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## **HEALTH AND SAFETY CODE - HSC**

DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT [11000 - 11651] ( Division 10 repealed and added by Stats. 1972, Ch. 1407.)

CHAPTER 4. Prescriptions [11150 - 11209] (Chapter 4 added by Stats. 1972, Ch. 1407.)

ARTICLE 1. Requirements of Prescriptions [11150 - 11180] (Article 1 added by Stats. 1972, Ch. 1407.)

11150. No person other than a physician, dentist, podiatrist, or veterinarian, or naturopathic doctor acting pursuant to Section 3640.7 of the Business and Professions Code, or pharmacist acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or within the scope of Section 4052.1, 4052.2, or 4052.6 of the Business and Professions Code, a registered nurse acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107, a certified nurse-midwife acting within the scope of Section 2746.51 of the Business and Professions Code, a nurse practitioner acting within the scope of Section 2836.1 of the Business and Professions Code, a physician assistant acting within the scope of a project authorized under Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 or Section 3502.1 of the Business and Professions Code, a naturopathic doctor acting within the scope of Section 3640.5 of the Business and Professions Code, or an optometrist acting within the scope of Section 3041 of the Business and Professions Code, or an out-of-state prescriber acting pursuant to Section 4005 of the Business and Professions Code shall write or issue a prescription.

(Amended by Stats. 2014, Ch. 319, Sec. 5. (SB 1039) Effective January 1, 2015.)

- 11150.2. (a) Notwithstanding any other law, if cannabinoids are excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of cannabinoids is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within their scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.
- (b) For purposes of this chapter, upon the effective date of one of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of cannabinoids may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.
- (c) This section does not apply to any product containing cannabinoids that is made or derived from industrial hemp, as defined in Section 11018.5 and regulated pursuant to that section.

(Amended by Stats. 2021, Ch. 618, Sec. 4. (AB 527) Effective January 1, 2022.)

- 11150.3. (a) Notwithstanding any other law, if a substance listed in Schedule I of Section 11054 is excluded from Schedule I of the federal Controlled Substances Act and placed on a schedule of the act other than Schedule I, or if a product composed of one of these substances is approved by the federal Food and Drug Administration and either placed on a schedule of the act other than Schedule I, or exempted from one or more provisions of the act, so as to permit a physician, pharmacist, or other authorized healing arts licensee acting within their scope of practice, to prescribe, furnish, or dispense that product, the physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses that product in accordance with federal law shall be deemed to be in compliance with state law governing those acts.
- (b) For purposes of this chapter, upon the effective date of any of the changes in federal law described in subdivision (a), notwithstanding any other state law, a product composed of the excluded substance may be prescribed, furnished, dispensed, transferred, transported, possessed, or used in accordance with federal law and is authorized pursuant to state law.
- (c) This section does not apply to cannabis or a cannabis product, as defined in Section 26001 of the Business and Professions Code. However, cannabis or cannabis products may be authorized pursuant to Section 11150.2.

**11150.6.** Notwithstanding Section 11150.5 or subdivision (a) of Section 11054, methaqualone, its salts, isomers, and salts of its isomers shall be deemed to be classified in Schedule I for the purposes of this chapter.

(Added by Stats. 1984, Ch. 22, Sec. 1. Effective March 1, 1984.)

<u>11151.</u> A prescription written by an unlicensed person lawfully practicing medicine pursuant to Section 2065 of the Business and Professions Code, shall be filled only at a pharmacy maintained in the hospital which employs such unlicensed person.

(Amended by Stats. 1986, Ch. 248, Sec. 144.)

**11152.** No person shall write, issue, fill, compound, or dispense a prescription that does not conform to this division. (*Added by Stats.* 1972, *Ch.* 1407.)

- 11153. (a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of their professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized research; or (2) an order for a person with substance use disorder or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep them comfortable by maintaining customary use.
- (b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment.
- (c) No provision of the amendments to this section enacted during the second year of the 1981–82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

(Amended by Stats. 2023, Ch. 21, Sec. 4. (AB 1130) Effective January 1, 2024.)

- **11153.5.** (a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes.
- (b) Anyone who violates this section knowing, or having a conscious disregard for the fact, that the controlled substances are for other than a legitimate medical purpose shall be punishable by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment.
- (c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

(Amended by Stats. 2011, Ch. 15, Sec. 149. (AB 109) Effective April 4, 2011. Operative October 1, 2011, by Sec. 636 of Ch. 15, as amended by Stats. 2011, Ch. 39, Sec. 68.)

- 11154. (a) Except in the regular practice of his or her profession, no person shall knowingly prescribe, administer, dispense, or furnish a controlled substance to or for any person or animal which is not under his or her treatment for a pathology or condition other than addiction to a controlled substance, except as provided in this division.
- (b) No person shall knowingly solicit, direct, induce, aid, or encourage a practitioner authorized to write a prescription to unlawfully prescribe, administer, dispense, or furnish a controlled substance.

(Amended by Stats. 1982, Ch. 1403, Sec. 1.)

