

Statutory Changes in Pharmacy Law

Unless otherwise noted, the provisions take effect January 1, 2022

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

Business and Professions Code Changes

115.5. Expedited Licensure Process (Repealed 7/1/2022)

- (a) A board within the department shall expedite the licensure process for an applicant who meets both of the following requirements:
 - (1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.
 - (2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which the applicant seeks a license from the board.
- (b) A board may adopt regulations necessary to administer this section.
- (c) This section shall remain in effect only until July 1, 2022, and as of that date is repealed.

115.5. Expedited Licensure Process (Operative 7/1/2022)

- (a) A board within the department shall expedite the licensure process and waive the licensure application fee and the initial or original license fee charged by the board for an applicant who meets both of the following requirements:
 - (1) Supplies evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.
 - (2) Holds a current license in another state, district, or territory of the United States in the profession or vocation for which the applicant seeks a license from the board.
- (b) A board may adopt regulations necessary to administer this section.
- (c) This section shall become operative on July 1, 2022.

115.6. Temporary Licensure Process for Spouses of the Armed Forces (Operative 7/1/2023)

- (a)(1) Except as provided in subdivision (j), a board within the department shall, after appropriate investigation, issue a temporary license to practice a profession or vocation to an applicant who meets the requirements set forth in subdivisions (c) and (d).
- (2) Revenues from fees for temporary licenses issued by the California Board of Accountancy shall be credited to the Accountancy Fund in accordance with Section 5132.
- (b) The board may conduct an investigation of an applicant for purposes of denying or revoking a temporary license issued pursuant to this section. This investigation may include a criminal background check.
- (c) An applicant seeking a temporary license pursuant to this section shall meet the following requirements:
 - (1) The applicant shall supply evidence satisfactory to the board that the applicant is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States who is assigned to a duty station in this state under official active duty military orders.
 - (2) The applicant shall hold a current, active, and unrestricted license that confers upon the applicant the authority to practice, in another state, district, or territory of the United States, the profession or vocation within the same scope for which the applicant seeks a temporary license from the board.
 - (3) The applicant shall submit an application to the board that shall include a signed affidavit attesting to the fact that the applicant meets all of the requirements for the temporary license, and that the information submitted in the application is accurate, to the best of the applicant's knowledge. The application shall also include written verification from the applicant's original licensing jurisdiction stating that the applicant's license is in good standing in that jurisdiction.
 - (4) The applicant shall not have committed an act in any jurisdiction that would have constituted grounds for denial, suspension, or revocation of the license under this code at the time the act was committed. A violation of this paragraph may be grounds for the denial or revocation of a temporary license issued by the board.
 - (5) The applicant shall not have been disciplined by a licensing entity in another jurisdiction and shall not be the subject of an unresolved complaint, review procedure, or disciplinary proceeding conducted by a licensing entity in another jurisdiction.
- (6)(A) The applicant shall, upon request by a board, furnish a full set of fingerprints for purposes of conducting a criminal background check.

- (B) The board shall request a fingerprint-based criminal history information check from the Department of Justice in accordance with subdivision (u) of Section 11105 of the Penal Code and the Department of Justice shall furnish state or federal criminal history information in accordance with subdivision (p) of Section 11105 of the Penal Code.
- (d) The applicant shall pass a California law and ethics examination if otherwise required by the board for the profession or vocation for which the applicant seeks licensure.
- (e) Except as specified in subdivision (g), a board shall issue a temporary license pursuant to this section within 30 days of receiving documentation that the applicant has met the requirements specified in subdivisions (c) and (d) if the results of the criminal background check do not show grounds for denial.
- (f)(1) A temporary license issued pursuant to this section may be immediately terminated upon a finding that the temporary licenseholder failed to meet any of the requirements described in subdivision (c) or (d) or provided substantively inaccurate information that would affect the person's eligibility for temporary licensure. Upon termination of the temporary license, the board shall issue a notice of termination that shall require the temporary licenseholder to immediately cease the practice of the licensed profession upon receipt.
- (2) Notwithstanding any other law, if, after notice and an opportunity to be heard, a board finds that a temporary licenseholder engaged in unprofessional conduct or any other act that is a cause for discipline by the board, the board shall revoke the temporary license.
- (g) An applicant seeking a temporary license as a civil engineer, geotechnical engineer, structural engineer, land surveyor, professional geologist, professional geophysicist, certified engineering geologist, or certified hydrogeologist pursuant to this section shall successfully pass the appropriate California-specific examination or examinations required for licensure in those respective professions by the Board for Professional Engineers, Land Surveyors, and Geologists. The board shall issue a temporary license pursuant to this subdivision within 30 days of receiving documentation that the applicant has met the requirements specified in this subdivision and subdivisions (c) and (d) if the results of the criminal background check do not show grounds for denial.
- (h) A temporary license issued pursuant to this section is nonrenewable and shall expire 12 months after issuance, upon issuance or denial of a standard license, upon issuance or denial of a license by endorsement, or upon issuance or denial of an expedited license pursuant to Section 115.5, whichever occurs first.
- (i) A board shall submit to the department for approval, if necessary to implement this section, draft regulations necessary to administer this section. These regulations shall be adopted pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

(j)(1) This section shall not apply to a board that has a process in place by which an out-of-state licensed applicant in good standing who is married to, or in a domestic partnership or other legal union with, an active duty member of the Armed Forces of the United States is able to receive expedited, temporary authorization to practice while meeting state-specific requirements for a period of at least one year or is able to receive an expedited license by endorsement with no additional requirements superseding those described in subdivisions (c) and (d).

(2) This section shall apply only to the extent that it does not amend an initiative or violate constitutional requirements.

(k) This section shall become operative on July 1, 2023.

115.8. Military, Veteran, and Spouse licensure Annual Reporting

The Department of Consumer Affairs shall compile information on military, veteran, 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:

(a) The number of applications for a temporary license submitted by active duty servicemembers, veterans, or military spouses per calendar year, pursuant to Section 115.6.

(b) The number of applications for expedited licenses submitted by veterans and active duty spouses pursuant to Sections 115.4 and 115.5.

(c) The number of licenses issued and denied per calendar 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 year.

(e) The number of applications for waived renewal fees received and granted pursuant to Section 114.3 per calendar 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.

115.9. Military Spouse Licensing Options

The department and each board within the department shall publish information pertinent to all licensing options available to military spouses on the home page of the internet website of the department or board, as applicable, including, but not limited to, the following:

(a) The process for expediting applications for military spouses.

(b) The availability of temporary licensure, the requirements for obtaining a temporary license, and length of time a temporary license is active.

(c) The requirements for full, permanent licensure by endorsement or credential for out-of-state applicants.

650. Rebates or Discounts for Referral Prohibited

- (a) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest, or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.
- (b) The payment or receipt of consideration for services other than the referral of patients ~~which~~ that is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.
- (c) The offer, delivery, receipt, or acceptance of any consideration between a federally qualified health center, as defined in Section 1396d(l)(2)(B) of Title 42 of the United States Code, and any individual or entity providing goods, items, services, donations, loans, or a combination thereof to the health center entity pursuant to a contract, lease, grant, loan, or other agreement, if that agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center, shall be ~~permitted~~ authorized only to the extent sanctioned or permitted by federal law.
- (d) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2 of this code, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, ~~clinic (including clinic, including~~ entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), Code, or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility, provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.
- (e) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2 of this code, it shall not be unlawful to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, as described in subsections (x) and (y) of Section 1001.952 of Title 42 of the Code of Federal Regulations, as amended October 4, 2007, as published in the Federal Register (72 Fed. Reg. 56632 and 56644), and as ~~subsequently amended versions-~~ amended.

- (f) “Health care facility” means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Public Health under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.
- (g) Notwithstanding ~~the other subdivisions of~~ this section or any other provision of law, the payment or receipt of consideration for advertising, wherein a licensee offers or sells services through a third-party advertiser, shall not constitute a referral of patients when the third-party advertiser does not itself recommend, endorse, or otherwise select a licensee. The fee paid to the third-party advertiser shall be commensurate with the service provided by the third-party advertiser. If the licensee determines, after consultation with the purchaser of the service, that the service provided by the licensee is ~~not appropriate~~ inappropriate for the purchaser or if the purchaser elects not to receive the service for any reason and requests a refund, the purchaser shall receive a refund of the full purchase price as determined by the terms of the advertising service agreement between the third-party advertiser and the licensee. The licensee shall disclose in the advertisement that a consultation is required and that the purchaser will receive a refund if ~~not eligible~~ ineligible to receive the service. This subdivision shall not apply to basic health care services, as defined in subdivision (b) of Section 1345 of the Health and Safety Code, or essential health benefits, as defined in Section 1367.005 of the Health and Safety Code and Section 10112.27 of the Insurance Code. The entity that provides the advertising shall be able to demonstrate that the licensee consented in writing to the requirements of this subdivision. A third-party advertiser shall make available to prospective purchasers advertisements for services of all licensees then advertising through the third-party advertiser in the applicable geographic region. In any advertisement offering a discount price for a service, the licensee shall also disclose the regular, nondiscounted price for that service.
- (h) To the extent consistent with federal law, regulations, or guidance, the payment or receipt of consideration for internet-based advertising, appointment booking, or any service that provides information and resources to prospective patients of licensees shall not constitute a referral of a patient if the internet-based service provider does not recommend or endorse a specific licensee to a prospective patient.
- ~~(h)~~ (i) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in a county jail for not more than one year, or by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by a fine not exceeding fifty thousand dollars (\$50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or by that imprisonment and a fine of fifty thousand dollars (\$50,000).

Section 688 Electronic Data Transmission Prescriptions (E-Prescriptions)

- (a) On and after January 1, 2022, a health care practitioner authorized to issue a prescription pursuant to Section 4040 shall have the capability to issue an electronic data transmission prescription, as defined under Section 4040, on behalf of a patient and to transmit that electronic data transmission prescription to a pharmacy selected by the patient.
- (b) On and after January 1, 2022, a pharmacy, pharmacist, or other practitioner authorized under California law to dispense or furnish a prescription pursuant to Section 4040 shall have the capability to receive an electronic data transmission prescription on behalf of a patient.
- (c) For a prescription for a controlled substance, as defined by Section 4021, generation and transmission of the electronic data transmission prescription shall comply with Parts 1300, 1304, 1306, and 1311 of Title 21 of the Code of Federal Regulations, as amended from time to time.
- (d) On and after January 1, 2022, a prescription prescribed by a health care practitioner shall be issued as an electronic data transmission prescription. This subdivision shall not apply to prescriptions issued pursuant to subdivision (e).
- (e) Subdivision (d) shall not apply to any of the following:

 - (1) The prescription is issued pursuant to Section 11159.2 of the Health and Safety Code.
 - (2) An electronic data transmission prescription is not available due to a temporary technological or electrical failure. For purposes of this paragraph, “temporary technological or electrical failure” means failure of a computer system, application, or device, or the loss of electrical power to that system, application, or device, or any other service interruption affecting the certified electronic data transmission prescription application used to transmit the prescription.
 - (3) The prescribing health care practitioner is issuing a prescription to be dispensed by a pharmacy located outside California.
 - (4)(A) The prescription is issued in a hospital emergency department or urgent care clinic and one or more of the following conditions are present:

 - (i) The patient resides outside California.
 - (ii) The patient resides outside the geographic area of the hospital.
 - (iii) The patient is homeless or indigent and does not have a preferred pharmacy.
 - (iv) The prescription is issued at a time when a patient’s regular or preferred pharmacy is likely to be closed.
- (B) Under any of the conditions described in subparagraph (A), a prescription shall be electronically issued but does not require electronic transmission and may be provided directly to the patient.

