fifty-three dollars (\$453) and may be increased to six hundred thirty-nine dollars (\$639).
- (ab) The application and initial license fee for a remote dispensing site pharmacy application shall be one thousand seven hundred thirty dollars (\$1,730) and may be increased to two thousand four hundred forty dollars (\$2,440). The fee for the annual renewal shall be one thousand twenty-five dollars (\$1,025) and may be increased to two thousand dollars (\$2,000). The fee for a temporary license shall be eight hundred ninety dollars (\$890) and may be increased to one thousand one hundred ninety-nine dollars (\$1,199).

- (ac) The application and initial license fee to operate EMSADDS shall be one hundred fifty dollars (\$150) and may be increased to three hundred eighty dollars (\$380) per machine. The fee for the annual renewal shall be two hundred dollars (\$200) and may be increased to two hundred seventy-three dollars (\$273). The license fee may not be transferred to a different location if the EMSADDS is moved. The application and renewal fee for a licensed wholesaler that is also an emergency medical services provider agency shall be eight hundred ten dollars (\$810) and may be increased to one thousand one hundred forty-three dollars (\$1,143).
- (ad) The fee for application and issuance of an initial license as a designated paramedic shall be three hundred fifty dollars (\$350) and may be increased to four hundred ninety-four dollars (\$494). The fee of biennial renewal shall be two hundred dollars (\$200) and may be increased to two hundred ninety-two dollars (\$292).
- (ae) The fee for an application for an advanced practice pharmacist license and renewal of advanced practice pharmacist license shall be three hundred dollars (\$300) and may be increased to four hundred eighteen dollars (\$418).
- (af) This section shall become operative on January 1, 2025.

4427.8.

- (a) This article shall become operative on July 1, 2019.
- (b) On or before January 1, 2024,2025, 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.

Civil Code

56.05.

For purposes of this part:

- (a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.
- (b) "Authorized recipient" means a person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.
- (c) "Confidential communications request" means a request by a subscriber or enrollee that health care service plan communications containing medical information be

communicated to them at a specific mail or email address or specific telephone number, as designated by the subscriber or enrollee.

- (d) "Contractor" means a person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).
- (e) "Enrollee" has the same meaning as that term is defined in Section 1345 of the Health and Safety Code.
- (f) "Expiration date or event" means a specified date or an occurrence relating to the individual to whom the medical information pertains or the purpose of the use or disclosure, after which the provider of health care, health care service plan, pharmaceutical company, or contractor is no longer authorized to disclose the medical information.
- (f)(g) "Health care service plan" means an entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).
- (g)(h) "Licensed health care professional" means a person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.
- (h)(i) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.
- "Marketing" does not include any of the following:
- (1) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.
- (2) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.
- (3) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in

Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

- (A) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.
- (B) The individual is provided the opportunity to opt out of receiving future remunerated communications.
- (C) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications. Further communication shall not be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt-out request.
- (i)(j) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental health application information, reproductive or sexual health application information, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the identity of the individual.
- (j)(k) "Mental health application information" means information related to a consumer's inferred or diagnosed mental health or substance use disorder, as defined in Section 1374.72 of the Health and Safety Code, collected by a mental health digital service.
- (k)(I) "Mental health digital service" means a mobile-based application or internet website that collects mental health application information from a consumer, markets itself as facilitating mental health services to a consumer, and uses the information to facilitate mental health services to a consumer.
- (<u>l)(m)</u> "Patient" means a natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.
- (m)(n) "Pharmaceutical company" means a company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

- (n)(o) "Protected individual" means any adult covered by the subscriber's health care service plan or a minor who can consent to a health care service without the consent of a parent or legal guardian, pursuant to state or federal law. "Protected individual" does not include an individual that lacks the capacity to give informed consent for health care pursuant to Section 813 of the Probate Code.
- (e)(p) "Provider of health care" means a person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; a person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; a person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; or a clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.
- (q) "Reproductive or sexual health application information" means information about a consumer's reproductive health, menstrual cycle, fertility, pregnancy, pregnancy outcome, plans to conceive, or type of sexual activity collected by a reproductive or sexual health digital service, including, but not limited to, information from which one can infer someone's pregnancy status, menstrual cycle, fertility, hormone levels, birth control use, sexual activity, or gender identity.
- (r) "Reproductive or sexual health digital service" means a mobile-based application or internet website that collects reproductive or sexual health application information from a consumer, markets itself as facilitating reproductive or sexual health services to a consumer, and uses the information to facilitate reproductive or sexual health services to a consumer.
- (p)(s) "Sensitive services" means all health care services related to mental or behavioral health, sexual and reproductive health, sexually transmitted infections, substance use disorder, gender affirming care, and intimate partner violence, and includes services described in Sections 6924, 6925, 6926, 6927, 6928, 6929, and 6930 of the Family Code, and Sections 121020 and 124260 of the Health and Safety Code, obtained by a patient at or above the minimum age specified for consenting to the service specified in the section.
- (q)(t) "Subscriber" has the same meaning as that term is defined in Section 1345 of the Health and Safety Code.

56.06.

(a) Any business organized for the purpose of maintaining medical information 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 their the individual's 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 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 their the individual's 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 that offers a mental health digital service to a consumer for the purpose of allowing the individual to manage the individual's 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.
- (e) Any business that offers a reproductive or sexual health digital service to a consumer for the purpose of allowing the individual to manage the individual's 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, but not limited to, laws that specifically incorporate by reference the definitions of this part.
- (e)(f) 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.
- (f)(g) Any business described in this section is subject to the penalties for improper use and disclosure of medical information prescribed in this part.

56.101.

- (a) Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall do so in a manner that preserves the confidentiality of the information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical information shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.
- (b)(1) An electronic health record system or electronic medical record system shall do <u>all of</u> the following:
- (A) Protect and preserve the integrity of electronic medical information.
- (B) Automatically record and preserve any change or deletion of any electronically stored medical information. The record of any change or deletion shall include the identity of the person who accessed and changed the medical information, the date and time the medical information was accessed, and the change that was made to the medical information.
- (2) A patient's right to access or receive a copy of his or her the patient's electronic medical records upon request shall be consistent with applicable state and federal laws governing patient access to, and the use and disclosures of, medical information.
- (c)(1) A business, as described in Section 56.06, that electronically stores or maintains medical information on the provision of sensitive services, including, but not limited to, on an electronic health record system or electronic medical record system, on behalf of a provider of health care, health care service plan, pharmaceutical company, contractor, or employer, shall develop capabilities, policies, and procedures, on or before July 1, 2024, to enable all of the following:
- (A) Limit user access privileges to information systems that contain medical information related to gender affirming care, abortion and abortion-related services, and contraception only to those persons who are authorized to access specified medical information.
- (B) Prevent the disclosure, access, transfer, transmission, or processing of medical information related to gender affirming care, abortion and abortion-related services, and contraception to persons and entities outside of this state in accordance to this part.
- (C) Segregate medical information related to gender affirming care, abortion and abortion-related services, and contraception from the rest of the patient's record.
- (D) Provide the ability to automatically disable access to segregated medical information related to gender affirming care, abortion and abortion-related services, and contraception by individuals and entities in another state.
- (2) Any fees charged to providers of health care, health care service plans, pharmaceutical company, contractors, employers, or patients to comply with this subdivision shall be consistent with Section 171.302 of Title 45 of the Code of Federal Regulations.

- (3) For the purposes of this subdivision, "gender affirming care" means gender affirming health care and gender affirming mental health care as defined in subdivision (b) of Section 16010.2 of the Welfare and Institutions Code.
- (4) This subdivision does not apply to a provider of health care, as defined in Section 56.05.
- (c)(d) This section shall apply to an "electronic medical record" or "electronic health record" that meets the definition of "electronic health record," as that term is defined in Section 17921(5) of Title 42 of the United States Code.

56.108.

- (a) Notwithstanding subdivisions (b) and (c) of Section 56.10 or subdivision (c) of Section 56.20, a provider of health care, health care service plan, contractor, or employer shall not release medical information related to an individual seeking or obtaining an abortion in response to a subpoena or request if that subpoena or request is based on either another state's laws that interfere with a person's rights under the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code) or a foreign penal civil action, as defined in Section 2029,200 of the Code of Civil Procedure.
- (b) A provider of health care, health care service plan, contractor, or employer shall not release medical information that would identify an individual or that is related to an individual seeking or obtaining an abortion to law enforcement for either of the following purposes, unless that release is pursuant to a subpoena not otherwise prohibited by subdivision (a):
- (1) Enforcement of another state's law that would interfere with a person's rights under the Reproductive Privacy Act (Article 2.5 (commencing with Section 123460) of Chapter 2 of Part 2 of Division 106 of the Health and Safety Code).
- (2) Enforcement of a foreign penal civil action, as defined in Section 2029.200 of the Code of Civil Procedure.
- (c) Notwithstanding subdivisions (b) and (c) of Section 56.10 or subdivision (c) of Section 56.20, a provider of health care, health care service plan, contractor, or employer shall not cooperate with any inquiry or investigation by, or provide medical information to, any individual, agency, or department from another state or, to the extent permitted by federal law, to a federal law enforcement agency that would identify an individual and that is related to an individual seeking or obtaining an abortion or abortion-related services that are lawful under the laws of this state, unless the request for medical information is authorized under Section 56.110.
- (d) This section does not prohibit compliance with the investigation of activity that is punishable as a crime under the laws of this state.

56.110.

- (a) Notwithstanding subdivision (c) of Section 56.10, a provider of health care, health care service plan, pharmaceutical company, contractor, or employer shall not knowingly disclose, transmit, transfer, share, or grant access to medical information in an electronic health records system or through a health information exchange that would identify an individual and that is related to an individual seeking, obtaining, providing, supporting, or aiding in the performance of an abortion that is lawful under the laws of this state to any individual or entity from another state, unless the disclosure, transmittal, transfer, sharing, or granting of access is authorized under any of the following conditions:
- (1) In accordance with a valid, written authorization pursuant to Section 56.11 that clearly states that medical information on abortion or abortion-related services may be disclosed, and only to the extent and for the purposes expressly stated in the authorization.
- (2) In accordance with paragraphs (2) and (3) of subdivision (c) of Section 56.10, to the extent necessary to allow responsibility for payment to be determined and payment to be made or to the extent that it is not further disclosed by the recipient in a way that would violate this part.
- (3) In accordance with paragraphs (4) and (5) of subdivision (c) of Section 56.10 for the purpose of accreditation, in reviewing the competence or qualifications of health care professionals, or in reviewing health care services with respect to medical necessity, level of care, quality of care, or justification of charges.
- (4) In accordance with paragraph (7) of subdivision (c) of Section 56.10, for the purpose of bona fide research. Institutional Review Boards shall consider the potential harm to the patient and the patient's privacy when the research uses data that contains information related to abortion or abortion-related services and the research is performed out of state.
- (b) Notwithstanding subdivision (a), the content of the health records containing medical information described in subdivision (a) shall be disclosed to any of the following:
- (1) A patient, or their personal representative, consistent with the Patient Access to Health Records Act (Chapter 1 (commencing with Section 123100) of Part 1 of Division 106 of the Health and Safety Code).
- (2) In response to an order of a California or federal court, but only to the extent clearly stated in the order and consistent with Section 1543 of the Penal Code, if applicable, and only if all information about the patient's identity and records are protected from public scrutiny through mechanisms, including, but not limited to, a sealed proceeding or court record.
- (3) When expressly required by federal law that preempts California law, but only to the extent expressly required.
- (c) Nothing in this section shall prohibit a provider of health care, health care service plan, pharmaceutical company, contractor, or employer from cooperating or complying

with the investigation of activity that is punishable as a crime under the laws of California, and that took place in California.

(d) A provider of health care, as defined in Section 56.05, shall not be subject to liability for damages or to civil or enforcement actions, including disciplinary actions, fines, or penalties, for failure to meet the requirements of this section before January 31, 2026, if the provider of health care is working diligently and in good faith to come into compliance with this section.

Corporations Code

14700.

- (a) No person shall acquire, directly or indirectly, any voting securities or assets of a retail grocery firm or retail drug firm unless both parties give, or in the case of a tender offer, the acquiring party gives, written notice to the Attorney General in accordance with this part.
- (b) For purposes of this part, the following definitions apply:
- (1) "Acquiring party" means a person by whom or on whose behalf the merger or other acquisition of control is to be effected and is either of the following:
- (A) Is required to provide notice of the merger or acquisition to the Federal Trade Commission or the United States Department of Justice pursuant to the federal Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. Sec. 18a).
- (B) Is acquiring more than a total of 20 retail drug firms or retail grocery firms.
- (2) "Retail drug firm" means a person, as defined in Section 18 of the Labor Code, including a proprietorship, joint venture, corporate officer or executive, that has one or more businesses or establishments located within the state and is identified as a retail business or establishment in the North American Industry Classification System within the retail trade category 45611.
- (3) "Retail grocery firm" means a person, as defined in Section 18 of the Labor Code, including a proprietorship, joint venture, corporate officer or executive, that has one or more businesses or establishments located within the state and is identified as a retail business or establishment in the North American Industry Classification System within the retail trade category 44511 and 455211.