11155. Any physician, who by court order or order of any state or governmental agency, or who voluntarily surrenders his controlled substance privileges, shall not possess, administer, dispense, or prescribe a controlled substance unless and until such privileges have been restored, and he has obtained current registration from the appropriate federal agency as provided by law.

(Added by Stats. 1972, Ch. 1407.)

- <u>11156.</u> (a) Except as provided in Section 2241 of the Business and Professions Code, no person shall prescribe for, or administer, or dispense a controlled substance to, a person with substance use disorder, or to any person representing themselves as such, except as permitted by this division.
- (b) (1) For purposes of this section, "person with substance use disorder" means a person whose actions are characterized by craving in combination with one or more of the following:
  - (A) Impaired control over drug use.
  - (B) Compulsive use.
  - (C) Continued use despite harm.
  - (2) Notwithstanding paragraph (1), a person whose drug-seeking behavior is primarily due to the inadequate control of pain is not a person with substance use disorder within the meaning of this section.

(Amended by Stats. 2023, Ch. 21, Sec. 5. (AB 1130) Effective January 1, 2024.)

<u>11157.</u> No person shall issue a prescription that is false or fictitious in any respect.

(Added by Stats. 1972, Ch. 1407.)

- 11158. (a) Except as provided in Section 11159 or in subdivision (b) of this section, no controlled substance classified in Schedule II shall be dispensed without a prescription meeting the requirements of this chapter. Except as provided in Section 11159 or when dispensed directly to an ultimate user by a practitioner, other than a pharmacist or pharmacy, no controlled substance classified in Schedule III, IV, or V may be dispensed without a prescription meeting the requirements of this chapter.
- (b) A practitioner specified in Section 11150 may dispense a controlled substance classified in Schedule II, which may be from a hospital pharmacy inventory, directly to an ultimate user in either of the following circumstances:
  - (1) In an amount not to exceed a 72-hour supply for the patient in accordance with directions for use given by the dispensing practitioner only where the patient is not expected to require any additional amount of the controlled substance beyond the 72 hours.
  - (2) For the purpose of initiating maintenance treatment or detoxification treatment, or both, for a person with an opioid use disorder. Not more than a three-day supply of such medication may be dispensed to the person at one time while arrangements are being made for referral for treatment. Such emergency treatment may not be renewed or extended.
- (c) Except as otherwise prohibited or limited by law, a practitioner specified in Section 11150, may administer controlled substances in the regular practice of their profession.

(Amended by Stats. 2024, Ch. 634, Sec. 2. (AB 2115) Effective September 27, 2024.)

- 11158.1. (a) Except when a patient is being treated as set forth in Sections 11159, 11159.2, and 11167.5, and Article 2 (commencing with Section 11215) of Chapter 5, pertaining to the treatment of persons with substance use disorder, except when a patient is currently receiving hospice care, a prescriber shall discuss all of the following information with the patient, or if the patient is a minor, the minor, the minor's parent or guardian, or another adult authorized to consent to the minor's medical treatment, before directly dispensing or issuing to a patient the first prescription in a single course of treatment for a controlled substance containing an opioid:
  - (1) The risks of addiction and overdose associated with the use of opioids.
  - (2) The increased risk of addiction to an opioid for an individual who is suffering from both mental and substance abuse disorders.
  - (3) The danger of taking an opioid with a benzodiazepine, alcohol, or another central nervous system depressant.
  - (4) Any other information required by law.
- (b) This section does not apply in any of the following circumstances:
  - (1) If the patient's treatment includes emergency services and care as defined in Section 1317.1.
  - (2) If the patient's treatment is associated with, or incidental to, an emergency surgery, regardless of whether the surgery is performed on an inpatient or outpatient basis.

- (3) If, in the prescriber's professional judgment, fulfilling the requirements of subdivision (a) would be detrimental to the patient's health or safety, or in violation of the patient's legal rights regarding confidentiality.
- (c) Notwithstanding any other law, including Section 11374, failure to comply with this section shall not constitute a criminal offense. (Amended by Stats. 2024, Ch. 862, Sec. 1. (SB 607) Effective January 1, 2025.)
- 11159. An order for controlled substances for use by a patient in a county or licensed hospital shall be exempt from all requirements of this article, but shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually administered. The record of such orders shall be maintained as a hospital record for a minimum of seven years.

(Added by Stats. 1972, Ch. 1407.)

11159.1. An order for controlled substances furnished to a patient in a clinic which has a permit issued pursuant to Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code, except an order for a Schedule II controlled substance, shall be exempt from the prescription requirements of this article and shall be in writing on the patient's record, signed by the prescriber, dated, and shall state the name and quantity of the controlled substance ordered and the quantity actually furnished. The record of the order shall be maintained as a clinic record for a minimum of seven years. This section shall apply only to a clinic that has obtained a permit under the provisions of Article 13 (commencing with Section 4180) of Chapter 9 of Division 2 of the Business and Professions Code.

Clinics that furnish controlled substances shall be required to keep a separate record of the furnishing of those drugs which shall be available for review and inspection by all properly authorized personnel.

(Amended by Stats. 2004, Ch. 695, Sec. 52. Effective January 1, 2005.)