- (5) The prescription is issued by a veterinarian.
- (6) The prescription is for eyeglasses or contact lenses.
- (7) The prescribing health care practitioner and the dispenser are the same entity.
- (8) The prescription is issued by a prescribing health care practitioner under circumstances whereby the practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by an electronic data transmission prescription in a timely manner, and the delay would adversely impact the patient's medical condition.
- (9) The prescription that is issued includes elements not covered by the latest version of the National Council for Prescription Drug Programs' SCRIPT standard, as amended from time to time.
- (f) A health care practitioner who issues a prescription for a controlled substance but does not transmit the prescription as an electronic data transmission prescription shall document the reason in the patient's medical record as soon as practicable and within 72 hours of the end of the technological or electrical failure that prevented the electronic data transmission of the prescription.
- (g) A pharmacy that receives an electronic data transmission prescription from a prescribing health care practitioner who has issued the prescription but has not dispensed the medication to the patient shall, at the request of the patient or a person authorized to make a request on behalf of the patient, immediately transfer or forward the electronic data transmission prescription to an alternative pharmacy designated by the requester.
- (h) If a pharmacy, or its staff, is aware than an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, the pharmacy shall immediately notify the prescribing health care practitioner.
- (i) A pharmacist who receives a written, oral, or faxed prescription shall not be required to verify that the prescription properly falls under one of the exceptions in subdivision (e). Pharmacists may continue to dispense medications from legally valid written, oral, or fax prescriptions pursuant to this division.
- (j) A health care practitioner, pharmacist, or pharmacy who fails to meet the applicable requirements of this section shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board. This section does not create a private right of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.
- (k) This section shall not apply to a health care practitioner, pharmacist, or pharmacy when providing health care services to an inmate, individual on parole, or youth under the jurisdiction of the Department of Corrections and Rehabilitation.

1206.5. Clinical Laboratory Testing

- (a) Notwithstanding subdivision (b) of Section 1206 and except as otherwise provided in Sections 1206.6 and 1241, no person shall perform a clinical laboratory test or examination classified as waived under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
 - (2) A licensed podiatrist, a licensed dentist, or a licensed naturopathic doctor, if the results of the tests can be lawfully utilized within ~~his or her~~ their practice.
 - (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
 - (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
 - (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
 - (6) A person licensed under Chapter 6 (commencing with Section 2700).
 - (7) A person licensed under Chapter 6.5 (commencing with Section 2840).
 - (8) A perfusionist if authorized by and performed in compliance with Section 2590.
 - (9) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
 - (10) A medical assistant, as defined in Section 2069, if the waived test is performed pursuant to a specific authorization meeting the requirements of Section 2069.
 - (11) A pharmacist, as defined in Section 4036, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2, ~~or~~ if performing skin puncture in the course of performing routine patient assessment procedures in compliance with Section ~~4052.4~~ 4052.1, or if performing testing as authorized in Section 4052.4.
 - (12) A naturopathic assistant, as defined in Sections 3613 and 3640.2, if the waived test is performed pursuant to a specific authorization meeting the requirements of Sections 3613 and 3640.2.
 - (13) A licensed optometrist as authorized under Chapter 7 (commencing with Section 3000).
 - (14) Other health care personnel providing direct patient care.

- (15) Any other person performing nondiagnostic testing pursuant to Section 1244.
- (b) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of moderate complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
 - (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within ~~his or her~~ their practice.
 - (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory.
 - (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code.
 - (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.
 - (6) A person licensed under Chapter 6 (commencing with Section 2700).
 - (7) A perfusionist if authorized by and performed in compliance with Section 2590.
 - (8) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
 - (9) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
 - (10) Any person if performing blood gas analysis in compliance with Section 1245.
 - (11) (A) A person certified or licensed as an "Emergency Medical Technician II" or paramedic pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code while providing prehospital medical care, a person licensed as a psychiatric technician under Chapter 10 (commencing with Section 4500) of Division 2, as a vocational nurse pursuant to Chapter 6.5 (commencing with Section 2840), or as a midwife licensed pursuant to Article 24 (commencing with Section 2505) of Chapter 5, or certified by the department pursuant to Division 5 (commencing with Section 70001) of Title 22 of the California Code of Regulations as a nurse assistant or a home health aide, who provides direct patient care, if the person is performing the test as an adjunct to the provision of direct patient care by the person, is utilizing a point-of-care laboratory testing device at a site for which a laboratory license or registration has been issued, meets the minimum clinical laboratory education, training, and experience requirements set forth in

- regulations adopted by the department, and has demonstrated to the satisfaction of the laboratory director that ~~he or she~~ the person is competent in the operation of the point-of-care laboratory testing device for each analyte to be reported.
- (B) Prior to being authorized by the laboratory director to perform laboratory tests or examinations, testing personnel identified in subparagraph (A) shall participate in a preceptor program until they are able to perform the clinical laboratory tests or examinations authorized in this section with results that are deemed accurate and skills that are deemed competent by the preceptor. For the purposes of this section, a “preceptor program” means an organized system that meets regulatory requirements in which a preceptor provides and documents personal observation and critical evaluation, including review of accuracy, reliability, and validity, of laboratory testing performed.
- (12) Any other person within a physician office laboratory if the test is performed under the supervision of the patient’s physician and surgeon or podiatrist who shall be accessible to the laboratory to provide onsite, telephone, or electronic consultation as needed, and shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of the clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (13) A pharmacist, if ordering drug therapy-related laboratory tests in compliance with paragraph (2) of subdivision (a) of Section 4052.1 or paragraph (2) of subdivision (a) of Section 4052.2.
- (c) Notwithstanding subdivision (b) of Section 1206, no person shall perform clinical laboratory tests or examinations classified as of high complexity under CLIA unless the clinical laboratory test or examination is performed under the overall operation and administration of the laboratory director, as described in Section 1209, including, but not limited to, documentation by the laboratory director of the adequacy of the qualifications and competency of the personnel, and the test is performed by any of the following persons:
- (1) A licensed physician and surgeon holding a M.D. or D.O. degree.
 - (2) A licensed podiatrist or a licensed dentist if the results of the tests can be lawfully utilized within ~~his or her~~ their practice.
 - (3) A person licensed under this chapter to engage in clinical laboratory practice or to direct a clinical laboratory if the test or examination is within a specialty or subspecialty authorized by the person’s licensure.
 - (4) A person authorized to perform tests pursuant to a certificate issued under Article 5 (commencing with Section 101150) of Chapter 2 of Part 3 of Division 101 of the Health and Safety Code if the test or examination is within a specialty or subspecialty authorized by the person’s certification.
 - (5) A licensed physician assistant if authorized by a supervising physician and surgeon in accordance with Section 3502 or 3535.

- (6) A perfusionist if authorized by and performed in compliance with Section 2590.
 - (7) A respiratory care practitioner if authorized by and performed in compliance with Chapter 8.3 (commencing with Section 3700).
 - (8) A person performing nuclear medicine technology if authorized by and performed in compliance with Article 6 (commencing with Section 107150) of Chapter 4 of Part 1 of Division 104 of the Health and Safety Code.
 - (9) Any person if performing blood gas analysis in compliance with Section 1245.
 - (10) Any other person within a physician office laboratory if the test is performed under the onsite supervision of the patient's physician and surgeon or podiatrist who shall: (A) ensure that the person is performing test methods as required for accurate and reliable tests; and (B) have personal knowledge of the results of clinical laboratory testing or examination performed by that person before the test results are reported from the laboratory.
- (d) Clinical laboratory examinations classified as provider-performed microscopy under CLIA may be personally performed using a brightfield or phase/contrast microscope by one of the following practitioners:
- (1) A licensed physician and surgeon using the microscope during the patient's visit on a specimen obtained from ~~his or her~~ their own patient or from a patient of a group medical practice of which the physician is a member or employee.
 - (2) A nurse midwife holding a certificate as specified by Section 2746.5, a licensed nurse practitioner as specified in Section 2835.5, or a licensed physician assistant acting under the supervision of a physician pursuant to Section 3502 using the microscope during the patient's visit on a specimen obtained from ~~his or her~~ their own patient or from the patient of a clinic, group medical practice, or other health care provider of which the certified nurse midwife, licensed nurse practitioner, or licensed physician assistant is an employee.
 - (3) A licensed dentist using the microscope during the patient's visit on a specimen obtained from ~~his or her~~ their own patient or from a patient of a group dental practice of which the dentist is a member or an employee.

1209. Clinical Laboratory Definitions

- (a) As used in this chapter, "laboratory director" means any person who is any of the following:
- (1) A duly licensed physician and surgeon.
 - (2) Only for purposes of a clinical laboratory test or examination classified as waived, is any of the following:
 - (A) A duly licensed clinical laboratory scientist.
 - (B) A duly licensed limited clinical laboratory scientist.
 - (C) A duly licensed naturopathic doctor.

- (D) A duly licensed optometrist serving as the director of a laboratory that only performs clinical laboratory tests authorized in paragraph (10) of subdivision (d) of Section 3041.
 - (E) A duly licensed dentist serving as the director of a laboratory that performs only clinical laboratory tests authorized within the scope of practice of dentistry as delineated under Section 1625.
 - (F) A pharmacist-in-charge of a pharmacy serving as the director of a laboratory that only performs tests waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a), as authorized by the Pharmacy Law (Chapter 9 (commencing with Section 4000)).
- (3) Licensed to direct a clinical laboratory under this chapter.
- (b)(1) A person defined in paragraph (1) or (3) of subdivision (a) who is identified as the CLIA laboratory director of a laboratory that performs clinical laboratory tests classified as moderate or high complexity shall also meet the laboratory director qualifications under CLIA for the type and complexity of tests being offered by the laboratory.
- (2) As used in this subdivision, "CLIA laboratory director" means the person identified as the laboratory director on the CLIA certificate issued to the laboratory by the federal Centers for Medicare and Medicaid Services (CMS).
- (c) The laboratory director, if qualified under CLIA, may perform the duties of the technical consultant, technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to persons qualified under CLIA. If the laboratory director reapportions performance of those responsibilities or duties, ~~he or she~~ they shall remain responsible for ensuring that all those duties and responsibilities are properly performed.
- (d)(1) The laboratory director is responsible for the overall operation and administration of the clinical laboratory, including administering the technical and scientific operation of a clinical laboratory, the selection and supervision of procedures, the reporting of results, and active participation in its operations to the extent necessary to ensure compliance with this act and CLIA. ~~He or she~~ They shall be responsible for the proper performance of all laboratory work of all subordinates and shall employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests, and report test results in accordance with the personnel qualifications, duties, and responsibilities described in CLIA and this chapter.
- (2) Where a point-of-care laboratory testing device is utilized and provides results for more than one analyte, the testing personnel may perform and report the results of all tests ordered for each analyte for which ~~he or she has~~ they have been found by the laboratory director to be competent to perform and report.