<u>14701.</u>

- (a) The written notice shall be filed with the Attorney General no less than 180 days before the acquisition is made effective. The notice shall be made under oath or affirmation, and shall comply with the requirements of subdivision (c).
- (b) If any transaction requiring written notice pursuant to this subdivision commences before the effective date of this section, the written notice shall be given to the Attorney General within 30 days before the transaction is made effective. Upon receiving notice, the Attorney General has 180 days to evaluate the transaction, during which time the

- effective date of the transaction shall be tolled. If any material change occurs in the facts set forth in the written notice filed with the Attorney General, an amendment setting forth the change and copies of all documents and other material relevant to the change shall be filed with the Attorney General within two business days after the amendment is made by, or provided to, the acquiring party.
- (c) The notice required to be given to the Attorney General shall comply with either of the following:
- (1) If the acquiring party is required to file notice with the Federal Trade Commission or the United States Department of Justice pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (15 U.S.C. Sec. 18a), the notice shall contain the same form and additional documentary material required under that act and any implementing regulations under that act.
- (2) If the acquiring party is not required to file notice with the Federal Trade Commission or the United States Department of Justice, as specified in paragraph (1), the notice shall contain all of the following information:
- (A) The name and address of each acquiring party and a report of the nature of its business operations during the past five years or for a lesser period if the person and their predecessors have been in existence less than five years.
- (B) An informative description of the business intended to be done by the person and the person's subsidiaries, including, but not limited to, documents concerning its business or corporate structure, governance, or management.
- (C) A list of all individuals who are or have been selected to become directors or executive officers or who perform or will perform functions appropriate to the positions.
- (D) The source, nature, and amount of the consideration used or to be used in effecting the merger or other acquisition of control, a description of any transaction in which funds were or are to be obtained, including any pledge of the drug or grocery retail firm's stock or the stock of any of its subsidiaries or controlling affiliates, and the identity of persons furnishing the consideration. If a source of the consideration is a loan made in the lender's ordinary course of business, the identity of the lender shall remain confidential upon request of the person filing the statement.
- (E) Fully audited financial information as to the earnings and financial condition of each acquiring party for the preceding five fiscal years or for a lesser period if the acquiring party and its predecessors have been in existence for less than five years, and similar unaudited information as of a date not earlier than 90 days before the written notice.
- (F) Any plans or proposals that an acquiring party may have to liquidate the retail grocery or retail drug firms, to sell its assets or merge or consolidate it with any person, or to make any other material change in its business or corporate structure or management.
- (G) The information required to assess the competitive effects of the proposed acquisition, giving particular attention to the effects on the proposed chain retail grocery store acquisition on consumers, including, but not limited to, consumer choice, food pricing, access to food, and food deserts, and factors affecting the supply of

- experienced grocery workers, including wages, benefits, and unemployment and chain retail pharmacy on patients, including, but not limited to, patient choice, medicine pricing, access to medications, and factors affecting the supply of licensed pharmacists, pharmacy technicians, and pharmacists-in-charge.
- (H) Information required to assess the economic and community impact of any planned divestiture or store closures, including, but not limited to, the impact on food deserts, food supply, economic mobility, unemployment, and small businesses.
- (d) The Attorney General shall charge the acquiring party a filing fee for the cost to the Attorney General to receive, review, and analyze any notice under this section, which shall not exceed the reasonable regulatory costs to the Attorney General incident to performing its administrative duties under this section. The fee shall be based on the size of the transaction as of the date of the filing of the notice, but shall not exceed .00045 percent of the combined sales of the parties to the merger or acquisition for the fiscal year prior to the filing of the notice.
- (e) The Attorney General may use the notice, documents, and information disclosed under to this section in a judicial action in state or federal court or an administrative action involving the merger or acquisition.

- (a) The Attorney General may adopt regulations to effectuate this part that are necessary or appropriate for the protection of workers, consumers, and the public interest.
- (b) The regulations may specify exemptions from the notice requirement for acquisitions that, by virtue of the size, business volume, or number of employees are unlikely to materially affect competitive markets in California.
- (c) The regulations may authorize the Attorney General to request additional materials.
- (d) The regulations may authorize adjustments in the filing fee, based on the size of the transaction, subject to the maximum amount set forth in subdivision (d) of Section 14701.

14703.

If the Attorney General determines that they cannot complete an evaluation of the competitive effects of the acquisition before the parties intend to consummate the acquisition, the Attorney General may seek an order from the Superior Court of the County of Sacramento temporarily staying or preliminarily enjoining the acquisition for such time as is reasonably necessary for the Attorney General to complete the analysis.

14704.

(a) For acquisitions to which Section 18a of Title 15 of the United States Code applies, the Attorney General shall consider the extent to which information required to be

submitted to the United States Department of Justice and the Federal Trade
Commission may satisfy some or all of the need to carry out the applicable state laws.
Any information that has been submitted to the Attorney General under provisions of federal law rendering them confidential shall be deemed to be confidential under California law.

- (b) The submitting party may designate information submitted pursuant to this part as privileged or confidential. If the Attorney General disputes any claim of privilege or confidentiality, the Attorney General may give notice to the submitting party of that fact and give the submitting party, or other person interested in the claim of privilege or confidentiality, an opportunity to seek an order from the Superior Court of the County of Sacramento requiring the Attorney General not to make the designated information public. Except for information that the Attorney General agrees is privileged or confidential, or the court so determines, the information shall be available to the public under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code).
- (c) The Attorney General may disclose any notice and information filed under this part to the attorney general of any other state, the Federal Trade Commission, the United States Department of Justice, or to another state agency, as long as that other state attorney general, state agency, or federal agency operates under a law substantially similar to this statute to guarantee the privileged or confidential nature of the notice and information disclosed.

<u>14706.</u>

Nothing in this section or any other law shall preclude the Attorney General or any person from bringing an action pursuant to this article or any other law to enjoin or seek divestiture of assets or ownership interests obtained in a completed acquisition or otherwise to restore competition.

14707.

- (a) The failure to provide written notice, amendment to written notice, or other material required to be provided pursuant to this part shall be a violation of this part.
- (b) In addition to any legal remedies the Attorney General may have, the Attorney General shall be entitled to injunctive relief and other equitable remedies a court deems appropriate for a violation of this part, shall be entitled to recover its attorney's fees and costs incurred in remedying each violation, and shall be entitled to civil penalties of up to twenty thousand dollars (\$20,000) for each day of noncompliance with the requirements of Section 14700.

Education Code

49414.7.

- (a) School districts, county offices of education, and charter schools may provide emergency stock albuterol inhalers, including, if necessary, single-use disposable holding chambers, to school nurses or trained personnel who have volunteered pursuant to subdivision (d), and school nurses or trained personnel may use an emergency stock albuterol inhaler to provide emergency medical aid to persons suffering, or reasonably believed to be suffering, from respiratory distress.
- (b) For purposes of this section, the following definitions apply:
- (1) "Albuterol" means a bronchodilator used to open the airways by relaxing the muscles around the bronchial tubes.
- (2) "Authorizing physician and surgeon" may include, but is not limited to, a physician and surgeon employed by, or contracting with, a local educational agency, a medical director of the local health department, or a local emergency medical services director.
- (3) "Inhaler" means a device used for the delivery of prescribed asthma medication that is inhaled.
- (4) "Local educational agency" means a school district, county office of education, or charter school.
- (5) "Metered-dose inhaler (MDI)" means a pressurized sprayer that delivers a measured amount of a medication.
- (6) "Qualified supervisor of health" may include, but is not limited to, a school nurse.
- (7) "Respiratory distress" means the sudden appearance of signs and symptoms of difficulty breathing. Signs and symptoms of respiratory distress may include one or more of the following:
- (A) Complaints of a tight chest or chest pain.
- (B) Wheezing or noisy breathing.
- (C) Persistent coughing.
- (D) Difficulty breathing.
- (E) Appears to be in distress.
- (F) Lips or fingernails turning blue.
- (G) Shortness of breath.
- (8) "Stock albuterol inhaler" means albuterol medication in the form of a metered-dose inhaler (MDI) that is ordered by a health care provider and is not prescribed for a specific person and also includes, if necessary, a single-use disposable holding chamber.
- (9) "Volunteer" or "trained personnel" means an employee who has volunteered to administer stock albuterol inhalers to a person if the person is suffering, or reasonably

believed to be suffering, from respiratory distress, has been designated by a school, and has received training pursuant to subdivision (d).

- (c) Each private elementary and secondary school in the state may voluntarily determine whether or not to make emergency stock albuterol inhalers and trained personnel available at its school. In making this determination, a school shall evaluate the emergency medical response time to the school and determine whether initiating emergency medical services is an acceptable alternative to stock albuterol inhalers and trained personnel. A private elementary or secondary school choosing to exercise the authority provided under this subdivision shall not receive state funds specifically for purposes of this subdivision.
- (d) (1) Each public and private elementary and secondary school in the state may designate one or more volunteers to receive initial and annual refresher training, based on the standards developed pursuant to subdivision (e), regarding the storage and emergency use of a stock albuterol inhaler from the school nurse or other qualified person designated by an authorizing physician and surgeon.
- (2) Schools are encouraged and recommended to have a minimum of two trained school employees.
- (e)(1) The Superintendent shall establish, and post on the department's internet website, minimum standards of training for the administration of stock albuterol inhalers that satisfies the requirements of paragraph (2). Every five years, or sooner as deemed necessary by the Superintendent, the Superintendent shall review minimum standards of training for the administration of stock albuterol inhalers that satisfy the requirements of paragraph (2). For purposes of this subdivision, the Superintendent shall consult with organizations and providers with expertise in administering stock albuterol inhalers and administering medication in a school environment, including, but not limited to, the State Department of Public Health, the Emergency Medical Services Authority, the American Academy of Allergy, Asthma and Immunology, the California School Nurses Organization, the California Medical Association, the American Academy of Pediatrics, the California Society of Allergy, Asthma and Immunology, the American College of Allergy, Asthma and Immunology, and others.
- (2) Training established pursuant to this subdivision shall include all of the following:
- (A) Techniques for recognizing symptoms of respiratory distress.
- (B) Standards and procedures for the storage, restocking, and emergency use of stock albuterol inhalers.
- (C) Emergency followup procedures, including calling the emergency 911 telephone number and contacting, if possible, the pupil's parent or guardian and physician.
- (D) Recommendations on the necessity of instruction and certification in cardiopulmonary resuscitation.
- (E) Written materials covering the information required under this subdivision.
- (3) Training established pursuant to this subdivision shall be consistent with the most recent guidelines for medication administration issued by the department.

- (4) Training established pursuant to this subdivision shall be provided to a volunteer during the volunteer's regular working hours and at no cost to the volunteer.
- (5) A school shall retain for reference the written materials prepared under subparagraph (E) of paragraph (2).
- (f) Any local educational agency electing to utilize stock albuterol inhalers for emergency aid shall distribute a notice at least once per school year to all staff that contains the following information:
- (1) A description of the volunteer request stating that the request is for volunteers to be trained to administer a stock albuterol inhaler to a person if the person is suffering, or reasonably believed to be suffering, from respiratory distress, as specified in subdivision (b).
- (2) A description of the training that the volunteer will receive pursuant to subdivision (d).
- (g)(1) A qualified supervisor of health at a local educational agency electing to utilize stock albuterol inhalers for emergency aid shall obtain from an authorizing physician and surgeon a prescription for each school for stock albuterol inhalers. A qualified supervisor of health at a local educational agency shall be responsible for stocking the stock albuterol inhalers and restocking it if it is used.
- (2) If a local educational agency does not have a qualified supervisor of health, an administrator at the local educational agency shall carry out the duties specified in paragraph (1).
- (3) A prescription pursuant to this subdivision may be filled by local or mail order pharmacies or stock albuterol inhaler manufacturers.
- (4) An authorizing physician and surgeon shall not be subject to professional review, be liable in a civil action, or be subject to criminal prosecution for the issuance of a prescription or order pursuant to this section, unless the physician and surgeon's issuance of the prescription or order constitutes gross negligence or willful or malicious conduct.
- (h) A school nurse or, if the school does not have a school nurse or the school nurse is not onsite or available, a volunteer may administer a stock albuterol inhaler to a person exhibiting potentially life-threatening symptoms of respiratory distress at school or a school activity when a physician is not immediately available. If the stock albuterol inhaler is used, it shall be restocked as soon as reasonably possible, but no later than two weeks after it is used. Stock albuterol inhalers shall be restocked before their expiration date.
- (i) A volunteer shall initiate emergency medical services or other appropriate medical followup in accordance with the training materials retained pursuant to paragraph (5) of subdivision (e).
- (j) (1) A local educational agency electing to utilize stock albuterol inhalers for emergency aid shall not be liable for any civil damages resulting from any act or omission, other than an act or omission constituting gross negligence or willful and

- wanton misconduct, in the emergency administration of an albuterol inhaler by any of its school nurses or trained volunteers who have volunteered pursuant to subdivision (d).
- (2) An employee who volunteers under this section shall be provided defense and indemnification by the local educational agency for any and all civil liability, in accordance with, but not limited to, that provided in Division 3.6 (commencing with Section 810) of Title 1 of the Government Code. This information shall be reduced to writing, provided to the volunteer, and retained in the volunteer's personnel file.
- (k) A state agency, the department, or a public school may accept gifts, grants, and donations from any source for the support of the public school carrying out the provisions of this section, including, but not limited to, the acceptance of stock albuterol inhalers from a manufacturer or wholesaler.