- 11159.2. (a) Notwithstanding any other provision of law, a prescription for a controlled substance for use by a patient who has a terminal illness may be written on a prescription form that does not meet the requirements of Section 11162.1 if the prescription meets the following requirements:
  - (1) Contain the information specified in subdivision (a) of Section 11164.
  - (2) Indicate that the prescriber has certified that the patient is terminally ill by the words "11159.2 exemption."
- (b) A pharmacist may fill a prescription pursuant to this section when there is a technical error in the certification required by paragraph (2) of subdivision (a), provided that he or she has personal knowledge of the patient's terminal illness, and subsequently returns the prescription to the prescriber for correction within 72 hours.
- (c) For purposes of this section, "terminally ill" means a patient who meets all of the following conditions:
  - (1) In the reasonable medical judgment of the prescribing physician, the patient has been determined to be suffering from an illness that is incurable and irreversible.
  - (2) In the reasonable medical judgment of the prescribing physician, the patient's illness will, if the illness takes its normal course, bring about the death of the patient within a period of one year.
  - (3) The patient's treatment by the physician prescribing a controlled substance pursuant to this section primarily is for the control of pain, symptom management, or both, rather than for cure of the illness.
- (d) This section shall become operative on July 1, 2004.

(Amended by Stats. 2005, Ch. 487, Sec. 1. Effective January 1, 2006.)

- 11159.3. (a) Notwithstanding any other law, during a declared local, state, or federal emergency, if the California State Board of Pharmacy issues a notice that the board is waiving the application of the provisions of, or regulations adopted pursuant to, the Pharmacy Law, as specified in subdivision (b) of Section 4062 of the Business and Professions Code, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription form meets the requirements of Section 11162.1, if the prescription meets the following requirements:
  - (1) Contains the information specified in subdivision (a) of Section 11164.
  - (2) Indicates that the patient is affected by a declared emergency with the words "11159.3 exemption" or a similar statement.

- (3) Is written and dispensed within the first two weeks of the notice issued by the board.
- (b) A pharmacist filling a prescription pursuant to this section shall do all of the following:
  - (1) Exercise appropriate professional judgment, including reviewing the patient's activity report from the CURES Prescription Drug Monitoring Program before dispensing the medication.
  - (2) If the prescription is for a Schedule II controlled substance, dispense no greater than the amount needed for a seven-day supply.
  - (3) Require the patient to first demonstrate, to the satisfaction of the pharmacist, their inability to access medications. This demonstration may include, but is not limited to, verification of residency within an evacuation area.
- (c) A pharmacist shall not refill a prescription that has been dispensed pursuant to this section.

(Added by Stats. 2019, Ch. 705, Sec. 1. (SB 569) Effective January 1, 2020.)

- 11161. (a) When a practitioner is named in a warrant of arrest or is charged in an accusatory pleading with a felony violation of Section 11153, 11154, 11156, 11157, 11170, 11173, 11350, 11351, 11352, 11353, 11353.5, 11377, 11378, 11378.5, 11379, 11379.5, or 11379.6, the court in which the accusatory pleading is filed or the magistrate who issued the warrant of arrest shall, upon the motion of a law enforcement agency which is supported by reasonable cause, issue an order which requires the practitioner to surrender to the clerk of the court all controlled substance prescription forms in the practitioner's possession at a time set in the order and which prohibits the practitioner from obtaining, ordering, or using any additional prescription forms. The law enforcement agency obtaining the order shall notify the Department of Justice of this order. Except as provided in subdivisions (b) and (e) of this section, the order shall remain in effect until further order of the court. Any practitioner possessing prescription forms in violation of the order is guilty of a misdemeanor.
- (b) The order provided by subdivision (a) shall be vacated if the court or magistrate finds that the underlying violation or violations are not supported by reasonable cause at a hearing held within two court days after the practitioner files and personally serves upon the prosecuting attorney and the law enforcement agency that obtained the order, a notice of motion to vacate the order with any affidavits on which the practitioner relies. At the hearing, the burden of proof, by a preponderance of the evidence, is on the prosecution. Evidence presented at the hearing shall be limited to the warrant of arrest with supporting affidavits, the motion to require the defendant to surrender controlled substance prescription forms and to prohibit the defendant from obtaining, ordering, or using controlled substance prescription forms, with supporting affidavits, the sworn complaint together with any documents or reports incorporated by reference thereto which, if based on information and belief, state the basis for the information, or any other documents of similar reliability as well as affidavits and counter affidavits submitted by the prosecution and defense. Granting of the motion to vacate the order is no bar to prosecution of the alleged violation or violations.
- (c) The defendant may elect to challenge the order issued under subdivision (a) at the preliminary examination. At that hearing, the evidence shall be limited to that set forth in subdivision (b) and any other evidence otherwise admissible at the preliminary examination.
- (d) If the practitioner has not moved to vacate the order issued under subdivision (a) by the time of the preliminary examination and he or she is held to answer on the underlying violation or violations, the practitioner shall be precluded from afterwards moving to vacate the order. If the defendant is not held to answer on the underlying charge or charges at the conclusion of the preliminary examination, the order issued under subdivision (a) shall be vacated.
- (e) Notwithstanding subdivision (d), any practitioner who is diverted pursuant to Chapter 2.5 (commencing with Section 1000) of Title 7 of Part 2 of the Penal Code may file a motion to vacate the order issued under subdivision (a).
- (f) This section shall become operative on November 1, 2004.