- (e) As part of the overall operation and administration, the laboratory director of a registered laboratory shall document the adequacy of the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory test procedures and examinations. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for personnel, in addition to any CLIA requirements relative to the education or training of personnel.
- (f) As part of the overall operation and administration, the laboratory director of a licensed laboratory shall do all of the following:
 - (1) Ensure that all personnel, prior to testing biological specimens, have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. In determining the adequacy of qualifications, the laboratory director shall comply with any regulations adopted by the department that specify the minimum qualifications for, and the type of procedures that may be performed by, personnel in addition to any CLIA requirements relative to the education or training of personnel. Any regulations adopted pursuant to this section that specify the type of procedure that may be performed by testing personnel shall be based on the skills, knowledge, and tasks required to perform the type of procedure in question.
 - (2) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to ensure that they are competent and maintain their competency to process biological specimens, perform test procedures, and report test results promptly and proficiently, and, whenever necessary, identify needs for remedial training or continuing education to improve skills.
 - (3) Specify in writing the responsibilities and duties of each individual engaged in the performance of the preanalytic, analytic, and postanalytic phases of clinical laboratory tests or examinations, including which clinical laboratory tests or examinations the individual is authorized to perform, whether supervision is required for the individual to perform specimen processing, test performance, or results reporting, and whether consultant, supervisor, or director review is required prior to the individual reporting patient test results.
- (g) The competency and performance of staff of a licensed laboratory shall be evaluated and documented by the laboratory director, or by a person who qualifies as a technical consultant or a technical supervisor under CLIA depending on the type and complexity of tests being offered by the laboratory.
 - (1) The procedures for evaluating the competency of the staff shall include, but are not limited to, all of the following:

- (A) Direct observations of routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing.
 - (B) Monitoring the recording and reporting of test results.
 - (C) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.
 - (D) Direct observation of performance of instrument maintenance and function checks.
 - (E) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.
 - (F) Assessment of problem-solving skills.
- (2) Evaluation and documentation of staff competency and performance shall occur at least semiannually during the first year an individual tests biological specimen. Thereafter, evaluations shall be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance shall be reevaluated to include the use of the new test methodology or instrumentation.
- (h) The laboratory director of each clinical laboratory of an acute care hospital shall be a physician and surgeon who is a qualified pathologist, except as follows:
- (1) If a qualified pathologist is not available, a physician and surgeon or a clinical laboratory bioanalyst qualified as a laboratory director under subdivision (a) may direct the laboratory. However, a qualified pathologist shall be available for consultation at suitable intervals to ensure high-quality service.
 - (2) If there are two or more clinical laboratories of an acute care hospital, those additional clinical laboratories that are limited to the performance of blood gas analysis, blood electrolyte analysis, or both, may be directed by a physician and surgeon qualified as a laboratory director under subdivision (a), irrespective of whether a pathologist is available.
- As used in this subdivision, a qualified pathologist is a physician and surgeon certified or eligible for certification in clinical or anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology.
- (i) Subdivision (h) does not apply to any director of a clinical laboratory of an acute care hospital acting in that capacity on or before January 1, 1988.
 - (j) A laboratory director may serve as the director of up to the maximum number of laboratories stipulated by CLIA, as defined under Section 1202.5.

This section shall remain in effect only until January 1, 2026, and as of that date is repealed.

4001. Board of Pharmacy; Appointment; Terms

- (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.
- (b) The Governor shall appoint seven ~~competent pharmacists who~~ pharmacists who are licensees in good standing and who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600. Each appointing authority has power to remove from office at any time any member of the board appointed by that authority pursuant to Section 106.
- (c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, a compounding pharmacy specializing in human drug preparations, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a “chain community pharmacy” means a chain of 75 or more stores in California under the same ownership, and an “independent community pharmacy” means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.
- (d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of their successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.
- (e) Each member of the board shall receive a per diem and expenses as provided in Section 103.
- (f) This section shall remain in effect only until January 1, ~~2022~~, 2026, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

4002. Officers

- (a) The board shall elect a president, a vice president, and a treasurer. The officers of the board shall be elected by a majority of the membership of the board.
- (b) The principal office of the board shall be located in Sacramento. The board shall hold a meeting at least once in every four months. Members of the board may meet by teleconference pursuant to Section 11123 of the Government Code. Seven members of the board constitute a quorum.

4003. Executive Officer; Records; Revenue

- (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in them by this chapter. The executive officer ~~may or may~~ shall not be a member of the ~~board~~ board as the board may determine.
- (b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of their duties.
- (c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.
- (d) The executive officer shall give receipts for all money received by them and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of them by the board.
- (e) This section shall remain in effect only until January 1, ~~2022~~, 2026, and as of that date is repealed.

4008. Inspectors; Authority as Public Officers

- (a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.
- (b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.
- (c)(1)(A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person

to be arrested has, in ~~his or her~~ the officer's presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

- (B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, ~~he or she~~ the arresting officer may make an arrest although the violation or suspected violation did not occur in ~~his or her~~ their presence.
- (2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.
- (d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of ~~his or her~~ that person's authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose ~~his or her~~ their right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.
- (e) Any inspector may serve all processes and notices throughout the state.
- (f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119.
- (g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery system to inspect that automated drug delivery system or proposed location pursuant to Article 25 (commencing with Section 4427).
- ~~(h) This section shall become operative on July 1, 2019.~~

4013. Board-Licensed Facilities to Join E-Mail Notification List

- (a) Any facility licensed by the board shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.
- (b) Any facility licensed by the board shall update its email address with the board's email notification list within 30 days of a change in the facility's email address.
- (c) An owner of two or more facilities licensed by the board may comply with subdivisions (a) and (b) by subscribing a single email address to the board's email

notification list, where the owner maintains an electronic notice system within all of its licensed facilities that, upon receipt of an email notification from the board, immediately transmits electronic notice of the same notification to all of its licensed facilities. If an owner chooses to comply with this section by using such an electronic notice system, the owner shall register the electronic notice system with the board ~~by July 1, 2011,~~ ~~or~~ within 60 days of initial licensure, ~~whichever is later,~~ licensure informing the board of the single email address to be utilized by the owner, describing the electronic notice system, and listing all facilities to which immediate notice will be provided. The owner shall update its email address with the board's email notification list within 30 days of any change in the owner's email address.

- (d)(1) Each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in this state shall join the board's email notification list within 60 days of obtaining a license or at the time of license renewal.
- (2) Each pharmacist, intern pharmacist, pharmacy technician, designated representative, and designated representative-3PL licensed in this state shall update ~~his or her~~ their email address with the board's email notification list within 30 days of a change in the licensee's email address.
- (3) The email address provided by a licensee shall not be posted on the board's online license verification system.
- (4) The board shall, with each renewal application, remind licensees of their obligation to report and keep current their email address with the board's email notification list.
- ~~(5) This subdivision shall become operative on July 1, 2017.~~

4017.3. Automated Drug Delivery System; Automated Unit Dose System; Automated Patient Dispensing System

- (a) An "automated drug delivery system" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
- (b) An "automated unit dose system" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.
- (c) An "automated patient dispensing system" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.
- ~~(d) This section shall become operative on July 1, 2019.~~

4022.5. Designated Representative; Designated Representative in-Charge

- (a) “Designated representative” means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.
- (b) “Designated representative-in-charge” means a designated representative or designated representative-reverse distributor, or a pharmacist licensed in the home state proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler’s or veterinary food-animal drug retailer’s compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

4022.7. Designated Representative-3PL; Responsible Manager

- (a) “Designated representative-3PL” means an individual to whom a license has been granted pursuant to Section 4053.1. A pharmacist fulfilling the duties of Section 4053.1 shall not be required to obtain a license as a designated representative-3PL.
- (b) “Responsible manager” means a designated representative-3PL selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

4039. Physician; Other Practitioners Defined

“Physicians,” “dentists,” “optometrists,” “pharmacists,” ~~“podiatrists,”~~ “doctors of podiatric medicine,” “veterinarians,” “veterinary surgeons,” “registered nurses,” “naturopathic doctors,” and ~~“physician’s~~ “physician assistants” are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state.

“Physician” means and includes any person holding a valid and unrevoked physician’s and surgeon’s certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California, and includes an unlicensed person lawfully practicing medicine pursuant to Section 2065, when acting within the scope of that section.

4040. Prescription; Content Requirements

- (a) “Prescription” means an oral, written, or electronic transmission order that is both of the following:
 - (1) Given individually for the person or persons for whom ordered that includes all of the following:
 - (A) The name or names and address of the patient or patients.
 - (B) The name and quantity of the drug or device prescribed and the directions for use.

- (C) The date of issue.
 - (D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, ~~his or her~~ the prescriber's license classification, and ~~his or her~~ the prescriber's federal registry number, if a controlled substance is prescribed.
 - (E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.
 - (F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.
- (2) Issued by a physician, dentist, optometrist, ~~pediatrist,~~ doctor of podiatric medicine, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.
- (b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.
 - (c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.
 - (d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
 - ~~(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or~~

~~limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.~~

4052. Furnishing to Prescriber; Permitted Pharmacist Procedures

(a) Notwithstanding any other law, a pharmacist ~~may:~~ may do all of the following:

- (1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.
- (2) Transmit a valid prescription to another pharmacist.
- (3) Administer drugs and biological products that have been ordered by a prescriber.
- (4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.
- (5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.
- (6) Perform procedures or functions as authorized by Section 4052.6.
- (7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.
- (8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.
- (9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.
- (10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):
 - (A)(i) Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.
 - (ii) Nicotine replacement products, as authorized by Section 4052.9.
 - (iii) Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.
 - (iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

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

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

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

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

(13) Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

(14) Provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law.