Government Code

9795.

- (a)(1)(A) Any report required or requested by law-law, or identified in the Legislative Analyst's Supplemental Report of the Budget Act, to be submitted by a state or local agency to the a committee of the Legislature or the Members of either house of the Legislature generally, shall instead be submitted as a printed copy to the Secretary of the Senate, as an electronic copy to the Chief Clerk of the Assembly, and as an electronic or printed copy to the Legislative Counsel. Each report shall include a summary of its contents, not to exceed one page in length. If the report is submitted by a state agency, that agency shall also provide an electronic copy of the summary directly to each member of the appropriate house or houses of the Legislature. Notice of receipt of the report shall also be recorded in the journal of the appropriate house or houses of the Legislature by the secretary or clerk of that house.
- (B) Notwithstanding subparagraph (A), reports of the State Bar of California may be submitted electronically to the Secretary of the Senate.
- (2) In addition to to, and as part of of, the information made available to the public in electronic form pursuant to Section 10248, the Legislative Counsel shall make available a list of the reports submitted by state and local agencies, as specified in paragraph (1). If the Legislative Counsel receives a request from a member of the public for a report contained in the list, the Legislative Counsel is not required to provide a copy of the report and may refer the requester to the state or local agency, as the case may be, that authored the report, or to the California State Library as the final repository of public information.
- (b) No-A report shall <u>not</u> be distributed to a Member of the Legislature unless specifically requested by that Member.
- (c) Compliance with subdivision (a) shall be deemed to be full compliance with subdivision (c) of Section 10242.5.

- (d) A state agency report and summary subject to this section shall include an Internet Web site where the report can be downloaded and telephone number to call to order a hard copy of the report. A report submitted by a state agency subject to this section shall also be posted at the agency's Internet Web site.
- (e) For purposes of this section, "report" includes any study or audit.

Public computer network; required legislative information.

- (a) The Legislative Counsel shall, with the advice of the Assembly Committee on Rules and the Senate Committee on Rules, make all of the following information available to the public in electronic form:
- (1) The legislative calendar, the schedule of legislative committee hearings, a list of matters pending on the floors of both houses of the Legislature, and a list of the committees of the Legislature and their members.
- (2) The text of each bill introduced in each current legislative session, including each amended, enrolled, and chaptered form of each bill.
- (3) The bill history of each bill introduced and amended in each current legislative session.
- (4) The bill status of each bill introduced and amended in each current legislative session.
- (5) All bill analyses prepared by legislative committees in connection with each bill in each current legislative session.
- (6) All audiovisual recordings of legislative proceedings that have been caused to be made by the Legislature in accordance with paragraph (2) of subdivision (c) of Section 7 of Article IV of the California Constitution. Each recording shall remain accessible to the public through the Internet and downloadable for a minimum period of 20 years following the date on which the recording was made and shall then be archived in a secure format.
- (7) All vote information concerning each bill in each current legislative session.
- (8) Any veto message concerning a bill in each current legislative session.
- (9) The California Codes.
- (10) The California Constitution.
- (11) All statutes enacted on or after January 1, 1993.
- (12) A link to the list of state and local agency reports required by paragraph (2) of subdivision (a) of Section 9795.
- (b) The information identified in subdivision (a) shall be made available to the public by means of access by way of the largest nonproprietary, nonprofit cooperative public computer network. The information shall be made available in one or more formats and

by one or more means in order to provide the greatest feasible access to the general public in this state. Any person who accesses the information may access all or any part of the information. The information may also be made available by any other means of access that would facilitate public access to the information. The information that is maintained in the legislative information system that is operated and maintained by the Legislative Counsel shall be made available in the shortest feasible time after the information system shall be made available in the shortest feasible time after it is available to the Legislative Counsel.

- (c) Any documentation that describes the electronic digital formats of the information identified in subdivision (a) and is available to the public shall be made available by means of access by way of the computer network specified in subdivision (b).
- (d) Personal information concerning a person who accesses the information may be maintained only for the purpose of providing service to the person.
- (e) No fee or other charge may be imposed by the Legislative Counsel The Legislative Counsel shall not impose a fee or other charge as a condition of accessing the information that is accessible by way of the computer network specified in subdivision (b).
- (f) The electronic public access provided by way of the computer network specified in subdivision (b) shall be in addition to other electronic or print distribution of the information.
- (g) No-An action taken pursuant to this section shall be deemed to does not alter or relinquish any copyright or other proprietary interest or entitlement of the State of California relating to any of the information made available pursuant to this section.

54953.

- (a) All meetings of the legislative body of a local agency shall be open and public, and all persons shall be permitted to attend any meeting of the legislative body of a local agency, except as otherwise provided in this chapter.
- (b)(1) Notwithstanding any other provision of law, the legislative body of a local agency may use teleconferencing for the benefit of the public and the legislative body of a local agency in connection with any meeting or proceeding authorized by law. The teleconferenced meeting or proceeding shall comply with all otherwise applicable requirements of this chapter and all otherwise applicable provisions of law relating to a specific type of meeting or proceeding.
- (2) Teleconferencing, as authorized by this section, may be used for all purposes in connection with any meeting within the subject matter jurisdiction of the legislative body. If the legislative body of a local agency elects to use teleconferencing, the legislative body of a local agency shall comply with all of the following:
- (A) All votes taken during a teleconferenced meeting shall be by rollcall.

- (B) The teleconferenced meetings shall be conducted in a manner that protects the statutory and constitutional rights of the parties or the public appearing before the legislative body of a local agency.
- (C) The legislative body shall give notice of the meeting and post agendas as otherwise required by this chapter.
- (D) The legislative body shall allow members of the public to access the meeting and the agenda shall provide an opportunity for members of the public to address the legislative body directly pursuant to Section 54954.3.
- (3) If the legislative body of a local agency elects to use teleconferencing, it shall post agendas at all teleconference locations. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the public. During the teleconference, at least a quorum of the members of the legislative body shall participate from locations within the boundaries of the territory over which the local agency exercises jurisdiction, except as provided in subdivisions (d) and (e).
- (c)(1) No legislative body shall take action by secret ballot, whether preliminary or final.
- (2) The legislative body of a local agency shall publicly report any action taken and the vote or abstention on that action of each member present for the action.
- (3) Prior to taking final action, the legislative body shall orally report a summary of a recommendation for a final action on the salaries, salary schedules, or compensation paid in the form of fringe benefits of a local agency executive, as defined in subdivision (d) of Section 3511.1, during the open meeting in which the final action is to be taken. This paragraph shall not affect the public's right under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1) to inspect or copy records created or received in the process of developing the recommendation.
- (d)(1) Notwithstanding the provisions relating to a quorum in paragraph (3) of subdivision (b), if a health authority conducts a teleconference meeting, members who are outside the jurisdiction of the authority may be counted toward the establishment of a quorum when participating in the teleconference if at least 50 percent of the number of members that would establish a quorum are present within the boundaries of the territory over which the authority exercises jurisdiction, and the health authority provides a teleconference number, and associated access codes, if any, that allows any person to call in to participate in the meeting and the number and access codes are identified in the notice and agenda of the meeting.
- (2) Nothing in this subdivision shall be construed as discouraging health authority members from regularly meeting at a common physical site within the jurisdiction of the authority or from using teleconference locations within or near the jurisdiction of the authority. A teleconference meeting for which a quorum is established pursuant to this subdivision shall be subject to all other requirements of this section.
- (3) For purposes of this subdivision, a health authority means any entity created pursuant to Sections 14018.7, 14087.31, 14087.35, 14087.36, 14087.38, and 14087.9605 of the Welfare and Institutions Code, any joint powers authority created

- pursuant to Article 1 (commencing with Section 6500) of Chapter 5 of Division 7 for the purpose of contracting pursuant to Section 14087.3 of the Welfare and Institutions Code, and any advisory committee to a county-sponsored health plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code if the advisory committee has 12 or more members.
- (e)(1) The legislative body of a local agency may use teleconferencing without complying with the requirements of paragraph (3) of subdivision (b) if the legislative body complies with the requirements of paragraph (2) of this subdivision in any either of the following circumstances:
- (A) The legislative body holds a meeting during a proclaimed state of emergency, and state or local officials have imposed or recommended measures to promote social distancing.
- (B)(A) The legislative body holds a meeting during a proclaimed state of emergency for the purpose of determining, by majority vote, whether as a result of the emergency, meeting in person would present imminent risks to the health or safety of attendees.
- (C)(B) The legislative body holds a meeting during a proclaimed state of emergency and has determined, by majority vote, pursuant to subparagraph (B), (A), that, as a result of the emergency, meeting in person would present imminent risks to the health or safety of attendees.
- (2) A legislative body that holds a meeting pursuant to this subdivision shall do all of the following:
- (A) In each instance in which notice of the time of the teleconferenced meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body shall also give notice of the means by which members of the public may access the meeting and offer public comment. The agenda shall identify and include an opportunity for all persons to attend via a call-in option or an internet-based service option.
- (B) In the event of a disruption that prevents the legislative body from broadcasting the meeting to members of the public using the call-in option or internet-based service option, or in the event of a disruption within the local agency's control that prevents members of the public from offering public comments using the call-in option or internet-based service option, the legislative body shall take no further action on items appearing on the meeting agenda until public access to the meeting via the call-in option or internet-based service option is restored. Actions taken on agenda items during a disruption that prevents the legislative body from broadcasting the meeting may be challenged pursuant to Section 54960.1.
- (C) The legislative body shall not require public comments to be submitted in advance of the meeting and must provide an opportunity for the public to address the legislative body and offer comment in real time.
- (D) Notwithstanding Section 54953.3, an individual desiring to provide public comment through the use of an internet website, or other online platform, not under the control of the local legislative body, that requires registration to log in to a teleconference may be

required to register as required by the third-party internet website or online platform to participate.

- (E)(i) A legislative body that provides a timed public comment period for each agenda item shall not close the public comment period for the agenda item, or the opportunity to register, pursuant to subparagraph (F), (D), to provide public comment until that timed public comment period has elapsed.
- (ii) A legislative body that does not provide a timed public comment period, but takes public comment separately on each agenda item, shall allow a reasonable amount of time per agenda item to allow public members the opportunity to provide public comment, including time for members of the public to register pursuant to subparagraph (F), (D), or otherwise be recognized for the purpose of providing public comment.
- (iii) A legislative body that provides a timed general public comment period that does not correspond to a specific agenda item shall not close the public comment period or the opportunity to register, pursuant to subparagraph (F), (D), until the timed general public comment period has elapsed.
- (3) If a state of emergency remains active, or state or local officials have imposed or recommended measures to promote social distancing, in order to continue to teleconference without compliance with paragraph (3) of subdivision (b), the legislative body shall, not later than 30 45 days after teleconferencing for the first time pursuant to subparagraph (A), (B), (A) or (C) (B) of paragraph (1), and every 30 45 days thereafter, make the following findings by majority vote:
- (A) The legislative body has reconsidered the circumstances of the state of emergency.
- (B) Any of the following circumstances exist:
- (i)(B) The state of emergency continues to directly impact the ability of the members to meet safely in person.
- (ii) State or local officials continue to impose or recommend measures to promote social distancing.
- (4) This subdivision shall not be construed to require the legislative body to provide a physical location from which the public may attend or comment.
- (f) (1) The legislative body of a local agency may use teleconferencing without complying with paragraph (3) of subdivision (b) if, during the teleconference meeting, at least a quorum of the members of the legislative body participates in person from a singular physical location clearly identified on the agenda, which location shall be open to the public and situated within the boundaries of the territory over which the local agency exercises jurisdiction and the legislative body complies with all of the following:
- (A) The legislative body shall provide at least one of the following as a means by which the public may remotely hear and visually observe the meeting, and remotely address the legislative body:
- (i) A two-way audiovisual platform.