(Amended by Stats. 2005, Ch. 487, Sec. 2. Effective January 1, 2006.)

- <u>11161.5.</u> (a) Prescription forms for controlled substance prescriptions shall be obtained from security printers approved by the Department of Justice.
- (b) The department may approve security printer applications after the applicant has provided the following information:
  - (1) Name, address, and telephone number of the applicant.
  - (2) Policies and procedures of the applicant for verifying the identity of the prescriber ordering controlled substance prescription forms.
  - (3) Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers.

- (4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; all managing general partners, if any; and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms.
  - (B) A report containing this information shall be made on an annual basis and within 30 days after any change of office, principal corporate officers, managing general partner, or of any person described in subparagraph (A).
- (5) (A) A signed statement indicating whether the applicant, any principal corporate officer, any managing general partner, or any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, has ever been convicted of, or pled no contest to, a violation of any law of a foreign country, the United States, or any state, or of any local ordinance.
  - (B) The department shall provide the applicant and any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor of the applicant who has direct access to, or management or control of, controlled substance prescription forms, with the means and direction to provide fingerprints and related information, in a manner specified by the department, for the purpose of completing state, federal, or foreign criminal background checks.
  - (C) Any applicant described in subdivision (b) shall submit his or her fingerprint images and related information to the department, for the purpose of the department obtaining information as to the existence and nature of a record of state, federal, or foreign level convictions and state, federal, or foreign level arrests for which the department establishes that the applicant was released on bail or on his or her own recognizance pending trial, as described in subdivision (I) of Section 11105 of the Penal Code. Requests for federal level criminal offender record information received by the department pursuant to this section shall be forwarded to the Federal Bureau of Investigation by the department.
  - (D) The department shall assess against each security printer applicant a fee determined by the department to be sufficient to cover all processing, maintenance, and investigative costs generated from or associated with completing state, federal, or foreign background checks and inspections of security printers pursuant to this section with respect to that applicant; the fee shall be paid by the applicant at the time he or she submits the security printer application, fingerprints, and related information to the department.
  - (E) The department shall retain fingerprint impressions and related information for subsequent arrest notification pursuant to Section 11105.2 of the Penal Code for all applicants.
- (c) The department may, within 60 calendar days of receipt of the application from the applicant, deny the security printer application.
- (d) The department may deny a security printer application on any of the following grounds:
  - (1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.
  - (2) The applicant committed any act involving dishonesty, fraud, or deceit with the intent to substantially benefit himself, herself, or another, or substantially injure another.
  - (3) The applicant committed any act that would constitute a violation of this division.
  - (4) The applicant knowingly made a false statement of fact required to be revealed in the application to produce controlled substance prescription forms.
  - (5) The department determines that the applicant failed to demonstrate adequate security procedures relating to the production and distribution of controlled substance prescription forms.
  - (6) The department determines that the applicant has submitted an incomplete application.
  - (7) As a condition for its approval as a security printer, an applicant shall authorize the Department of Justice to make any examination of the books and records of the applicant, or to visit and inspect the applicant during business hours, to the extent deemed necessary by the board or department to properly enforce this section.
- (e) An approved applicant shall submit an exemplar of a controlled substance prescription form, with all security features, to the Department of Justice within 30 days of initial production.

- (f) The department shall maintain a list of approved security printers and the department shall make this information available to prescribers and other appropriate government agencies, including the Board of Pharmacy.
- (g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).
- (h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.
- (i) Security printers shall retain ordering and delivery records in a readily retrievable manner for individual prescribers for three years.
- (j) Security printers shall produce ordering and delivery records upon request by an authorized officer of the law as defined in Section 4017 of the Business and Professions Code.
- (k) Security printers shall report any theft or loss of controlled substance prescription forms to the Department of Justice via fax or email within 24 hours of the theft or loss.
- (I) (1) The department shall impose restrictions, sanctions, or penalties, subject to subdivisions (m) and (n), against security printers who are not in compliance with this division pursuant to regulations implemented pursuant to this division and shall revoke its approval of a security printer for a violation of this division or action that would permit a denial pursuant to subdivision (d) of this section.
  - (2) When the department revokes its approval, it shall notify the appropriate licensing boards and remove the security printer from the list of approved security printers.
- (m) The following violations by security printers shall be punishable pursuant to subdivision (n):
  - (1) Failure to comply with the Security Printer Guidelines established by the Security Printer Program as a condition of approval.
  - (2) Failure to take reasonable precautions to prevent any dishonest act or illegal activity related to the access and control of security prescription forms.
  - (3) Theft or fraudulent use of a prescriber's identity in order to obtain security prescription forms.
- (n) A security printer approved pursuant to subdivision (b) shall be subject to the following penalties for actions leading to the denial of a security printer application specified in subdivision (d) or for a violation specified in subdivision (m):
  - (1) For a first violation, a fine not to exceed one thousand dollars (\$1,000).
  - (2) For a second or subsequent violation, a fine not to exceed two thousand five hundred dollars (\$2,500) for each violation.
  - (3) For a third or subsequent violation, a filing of an administrative disciplinary action seeking to suspend or revoke security printer approval.
- (o) In order to facilitate the standardization of all prescription forms and the serialization of prescription forms with unique identifiers, the Department of Justice may cease issuing new approvals of security printers to the extent necessary to achieve these purposes. The department may, pursuant to regulation, reduce the number of currently approved security printers to no fewer than three vendors. The department shall ensure that any reduction or limitation of approved security printers does not impact the ability of vendors to meet demand for prescription forms.