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

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

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

4052.4. Skin Puncture by Pharmacist; Conditions Permitting

(a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment

procedures” means: (a) procedures that a patient could, with or without a prescription, perform for ~~himself~~themselves, or ~~herself~~or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:

(1) The test meets the criteria in subparagraph (A) or (B) and does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.

(A) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:

(i) SARS-CoV-2 or other respiratory illness, condition or disease.

(ii) Mononucleosis.

(iii) Sexually transmitted infection.

(iv) Strep throat.

(v) Anemia.

(vi) Cardiovascular health.

(vii) Conjunctivitis.

(viii) Urinary tract infection.

(ix) Liver and kidney function or infection.

(x) Thyroid function.

(xi) Substance use disorder.

(xii) Diabetes.

(B) Other tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration and approved by the board by regulation, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health.

- (2) The pharmacist completes the testing in a pharmacy laboratory that is appropriately licensed in California as a laboratory pursuant to Section 1265, unless otherwise authorized in law.
- (3) The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures maintained pursuant to subdivision (b) of Section 4119.10, and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested, as applicable.

4052.6. Advanced Practice Pharmacist; Permitted Procedures

- (a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
 - (1) Perform patient assessments.
 - (2) Order and interpret drug therapy-related tests.
 - (3) Refer patients to other health care providers.
 - (4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
 - (5) Initiate, adjust, or discontinue drug therapy in the manner specified in ~~paragraph (4) of subdivision (a) of Section 4052.2.~~ therapy.
- (b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.
- (c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.
- (d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.
- (e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

4052.8. Initiation and Administration of Vaccines; Requirements

- (a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer any ~~COVID-19 vaccines~~ vaccine that has been approved or authorized by the federal Food and Drug Administration (~~FDA~~), ~~or vaccines listed on the routine immunization schedules recommended by the~~ and received a federal Advisory Committee on Immunization Practices (~~ACIP~~), ~~in compliance with individual ACIP vaccine recommendations, and~~ individual vaccine recommendation published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.
- (b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:
- (1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.
 - (2) Be certified in basic life support.
 - (3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.
- (c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer

- (a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.
- (b) An individual who is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
- (1) ~~He or she~~ The individual shall be a high school graduate ~~or graduate~~, possess a general education development

certificate equivalent, equivalent, or have earned a degree from an accredited postsecondary institution.

- (2) ~~He or she~~ The individual shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
 - (3) ~~He or she~~ The individual shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
 - (A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
 - (B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
 - (C) Knowledge and understanding of quality control systems.
 - (D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
 - (E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.
 - (4) The board may, by regulation, require training programs to include additional material.
 - (5) The board ~~may~~ shall not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
- (c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
 - (d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
 - (e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

4053.1. Designated Representative-3PL to Supervise Third-Party Logistics Provider

- (a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.
- (b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
 - (1) ~~He or she~~ The individual shall be a high school ~~graduate or graduate~~, possess a general education development certificate ~~equivalent~~, equivalent, or have earned a degree from an accredited postsecondary institution.
 - (2) ~~He or she~~ The individual shall meet one of the following requirements:
 - (A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.
 - (B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.
 - (C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
 - (3)(A) ~~He or she~~ The individual shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
 - (i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
 - (ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
 - (iii) Knowledge and understanding of quality control systems.
 - (iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
 - (B) The board may, by regulation, require the training program required under this paragraph to include additional material.

- (C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.
- (c) A third-party logistics provider shall not operate without at least one designated representative-3PL present at each of its licensed places of business as required under Section 4160.

4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements

- (a) Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.
- (b) An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
 - (1) ~~He or she~~ The individual shall be a high school graduate ~~or graduate~~, possess a general education development certificate ~~equivalent~~, equivalent, or have earned a degree from an accredited postsecondary institution.
 - (2) ~~He or she~~ The individual shall meet one of the following requirements:
 - (A) Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.
 - (B) Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.
 - (C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
 - (3)(A) ~~He or she~~ The individual shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
 - (i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
 - (ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

- (iii) Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.
 - (iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
- (B) The board may, by regulation, require the training program required under this paragraph to include additional material.
- (C) The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.
- (c) A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

4076. Prescription Container - Requirements for Labeling

- (a) A pharmacist shall not dispense ~~any~~ a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:
- (1) Except when the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.
 - (2) The directions for the use of the drug.
 - (3) The name of the patient or patients.
 - (4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the physician assistant who functions pursuant to Section 3502.1, the

naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

- (5) The date of issue.
 - (6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
 - (7) The strength of the drug or drugs dispensed.
 - (8) The quantity of the drug or drugs dispensed.
 - (9) The expiration date of the effectiveness of the drug dispensed.
 - (10) The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
 - (11)(A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
 - (i) Prescriptions dispensed by a veterinarian.
 - (ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
 - (iii) Dispensed medications for which no physical description exists in any a commercially available database.
 - (B) This paragraph applies to outpatient pharmacies only.
 - (C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
 - (D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.
- (b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.
 - (c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1 or protocol, the

physician assistant who functions pursuant to Section 3502.1, the naturopathic doctor who functions pursuant to a standardized procedure or protocol described in Section 3640.5, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to Section 4052.1, 4052.2, or 4052.6.

- (d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within ~~his or her~~ the scope of practice.
- (e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.
- (f) Notwithstanding subdivision (a) or any other law, a pharmacist may dispense a drug prescribed pursuant to Section 120582 of the Health and Safety Code and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words "expedited partner therapy" or the letters "EPT."
- (g) A pharmacist who prescribes, dispenses, furnishes, or otherwise renders EPT, as authorized in subdivision (f), shall not be liable in, and shall not be subject to, a civil, criminal, or administrative action, sanction, or penalty for rendering EPT, if the use of EPT is in compliance with this section, except in cases of intentional misconduct, gross negligence, or wanton or reckless activity.
- (h) A pharmacist who provides EPT under this section shall provide written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions.

4083. Orders of Correction

- (a) An inspector may issue an order of correction to a licensee directing the licensee to comply with this chapter or regulations adopted pursuant to this chapter.
- (b) The order of correction shall be in writing and shall describe in detail the nature and facts of the violation, including a reference to the statute or regulations violated.
- (c) The order of correction shall inform the licensee that within 30 days of service of the order of correction, the licensee may do either of the following:
 - (1) Submit a written request for an office conference with the board's executive officer to contest the order of correction.
 - (A) Upon a timely request, the executive officer, or ~~his or her~~ designee, designee of the executive officer, shall hold an office

conference with the licensee or the licensee's legal counsel or authorized representative. Unless so authorized by the executive officer, or ~~his or her designee, designee of the executive officer~~, no individual other than the licensee's legal counsel or authorized representative may accompany the licensee to the office conference.

- (B) Prior to or at the office conference, the licensee may submit to the executive officer declarations and documents pertinent to the subject matter of the order of correction.
 - (C) The office conference is intended to be an informal proceeding and shall not be subject to the provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340), Chapter 4 (commencing with Section 11370), Chapter 4.5 (commencing with Section 11400), and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code).
 - (D) The executive officer, or ~~his or her designee, designee of the executive officer~~, may affirm, modify, or withdraw the order of correction. Within 14 calendar days from the date of the office conference, the executive officer, or ~~his or her designee, designee of the executive officer~~, shall personally serve or send by certified mail to the licensee's address of record with the board a written decision. This decision shall be deemed the final administrative decision concerning the order of correction.
 - (E) Judicial review of the decision may be had by filing a petition for a writ of mandate in accordance with the provisions of Section 1094.5 of the Code of Civil Procedure within 30 days of the date the decision was personally served or sent by certified mail. The judicial review shall extend to the question of whether or not there was a prejudicial abuse of discretion in the issuance of the order of correction.
- (2) Comply with the order of correction and submit a written corrective action plan to the inspector documenting compliance. If an office conference is not requested pursuant to this section, compliance with the order of correction shall not constitute an admission of the violation noted in the order of correction.
- (d) The order of correction shall be served upon the licensee personally or by certified mail at the licensee's address of record with the board. If the licensee is served by certified mail, service shall be effective upon deposit in the United States mail.
 - (e) The licensee shall maintain and have readily available on the pharmacy premises a copy of the order of correction and corrective action plan for at least three years from the date of issuance of the order of correction.
 - (f) Nothing in this section shall in any way limit the board's authority or ability to do any of the following:

- (1) Issue a citation pursuant to Section 125.9, 148, or 4067 or pursuant to Section 1775, 1775.15, 1777, or 1778 of Title 16 of the California Code of Regulations.
 - (2) Issue a letter of admonishment pursuant to Section 4315.
 - (3) Institute disciplinary proceedings pursuant to Article 19 (commencing with Section 4300).
- (g) Unless a writ of mandate is filed, a citation issued, a letter of admonishment issued, or a disciplinary proceeding instituted, an order of correction shall not be considered a public record and shall not be disclosed pursuant to a request under the California Public Records Act (~~Chapter 3.5~~ Division 10 (commencing with Section ~~6250~~) of ~~Division 7~~ of 7920.000) of Title 1 of the Government Code).

**4110. License Required; Temporary Permit upon Transfer of Ownership;
Temporary Use of Mobile Pharmacy**

- (a) No person shall conduct a pharmacy in the State of California unless ~~he or she~~ has they have obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The ~~board~~ license shall not be renewed unless the applicant includes necessary matters identified by the board in the renewal application, including, but not limited to, notification to the board regarding compounding practices, including compounded human drug preparations distributed outside of the state. The board may, by regulation, determine the circumstances under which a license may be transferred.
- (b) The board may, at its discretion, issue a temporary permit upon the conditions and for any periods of time as the board determines to be in the public interest. A temporary permit fee shall be required in an amount established by the board as specified in subdivision (a) of Section 4400. When needed to protect public safety, a temporary permit may be issued for a period not to exceed 180 days, and may be issued subject to terms and conditions the board deems necessary. If the board determines a temporary permit was issued by mistake or denies the application for a permanent license or registration, the temporary license or registration shall terminate upon either personal service of the notice of termination upon the permitholder or service by certified mail, return receipt requested, at the permitholder's address of record with the board, whichever comes first. Neither for purposes of retaining a temporary permit nor for purposes of any disciplinary or license denial proceeding before the board shall the temporary permitholder be deemed to have a vested property right or interest in the permit.
- (c) The board may allow the temporary use of a mobile pharmacy when a pharmacy is destroyed or damaged, the mobile pharmacy is necessary to protect the health and safety of the public, and the following conditions are met:

- (1) The mobile pharmacy shall provide services only on or immediately contiguous to the site of the damaged or destroyed pharmacy.
- (2) The mobile pharmacy is under the control and management of the pharmacist-in-charge of the pharmacy that was destroyed or damaged.
- (3) A licensed pharmacist is on the premises while drugs are being dispensed.
- (4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
- (5) The pharmacy operating the mobile pharmacy provides the board with records of the destruction of, or damage to, the pharmacy and an expected restoration date.
- (6) Within three calendar days of restoration of the pharmacy services, the board is provided with notice of the restoration of the permanent pharmacy.
- (7) The mobile pharmacy is not operated for more than 48 hours following the restoration of the permanent pharmacy.