- (ii) A two-way telephonic service and a live webcasting of the meeting.
- (B) In each instance in which notice of the time of the teleconferenced meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body shall also give notice of the means by which members of the public may access the meeting and offer public comment.
- (C) The agenda shall identify and include an opportunity for all persons to attend and address the legislative body directly pursuant to Section 54954.3 via a call-in option, via an internet-based service option, and at the in-person location of the meeting.
- (D) In the event of a disruption that prevents the legislative body from broadcasting the meeting to members of the public using the call-in option or internet-based service option, or in the event of a disruption within the local agency's control that prevents members of the public from offering public comments using the call-in option or internet-based service option, the legislative body shall take no further action on items appearing on the meeting agenda until public access to the meeting via the call-in option or internet-based service option is restored. Actions taken on agenda items during a disruption that prevents the legislative body from broadcasting the meeting may be challenged pursuant to Section 54960.1.
- (E) The legislative body shall not require public comments to be submitted in advance of the meeting and must provide an opportunity for the public to address the legislative body and offer comment in real time.
- (F) Notwithstanding Section 54953.3, an individual desiring to provide public comment through the use of an internet website, or other online platform, not under the control of the local legislative body, that requires registration to log in to a teleconference may be required to register as required by the third-party internet website or online platform to participate.
- (2) A member of the legislative body shall only participate in the meeting remotely pursuant to this subdivision, if all of the following requirements are met:
- (A) One of the following circumstances applies:
- (i) The member notifies the legislative body at the earliest opportunity possible, including at the start of a regular meeting, of their need to participate remotely for just cause, including a general description of the circumstances relating to their need to appear remotely at the given meeting. The provisions of this clause shall not be used by any member of the legislative body for more than two meetings per calendar year.
- (ii) The member requests the legislative body to allow them to participate in the meeting remotely due to emergency circumstances and the legislative body takes action to approve the request. The legislative body shall request a general description of the circumstances relating to their need to appear remotely at the given meeting. A general description of an item generally need not exceed 20 words and shall not require the member to disclose any medical diagnosis or disability, or any personal medical information that is already exempt under existing law, such as the Confidentiality of Medical Information Act (Chapter 1 (commencing with Section 56) of Part 2.6 of Division 1 of the Civil Code). For the purposes of this clause, the following requirements apply:

- (I) A member shall make a request to participate remotely at a meeting pursuant to this clause as soon as possible. The member shall make a separate request for each meeting in which they seek to participate remotely.
- (II) The legislative body may take action on a request to participate remotely at the earliest opportunity. If the request does not allow sufficient time to place proposed action on such a request on the posted agenda for the meeting for which the request is made, the legislative body may take action at the beginning of the meeting in accordance with paragraph (4) of subdivision (b) of Section 54954.2.
- (B) The member shall publicly disclose at the meeting before any action is taken, whether any other individuals 18 years of age or older are present in the room at the remote location with the member, and the general nature of the member's relationship with any such individuals.
- (C) The member shall participate through both audio and visual technology.
- (3) The provisions of this subdivision shall not serve as a means for any member of a legislative body to participate in meetings of the legislative body solely by teleconference from a remote location for a period of more than three consecutive months or 20 percent of the regular meetings for the local agency within a calendar year, or more than two meetings if the legislative body regularly meets fewer than 10 times per calendar year.
- (g) The legislative body shall have and implement a procedure for receiving and swiftly resolving requests for reasonable accommodation for individuals with disabilities, consistent with the federal Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and resolving any doubt in favor of accessibility. In each instance in which notice of the time of the meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body shall also give notice of the procedure for receiving and resolving requests for accommodation.
- (h) The legislative body shall conduct meetings subject to this chapter consistent with applicable civil rights and nondiscrimination laws.
- (i)(1) Nothing in this section shall prohibit a legislative body from providing the public with additional teleconference locations.
- (2) Nothing in this section shall prohibit a legislative body from providing members of the public with additional physical locations in which the public may observe and address the legislative body by electronic means.
- (j) For the purposes of this section, the following definitions shall apply:
- (1) "Emergency circumstances" means a physical or family medical emergency that prevents a member from attending in person.
- (2) "Just cause" means any of the following:
- (A) A childcare or caregiving need of a child, parent, grandparent, grandchild, sibling, spouse, or domestic partner that requires them to participate remotely. "Child," "parent," "grandparent," "grandchild," and "sibling" have the same meaning as those terms do in Section 12945.2.

- (B) A contagious illness that prevents a member from attending in person.
- (C) A need related to a physical or mental disability as defined in Sections 12926 and 12926.1 not otherwise accommodated by subdivision (g).
- (D) Travel while on official business of the legislative body or another state or local agency.
- (3) "Remote location" means a location from which a member of a legislative body participates in a meeting pursuant to subdivision (f), other than any physical meeting location designated in the notice of the meeting. Remote locations need not be accessible to the public.
- (4) "Remote participation" means participation in a meeting by teleconference at a location other than any physical meeting location designated in the notice of the meeting. Watching or listening to a meeting via webcasting or another similar electronic medium that does not permit members to interactively hear, discuss, or deliberate on matters, does not constitute remote participation.
- (5) "State of emergency" means a state of emergency proclaimed pursuant to Section 8625 of the California Emergency Services Act (Article 1 (commencing with Section 8550) of Chapter 7 of Division 1 of Title 2).
- (6) "Teleconference" means a meeting of a legislative body, the members of which are in different locations, connected by electronic means, through either audio or video, or both.
- (7) "Two-way audiovisual platform" means an online platform that provides participants with the ability to participate in a meeting via both an interactive video conference and a two-way telephonic function.
- (8) "Two-way telephonic service" means a telephone service that does not require internet access, is not provided as part of a two-way audiovisual platform, and allows participants to dial a telephone number to listen and verbally participate.
- (9) "Webcasting" means a streaming video broadcast online or on television, using streaming media technology to distribute a single content source to many simultaneous listeners and viewers.
- (k) This section shall remain in effect only until January 1, 2024, 2026, and as of that date is repealed.

- (a) All meetings of the legislative body of a local agency shall be open and public, and all persons shall be permitted to attend any meeting of the legislative body of a local agency, except as otherwise provided in this chapter.
- (b) (1) Notwithstanding any other provision of law, the legislative body of a local agency may use teleconferencing for the benefit of the public and the legislative body of a local agency in connection with any meeting or proceeding authorized by law. The

teleconferenced meeting or proceeding shall comply with all otherwise applicable requirements of this chapter and all otherwise applicable provisions of law relating to a specific type of meeting or proceeding.

- (2) Teleconferencing, as authorized by this section, may be used for all purposes in connection with any meeting within the subject matter jurisdiction of the legislative body. If the legislative body of a local agency elects to use teleconferencing, the legislative body of a local agency shall comply with all of the following:
- (A) All votes taken during a teleconferenced meeting shall be by rollcall.
- (B) The teleconferenced meetings shall be conducted in a manner that protects the statutory and constitutional rights of the parties or the public appearing before the legislative body of a local agency.
- (C) The legislative body shall give notice of the meeting and post agendas as otherwise required by this chapter.
- (D) The legislative body shall allow members of the public to access the meeting and the agenda shall provide an opportunity for members of the public to address the legislative body directly pursuant to Section 54954.3.
- (3) If the legislative body of a local agency elects to use teleconferencing, it shall post agendas at all teleconference locations. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the public. During the teleconference, at least a quorum of the members of the legislative body shall participate from locations within the boundaries of the territory over which the local agency exercises jurisdiction, except as provided in subdivisions (d) and (e).
- (c) (1) No legislative body shall take action by secret ballot, whether preliminary or final.
- (2) The legislative body of a local agency shall publicly report any action taken and the vote or abstention on that action of each member present for the action.
- (3) Prior to taking final action, the legislative body shall orally report a summary of a recommendation for a final action on the salaries, salary schedules, or compensation paid in the form of fringe benefits of a local agency executive, as defined in subdivision (d) of Section 3511.1, during the open meeting in which the final action is to be taken. This paragraph shall not affect the public's right under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1) to inspect or copy records created or received in the process of developing the recommendation.
- (d)(1) Notwithstanding the provisions relating to a quorum in paragraph (3) of subdivision (b), if a health authority conducts a teleconference meeting, members who are outside the jurisdiction of the authority may be counted toward the establishment of a quorum when participating in the teleconference if at least 50 percent of the number of members that would establish a quorum are present within the boundaries of the territory over which the authority exercises jurisdiction, and the health authority provides a teleconference number, and associated access codes, if any, that allows any person to call in to participate in the meeting and the number and access codes are identified in the notice and agenda of the meeting.

- (2) Nothing in this subdivision shall be construed as discouraging health authority members from regularly meeting at a common physical site within the jurisdiction of the authority or from using teleconference locations within or near the jurisdiction of the authority. A teleconference meeting for which a quorum is established pursuant to this subdivision shall be subject to all other requirements of this section.
- (3) For purposes of this subdivision, a health authority means any entity created pursuant to Sections 14018.7, 14087.31, 14087.35, 14087.36, 14087.38, and 14087.9605 of the Welfare and Institutions Code, any joint powers authority created pursuant to Article 1 (commencing with Section 6500) of Chapter 5 of Division 7 for the purpose of contracting pursuant to Section 14087.3 of the Welfare and Institutions Code, and any advisory committee to a county-sponsored health plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code if the advisory committee has 12 or more members.
- (e)(1) The legislative body of a local agency may use teleconferencing without complying with the requirements of paragraph (3) of subdivision (b) if the legislative body complies with the requirements of paragraph (2) of this subdivision in any either of the following circumstances:
- (A) The legislative body holds a meeting during a proclaimed state of emergency, and state or local officials have imposed or recommended measures to promote social distancing.
- (B)(A) The legislative body holds a meeting during a proclaimed state of emergency for the purpose of determining, by majority vote, whether as a result of the emergency, meeting in person would present imminent risks to the health or safety of attendees.
- (C)(B) The legislative body holds a meeting during a proclaimed state of emergency and has determined, by majority vote, pursuant to subparagraph (B), (A), that, as a result of the emergency, meeting in person would present imminent risks to the health or safety of attendees.
- (2) A legislative body that holds a meeting pursuant to this subdivision shall do all of the following:
- (A) In each instance in which notice of the time of the teleconferenced meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body shall also give notice of the means by which members of the public may access the meeting and offer public comment. The agenda shall identify and include an opportunity for all persons to attend via a call-in option or an internet-based service option.
- (B) In the event of a disruption that prevents the legislative body from broadcasting the meeting to members of the public using the call-in option or internet-based service option, or in the event of a disruption within the local agency's control that prevents members of the public from offering public comments using the call-in option or internet-based service option, the legislative body shall take no further action on items appearing on the meeting agenda until public access to the meeting via the call-in option or internet-based service option is restored. Actions taken on agenda items during a disruption that prevents the legislative body from broadcasting the meeting may be challenged pursuant to Section 54960.1.