(Amended by Stats. 2018, Ch. 479, Sec. 2. (AB 1753) Effective January 1, 2019.)

- 11161.7. (a) When a prescriber's authority to prescribe controlled substances is restricted by civil, criminal, or administrative action, or by an order of the court issued pursuant to Section 11161, the law enforcement agency or licensing board that sought the restrictions shall provide the name, category of licensure, license number, and the nature of the restrictions imposed on the prescriber to security printers, the Department of Justice, and the Board of Pharmacy.
- (b) The Board of Pharmacy shall make available the information required by subdivision (a) to pharmacies and security printers to prevent the dispensing of controlled substance prescriptions issued by the prescriber and the ordering of additional controlled substance prescription forms by the restricted prescriber.

(Added by Stats. 2003, Ch. 406, Sec. 7. Effective January 1, 2004.)

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

- (1) A latent, repetitive "void" pattern shall be printed across the entire front of the prescription blank; if a prescription is scanned or photocopied, the word "void" shall appear in a pattern across the entire front of the prescription.
- (2) A watermark shall be printed on the backside of the prescription blank; the watermark shall consist of the words "California Security Prescription."
- (3) A chemical void protection that prevents alteration by chemical washing.
- (4) A feature printed in thermochromic ink.
- (5) An area of opaque writing so that the writing disappears if the prescription is lightened.
- (6) A description of the security features included on each prescription form.
- (7) (A) Six quantity check off boxes shall be printed on the form so that the prescriber may indicate the quantity by checking the applicable box where the following quantities shall appear:

1-24

25-49

50-74

75-100

101-150

151 and over.

- (B) In conjunction with the quantity boxes, a space shall be provided to designate the units referenced in the quantity boxes when the drug is not in tablet or capsule form.
- (8) Prescription blanks shall contain a statement printed on the bottom of the prescription blank that the "Prescription is void if the number of drugs prescribed is not noted."
- (9) The preprinted name, category of licensure, license number, federal controlled substance registration number, and address of the prescribing practitioner.
- (10) Check boxes shall be printed on the form so that the prescriber may indicate the number of refills ordered.
- (11) The date of origin of the prescription.
- (12) A check box indicating the prescriber's order not to substitute.
- (13) An identifying number assigned to the approved security printer by the Department of Justice.
- (14) (A) A check box by the name of each prescriber when a prescription form lists multiple prescribers.
  - (B) Each prescriber who signs the prescription form shall identify themselves as the prescriber by checking the box by the prescriber's name.
- (15) A uniquely serialized number, in a manner prescribed by the Department of Justice in accordance with Section 11162.2.
- (b) Each batch of controlled substance prescription forms shall have the lot number printed on the form and each form within that batch shall be numbered sequentially beginning with the numeral one.
- (c) (1) A prescriber designated by a licensed health care facility, a clinic specified in Section 1200, or a clinic specified in subdivision (a) of Section 1206 that has 25 or more physicians or surgeons may order controlled substance prescription forms for use by prescribers when treating patients in that facility without the information required in paragraph (9) of subdivision (a) or paragraph (3).
  - (2) Forms ordered pursuant to this subdivision shall have the name, category of licensure, license number, and federal controlled substance registration number of the designated prescriber and the name, address, category of licensure, and license number of the licensed health care facility the clinic specified in Section 1200, or the clinic specified in Section 1206 that has 25 or more physicians or surgeons preprinted on the form. Licensed health care facilities or clinics exempt under Section 1206 are not required to preprint the category of licensure and license number of their facility or clinic.
  - (3) Forms ordered pursuant to this section shall not be valid prescriptions without the name, category of licensure, license number, and federal controlled substance registration number of the prescriber on the form.
  - (4) (A) Except as provided in subparagraph (B), the designated prescriber shall maintain a record of the prescribers to whom the controlled substance prescription forms are issued, that shall include the name, category of licensure, license number, federal

controlled substance registration number, and quantity of controlled substance prescription forms issued to each prescriber. The record shall be maintained in the health facility for three years.

- (B) Forms ordered pursuant to this subdivision that are printed by a computerized prescription generation system shall not be subject to subparagraph (A) or paragraph (7) of subdivision (a). Forms printed pursuant to this subdivision that are printed by a computerized prescription generation system may contain the prescriber's name, category of professional licensure, license number, federal controlled substance registration number, and the date of the prescription.
- (d) Within the next working day following delivery, a security printer shall submit via web-based application, as specified by the Department of Justice, all of the following information for all prescription forms delivered:
  - (1) Serial numbers of all prescription forms delivered.
  - (2) All prescriber names and Drug Enforcement Administration Controlled Substance Registration Certificate numbers displayed on the prescription forms.
  - (3) The delivery shipment recipient names.
  - (4) The date of delivery.