4113.7. Chain Community Pharmacies: Quotas

- (a) A chain community pharmacy, as defined in subdivision (c) of Section 4001, shall not establish a quota related to the duties for which a pharmacist or pharmacy technician license is required.
- (b) A chain community pharmacy shall not, through employees, contractors, or third parties, communicate the existence of quotas, that are illegal pursuant to this section, to pharmacists or pharmacy technicians who are employees of the chain community pharmacy or with whom the chain community pharmacy contracts.
- (c)(1) For purposes of this section, "quota" means a fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required, against which the chain community pharmacy or its agent measures or evaluates the number of times either an individual pharmacist or pharmacy technician performs tasks or provides services while on duty. "Quota" includes a fixed number or formula related to any of the following:
 - (A) Prescriptions filled.
 - (B) Services rendered to patients.
 - (C) Programs offered to patients.
 - (D) Revenue obtained.
- (2) For purposes of this section, "quota" does not mean any of the following:
 - (A) A measurement of the revenue earned by a particular licensed chain community pharmacy not calculated in relation to, or measured by, the tasks performed, or services provided by, individual pharmacists or pharmacy technicians.

- (B) Any evaluation or measurement of the competence, performance, or quality of care provided to patients of a pharmacist or pharmacy technician if the evaluation does not use quotas, as defined in paragraph (1).
- (C) Any performance metric required by state or federal regulators that does not use quotas, as defined in paragraph (1).
- (d) This section does not prohibit a chain community pharmacy from establishing policies and procedures that assist in assessing the competency and performance of a pharmacist or pharmacy technician in providing care to patients if the measurements used are not, or do not include, quotas, as defined in subdivision (c).

4119.10

A pharmacy located in the state may use pharmacists to perform FDA-approved or -authorized tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:

- (a) The pharmacy is appropriately licensed as a laboratory under Section 1265.
- (b) The pharmacy maintains policies and procedures that do all of the following:
 - (1) Establish the initial training requirements, including specimen collection techniques relevant to a test being performed at the pharmacy, and ongoing training.
 - (2) Establish safety precautions necessary to protect pharmacy staff and consumers and to reduce the risk of transmission, consistent with Cal-OSHA and CDC requirements, including, but not limited to, provisions for the use of personal protective equipment, cleaning and sanitizing procedures, appropriate biohazard waste requirements, and space requirements for pharmacy staff and consumers.
 - (3) Ensure the availability of dedicated physically distanced space or other segregated space that provides for privacy during the testing process and private consultation with the pharmacist, and limits potential contamination of other consumers in the pharmacy.
 - (4) Establish requirements for providing test results to the patient in a nonverbal manner, complying with mandatory reporting requirements to local and state reporting systems, and notifying the patient's health care providers if consent is provided, and referral to licensed sources of care for confirmation, diagnosis, and treatment as appropriate for followup to positive test results. A health care provider shall not be held personally liable for test results, or for any actions or inactions related to test results they did not receive, have knowledge of, or otherwise have access to.

- (5) Establish requirements for the pharmacist-in-charge serving as the pharmacy laboratory director to report any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.
- (6) Ensure documentation of testing equipment maintenance and calibration.
- (7) Ensure appropriate storage and handling of specimens, testing reagents, and other supplies or equipment that require specialized storage or handling. Specimen collection shall not include vaginal swab, venipuncture, or the collection of seminal fluid.
- (c) The test is authorized to be administered by a pharmacist pursuant to paragraph (1) of subdivision (b) of Section 4052.4.
- (d) The pharmacist-in-charge does both of the following:
 - (1) Annually reviews the policies and procedures maintained pursuant to subdivision (b), assesses the pharmacy's compliance with its policies, and documents corrective actions to be taken when noncompliance is found.
 - (2) Maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years from the date of completion.
- (e) The pharmacy maintains documentation related to performing tests that demonstrates compliance with this section, which shall include the name of the pharmacist performing the test, the results of the test, and communication of results to a patient's primary medical provider, and is maintained in a readily retrievable format for a period of three years from the date of creation.

4119.11. Automated Patient Dispensing Systems

- (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~~patient, if all of the following requirements are met:
- (1) The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:
 - (A) Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.
 - (B) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.
 - (C) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.
 - (D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing

system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.

- (E) Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.
 - (F) Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system ~~in~~ if ~~the event~~ ~~the~~ automated patient dispensing system is disabled or malfunctions.
- (2) The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).
 - (3) The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.
 - (4) A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.
 - (5) Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.
 - (6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.
 - (7) The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.
 - (8) The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.

- (9) Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.
 - (10) The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.
 - (11) The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.
- (e) Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.
 - (f) The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
 - (g) The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility and be delivered to the ~~facility~~ facility, if all of the following conditions are met:
 - (1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
 - (2) The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
 - (3) The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.
 - (h) Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and

shall be the responsibility of the pharmacy. ~~The review shall be conducted~~ A pharmacist shall conduct the review on a monthly ~~basis by a pharmacist~~ and 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 ~~an annual~~ 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.

4126.10. Distributing Compounded Human Drug Preparations Interstate; Conditions

- (a) A pharmacy located in California may distribute compounded human drug preparations interstate only if all of the following conditions are met:
 - (1) Between January 1 and March 31 of each year, the pharmacy reports all required data for the previous calendar year into the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the United States Food and Drug Administration (FDA) to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products.
 - (2) On an annual basis, in connection with and as a condition of renewal of the pharmacy's license, the pharmacist-in-charge of the pharmacy certifies that the reporting requirements of paragraph (1) have been satisfied.
 - (3) The pharmacy reports any adverse drug experience and product quality issue for any compounded product to the board within 12 hours after the pharmacy receives notice of the adverse drug experience or product quality issue.
- (b) Information reported by the board to the FDA directly or through the Information Sharing Network established by the National Association of Boards of Pharmacy in conjunction with the FDA to implement the Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products shall not be subject to public disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

4127.3. Cease and Desist Order; Hearing

- (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that a pharmacy compounding sterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the pharmacy to immediately cease and desist from compounding sterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.
- (b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the owner a notice setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections.
- (c) The order shall provide that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with ~~the requirements of~~ Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. ~~Review of the decision of the president of the board may be sought by the owner or person in possession or control of the pharmacy.~~ The owner or person in possession or control of the pharmacy may seek review of the decision of the president of the board pursuant to Section 1094.5 of the Code of Civil Procedure.
- (d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4129. Outsourcing Facility; License Required

- (a) A facility ~~licensed~~ registered as an outsourcing facility with the federal Food and Drug Administration (FDA) shall be concurrently licensed with the board as an outsourcing facility if it compounds sterile medication or nonsterile medication for nonpatient-specific distribution within or into California.
- (b) A facility premises licensed with the board as a sterile compounding pharmacy shall not be concurrently licensed with the board as an outsourcing facility at the same location.
- (c) The board may adopt regulations in accordance with the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) to establish policies, guidelines, and procedures to implement this article.

- (d) The board shall review any formal requirements or guidance documents developed by the FDA regarding outsourcing facilities within 90 days after their release in order to determine whether revisions are necessary for any regulations promulgated by the board.
- (e) An outsourcing facility licensed by the board ~~shall not perform the duties of a pharmacy, such as filling individual prescriptions for individual patients.~~ dispensing patient-specific compounded preparations pursuant to a prescription for an individual patient shall not be required to be licensed as a pharmacy, but shall otherwise comply with the same requirements of a pharmacy.

4129.4. Cease and Desist Order

- (a) Whenever the board has a reasonable belief, based on information obtained during an inspection or investigation by the board, that an outsourcing facility compounding sterile drug products or nonsterile drug products poses an immediate threat to the public health or safety, the executive officer of the board may issue an order to the outsourcing facility to immediately cease and desist compounding sterile drug products or nonsterile drug products. The cease and desist order shall remain in effect for no more than 30 days or the date of a hearing seeking an interim suspension order, whichever is earlier.
- (b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue a notice to the owner setting forth the acts or omissions with which the owner is charged, specifying the pertinent code section or sections and any regulations.
- (c) The cease and desist order shall state that the owner, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the owner's contest of the cease and desist order shall comply with ~~the requirements of~~ Section 11425.10 of the Government Code. The hearing shall be held no later than five business days after the date the request of the owner is received by the board. The president shall render a written decision within five business days after the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. ~~Review of the decision may be sought by the~~ The owner or person in possession or control of the outsourcing facility may seek review of the decision pursuant to Section 1094.5 of the Code of Civil Procedure.
- (d) Failure to comply with a cease and desist order issued pursuant to this section shall be unprofessional conduct.

4161. Nonresident Wholesaler Requirements

- (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.
- (l) The registration fee shall be the fee specified in subdivision (f) of Section 4400.

Article 11.7 Cancer Medication Collection and Distribution: Registry of Participating Practitioners

4169.7. Cancer Medication Recycling

- (a) A participating practitioner in the collection and distribution of unused cancer medications pursuant to the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code shall be registered with a surplus medication collection and distribution intermediary, as defined in Section 150401 of the Health and Safety Code, in accordance with this section. The registration shall be renewed annually.
- (b) An application for registration with a surplus medication collection and distribution intermediary shall be made on a form, which may be in an electronic format, furnished by the surplus medication collection and distribution intermediary, and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant.
- (c) Upon the approval of an application by a surplus medication collection and distribution intermediary, and payment of a fee in an amount not to exceed three hundred dollars (\$300) to the surplus medication collection and distribution intermediary for processing the application and issuing or renewing the registration, the surplus medication collection and distribution intermediary shall issue or renew a registration certificate to operate as a participating practitioner, if the practitioner has complied with all of the provisions of this chapter.
- (d) A surplus medication collection and distribution intermediary shall do all of the following:

 - (1) Create a registry, not to exceed 50 participating practitioners.
 - (2) Develop a donor form that may be in an electronic format and that shall include all of the following information:

 - (A) The date the medication was donated.
 - (B) The name, address, and telephone number of the donor.
 - (C) The name, strength, and quantity of the medication.
 - (D) The manufacturer and lot number, if applicable, of the medication.
 - (E) The name and dated signature of the practitioner who is accepting and inspecting the donated medication.
 - (F) An acknowledgment that the medication was handled and stored in accordance with the physician's order and per the manufacturer's recommendation.
 - (3) Develop a recipient form, which may be in an electronic format, and which shall include all of the following:

 - (A) The date the recipient received the medication.
 - (B) The name, address, and telephone number of the recipient.