- (C) The legislative body shall not require public comments to be submitted in advance of the meeting and must provide an opportunity for the public to address the legislative body and offer comment in real time.
- (D) Notwithstanding Section 54953.3, an individual desiring to provide public comment through the use of an internet website, or other online platform, not under the control of the local legislative body, that requires registration to log in to a teleconference may be required to register as required by the third-party internet website or online platform to participate.
- (E)(i) A legislative body that provides a timed public comment period for each agenda item shall not close the public comment period for the agenda item, or the opportunity to register, pursuant to subparagraph (F), (D), to provide public comment until that timed public comment period has elapsed.
- (ii) A legislative body that does not provide a timed public comment period, but takes public comment separately on each agenda item, shall allow a reasonable amount of time per agenda item to allow public members the opportunity to provide public comment, including time for members of the public to register pursuant to subparagraph (F), (D), or otherwise be recognized for the purpose of providing public comment.
- (iii) A legislative body that provides a timed general public comment period that does not correspond to a specific agenda item shall not close the public comment period or the opportunity to register, pursuant to subparagraph (F), (D), until the timed general public comment period has elapsed.
- (3) If a state of emergency remains active, or state or local officials have imposed or recommended measures to promote social distancing, in order to continue to teleconference without compliance with paragraph (3) of subdivision (b), the legislative body shall, not later than 30-45 days after teleconferencing for the first time pursuant to subparagraph (A), (B), (A) or (C)-(B) of paragraph (1), and every 30-45 days thereafter, make the following findings by majority vote:
- (A) The legislative body has reconsidered the circumstances of the state of emergency.
- (B) Any of the following circumstances exist:
- (i)(B) The state of emergency continues to directly impact the ability of the members to meet safely in person.
- (ii) State or local officials continue to impose or recommend measures to promote social distancing.
- (4) This subdivision shall not be construed to require the legislative body to provide a physical location from which the public may attend or comment.
- (f)(1) The legislative body of a local agency may use teleconferencing without complying with paragraph (3) of subdivision (b) if, during the teleconference meeting, at least a quorum of the members of the legislative body participates in person from a singular physical location clearly identified on the agenda, which location shall be open to the

public and situated within the boundaries of the territory over which the local agency exercises jurisdiction and the legislative body complies with all of the following:

- (A) The legislative body shall provide at least one of the following as a means by which the public may remotely hear and visually observe the meeting, and remotely address the legislative body:
- (i) A two-way audiovisual platform.
- (ii) A two-way telephonic service and a live webcasting of the meeting.
- (B) In each instance in which notice of the time of the teleconferenced meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body shall also give notice of the means by which members of the public may access the meeting and offer public comment.
- (C) The agenda shall identify and include an opportunity for all persons to attend and address the legislative body directly pursuant to Section 54954.3 via a call-in option, via an internet-based service option, and at the in-person location of the meeting.
- (D) In the event of a disruption that prevents the legislative body from broadcasting the meeting to members of the public using the call-in option or internet-based service option, or in the event of a disruption within the local agency's control that prevents members of the public from offering public comments using the call-in option or internet-based service option, the legislative body shall take no further action on items appearing on the meeting agenda until public access to the meeting via the call-in option or internet-based service option is restored. Actions taken on agenda items during a disruption that prevents the legislative body from broadcasting the meeting may be challenged pursuant to Section 54960.1.
- (E) The legislative body shall not require public comments to be submitted in advance of the meeting and must provide an opportunity for the public to address the legislative body and offer comment in real time.
- (F) Notwithstanding Section 54953.3, an individual desiring to provide public comment through the use of an internet website, or other online platform, not under the control of the local legislative body, that requires registration to log in to a teleconference may be required to register as required by the third-party internet website or online platform to participate.
- (2) A member of the legislative body shall only participate in the meeting remotely pursuant to this subdivision, if all of the following requirements are met:
- (A) One of the following circumstances applies:
- (i) The member notifies the legislative body at the earliest opportunity possible, including at the start of a regular meeting, of their need to participate remotely for just cause, including a general description of the circumstances relating to their need to appear remotely at the given meeting. The provisions of this clause shall not be used by any member of the legislative body for more than two meetings per calendar year.
- (ii) The member requests the legislative body to allow them to participate in the meeting remotely due to emergency circumstances and the legislative body takes action to

approve the request. The legislative body shall request a general description of the circumstances relating to their need to appear remotely at the given meeting. A general description of an item generally need not exceed 20 words and shall not require the member to disclose any medical diagnosis or disability, or any personal medical information that is already exempt under existing law, such as the Confidentiality of Medical Information Act (Chapter 1 (commencing with Section 56) of Part 2.6 of Division 1 of the Civil Code). For the purposes of this clause, the following requirements apply:

- (I) A member shall make a request to participate remotely at a meeting pursuant to this clause as soon as possible. The member shall make a separate request for each meeting in which they seek to participate remotely.
- (II) The legislative body may take action on a request to participate remotely at the earliest opportunity. If the request does not allow sufficient time to place proposed action on such a request on the posted agenda for the meeting for which the request is made, the legislative body may take action at the beginning of the meeting in accordance with paragraph (4) of subdivision (b) of Section 54954.2.
- (B) The member shall publicly disclose at the meeting before any action is taken, whether any other individuals 18 years of age or older are present in the room at the remote location with the member, and the general nature of the member's relationship with any such individuals.
- (C) The member shall participate through both audio and visual technology.
- (3) The provisions of this subdivision shall not serve as a means for any member of a legislative body to participate in meetings of the legislative body solely by teleconference from a remote location for a period of more than three consecutive months or 20 percent of the regular meetings for the local agency within a calendar year, or more than two meetings if the legislative body regularly meets fewer than 10 times per calendar year.
- (g) The legislative body shall have and implement a procedure for receiving and swiftly resolving requests for reasonable accommodation for individuals with disabilities, consistent with the federal Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and resolving any doubt in favor of accessibility. In each instance in which notice of the time of the meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body shall also give notice of the procedure for receiving and resolving requests for accommodation.
- (h) The legislative body shall conduct meetings subject to this chapter consistent with applicable civil rights and nondiscrimination laws.
- (i)(1) Nothing in this section shall prohibit a legislative body from providing the public with additional teleconference locations.
- (2) Nothing in this section shall prohibit a legislative body from providing members of the public with additional physical locations in which the public may observe and address the legislative body by electronic means.
- (j) For the purposes of this section, the following definitions shall apply:

- (1) "Emergency circumstances" means a physical or family medical emergency that prevents a member from attending in person.
- (2) "Just cause" means any of the following:
- (A) A childcare or caregiving need of a child, parent, grandparent, grandchild, sibling, spouse, or domestic partner that requires them to participate remotely. "Child," "parent," "grandparent," "grandchild," and "sibling" have the same meaning as those terms do in Section 12945.2.
- (B) A contagious illness that prevents a member from attending in person.
- (C) A need related to a physical or mental disability as defined in Sections 12926 and 12926.1 not otherwise accommodated by subdivision (g).
- (D) Travel while on official business of the legislative body or another state or local agency.
- (E) An immunocompromised child, parent, grandparent, grandchild, sibling, spouse, or domestic partner that requires them to participate remotely.
- (3) "Remote location" means a location from which a member of a legislative body participates in a meeting pursuant to subdivision (f), other than any physical meeting location designated in the notice of the meeting. Remote locations need not be accessible to the public.
- (4) "Remote participation" means participation in a meeting by teleconference at a location other than any physical meeting location designated in the notice of the meeting. Watching or listening to a meeting via webcasting or another similar electronic medium that does not permit members to interactively hear, discuss, or deliberate on matters, does not constitute remote participation.
- (5) "State of emergency" means a state of emergency proclaimed pursuant to Section 8625 of the California Emergency Services Act (Article 1 (commencing with Section 8550) of Chapter 7 of Division 1 of Title 2).
- (6) "Teleconference" means a meeting of a legislative body, the members of which are in different locations, connected by electronic means, through either audio or video, or both.
- (7) "Two-way audiovisual platform" means an online platform that provides participants with the ability to participate in a meeting via both an interactive video conference and a two-way telephonic function.
- (8) "Two-way telephonic service" means a telephone service that does not require internet access, is not provided as part of a two-way audiovisual platform, and allows participants to dial a telephone number to listen and verbally participate.
- (9) "Webcasting" means a streaming video broadcast online or on television, using streaming media technology to distribute a single content source to many simultaneous listeners and viewers.
- (k) This section shall remain in effect only until January 1, 2024, 2026, and as of that date is repealed.

54953.

- (a) All meetings of the legislative body of a local agency shall be open and public, and all persons shall be permitted to attend any meeting of the legislative body of a local agency, except as otherwise provided in this chapter.
- (b)(1) Notwithstanding any other provision of law, the legislative body of a local agency may use teleconferencing for the benefit of the public and the legislative body of a local agency in connection with any meeting or proceeding authorized by law. The teleconferenced meeting or proceeding shall comply with all otherwise applicable requirements of this chapter and all otherwise applicable provisions of law relating to a specific type of meeting or proceeding.
- (2) Teleconferencing, as authorized by this section, may be used for all purposes in connection with any meeting within the subject matter jurisdiction of the legislative body. If the legislative body of a local agency elects to use teleconferencing, the legislative body of a local agency shall comply with all of the following:
- (A) All votes taken during a teleconferenced meeting shall be by rollcall.
- (B) The teleconferenced meetings shall be conducted in a manner that protects the statutory and constitutional rights of the parties or the public appearing before the legislative body of a local agency.
- (C) The legislative body shall give notice of the meeting and post agendas as otherwise required by this chapter.
- (D) The legislative body shall allow members of the public to access the meeting and the agenda shall provide an opportunity for members of the public to address the legislative body directly pursuant to Section 54954.3.
- (3) If the legislative body of a local agency elects to use teleconferencing, it shall post agendas at all teleconference locations. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the public. During the teleconference, at least a quorum of the members of the legislative body shall participate from locations within the boundaries of the territory over which the local agency exercises jurisdiction, except as provided in subdivision (d). subdivisions (d) and (e).
- (c) (1) No legislative body shall take action by secret ballot, whether preliminary or final.
- (2) The legislative body of a local agency shall publicly report any action taken and the vote or abstention on that action of each member present for the action.
- (3) Prior to taking final action, the legislative body shall orally report a summary of a recommendation for a final action on the salaries, salary schedules, or compensation paid in the form of fringe benefits of a local agency executive, as defined in subdivision (d) of Section 3511.1, during the open meeting in which the final action is to be taken. This paragraph shall not affect the public's right under the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1) to inspect or copy records created or received in the process of developing the recommendation.

- (d) (1) Notwithstanding the provisions relating to a quorum in paragraph (3) of subdivision (b), if a health authority conducts a teleconference meeting, members who are outside the jurisdiction of the authority may be counted toward the establishment of a quorum when participating in the teleconference if at least 50 percent of the number of members that would establish a quorum are present within the boundaries of the territory over which the authority exercises jurisdiction, and the health authority provides a teleconference number, and associated access codes, if any, that allows any person to call in to participate in the meeting and the number and access codes are identified in the notice and agenda of the meeting.
- (2) Nothing in this subdivision shall be construed as discouraging health authority members from regularly meeting at a common physical site within the jurisdiction of the authority or from using teleconference locations within or near the jurisdiction of the authority. A teleconference meeting for which a quorum is established pursuant to this subdivision shall be subject to all other requirements of this section.
- (3) For purposes of this subdivision, a health authority means any entity created pursuant to Sections 14018.7, 14087.31, 14087.35, 14087.36, 14087.38, and 14087.9605 of the Welfare and Institutions Code, any joint powers authority created pursuant to Article 1 (commencing with Section 6500) of Chapter 5 of Division 7 for the purpose of contracting pursuant to Section 14087.3 of the Welfare and Institutions Code, and any advisory committee to a county-sponsored health plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code if the advisory committee has 12 or more members.
- (e)(1) The legislative body of a local agency may use teleconferencing without complying with the requirements of paragraph (3) of subdivision (b) if, during the teleconference meeting, at least a quorum of the members of the legislative body participates in person from a singular physical location clearly identified on the agenda, which location shall be open to the public and situated within the boundaries of the territory over which the local agency exercises jurisdiction and the legislative body complies with all of the following: if the legislative body complies with the requirements of paragraph (2) of this subdivision in either of the following circumstances:
- (A) The legislative body shall provide at least one of the following as a means by which the public may remotely hear and visually observe the meeting, and remotely address the legislative body: holds a meeting during a proclaimed state of emergency for the purpose of determining, by majority vote, whether as a result of the emergency, meeting in person would present imminent risks to the health or safety of attendees.
- (i)(B) A two-way audiovisual platform. The legislative body holds a meeting during a proclaimed state of emergency and has determined, by majority vote, pursuant to subparagraph (A), that, as a result of the emergency, meeting in person would present imminent risks to the health or safety of attendees.
- (ii)(2) A two-way telephonic service and a live webcasting of the meeting. <u>legislative</u> body that holds a meeting pursuant to this subdivision shall do all of the following:
- (B)(A) In each instance in which notice of the time of the teleconferenced meeting is otherwise given or the agenda for the meeting is otherwise posted, the legislative body

- shall also give notice of the means by which members of the public may access the meeting and offer public comment. The agenda shall identify and include an opportunity for all persons to attend via a call-in option or an internet-based service option.
- (C) The agenda shall identify and include an opportunity for all persons to attend and address the legislative body directly pursuant to Section 54954.3 via a call-in option, via an internet-based service option, and at the in-person location of the meeting.
- (D)(B) In the event of a disruption that prevents the legislative body from broadcasting the meeting to members of the public using the call-in option or internet-based service option, or in the event of a disruption within the local agency's control that prevents members of the public from offering public comments using the call-in option or internet-based service option, the legislative body shall take no further action on items appearing on the meeting agenda until public access to the meeting via the call-in option or internet-based service option is restored. Actions taken on agenda items during a disruption that prevents the legislative body from broadcasting the meeting may be challenged pursuant to Section 54960.1.
- (E)(C) The legislative body shall not require public comments to be submitted in advance of the meeting and must provide an opportunity for the public to address the legislative body and offer comment in real time.
- (F)(D) Notwithstanding Section 54953.3, an individual desiring to provide public comment through the use of an internet website, or other online platform, not under the control of the local legislative body, that requires registration to log in to a teleconference may be required to register as required by the third-party internet website or online platform to participate.
- (2) A member of the legislative body shall only participate in the meeting remotely pursuant to this subdivision, if all of the following requirements are met:
- (A) One of the following circumstances applies:
- (E)(i) The member notifies the legislative body at the earliest opportunity possible, including at the start of a regular meeting, of their need to participate remotely for just cause, including a general description of the circumstances relating to their need to appear remotely at the given meeting. The provisions of this clause shall not be used by any member of the legislative body for more than two meetings per calendar year. A legislative body that provides a timed public comment period for each agenda item shall not close the public comment period for the agenda item, or the opportunity to register, pursuant to subparagraph (D), to provide public comment until that timed public comment period has elapsed.
- (ii) A legislative body that does not provide a timed public comment period, but takes public comment separately on each agenda item, shall allow a reasonable amount of time per agenda item to allow public members the opportunity to provide public comment, including time for members of the public to register pursuant to subparagraph (D), or otherwise be recognized for the purpose of providing public comment.
- (iii) A legislative body that provides a timed general public comment period that does not correspond to a specific agenda item shall not close the public comment period or the

opportunity to register, pursuant to subparagraph (D), until the timed general public comment period has elapsed.