(Amended by Stats. 2019, Ch. 4, Sec. 1. (AB 149) Effective March 11, 2019.)

- 11162.2. (a) Notwithstanding any other law, the uniquely serialized number described in paragraph (15) of subdivision (a) of Section 11162.1 shall not be a required feature in the printing of new prescription forms produced by approved security printers until a date determined by the Department of Justice, which shall be no later than January 1, 2020.
- (b) Specifications for the serialized number shall be prescribed by the Department of Justice and shall meet the following minimum requirements:
  - (1) The serialized number shall be compliant with all state and federal requirements.
  - (2) The serialized number shall be utilizable as a barcode that may be scanned by dispensers.
  - (3) The serialized number shall be compliant with current National Council for Prescription Drug Program Standards.

(Added by Stats. 2019, Ch. 4, Sec. 2. (AB 149) Effective March 11, 2019.)

- 11162.5. (a) Every person who counterfeits a prescription blank purporting to be an official prescription blank prepared and issued pursuant to Section 11161.5, or knowingly possesses more than three counterfeited prescription blanks, shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code or by imprisonment in a county jail for not more than one year.
- (b) Every person who knowingly possesses three or fewer counterfeited prescription blanks purporting to be official prescription blanks prepared and issued pursuant to Section 11161.5, shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, or by a fine not exceeding one thousand dollars (\$1,000), or by both that fine and imprisonment.

(Amended by Stats. 2011, Ch. 15, Sec. 150. (AB 109) Effective April 4, 2011. Operative October 1, 2011, by Sec. 636 of Ch. 15, as amended by Stats. 2011, Ch. 39, Sec. 68.)

- <u>11162.6.</u> (a) Every person who counterfeits a controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail for not more than one year, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.
- (b) Every person who knowingly possesses a counterfeited controlled substance prescription form shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.
- (c) Every person who attempts to obtain or obtains a controlled substance prescription form under false pretenses shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.
- (d) Every person who fraudulently produces controlled substance prescription forms shall be guilty of a misdemeanor punishable by imprisonment in a county jail not exceeding six months, by a fine not exceeding one thousand dollars (\$1,000), or by both that imprisonment and fine.
- (e) This section shall become operative on July 1, 2004.

(Added by Stats. 2003, Ch. 406, Sec. 10. Effective January 1, 2004. Section operative July 1, 2004, by its own provisions.)

- **11164.** Except as provided in Section 11167, no person shall prescribe a controlled substance, nor shall any person fill, compound, or dispense a prescription for a controlled substance, unless it complies with the requirements of this section.
- (a) Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription form as specified in Section 11162.1 and shall meet the following requirements:
  - (1) The prescription shall be signed and dated by the prescriber in ink and shall contain the prescriber's address and telephone number; the name of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services; refill information, such as the number of refills ordered and whether the prescription is a first-time request or a refill; and the name, quantity, strength, and directions for use of the controlled substance prescribed.
  - (2) The prescription shall also contain the address of the person for whom the controlled substance is prescribed. If the prescriber does not specify this address on the prescription, the pharmacist filling the prescription or an employee acting under the direction of the pharmacist shall write or type the address on the prescription or maintain this information in a readily retrievable form in the pharmacy.
- (b) (1) Notwithstanding paragraph (1) of subdivision (a) of Section 11162.1, any controlled substance classified in Schedule III, IV, or V may be dispensed upon an oral or electronically transmitted prescription, which shall be produced in hard copy form and signed and dated by the pharmacist filling the prescription or by any other person expressly authorized by provisions of the Business and Professions Code. Any person who transmits, maintains, or receives any electronically transmitted prescription shall ensure the security, integrity, authority, and confidentiality of the prescription.
  - (2) The date of issue of the prescription and all the information required for a written prescription by subdivision (a) shall be included in the written record of the prescription; the pharmacist need not include the address, telephone number, license classification, or federal registry number of the prescriber or the address of the patient on the hard copy, if that information is readily retrievable in the pharmacy.
  - (3) Pursuant to an authorization of the prescriber, any agent of the prescriber on behalf of the prescriber may orally or electronically transmit a prescription for a controlled substance classified in Schedule III, IV, or V, if in these cases the written record of the prescription required by this subdivision specifies the name of the agent of the prescriber transmitting the prescription.
- (c) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.
- (d) Notwithstanding subdivisions (a) and (b), prescriptions for a controlled substance classified in Schedule V may be for more than one person in the same family with the same medical need.
- (e) (1) Notwithstanding any other law, a prescription written on a prescription form that was otherwise valid prior to January 1, 2019, but that does not comply with paragraph (15) of subdivision (a) of Section 11162.1, or a valid controlled substance prescription form approved by the Department of Justice as of January 1, 2019, is a valid prescription that may be filled, compounded, or dispensed until January 1, 2021.
  - (2) If the Department of Justice determines that there is an inadequate availability of compliant prescription forms to meet demand on or before the date described in paragraph (1), the department may extend the period during which prescriptions written on noncompliant prescription forms remain valid for a period no longer than an additional six months.