- (C) The name, strength, and quantity of the medication.
 - (D) The manufacturer and the lot number, if applicable, of the medication.
 - (E) The name and dated signature of the practitioner who is accepting and inspecting the donated medication.
 - (F) An acknowledgment that the donor is known to the practitioner and is a patient of record, and that there is no reason to believe that the donated prescription medication was improperly handled or stored.
 - (G) An acknowledgment that by accepting the donated prescription medication, the recipient accepts any risks that an accidental mishandling could create.
 - (H) An acknowledgment that the donor, the participating practitioner, and the surplus medication collection and distribution intermediary are released from liability arising from their participation pursuant to this article and the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code.
 - (I) An acknowledgment that the pharmaceutical manufacturer is released from liability of any claims or injury arising from the transfer of any prescription medication pursuant to this article and the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code.
 - (J) An acknowledgment that the recipient is receiving donated prescription medication and that the recipient is receiving the donated prescription medication at no cost.
- (e) A participating practitioner is exempt from licensure as a wholesaler.
 - (f) A participating practitioner shall keep and maintain for three years records created by the participating practitioner for purposes of this article.
 - (g) The board may request records from the distribution intermediary and participating practitioner to confirm compliance with this section and Section 150400 of the Health and Safety Code.
 - (h) The board may prohibit a participating practitioner from participating in the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code if the participating practitioner does not comply with the requirements of the program or this article. If the board prohibits a participating practitioner from participating in the program, it shall, within 15 days of making that determination, provide written notice to the participating practitioner and to the surplus medication collection and distribution intermediary that issued the participating practitioner a registration certificate to operate as a participating practitioner.
 - (i) For purposes of this section, the following definitions apply:

- (1) “Donor” means an individual who donates unused prescription medications to a participating practitioner for the purpose of redistribution to established patients of that practitioner.
- (2) “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program established pursuant to Division 117 (commencing with Section 150400) of the Health and Safety Code. “Ineligible drugs” include all controlled substances, including all opioids, all compounded medications, injectable medications, drugs that have an approved United States Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.
- (3) “Participating practitioner” means a person who is licensed to practice medicine by the Medical Board of California and is board certified in medical oncology or hematology and is registered with a surplus medication collection and distribution intermediary.
- (4) “Recipient” means an individual who voluntarily receives donated prescription medications.
- (5) “Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” as defined in Section 4022 or a “drug” as defined in Section 4025, that is prescribed as part of a cancer treatment plan and is in its original unopened, tamper-evident dose unit packaging that includes the drug’s lot number and expiration date. A cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit dose packaging is unopened.

4169.8. Cancer Medication Recycling Act

This article shall remain in effect only until January 1, 2027, and as of that date is repealed.

4202.6. Denial of Application

Notwithstanding Section 480, the board may deny an application for licensure under this chapter if the applicant has been convicted of a crime or subjected to formal discipline that would be grounds for denial of a federal registration to distribute controlled substances.

4210. Advanced Practice Pharmacist License

- (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:

~~(A)~~(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, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

~~(B)~~(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.

~~(C)~~(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).

4232.5. (Operative July 1, 2022)

(a) A pharmacist who, pursuant to any authority of this chapter, prescribes a Schedule II controlled substance, shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs.

(b) A pharmacist who has completed such a course within the last four years shall be deemed to have satisfied this requirement.

(c) This section shall become operative July 1, 2022.

4301.3. (Operative July 1, 2023; Repealed January 1, 2024)

- (a) On or before July 1, 2023, the board shall convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy and make recommendations to the Legislature about the outcome of these discussions through a report submitted pursuant to Section 9795 of the Government Code.
- (b) This section shall remain in effect only until January 1, 2024, and as of that date is repealed.

4312. Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock

- (a) The board may cancel the license of a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility~~ facility that is licensed by the board if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.
- (b) ~~If the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility~~ a facility license is canceled pursuant to subdivision (a) or revoked pursuant to ~~Article 19 (commencing with Section 4300)~~, or a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ this article, or a facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.
- (c) If a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility~~ facility licensed by the board is located, authorizing the board to enter the ~~wholesaler, third-party logistics provider,~~

~~pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility.

- (d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.
- (1) The licensee shall be notified of ~~his or her~~ the licensee's right to the remaining proceeds by personal service or by certified mail, postage prepaid.
 - (2) If a statute or regulation requires the licensee to file with the board ~~his or her~~ the licensee's address, and any change of address, the notice required by this subdivision may be sent by certified mail, postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.
 - (3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.
- (e) For the purposes of this section, "closed" means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.
- (f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

4314. Orders of Abatement

- (a) The board may issue citations containing fines and orders of abatement for any violation of Section 733, for any violation of this chapter or regulations adopted pursuant to this chapter, or for any violation of Division 116 (commencing with

Section 150200) of the Health and Safety Code, in accordance with Sections 125.9, 148, and 4005 and the regulations adopted pursuant to those sections.

- (b) Where appropriate, a citation issued by the board, as specified in this section, may subject the person or entity to whom the citation is issued to an administrative fine.
- (c) Notwithstanding any other provision of law, where appropriate, a citation issued by the board may contain an order of abatement. The order of abatement shall fix a reasonable time for abatement of the violation. It may also require the person or entity to whom the citation is issued to demonstrate how future compliance with the Pharmacy Law, and the regulations adopted pursuant thereto, will be accomplished. A demonstration may include, but is not limited to, submission of a corrective action plan, and requiring completion of up to six hours of continuing education courses in the subject matter specified in the order of abatement. Any continuing education courses required by the order of abatement shall be in addition to those required for license renewal.
- (d) Nothing in this section shall in any way limit the board from issuing a citation, fine, and order of abatement pursuant to Section 4067 or Section 56.36 of the Civil Code, and the regulations adopted pursuant to those sections.
- (e) The issuance of a citation pursuant to subdivision (b) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

4316. Cease and Desist Orders

- (a) The board, through its executive officer, is authorized to issue a cease and desist order for operating any facility under this chapter that requires licensure or for practicing any activity under this chapter that requires licensure without obtaining that licensure.
- (b) Whenever the board issues a cease and desist order pursuant to subdivision (a), the board shall immediately issue the facility a notice setting forth the acts or omissions with which it is charged, specifying the pertinent code section or sections and any regulations.
- (c) The order shall provide that the facility, within 15 days of receipt of the notice, may request a hearing before the president of the board to contest the cease and desist order. Consideration of the facility's contest of the cease and desist order shall comply with ~~the requirements of~~ Section 11425.10 of the Government Code. The hearing shall be held no later than five business days from the date the request of the owner is received by the board. The president shall render a written decision within five business days of the hearing. In the absence of the president of the board, the vice president of the board may conduct the hearing permitted by this subdivision. ~~Review of the decision of the president of the board may be sought by~~

~~the owner or person in possession or control of the facility~~ The owner or person in possession or control of the facility may seek review of the decision of the president of the board pursuant to Section 1094.5 of the Code of Civil Procedure.

4317. Chain Community Pharmacies: Quota Enforcement

The board may take an enforcement action against a chain community pharmacy, as defined in subdivision (c) of Section 4001, that violates Section 4113.7 unless, by clear and convincing evidence, the chain community pharmacy demonstrates that the violation was contrary to its policy.

4317.5.

- (a) The board may bring an action for fines for repeated violations of materially similar provisions of this chapter within five years by three or more pharmacies operating under common ownership or management within a chain community pharmacy, as follows: a third and, or subsequent violation may be punished by an administrative fine not to exceed one hundred thousand dollars (\$100,000) per violation.
- (b) The board may bring an action against a chain community pharmacy operating under common ownership or management for fines not to exceed one hundred fifty thousand dollars (\$150,000) for any violation of this chapter demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.
- (c) The board shall not bring an action for fines pursuant to subdivision (a) until at least six months have elapsed from the date the board determines that a violation has occurred unless the violation giving rise to the action resulted in actual harm to any consumer or serious potential harm to the public.
- (d) In an action brought by the board pursuant to subdivision (a), it shall be a defense for any pharmacy to establish either of the following:
 - (1) That the violation was contrary to a written policy that was communicated by the common owner or manager to all employees of the pharmacies where the violation occurred.
 - (2) That, within six months after the violation, the common owner or manager corrected all unlawful policies, communicated the change in policy or policies in writing to all pharmacies under its ownership or management, and provided proof of abatement of the violation to the board, so long as the violation did not result in actual harm to any consumer or serious potential harm to the public.
- (e) In determining the amount of the fine sought in an action brought pursuant to this section, the board shall consider relevant mitigating and aggravating factors, including, but not limited to, the good faith of the licensee, the communication of written changes to unlawful policies, the gravity of the violation, the potential harm

to patients, whether the violation affects the professional judgment or independence of pharmacists and pharmacy technicians, and the history of previous violations by the common owner or manager.

- (f) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.
- (g) For purposes of this section, "chain community pharmacy" shall have the same meaning as defined in Section 4001.
- (h) The fines in subdivisions (a) and (b) shall be imposed in accordance with Section 4314.
- (i) In connection with the board's first Joint Sunset Review Oversight Hearing pursuant to Section 9147.7 of the Government Code occurring after this section becomes operative, the board shall provide to the appropriate committees of the Legislature all of the following information:
 - (1) The number of actions brought pursuant to this section.
 - (2) The number of actions brought pursuant to this section that did not result in any fines.
 - (3) The types of violations giving rise to actions brought pursuant to this section.

4372. Confidential Records; Exception for Disciplinary Proceeding

All board records and records of the pharmacists recovery program pertaining to the treatment of a pharmacist or intern pharmacist in the program shall be kept confidential and are not subject to discovery, subpoena, or disclosure pursuant to ~~Chapter 3-5~~ Division 10 (commencing with Section ~~6250~~) ~~of Division 7 of~~ 7920.000) of Title 1 of the Government Code. However, board records and records of the pharmacists recovery program may be disclosed and testimony provided in connection with participation in the pharmacists recovery program, but only to the extent those records or testimony are relevant to the conduct for which the pharmacist or intern pharmacist was terminated from the pharmacists recovery program.

4427.3. Location Requirements

- (a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.
- (b) An ADDS shall be placed and operated in one of the following locations:
 - (1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
 - (2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

- (3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.
 - (4) A correctional clinic licensed pursuant to Section 4187.1.
 - (5) If the ADDS is an APDS, in a location as provided in Section 4427.6.
 - (6) If the ADDS is an AUDES, in a location as provided in subdivision (a) of Section 4427.65.
- (c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

4427.65. Additional AUDES Location Requirements

(a) In addition to the locations authorized in Section 4427.3, an automated unit dose system (AUDES) may also be located and operated in either of the following locations:

- (1) A facility licensed by this state with the statutory authority to provide pharmaceutical services.
- (2) Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director.

(b) The pharmacy operating the AUDES shall develop and implement, and review annually, written policies and procedures pertaining to the device.