- (ii)(3) The member requests—If a state of emergency remains active, in order to continue to teleconference without compliance with paragraph (3) of subdivision (b), the legislative body to allow them to participate in the meeting remotely due to emergency circumstances and the legislative body takes action to approve the request. The legislative body shall request a general description of the circumstances relating to their need to appear remotely at the given meeting. A general description of an item generally need not exceed 20 words and shall not require the member to disclose any medical diagnosis or disability, or any personal medical information that is already exempt under existing law, such as the Confidentiality of Medical Information Act (Chapter 1 (commencing with Section 56) of Part 2.6 of Division 1 of the Civil Code). For the purposes of this clause, the following requirements apply: shall, not later than 45 days after teleconferencing for the first time pursuant to subparagraph (A) or (B) of paragraph (1), and every 45 days thereafter, make the following findings by majority vote:
- (I) A member shall make a request to participate remotely at a meeting pursuant to this clause as soon as possible. The member shall make a separate request for each meeting in which they seek to participate remotely.
- (II)(A) The legislative body may take action on a request to participate remotely at the earliest opportunity. If the request does not allow sufficient time to place proposed action on such a request on the posted agenda for the meeting for which the request is made, the legislative body may take action at the beginning of the meeting in accordance with paragraph (4) of subdivision (b) of Section 54954.2. has reconsidered the circumstances of the state of emergency.
- (B) The member shall publicly disclose at the meeting before any action is taken whether any other individuals 18 years of age or older are present in the room at the remote location with the member, and the general nature of the member's relationship with any such individuals. state of emergency continues to directly impact the ability of the members to meet safely in person.
- (C) The member shall participate through both audio and visual technology.
- (3)(4) The provisions of this This subdivision shall not serve as a means for any member of a legislative body to participate in meetings of be construed to require the legislative body solely by teleconference from a remote location for a period of more than three consecutive months or 20 percent of the regular meetings for the local agency within a calendar year, or more than two meetings if the legislative body regularly meets fewer than 10 times per calendar year. to provide a physical location from which the public may attend or comment.
- (f) The legislative body shall have and implement a procedure for receiving and swiftly resolving requests for reasonable accommodation for individuals with disabilities, consistent with the federal Americans with Disabilities Act of 1990 (42 U.S.C. Sec. 12132), and resolving any doubt in favor of accessibility. In each instance in which notice of the time of the meeting is otherwise given or the agenda for the meeting is

- otherwise posted, the legislative body shall also give notice of the procedure for receiving and resolving requests for accommodation.
- (g) The legislative body shall conduct meetings subject to this chapter consistent with applicable civil rights and nondiscrimination laws.
- (h) (1) Nothing in this section shall prohibit a legislative body from providing the public with additional teleconference locations.
- (2) Nothing in this section shall prohibit a legislative body from providing members of the public with additional physical locations in which the public may observe and address the legislative body by electronic means.
- (i) For the purposes of this section, the following definitions shall apply:
- (1) "Emergency circumstances" means a physical or family medical emergency that prevents a member from attending in person.
- (2) "Just cause" means any of the following:
- (A) A childcare or caregiving need of a child, parent, grandparent, grandchild, sibling, spouse, or domestic partner that requires them to participate remotely. "Child," "parent," "grandparent," "grandchild," and "sibling" have the same meaning as those terms do in Section 12945.2.
- (B) A contagious illness that prevents a member from attending in person.
- (C) A need related to a physical or mental disability as defined in Sections 12926 and 12926.1 not otherwise accommodated by subdivision (f).
- (D) Travel while on official business of the legislative body or another state or local agency.
- (3)(1) "Remote location" means a location from which a member of a legislative body participates in a meeting pursuant to subdivision (e), other than any physical meeting location designated in the notice of the meeting. Remote locations need not be accessible to the public. "State of emergency" means a state of emergency proclaimed pursuant to Section 8625 of the California Emergency Services Act (Article 1 (commencing with Section 8550) of Chapter 7 of Division 1 of Title 2).
- (4) "Remote participation" means participation in a meeting by teleconference at a location other than any physical meeting location designated in the notice of the meeting. Watching or listening to a meeting via webcasting or another similar electronic medium that does not permit members to interactively hear, discuss, or deliberate on matters, does not constitute remote participation.
- (5)(2) "Teleconference" means a meeting of a legislative body, the members of which are in different locations, connected by electronic means, through either audio or video, or both.
- (6) "Two-way audiovisual platform" means an online platform that provides participants with the ability to participate in a meeting via both an interactive video conference and a two-way telephonic function.

- (7) "Two-way telephonic service" means a telephone service that does not require internet access, is not provided as part of a two-way audiovisual platform, and allows participants to dial a telephone number to listen and verbally participate.
- (8) "Webcasting" means a streaming video broadcast online or on television, using streaming media technology to distribute a single content source to many simultaneous listeners and viewers.
- (j) This section shall become operative January 1, 2024, shall remain in effect only until January 1, 2026, and as of that date is repealed.

54953.

- (a) All meetings of the legislative body of a local agency shall be open and public, and all persons shall be permitted to attend any meeting of the legislative body of a local agency, except as otherwise provided in this chapter.
- (b) (1) Notwithstanding any other provision of law, the legislative body of a local agency may use teleconferencing for the benefit of the public and the legislative body of a local agency in connection with any meeting or proceeding authorized by law. The teleconferenced meeting or proceeding shall comply with all requirements of this chapter and all otherwise applicable provisions of law relating to a specific type of meeting or proceeding.
- (2) Teleconferencing, as authorized by this section, may be used for all purposes in connection with any meeting within the subject matter jurisdiction of the legislative body. All votes taken during a teleconferenced meeting shall be by rollcall.
- (3) If the legislative body of a local agency elects to use teleconferencing, it shall post agendas at all teleconference locations and conduct teleconference meetings in a manner that protects the statutory and constitutional rights of the parties or the public appearing before the legislative body of a local agency. Each teleconference location shall be identified in the notice and agenda of the meeting or proceeding, and each teleconference location shall be accessible to the public. During the teleconference, at least a quorum of the members of the legislative body shall participate from locations within the boundaries of the territory over which the local agency exercises jurisdiction, except as provided in subdivision (d). The agenda shall provide an opportunity for members of the public to address the legislative body directly pursuant to Section 54954.3 at each teleconference location.
- (4) For the purposes of this section, "teleconference" means a meeting of a legislative body, the members of which are in different locations, connected by electronic means, through either audio or video, or both. Nothing in this section shall prohibit a local agency from providing the public with additional teleconference locations.
- (c) (1) No legislative body shall take action by secret ballot, whether preliminary or final.
- (2) The legislative body of a local agency shall publicly report any action taken and the vote or abstention on that action of each member present for the action.

- (3) Prior to taking final action, the legislative body shall orally report a summary of a recommendation for a final action on the salaries, salary schedules, or compensation paid in the form of fringe benefits of a local agency executive, as defined in subdivision (d) of Section 3511.1, during the open meeting in which the final action is to be taken. This paragraph shall not affect the public's right under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1) to inspect or copy records created or received in the process of developing the recommendation.
- (d) (1) Notwithstanding the provisions relating to a quorum in paragraph (3) of subdivision (b), if a health authority conducts a teleconference meeting, members who are outside the jurisdiction of the authority may be counted toward the establishment of a quorum when participating in the teleconference if at least 50 percent of the number of members that would establish a quorum are present within the boundaries of the territory over which the authority exercises jurisdiction, and the health authority provides a teleconference number, and associated access codes, if any, that allows any person to call in to participate in the meeting and the number and access codes are identified in the notice and agenda of the meeting.
- (2) Nothing in this subdivision shall be construed as discouraging health authority members from regularly meeting at a common physical site within the jurisdiction of the authority or from using teleconference locations within or near the jurisdiction of the authority. A teleconference meeting for which a quorum is established pursuant to this subdivision shall be subject to all other requirements of this section.
- (3) For purposes of this subdivision, a health authority means any entity created pursuant to Sections 14018.7, 14087.31, 14087.35, 14087.36, 14087.38, and 14087.9605 of the Welfare and Institutions Code, any joint powers authority created pursuant to Article 1 (commencing with Section 6500) of Chapter 5 of Division 7 for the purpose of contracting pursuant to Section 14087.3 of the Welfare and Institutions Code, and any advisory committee to a county-sponsored health plan licensed pursuant to Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code if the advisory committee has 12 or more members.
- (e) This section shall become operative January 1, 2026.

Health and Safety Code

1220.1

- (a) An application for licensure made pursuant to this chapter shall not be denied, nor shall any license issued pursuant to this chapter be suspended, revoked, or otherwise limited, on the basis of a civil judgment, criminal conviction, or disciplinary action imposed by another state if that judgment, conviction, or disciplinary action is based solely on the application of another state's law that interferes with a person's right to receive sensitive services that would be lawful if provided in this state.
- (b) This section does not apply to a civil judgment, criminal conviction, or disciplinary action imposed by another state based upon conduct in another state that would subject

- an applicant, licensee, or health care practitioner subject to this division to a similar claim, charge, or action under the laws of this state.
- (c) For purposes of this section, "sensitive services" has the same meaning as in Section 56.05 of the Civil Code.

1265.11.

- (a) An application for licensure made pursuant to this chapter shall not be denied, nor shall any license issued pursuant to this chapter be suspended, revoked, or otherwise limited, on the basis of a civil judgment, criminal conviction, or disciplinary action imposed by another state if that judgment, conviction, or disciplinary action is based solely on the application of another state's law that interferes with a person's right to receive sensitive services that would be lawful if provided in this state.
- (b) This section does not apply to a civil judgment, criminal conviction, or disciplinary action imposed by another state based upon conduct in another state that would subject an applicant, licensee, or health care practitioner subject to this division to a similar claim, charge, or action under the laws of this state.
- (c) For purposes of this section, "sensitive services" has the same meaning as in Section 56.05 of the Civil Code.

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.

- (6) A copayment or percentage coinsurance shall not exceed 50 percent of the cost to the plan, as described in Section 1300.67.24 of Title 28 of the California Code of Regulations.
- (7) If there is a generic equivalent to a brand name drug, a plan shall ensure that the enrollee is subject to the lowest cost sharing that would be applied, whether or not both the generic equivalent and the brand name drug are on the formulary. This paragraph shall not be construed to require both the generic equivalent and the brand name drug to be on the formulary.
- (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 comply with 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.

1367.206.

- (a) If there is more than one drug that is clinically appropriate for the treatment of a medical condition, a health care service plan that provides coverage for prescription drugs may require step therapy.
- (b) A health care service plan shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 1367.241 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee, taking into consideration the enrollee's needs and medical history, along with the professional judgment of the enrollee's provider. The basis of the provider's determination may include, but is not limited to, any of the following criteria:
- (1) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the enrollee in comparison to the requested prescription drug, based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.
- (2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.
- (3) The enrollee has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health care service plan may require the submission of documentation demonstrating that the enrollee tried the required prescription drug before it was discontinued.
- (4) The required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to do any of the following, as determined by the enrollee's prescribing provider:
- (A) Worsen a comorbid condition.
- (B) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.
- (C) Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care.
- (5) The enrollee is stable on a prescription drug selected by the enrollee's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.
- (c) A health care provider or prescribing provider may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the health care service plan's current utilization management processes.