(Amended by Stats. 2019, Ch. 4, Sec. 3. (AB 149) Effective March 11, 2019.)

- 11164.1. (a) (1) Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.
  - (2) A prescription for a Schedule II, Schedule IV, or Schedule V controlled substance dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165
- (b) A pharmacy may dispense a prescription for a Schedule III, Schedule IV, or Schedule V controlled substance from an out-of-state prescriber pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.
- (c) This section shall become operative on January 1, 2021.

(Repealed (in Sec. 3) and added by Stats. 2019, Ch. 677, Sec. 4. (AB 528) Effective January 1, 2020. Section operative January 1, 2021, by its own provisions.)

- 11164.5. (a) Notwithstanding Section 11164, if only recorded and stored electronically, on magnetic media, or in any other computerized form, the pharmacy's or hospital's computer system shall not permit the received information or the controlled substance dispensing information required by this section to be changed, obliterated, destroyed, or disposed of, for the record maintenance period required by law, once the information has been received by the pharmacy or the hospital and once the controlled substance has been dispensed, respectively. Once the controlled substance has been dispensed, if the previously created record is determined to be incorrect, a correcting addition may be made only by or with the approval of a pharmacist. After a pharmacist enters the change or enters his or her approval of the change into the computer, the resulting record shall include the correcting addition and the date it was made to the record, the identity of the person or pharmacist making the correction, and the identity of the pharmacist approving the correction.
- (b) Nothing in this section shall be construed to exempt any pharmacy or hospital dispensing Schedule II controlled substances pursuant to electronic transmission prescriptions from existing reporting requirements.

(Amended by Stats. 2016, Ch. 484, Sec. 55. (SB 1193) Effective January 1, 2017.)

- 11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.
- (b) The department may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.
- (c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.
  - (2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the department, for educational, peer review, statistical, or research purposes, if patient information, including information that may identify the patient, is not compromised. The University of California shall be provided access to identifiable data for research purposes if the requirements of subdivision (t) of Section 1798.24 of the Civil Code are satisfied. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The department shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.
    - (B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.
  - (3) The department shall, no later than January 1, 2021, adopt regulations regarding the access and use of the information within CURES. The department shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:
    - (A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.
    - (B) The purposes for which a health care practitioner may access information in CURES.
    - (C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.
    - (D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.
  - (4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data are provided and the health care practitioner

keeps a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

- (d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:
  - (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender and date of birth of the ultimate user.
  - (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a prescriber using the federal controlled substance registration number of a government-exempt facility.
  - (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
  - (4) National Drug Code (NDC) number of the controlled substance dispensed.
  - (5) Quantity of the controlled substance dispensed.
  - (6) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, if available.
  - (7) Number of refills ordered.
  - (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
  - (9) Prescribing date of the prescription.
  - (10) Date of dispensing of the prescription.
  - (11) The serial number for the corresponding prescription form, if applicable.
- (e) The department may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. A prescriber or dispenser invitee shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- (f) The department shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).
- (g) The department may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.
- (h) (1) The department may enter into an agreement with an entity operating an interstate data sharing hub, or an agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.
  - (2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the department pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the department for interstate data sharing of prescription drug monitoring program information.
  - (3) An agreement entered into by the department for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.
  - (4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if the authorized user is registered and in good standing with that state's prescription drug monitoring program.

- (5) The department shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).
- (i) Notwithstanding subdivision (d), a veterinarian shall report the information required by that subdivision to the department as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.
- (j) If the dispensing pharmacy, clinic, or other dispenser experiences a temporary technological or electrical failure, it shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within its control. The deadline for transmitting prescription information to the department or contracted prescription data processing vendor pursuant to subdivision (d) shall be extended until the failure is corrected. If the dispensing pharmacy, clinic, or other dispenser experiences technological limitations that are not reasonably within its control, or is impacted by a natural or manmade disaster, the deadline for transmitting prescription information to the department or contracted prescription data processing vendor shall be extended until normal operations have resumed.

(Amended by Stats. 2021, Ch. 618, Sec. 5. (AB 527) Effective January 1, 2022.)

- 11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, upon receipt of a federal Drug Enforcement Administration (DEA) registration, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).
  - (ii) A pharmacist shall, upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.
  - (iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.
  - (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) The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:
    - (i) Materially falsifying an application to access information contained in the CURES database.
    - (ii) Failing to maintain effective controls for access to the patient activity report.
    - (iii) Having their federal DEA registration suspended or revoked.
    - (iv) Violating a law governing controlled substances or another law for which the possession or use of a controlled substance is an element of the crime.
    - (v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.
  - (C) An authorized subscriber shall notify the department within 30 days of a change to the subscriber account.
  - (D) An approved health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

- (E) An approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system certifies all of the following:
  - (i) The entity will not use or disclose data received from the CURES database for a purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.
  - (ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:
    - (I) The date of the query.
    - (II) The time of the query.
    - (III) The first and last name of the patient queried.
    - (IV) The date of birth of the patient queried.
    - (V) The identification of the CURES user for whom the system is making the guery.
  - (iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.
  - (iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.
- (F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.
- (G) The department shall not access patient-identifiable information in an entity's health information technology system.
- (H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.
- (I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).
- (2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.
- (b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.
- (c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.
- (d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.
- (e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.