(c) The pharmacy shall operate the AUDES in compliance with the following requirements:

- (1) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.
- (2) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.
- (3)(A) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

- (B) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.
- (4) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

 - (A) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.
 - (B) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.
 - (C) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.
- (5) When used to provide pharmacy services pursuant to Section 4017.3 and this article, the automated drug delivery system shall be subject to all of the following requirements:

 - (A) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.
 - (B) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.
 - (C) The pharmacy providing services to the facility pursuant to this article shall control access to the drugs stored in the automated drug delivery system.
 - (D) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

- (E) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
 - (F) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.
 - (G) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient.
- (6) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all of the following conditions are met:
- (A) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
 - (B) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
 - (C) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.
- (7) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. A pharmacist shall conduct the review on a monthly basis, which shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

4427.7. Self-Assessment and Recordkeeping Requirements

- (a) A pharmacy holding an ADDS license shall complete ~~an annual~~ 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 ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.
- (b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

Health and Safety Code Changes

CHAPTER 4.9. Compassionate Access to Medical Cannabis Act or Ryan's Law

1649.

- (a) This chapter shall be known, and may be cited, as the "Compassionate Access to Medical Cannabis Act" or "Ryan's Law."
- (b) It is the intent of the Legislature in enacting this chapter to support the ability of a terminally ill patient to safely use medicinal cannabis within specified health care facilities in compliance with the Compassionate Use Act of 1996 and Article 2.5 (commencing with Section 11362.7) of Chapter 6 of Division 10.

1649.1.

Unless the context requires otherwise, the following definitions shall apply to 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.
 - (2) The meaning of "health care facility" shall not include a chemical dependency recovery hospital or a state hospital.
- (c) "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) "Patient" means an individual who is terminally ill.

(e) “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 health care facility shall permit patient use of medical cannabis and shall do all of the following:

- (1) Prohibit smoking or vaping as methods to use medicinal cannabis.
- (2) Include the use of medicinal cannabis within the patient’s medical records.
- (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.
- (4) Reasonably restrict the manner in which a patient stores and uses medicinal cannabis, including requiring the medicinal cannabis to be stored in a locked container, to ensure the safety of other patients, guests, and employees of the health care facility, compliance with other state laws, and the safe operations of the health care facility.
- (5) Develop and disseminate written guidelines for the use of medicinal cannabis within the health care facility pursuant to this chapter.

(b) This section does not apply to a patient receiving emergency services and care, as defined in Section 1317.1, or to the emergency department of a health care facility, as specified in subdivision (a) of Section 1250, while the patient is receiving emergency services and care.

1649.3.

Notwithstanding the classification of medicinal cannabis as a Schedule I drug and any other law, health facilities permitting patient use of medicinal cannabis shall comply with drug and medication requirements applicable to Schedule II, III, and IV drugs and shall be subject to enforcement actions by the State Department of Public Health.

1649.4.

This chapter does not require a health care facility to provide a patient with a recommendation to use medicinal cannabis in compliance with the Compassionate Use Act of 1996 and Article 2.5 (commencing with Section 11362.7) of Chapter 6 of Division 10 or include medicinal cannabis in a patient’s discharge plan.

1649.5.

(a) Compliance with this chapter shall not be a condition for obtaining, retaining, or renewing a license as a health care facility.

(b) This chapter does not reduce, expand, or otherwise modify the laws restricting the cultivation, possession, distribution, or use of cannabis that may be otherwise applicable, including, but not limited to, the Control, Regulate and Tax Adult Use of

Marijuana Act, an initiative measure enacted by the approval of Proposition 64 at the November 8, 2016, statewide general election, and any amendments to that act.

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, 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 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 rule 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.

11056. Schedule III Controlled Substances

- (a) The controlled substances listed in this section are included in Schedule III.
- (b) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
- (1) Those compounds, mixtures, or preparations in dosage unit form containing any stimulant substances listed in Schedule II which compounds, mixtures, or preparations were listed on August 25, 1971, as excepted compounds under Section 1308.32 of Title 21 of the Code of Federal Regulations, and any other drug of the quantitative composition shown in that list for those drugs or that is the same except that it contains a lesser quantity of controlled substances.
 - (2) Benzphetamine.
 - (3) Chlorphentermine.

- (4) Clortermine.
- (5) Mazindol.
- (6) Phendimetrazine.
- (c) Depressants. Unless specifically excepted ~~or~~ in Section 11059 or elsewhere, or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following substances having a depressant effect on the central nervous system:
 - (1) Any compound, mixture, or preparation containing any of the following:
 - (A) ~~Amobarbital~~ Amobarbital.
 - (B) ~~Secobarbital~~ Secobarbital.
 - (C) Pentobarbital or any salt thereof and one or more other active medicinal ingredients that are not listed in any schedule.
 - (2) Any suppository dosage form containing any of the following:
 - (A) ~~Amobarbital~~ Amobarbital.
 - (B) ~~Secobarbital~~ Secobarbital.
 - (C) Pentobarbital or any salt of any of these drugs and approved by the federal Food and Drug Administration for marketing only as a suppository.
 - (3) Any substance that contains any quantity of a derivative of barbituric acid or any salt thereof.
 - (4) Chlorhexadol.
 - (5) Lysergic acid.
 - (6) Lysergic acid amide.
 - (7) Methyprylon.
 - (8) Sulfondiethylmethane.
 - (9) Sulfonethylmethane.
 - (10) Sulfonmethane.
 - (11) Gamma hydroxybutyric acid, and its salts, ~~isomers~~ isomers, and salts of isomers, contained in a drug product for which an application has been approved under Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 355).
- (d) Nalorphine.

- (e) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
- (1) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.
 - (2) Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
 - (3) Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with one or more active nonnarcotic ingredients in recognized therapeutic amounts.
 - (4) Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
 - (5) Not more than 500 milligrams of opium per 100 milliliters or per 100 grams or not more than 25 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
 - (6) Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.
- (f) Anabolic steroids and chorionic gonadotropin. Any material, compound, mixture, or preparation containing chorionic gonadotropin or an anabolic steroid (excluding anabolic steroid products listed in the "Table of Exempt Anabolic Steroid Products" (Section 1308.34 of Title 21 of the Code of Federal Regulations), as exempt from the federal Controlled Substances Act (Section 801 and following of Title 21 of the United States Code)), including, but not limited to, the following:
- (1) Androisoxazole.
 - (2) Androstenediol.
 - (3) Bolandiol.
 - (4) Bolasterone.
 - (5) Boldenone.
 - (6) Chloromethandienone.
 - (7) Clostebol.
 - (8) Dihydromesterone.
 - (9) Ethylestrenol.

- (10) Fluoxymesterone.
 - (11) Formyldienolone.
 - (12) 4-Hydroxy-19-nortestosterone.
 - (13) Mesterolone.
 - (14) Methandriol.
 - (15) Methandrostenolone.
 - (16) Methenolone.
 - (17) 17-Methyltestosterone.
 - (18) Methyltrienolone.
 - (19) Nandrolone.
 - (20) Norbolethone.
 - (21) Norethandrolone.
 - (22) Normethandrolone.
 - (23) Oxandrolone.
 - (24) Oxymesterone.
 - (25) Oxymetholone.
 - (26) Quinbolone.
 - (27) Stanolone.
 - (28) Stanozolol.
 - (29) Stenbolone.
 - (30) Testosterone.
 - (31) Trenbolone.
 - (32) Human chorionic gonadotropin (hCG), except when possessed by, sold to, purchased by, transferred to, or administered by a licensed veterinarian, or a licensed veterinarian's designated agent, exclusively for veterinary use.
- (g) Ketamine. Any material, compound, mixture, or preparation containing ketamine.
- (h) Hallucinogenic substances. Any of the following hallucinogenic substances: dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the federal Food and Drug Administration.

11057. Schedule IV Controlled Substances

- (a) The controlled substances listed in this section are included in Schedule IV.
- (b) Schedule IV shall consist of the drugs and other substances, by whatever official name, common or usual name, chemical name, or brand name designated, listed in this section.
- (c) Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:
 - (1) Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.
 - (2) Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxybutane).
 - (3) Butorphanol.
- (d) Depressants. Unless specifically excepted ~~or~~ in Section 11059 or elsewhere, or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of those salts, isomers, and salts of isomers is possible within the specific chemical designation:
 - (1) Alprazolam.
 - (2) Barbital.
 - (3) Chloral betaine.
 - (4) Chloral hydrate.
 - (5) Chlordiazepoxide.
 - (6) Clobazam.
 - (7) Clonazepam.
 - (8) Clorazepate.
 - (9) Diazepam.
 - (10) Estazolam.
 - (11) Ethchlorvynol.
 - (12) Ethinamate.
 - (13) Flunitrazepam.
 - (14) Flurazepam.
 - (15) Halazepam.

- (16) Lorazepam.
 - (17) Mebutamate.
 - (18) Meprobamate.
 - (19) Methohexital.
 - (20) Methylphenobarbital (Mephobarbital).
 - (21) Midazolam.
 - (22) Nitrazepam.
 - (23) Oxazepam.
 - (24) Paraldehyde.
 - (25) Petrichoral.
 - (26) Phenobarbital.
 - (27) Prazepam.
 - (28) Quazepam.
 - (29) Temazepam.
 - (30) Triazolam.
 - (31) Zaleplon.
 - (32) Zolpidem.
- (e) Fenfluramine. Any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers, whenever the existence of those salts, isomers, and salts of isomers is possible:
- (1) Fenfluramine.
- (f) Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of those isomers is possible within the specific chemical designation:
- (1) Diethylpropion.
 - (2) Mazindol.
 - (3) Modafinil.
 - (4) Phentermine.
 - (5) Pemoline (including organometallic complexes and chelates thereof).

- (6) Pipradrol.
- (7) SPA ((-)-1-dimethylamino-1,2-diphenylethane).
- (8) Cathine ((+)-norpseudoephedrine).
- (g) Other substances. Unless specifically excepted or unless listed in another schedule, any material, compound, ~~mixture~~ mixture, or preparation which contains any quantity of pentazocine, including its salts.

11059.

- (a) Specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a derivative of barbituric acid or any salt thereof that are listed in the federal Table of Exempted Prescription Products and have been exempted pursuant to federal law or regulation (Section 1308.32 of Title 21 of the Code of Federal Regulations or its successors), are excepted from scheduling under subdivision (c) of Section 11056.
- (b) Specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a chlordiazepoxide or phenobarbital that are listed in the federal Table of Exempted Prescription Products and have been exempted from scheduling under federal law or regulation (Section 1308.32 of Title 21 of the Code of Federal Regulations or its successors) are excepted from scheduling under subdivision (d) of Section 11057.