- (d) An enrollee or the enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.
- (e)(1) This section does not prohibit either of the following: a health care provider from prescribing a prescription drug that is clinically appropriate.
- (1)(2) A-This section does not prohibit a health care service plan or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code, or interchangeable biological product product, as defined in Section 262(i)(3) of Title 42 of the United States Code, before providing coverage for the equivalent branded prescription drug.
- (2)(3) A health care provider from prescribing a prescription drug that is clinically appropriate. Paragraph (2) does not prohibit or supersede a step therapy exception request as described in subdivision (b).
- (f) 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.
- (g) For purposes of this section, "step therapy exception" means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual enrollee.
- (h) Commencing January 1, 2022, a health care service plan contract with a utilization review organization, medical group, or other contracted entity that performs utilization review or utilization management functions on a health care service plan's behalf shall include terms that require the contracted entity to comply with this section and Section 1367.241.

1368.5.

- (a) Every health care service plan that offers coverage for a service that is within the scope of practice of a duly licensed pharmacist may shall pay or reimburse the cost of the service performed by a pharmacist for the plan if the pharmacist otherwise provides services for the plan. at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the health care service plan has an out-of-network pharmacy benefit.
- (b) Payment or reimbursement may be made pursuant to this section for a service performed by a duly licensed pharmacist only when all of the following conditions are met:
- (1) The service performed is within the lawful scope of practice of the pharmacist.
- (2) The coverage otherwise provides reimbursement for identical services performed by other licensed health care providers.

(c) Nothing in this section shall require the plan to pay a claim to more than one provider for duplicate service or be interpreted to limit physician reimbursement.

1649.1.

Unless the context requires otherwise, the following definitions shall apply to <u>for purposes of</u> this chapter:

- (a) "Compassionate Use Act of 1996" means the initiative measure enacted by the approval of Proposition 215 at the November 5, 1996, statewide general election and found at Section 11362.5, and any amendments to that act.
- (b) (1) Except as provided in paragraph (2), "health care facility" means a health facility specified in subdivision (a), (c), (f), (i), or (n) of Section 1250. 1250 or a home health agency licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2.
- (2) The meaning of "health care facility" shall not include any of the following:
- (A) A chemical dependency recovery hospital.
- (B) A state hospital.
- (C) An emergency department of a health care facility, as specified in subdivision (a) of Section 1250, while the patient is receiving emergency services and care.
- (c) "Home health agency" means a private or public organization, including, but not limited to, any partnership, corporation, political subdivision of the state, or other government agency within the state, that provides, or arranges for the provision of, skilled nursing services, to persons in their temporary or permanent place of residence and is licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2.
- (e)(d) "Medicinal cannabis" means cannabis or a cannabis product used in compliance with the Compassionate Use Act of 1996 and Article 2.5 (commencing with Section 11362.7) of Chapter 6 of Division 10.
- (d)(e) "Patient" means an individual who is terminally ill. "Patient" does not include an individual receiving emergency services and care, as defined in Section 1317.1. meets one or both of the following criteria:

(1) Is terminally ill.

- (2) Is over 65 years of age with a chronic disease for which the patient has received a physician's assessment declaring that the patient has a serious medical condition, as defined by subdivision (h) of Section 11362.7 and that the use of medicinal cannabis is appropriate.
- (e)(f) "Terminally ill" means a medical condition resulting in a prognosis of life of one year or less, if the disease follows its natural course.

1649.2.

A (a) Except as provided in subdivision (b), a health care facility shall permit patient use of medical cannabis medicinal cannabis, as indicated by the attending physician, as

- <u>defined by Section 11362.7, in the patient's medical record</u> and shall do all of the following:
- (1)(A) A home health agency shall prohibit smoking or vaping immediately before or while home health agency staff are present in the residence.
- (a)(B) Prohibit All other health facilities shall prohibit smoking or vaping as methods to use medicinal cannabis.
- (b)(2) Include the use of medicinal cannabis within the patient's medical records.
- (c)(3) Require a patient to provide a copy of the patient's valid identification card, as described in Section 11362.715, or a copy of that patient's written documentation as defined in Section 11362.7.
- (d)(4) Require a patient or a primary caregiver, as defined in Section 11362.7, to be responsible for acquiring, retrieving, administering, and removing medicinal cannabis.
- (e)(5) Require medicinal cannabis to be stored securely at all times in a locked container in the patient's room, other designated area, or with the patient's primary caregiver. This requirement does not apply to a home health agency.
- (f)(6) Prohibit health care professionals and facility staff, professionals, health care facility staff, and home health agency staff, including, but not limited to, physicians, nurses, and pharmacists, from administering medicinal cannabis or retrieving medicinal cannabis from storage.
- (g)(7) Develop and disseminate written guidelines Develop, disseminate, and train health facility staff on the written guidelines developed by the facility for the use and disposal of medicinal cannabis within the health care facility pursuant to this chapter. This requirement does not apply to a home health agency.
- (8) Ensure that a patient is not denied admission to the health care facility in whole or in part because of the patient's use of medicinal cannabis.
- (b) Notwithstanding subdivision (a), a general acute care hospital specified in subdivision (a) of Section 1250 shall not permit a patient with a chronic disease to use medicinal cannabis.

1649.3.

- (a) Upon discharge, all remaining medicinal cannabis shall be removed by the patient or patient's primary caregiver. If a patient cannot remove the medicinal cannabis and does not have a primary caregiver that is available to remove the medicinal cannabis, the product shall be stored in a locked container until it is disposed of in accordance with the health facility policy and procedure governing medicinal cannabis.
- (b) Subdivision (a) does not apply to a home health agency licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2.

1649.6.

- (a) If a federal regulatory agency, the United States Department of Justice (US DOJ), or the federal Centers for Medicare and Medicaid Services (CMS) takes one of the following actions, or makes an inquiry about the health care facility's activities pursuant to Section 1649.2, a health care facility may suspend compliance with Section 1649.2 until the regulatory agency, the US DOJ, or CMS notifies the health care facility that it may resume permitting the use of medicinal cannabis within the facility:
- (1) A federal regulatory agency or the US DOJ initiates enforcement action action including a notice to suspend funding, against a health care facility related to the facility's compliance with a state-regulated medical marijuana program.
- (2) A federal regulatory agency, the US DOJ, or CMS issues a <u>rule-rule</u>, <u>guidance</u>, or otherwise provides notification to the health care facility that expressly prohibits the use of medical marijuana in health care facilities or otherwise prohibits compliance with a state-regulated medical marijuana program.
- (b) This section does not permit a health care facility to prohibit patient use of medicinal cannabis due solely to the fact that cannabis is a Schedule I drug pursuant to the federal Uniform Controlled Substances Act, or other federal constraints on the use of medicinal cannabis that were in existence prior to the enactment of this chapter.

1799.113.

- (a)(1) A person who, in good faith and not for compensation, renders emergency treatment at the scene of an opioid overdose or suspected opioid overdose by administering an opioid antagonist shall not be liable for civil damages resulting from an act or omission related to the rendering of the emergency treatment.
- (2) A person who, in good faith and not for compensation, furnishes an opioid antagonist to a person for use at the scene of an opioid overdose or suspected opioid overdose shall not be liable for civil damages resulting from an act or omission related to the furnishing of the opioid antagonist.
- (b) This section does not apply to an act or omission related to the rendering of emergency treatment at the scene of an opioid overdose or suspected opioid overdose by means of an opioid antagonist that constitutes gross negligence or willful or wanton misconduct.
- (c) For purposes of this section, both of the following apply:
- (1) A person who renders emergency treatment by means of an opioid antagonist, or who furnishes an opioid antagonist at the scene of an opioid overdose or suspected opioid overdose, and who is not compensated for doing so, but receives compensation for other actions as a result of their unrelated employment, is not "rendering emergency medical care or furnishing opioid antagonist for compensation."

(2) "Opioid antagonist" means naloxone hydrochloride or any other opioid antagonist that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose.

11150.3.

- (a) Notwithstanding any other law, if a substance listed in Schedule I of Section 11054 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 one of these substances 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 their 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 any of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of the excluded substance 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 cannabis or a cannabis product, as defined in Section 26001 of the Business and Professions Code. However, cannabis or cannabis products may be authorized pursuant to Section 11150.2.

11165.4.

- (a)(1)(A)(i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.
- (ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

- (iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.
- (B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.
- (2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.
- (b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.
- (c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:
- (1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:
- (A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
- (B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.
- (C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
- (D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
- (E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.
- (F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.
- (2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

- (3) If a health care practitioner prescribes, orders, administers, or furnishes buprenorphine or other controlled substance containing buprenorphine in the emergency department of a general acute care hospital.
- (3)(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:
- (A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
- (B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.
- (C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
- (D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
- (E) A place of practice, as defined in Section 1658 of the Business and Professions Code.
- (F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.
- (4)(5) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.
- (5)(6) (A) If all of the following circumstances are satisfied:
- (i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.
- (ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.
- (iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.
- (B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.
- (6)(7) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.

- (7)(8) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.
- (8)(9) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.
- (d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.
- (2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.
- (e) All applicable state and federal privacy laws govern the duties required by this section.
- (f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.
- (g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

<u>11870.</u>

For purposes of this chapter, the following definitions apply:

- (a) "Amusement park" means a gated facility that requires a ticket for entry, has attendance greater than 1,000,000 visitors annually, and operates 10 or more amusement rides regulated under Sections 7900 to 7919, inclusive, and Sections 7920 to 7932, inclusive, of the Labor Code.
- (b) "Auto-injector" means a disposable delivery device designed for the automatic injection of a premeasured dose of an opioid antagonist into the human body and approved by the United States Food and Drug Administration for layperson use.
- (c) "Opioid antagonist" means naloxone hydrochloride or another drug approved by the United States Food and Drug Administration that, when administered, negates or neutralizes in whole or in part the pharmacological effects of an opioid in the body, and has been approved for the treatment of an opioid overdose.

11871.

<u>Each stadium, concert venue, and amusement park shall, at all times, maintain unexpired doses of naloxone hydrochloride or any other opioid antagonist on its</u>

premises and ensure that at least two employees are aware of the location of the naloxone hydrochloride or other opioid antagonist.

<u>11872.</u>

- (a)(1) Notwithstanding any other law except for Division 5 (commencing with Section 6300) of the Labor Code and Chapters 3.2 (commencing with Section 330), 3.3 (commencing with Section 345), 3.5 (commencing with Section 401), 4 (commencing with Section 450), and 7 (commencing with Section 14000) of Division 1 of Title 8 of the California Code of Regulations, a person who, in good faith, administers naloxone hydrochloride or another opioid antagonist by nasal spray or by auto-injector on the premises of a stadium, concert venue, or amusement park to a person who appears to be experiencing an opioid overdose shall not be liable in a civil action, or be subject to criminal prosecution for their acts or omissions in administering the naloxone hydrochloride or another opioid antagonist.
- (2)(A) The protection specified in subdivision (a) shall not apply in a case of gross negligence or willful and wanton misconduct of the person who renders emergency care treatment by the use of naloxone hydrochloride or another opioid antagonist.
- (B) Subparagraph (A) shall not apply to an employee of a stadium, concert venue, or amusement park, or an employee of an entity that owns, occupies, or operates a stadium, concert venue, or amusement park.
- (b) Notwithstanding any other law except for Division 5 (commencing with Section 6300) of the Labor Code and Chapters 3.2 (commencing with Section 330), 3.3 (commencing with Section 345), 3.5 (commencing with Section 401), 4 (commencing with Section 450), and 7 (commencing with Section 14000) of Division 1 of Title 8 of the California Code of Regulations, a stadium, concert venue, or amusement park, or its employees, or an entity that owns, occupies, or operates a stadium, concert venue, or amusement park, or its employees, shall not be liable in a civil action, or be subject to criminal prosecution, for the administration of naloxone hydrochloride or another opioid antagonist on the premises of the stadium, concert venue, or amusement park, including by an employee of the stadium, concert venue, or amusement park, or by an employee of the entity that owns, occupies, or operates the stadium, concert venue, or amusement park.
- (c) Notwithstanding any other law except for Division 5 (commencing with Section 6300) of the Labor Code and Chapters 3.2 (commencing with Section 330), 3.3 (commencing with Section 345), 3.5 (commencing with Section 401), 4 (commencing with Section 450), and 7 (commencing with Section 14000) of Division 1 of Title 8 of the California Code of Regulations, a stadium, concert venue, or amusement park, or its employees, or an entity that owns, occupies, or operates a stadium, concert venue, or amusement park, or its employees, shall have no obligation to administer naloxone hydrochloride or another opioid antagonist in the event of an apparent opioid overdose on the premises of the stadium, concert venue, or amusement park, and shall not be liable in a civil action, or be subject to criminal prosecution, if they fail to identify an apparent opioid

<u>overdose or fail to administer naloxone hydrochloride or another opioid antagonist on</u> the premises of the stadium, concert venue, or amusement park.