11165.1. History of Controlled Substances Dispensed to an Individual/PDMP

- (a)(1)(A)(i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule ~~IV~~ V controlled substances pursuant to Section 11150 shall, ~~before July 1, 2016, or~~ upon receipt of a federal Drug Enforcement Administration (DEA) registration, ~~whichever occurs later,~~ submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to ~~that practitioner~~ the practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).
- (ii) A pharmacist shall, ~~before July 1, 2016, or upon licensure, whichever occurs later,~~ upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to ~~that pharmacist~~ the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.
- (iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to

electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.

- (iv) The department shall implement its duties described in clauses (i), (ii), and (iii) upon completion of any technological changes to the CURES database necessary to support clauses (i), (ii), and (iii), or by October 1, 2022, whichever is sooner.
- (B) ~~An application may be denied, or a subscriber may be suspended,~~ The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:
- (i) Materially falsifying an application to access information contained in the CURES database.
 - (ii) Failing to maintain effective controls for access to the patient activity report.
 - (iii) Having their federal DEA registration suspended or revoked.
 - (iv) Violating a law governing controlled substances or ~~any other another~~ law for which the possession or use of a controlled substance is an element of the crime.
 - (v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.
- (C) An authorized subscriber shall notify the department within 30 days of ~~any changes~~ a change to the subscriber account.
- (D) ~~Commencing no later than October 1, 2018, an~~ An approved health care practitioner, pharmacist, ~~and any or a~~ person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.
- (E) ~~Commencing no later than October 1, 2018, an~~ An approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system ~~can certify~~ certifies all of the following:
- (i) The entity will not use or disclose data received from the CURES database for ~~any a~~ purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

- (ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:
 - (I) The date of the query.
 - (II) The time of the query.
 - (III) The first and last name of the patient queried.
 - (IV) The date of birth of the patient queried.
 - (V) The identification of the CURES user for whom the system is making the query.
- (iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.
- (iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.
- (F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.
- (G) The department shall not access patient-identifiable information in an entity's health information technology system.
- (H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.
- (I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

- (2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule ~~IV~~ V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.
- (b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.
- (c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule ~~IV~~ V controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
- (d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.
- (e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and ~~1308.14~~ 1308.15 of Title 21 of the Code of Federal Regulations.
- (f) A health care practitioner, pharmacist, ~~and any or a~~ person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from ~~any~~ false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for ~~any a~~ resulting failure of the CURES database to accurately or timely report that information.
- (g) For purposes of this section, the following terms have the following meanings:
- (1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.
- (2) "Department" means the Department of Justice.
- (3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.
- (4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery

of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

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

(h) This section shall become ~~inoperative~~ 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, and, as of January 1, 2022, is repealed.~~ earlier.

121349. Legislative Findings and Declaration

- (a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.
- (b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.
- (c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Authorization shall be made after consultation with the local health officer and local law enforcement leadership, and after a period of public comment, as described in subdivision (e). In making the determination, the department shall balance the concerns of law enforcement with the public health benefits. The authorization

shall not be for more than two years. Before the end of the two-year period, the department may reauthorize the program in consultation with the local health officer and local law enforcement leadership.

- (d) In order for an entity to be authorized to conduct a project pursuant to this chapter, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:
- (1) The entity provides, directly or through referral, all of the following services:
 - (A) Drug abuse treatment services.
 - (B) HIV or hepatitis screening.
 - (C) Hepatitis A and hepatitis B vaccination.
 - (D) Screening for sexually transmitted infections.
 - (E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.
 - (F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.
 - (2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.
 - (3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:
 - (A) Provide needles and syringe exchange services for all of its participants.
 - (B) Provide HIV and viral hepatitis prevention education services for all of its participants.
 - (C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.
 - (4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:
 - (A) The total number of persons served.
 - (B) The total number of ~~syringes~~ needles and ~~needles-syringes~~ distributed, recovered, and disposed of.
 - (C) The total numbers and types of referrals to drug treatment and other services.
- (e) If the application is provisionally deemed appropriate by the department, the department shall, at least 45 days prior to approval of the application, provide for a period of public comment as follows:

- (1) Post on the department's internet website the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.
 - (2) Send a written and an email notice to the local health officer of the affected jurisdiction.
 - (3) Send a written and an email notice to the chief of police, the sheriff, or both, as appropriate, of the jurisdictions in which the program will operate.
- (f) The department shall establish and maintain on its internet website the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to this chapter.
- (g) The authorization provided under this section is only for a clean needle and syringe exchange project as described in Section 121349.1.
- (h)(1) Needle and syringe exchange services application submissions, authorizations, and operations performed pursuant to this chapter shall be exempt from review under the California Environmental Quality Act, Division 13 (commencing with Section 21000) of the Public Resources Code.
- (2) This subdivision is intended to be declaratory of existing law.
- ~~(h)~~(i) If the department, in its discretion, determines that a state authorized syringe exchange program continues to meet all standards set forth in subdivision (d) and that a public health need exists, it may administratively approve amendments to a program's operations including, but not limited to, modifications to the time, location, and type of services provided, including the designation as a fixed site or a mobile site. The amendment approval is not subject to the noticing requirements of subdivision (e).
- ~~(i)~~(j) The department shall have 30 business days to review and respond to the applicant's request for amendment of the authorization. If the department does not respond in writing within 30 business days, the request shall be deemed denied.
- (k) 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.

DIVISION 117. Cancer Medication Recycling Act

150400.

This division shall be known, and may be cited, as the Cancer Medication Recycling Act.

150401.

For purposes of this division, the following definitions apply:

- (a) "Donor" means an individual who donates unused prescription drugs to a participating practitioner for the purpose of redistribution to established patients of that practitioner.

- (b) “Ineligible drugs” means drugs that are not able to be accepted for redistribution as part of the program established pursuant to this division. “Ineligible drugs” include all controlled substances, including all opioids, all compounded medications, injectable medications, drugs that have an approved United States Food and Drug Administration Risk Evaluation and Mitigation Strategy (REMS) requirement, and all growth factor medications.
- (c) “Participating practitioner” means a person who is licensed to practice medicine by the Medical Board of California and is board certified in medical oncology or hematology and is registered with a surplus medication collection and distribution intermediary.
- (d) “Recipient” means an individual who voluntarily receives donated prescription medications.
- (e) “Surplus medication collection and distribution intermediary” means an entity licensed pursuant to Section 4169.5 of the Business and Professions Code as a surplus medication collection and distribution intermediary, as described in Section 150208.
- (f) “Unused cancer medication” or “medication” means a medication or drug, including a “dangerous drug” as defined in Section 4022 of the Business and Professions Code or a “drug” as defined in Section 4025 of the Business and Professions Code, that is prescribed as part of a cancer treatment plan and is in its original container or packaging.

150402.

An unused cancer medication that is not an ineligible drug as defined in subdivision (b) of Section 150401 may be donated to a participating practitioner, and a participating practitioner may accept and redistribute the donated prescription drugs.

150403.

- (a) A participating practitioner shall comply with all of the following:
- (1) Be registered with a surplus medication collection and distribution intermediary in order to participate in the program established pursuant to this division and Article 11.7 (commencing with Section 4169.7) of Chapter 9 of Division 2 of the Business and Professions Code.
 - (2) Only accept donated medications originally prescribed for use by established patients of that participating practitioner or practice.
 - (3) Distribute a medication only if it will not expire before the proper use by the recipient based on the participating practitioner’s directions for use.
 - (4) Refuse a medication that has previously been redistributed.
 - (5) Store all donated medications separately from all other medication stock.
 - (6) Store all donated medications in compliance with the manufacturer’s storage requirements per the drug monograph.

- (7) Remove or redact all confidential patient information, personal information, and any other information through which the prior patient could be identified from donated medications.
 - (8) Require all donors to read and sign the donor form approved by the surplus medication collection and distribution intermediary.
 - (9) Keep all donor forms and recipient forms in the records for at least three years.
 - (10) Examine the donated drug to determine that it has not been adulterated or misbranded and certify that the medication has been stored in compliance with the requirements of the product.
 - (11) Require all recipients of a donated medication to read and sign the recipient form approved by the surplus medication collection and distribution intermediary.
 - (12) Dispose of any donated medications that were collected but not redistributed in accordance with all local, state, and federal requirements for the disposal of medications.
 - (13) Monitor all United States Food and Drug Administration (FDA) or manufacturer recalls, market withdrawals, and safety alerts and communicate with recipients if medications they received may be impacted by the FDA action.
 - (14) Inspect all donated medications to determine that the drugs are unaltered, safe, and suitable for redistribution and meet all of the following conditions:
 - (A) Tamper-resistant packaging is unopened and intact or, in the case of unit dose packaging, the tamper-resistant dose packaging is intact for each dose donated.
 - (B) Tablets or capsules have a uniformity of color, shape, imprint or markings, texture, and odor.
 - (C) Liquids have a uniformity of color, thickness, particulates, transparency, and odor.
 - (D) The date of donation is less than six months from the date of the initial prescription or prescription refill.
 - (15) Establish policies and procedures for the administration of the cancer medication recycling program, including, but not limited to, criteria for determining medication distribution to patients. Provide the surplus medication collection and distribution intermediary with updated sections of their policy and procedures manual that indicate how the practitioner will accept, reuse, and keep records of donated medications, if requested.
- (b) A donor is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, as set forth in Part 5 (commencing with Section 109875) of Division 104, for an injury caused when donating, accepting, or dispensing medication in compliance with this division, unless an injury arising from the donated medication

is caused by the gross negligence, recklessness, or intentional conduct of the donor, or in cases of noncompliance with this division.

- (c) A participating practitioner that receives and redistributes a donated medication is not subject to a penalty pursuant to the Sherman Food, Drug, and Cosmetic Law, as set forth in Part 5 (commencing with Section 109875) of Division 104, resulting from the condition of the donated medication unless an injury arising from the donated medication is caused by the gross negligence, recklessness, or intentional conduct of the participating practitioner, in cases of noncompliance with this division, or in cases of malpractice unrelated to the quality of the medication.
- (d) The following persons and entities are not subject to criminal or civil liability for an injury caused when participating in the program established pursuant to this division, including, but not limited to, donating, accepting, or dispensing prescription drugs in compliance with this division:
- (1) A prescription drug manufacturer, wholesaler, or participating entity.
 - (2) A participating practitioner who accepts or dispenses prescription drugs.
 - (3) A donor, as defined in Section 150401.
 - (4) A surplus medication collection and distribution intermediary.
- (e) The immunities provided in subdivision (d) do not apply in cases of noncompliance with this division, gross negligence, recklessness, intentional conduct, or in cases of malpractice unrelated to the quality of the medication.
- (f) This division shall not affect disciplinary actions taken by licensing and regulatory agencies.

150404.

This division shall remain in effect only until January 1, 2027, and as of that date is repealed.

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