<u>Article 3. Prescription Drug Pricing for Covered Entities</u> 127470.

For purposes of this article:

- (a) "Covered drug" means a drug purchased by a covered entity that is subject to the federal pricing requirements set forth in Section 256b of Title 42 of the United States Code.
- (b) "Covered entity" means a provider defined as a covered entity in Section 256b of Title 42 of the United States Code.
- (c) "Pharmacy benefit manager" has the same meaning as defined in Section 4430 of the Business and Professions Code and includes a wholly or partially owned or controlled subsidiary of a pharmacy benefit manager.
- (d) "Specified pharmacy" means a pharmacy owned by, or under contract with, a covered entity that is registered with the 340B discount drug purchasing program to dispense covered drugs on behalf of the covered entity, whether in person or via mail.

<u>127471.</u>

- (a) A pharmacy benefit manager shall not impose any requirements, conditions, or exclusions that do either of the following:
- (1) Discriminate against a covered entity or a specified pharmacy in connection with dispensing covered drugs.
- (2) Prevent a covered entity from retaining the benefit of discounted pricing for the purchase of covered drugs.
- (b) Discrimination prohibited pursuant to subdivision (a) includes, but is not limited to, all of the following:
- (1) Payment terms, reimbursement methodologies, or other terms and conditions that distinguish between covered drugs and other drugs, account for the availability of discounts under the 340B discount drug purchasing program described in Section 256b of Title 42 of the United States Code in determining reimbursement, or are less favorable than the payment terms or reimbursement methodologies for similarly situated entities that are not furnishing or dispensing covered drugs.
- (2) Terms or conditions applied to covered entities or specified pharmacies based on the furnishing or dispensing of covered drugs or their status as a covered entity or specified pharmacy, including restrictions or requirements for participation in specialty,

- standard, or preferred pharmacy networks, or requirements related to the frequency or scope of audits.
- (3) Refusing to contract with or terminating a contract with a covered entity or specified pharmacy, or otherwise excluding a covered entity or specified pharmacy from a specialty, standard or preferred network, on the basis that the entity or pharmacy is a covered entity or a specified pharmacy or for reasons other than those that apply equally to entities or pharmacies that are not covered entities or specified pharmacies.
- (4) Retaliation against a covered entity or specified pharmacy based on its exercise of any right or remedy under this article.
- (5) Interfering with an individual's choice to receive a covered drug from a covered entity or specified pharmacy, whether in person or via direct delivery, mail, or other form of shipment.
- (6) Restricting or prohibiting a covered entity from raising a grievance or speaking publicly about any pharmacy benefit manager that violates this subdivision or from filing a legal action against a pharmacy benefit manager for violating this subdivision.
- (c) This section does not apply to the Medi-Cal program or the federal Medicare

 Program but does apply to pharmacy benefit managers that contract with managed care
 organizations that serve Medi-Cal or Medicare members.
- (d) The provisions of this section shall not be waived, voided, or nullified by contract.
- (e) This article shall only be implemented to the extent that it is consistent with Section 256b of Title 42 of the United States Code or any rules or regulations adopted thereunder.

Insurance Code

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 shall apply 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.
- (6) A copayment or percentage coinsurance shall not exceed 50 percent of the cost to the insurer, as described in Section 1300.67.24 of Title 28 of the California Code of Regulations.
- (7) If there is a generic equivalent to a brand name drug, an insurer shall ensure that the insured is subject to the lowest cost sharing that would be applied, whether or not both the generic equivalent and the brand name drug are on the formulary. This paragraph shall not be construed to require both the generic equivalent and the brand name drug to be on the formulary.
- (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 comply with 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.

10123.201.

- (a) A policy of health insurance that covers outpatient prescription drugs shall cover medically necessary drugs. The policy may provide for step therapy and prior authorization consistent with Section 1342.7 of the Health and Safety Code and any regulations adopted pursuant to that section.
- (b)(1) Commencing January 1, 2017, an insurer shall maintain a pharmacy and therapeutics committee that shall be responsible for developing, maintaining, and overseeing any drug formulary list. If the insurer delegates responsibility for the formulary to any entity, the obligation of the insurer to comply with this part shall not be waived.
- (2) The pharmacy and therapeutics committee board membership shall conform with both of the following:
- (A) Represent a sufficient number of clinical specialties to adequately meet the needs of insureds.
- (B) Consist of a majority of individuals who are practicing physicians, practicing pharmacists, and other practicing health professionals who are licensed to prescribe drugs.
- (3) Members of the board shall abstain from voting on any issue in which the member has a conflict of interest with respect to the issuer or a pharmaceutical manufacturer.
- (4) At least 20 percent of the board membership shall not have a conflict of interest with respect to the issuer or any pharmaceutical manufacturer.
- (5) The pharmacy and therapeutics committee shall meet at least quarterly and shall maintain written documentation of the rationale for its decisions regarding the development of, or revisions to, the formulary drug list.
- (6) The pharmacy and therapeutics committee shall do all of the following:
- (A) Develop and document procedures to ensure appropriate drug review and inclusion.
- (B) Base clinical decisions on the strength of the scientific evidence and standards of practice, including assessing peer-reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other related information.
- (C) Consider the therapeutic advantages of drugs in terms of safety and efficacy when selecting formulary drugs.
- (D) Review policies that guide exceptions and other utilization management processes, including drug utilization review, quantity limits, and therapeutic interchange.

- (E) Evaluate and analyze treatment protocols and procedures related to the insurer's formulary at least annually.
- (F) Review and approve all clinical prior authorization criteria, step therapy protocols, and quantity limit restrictions applied to each covered drug.
- (G) Review new United States Food and Drug Administration-approved drugs and new uses for existing drugs.
- (H) Ensure the insurer's formulary drug list or lists cover a range of drugs across a broad distribution of therapeutic categories and classes and recommended drug treatment regimens that treat all disease states and does not discourage enrollment by any group of insureds.
- (I) Ensure the insurer's formulary drug list or lists provide appropriate access to drugs that are included in broadly accepted treatment guidelines and that are indicative of general best practices at the time.
- (7) This subdivision shall be interpreted consistent with federal guidance issued under paragraph (3) of subdivision (a) of Section 156.122 of Title 45 of the Code of Federal Regulations. This subdivision shall apply to the individual, small group, and large group markets.
- (c)(1) A health insurer may impose prior authorization requirements on prescription drug benefits, consistent with the requirements of this part.
- (2)(A) If there is more than one drug that is clinically appropriate for the treatment of a medical condition, a health insurer may require step therapy.
- (B) A health insurer shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 10123.191 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the insured, taking into consideration the insured's needs and medical history, along with the professional judgment of the insured's provider. The basis of the provider's determination may include, but is not limited to, any of the following criteria:
- (i) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the insured in comparison to the requested prescription drug, based on the known clinical characteristics of the insured and the known characteristics and history of the insured's prescription drug regimen.
- (ii) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the insured and the known characteristics and history of the insured's prescription drug regimen.
- (iii) The insured has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The health

insurer may require the submission of documentation demonstrating that the insured tried the required prescription drug before it was discontinued.

- (iv) The required prescription drug is not clinically appropriate for the insured because the required drug is expected to do any of the following, as determined by the insured's prescribing provider:
- (I) Worsen a comorbid condition.
- (II) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.
- (III) Pose a significant barrier to adherence to, or compliance with, the insured's drug regimen or plan of care.
- (v) The insured is stable on a prescription drug selected by the insured's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.
- (C)(i) This section does not prohibit either of the following: a health care provider from prescribing a prescription drug that is clinically appropriate.
- (i)(ii) An-This section does not prohibit an insurer or utilization review organization from requiring an insured to try an AB-rated generic equivalent equivalent, biosimilar, as defined in Section 262(i)(2) of Title 42 of the United States Code, or interchangeable biological product product, as defined in Section 262(i)(3) of Title 42 of the United States Code, before providing coverage for the equivalent branded prescription drug.
- (ii)(iii) A health care provider from prescribing a prescription drug that is clinically appropriate. Clause (ii) does not prohibit or supersede a step therapy exception request as described in subparagraph (B) of paragraph (2) of subdivision (c).
- (3) An insurer shall provide coverage for the medically necessary dosage and quantity of the drug prescribed for the treatment of a medical condition consistent with professionally recognized standards of practice.
- (4) For plan years commencing on or after January 1, 2017, an insurer that provides essential health benefits shall allow an insured to access prescription drug benefits at an in-network retail pharmacy unless the prescription drug is subject to restricted distribution by the United States Food and Drug Administration or requires special handling, provider coordination, or patient education that cannot be provided by a retail pharmacy. A nongrandfathered individual or small group health insurer may charge an insured a different cost sharing for obtaining a covered drug at a retail pharmacy, but all cost sharing shall count toward the policy's annual limitation on cost sharing consistent with Section 10112.28.
- (d) A health care provider or prescribing provider may file an internal appeal of a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the health insurer's current utilization management processes.

- (e) An insured or the insured's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing an internal appeal with the health insurer pursuant to Section 2719 of the federal Public Health Service Act (42 U.S.C. Sec. 300gg-19) and any subsequent rules or regulations issued thereunder.
- (f) Every health insurer that provides prescription drug benefits shall maintain all of the following information, which shall be made available to the commissioner upon request:
- (1) The complete drug formulary or formularies of the insurer, if the insurer maintains a formulary, including a list of the prescription drugs on the formulary of the insurer by major therapeutic category with an indication of whether any drugs are preferred over other drugs.
- (2) Records developed by the pharmacy and therapeutics committee of the insurer, or by others responsible for developing, modifying, and overseeing formularies, including medical groups, individual practice associations, and contracting pharmaceutical benefit management companies, used to guide the drugs prescribed for the insureds of the insurer, that fully describe the reasoning behind formulary decisions.
- (3) Any insurer arrangements with prescribing providers, medical groups, individual practice associations, pharmacists, contracting pharmaceutical benefit management companies, or other entities that are associated with activities of the insurer to encourage formulary compliance or otherwise manage prescription drug benefits.
- (g) If an insurer provides prescription drug benefits, the commissioner shall, as part of its market conduct examination, review the performance of the insurer in providing those benefits, including, but not limited to, a review of the procedures and information maintained pursuant to this section, and describe the performance of the insurer as part of its report issued as part of its market conduct examination.
- (h) The commissioner shall not publicly disclose any information reviewed pursuant to this section that is determined by the commissioner to be confidential pursuant to state law.
- (i) For purposes of this section, the following definitions shall apply:
- (1) "Authorization" means approval by the health insurer to provide payment for the prescription drug.
- (2) "Step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.
- (3) "Step therapy exception" means a decision to override a generally applicable step therapy protocol in favor of coverage of the prescription drug prescribed by a health care provider for an individual insured.
- (4) "Utilization review organization" means an entity that conducts utilization review, other than a health insurer performing its own utilization review.

- (j) Nonformulary prescription drugs shall include any drug for which an insured's copayment or out-of-pocket costs are different than the copayment for a formulary prescription drug, except as otherwise provided by law or regulation.
- (k) This section does not affect an insured's or policyholder's eligibility to submit a complaint to the department for review or to apply to the department for an independent medical review under Article 3.5 (commencing with Section 10169).
- (I) This section does not restrict or impair the application of any other provision of this part.
- (m) This section and Section 10123.191 apply to both the health insurer and a utilization review organization that performs utilization review or utilization management functions on the insurer's behalf. Commencing January 1, 2022, a contract between a health insurer and a utilization review organization that performs utilization review or utilization management functions on the insurer's behalf shall include terms that require the utilization review organization to comply with this section and Section 10123.191.

10125.1.

- (a) Every insurer issuing group-disability insurance that covers hospital, medical, or surgical expenses that offers coverage for a service that is within the scope of practice of a duly licensed pharmacist may shall pay or reimburse the cost of the service performed by a pharmacist for the insurer if the pharmacist otherwise provides services for the insurer. at an in-network pharmacy or a pharmacist at an out-of-network pharmacy if the insurer has an out-of-network pharmacy benefit.
- (b) Payment or reimbursement may be made pursuant to this section for a service performed by a duly licensed pharmacist only when all of the following conditions are met:
- (1) The service performed is within the lawful scope of practice of the pharmacist.
- (2) The coverage otherwise provides reimbursement for identical services performed by other licensed health care providers.
- (c) Nothing in this section shall require the insurer to pay a claim to more than one provider for duplicate service or be interpreted to limit physician reimbursement.