- (f) A health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for a resulting failure of the CURES database to accurately or timely report that information.
- (g) For purposes of this section, the following terms have the following meanings:
  - (1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.
  - (2) "Department" means the Department of Justice.
  - (3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.
  - (4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.
- (h) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

(Amended (as added by Stats. 2019, Ch. 677, Sec. 8) by Stats. 2021, Ch. 77, Sec. 20. (AB 137) Effective July 16, 2021.)

- 11165.2. (a) The Department of Justice may conduct audits of the CURES Prescription Drug Monitoring Program system and its users.
- (b) The Department of Justice may establish, by regulation, a system for the issuance to a CURES Prescription Drug Monitoring Program subscriber of a citation which may contain an order of abatement, or an order to pay an administrative fine assessed by the Department of Justice if the subscriber is in violation of any provision of this chapter or any regulation adopted by the Department of Justice pursuant to this chapter.
- (c) The system shall contain the following provisions:
  - (1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law or regulation of the department determined to have been violated.
  - (2) Whenever appropriate, the citation shall contain an order of abatement establishing a reasonable time for abatement of the violation.
  - (3) In no event shall the administrative fine assessed by the department exceed two thousand five hundred dollars (\$2,500) for each violation. In assessing a fine, due consideration shall be given to the appropriateness of the amount of the fine with respect to such factors as the gravity of the violation, the good faith of the subscribers, and the history of previous violations.
  - (4) An order of abatement or a fine assessment issued pursuant to a citation shall inform the subscriber that if the subscriber desires a hearing to contest the finding of a violation, a hearing shall be requested by written notice to the CURES Prescription Drug Monitoring Program within 30 days of the date of issuance of the citation or assessment. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.
  - (5) In addition to requesting a hearing, the subscriber may, within 10 days after service of the citation, request in writing an opportunity for an informal conference with the department regarding the citation. At the conclusion of the informal conference, the department may affirm, modify, or dismiss the citation, including any fine levied or order of abatement issued. The decision shall be deemed to be a final order with regard to the citation issued, including the fine levied or the order of abatement which could include permanent suspension to the system, a monetary fine, or both, depending on the gravity of the violation. However, the subscriber does not waive its right to request a hearing to contest a citation by requesting an informal conference. If the citation is affirmed, a formal hearing may be requested within 30 days of the date the citation was affirmed. If the citation is dismissed after the informal conference, the request for a hearing on the matter of the citation shall be deemed to be withdrawn. If the citation, including any fine levied or order of abatement, is modified, the citation originally issued shall be considered withdrawn and a new citation issued. If a hearing is requested for a subsequent citation, it shall be requested within 30 days of service of that subsequent citation.
  - (6) Failure of a subscriber to pay a fine within 30 days of the date of assessment or comply with an order of abatement within the fixed time, unless the citation is being appealed, may result in disciplinary action taken by the department. If a citation is not contested and a fine is not paid, the subscriber account will be terminated:

- (A) A citation may be issued without the assessment of an administrative fine.
- (B) Assessment of administrative fines may be limited to only particular violations of law or department regulations.
- (d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine shall be represented as a satisfactory resolution of the matter for purposes of public disclosure.
- (e) Administrative fines collected pursuant to this section shall be deposited in the CURES Program Special Fund, available upon appropriation by the Legislature. These special funds shall provide support for costs associated with informal and formal hearings, maintenance, and updates to the CURES Prescription Drug Monitoring Program.
- (f) The sanctions authorized under this section shall be separate from, and in addition to, any other administrative, civil, or criminal remedies; however, a criminal action may not be initiated for a specific offense if a citation has been issued pursuant to this section for that offense, and a citation may not be issued pursuant to this section for a specific offense if a criminal action for that offense has been filed.
- (g) Nothing in this section shall be deemed to prevent the department from serving and prosecuting an accusation to suspend or revoke a subscriber if grounds for that suspension or revocation exist.

(Added by Stats. 2011, Ch. 418, Sec. 5. (SB 360) Effective January 1, 2012.)

11165.3. The theft or loss of prescription forms shall be reported immediately by the security printer or affected prescriber to the CURES Prescription Drug Monitoring Program, but no later than three days after the discovery of the theft or loss. This notification may be done in writing utilizing the approved Department of Justice form or may be reported by the authorized subscriber through the CURES Prescription Drug Monitoring Program.

(Amended by Stats. 2012, Ch. 867, Sec. 7. (SB 1144) Effective January 1, 2013.)

- 11165.4. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.
  - (ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.
  - (iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.
  - (B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.
  - (2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.
- (b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.
- (c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:
  - (1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:
    - (A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

- (B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.
- (C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
- (D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
- (E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.
- (F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.
- (2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.
- (3) If a health care practitioner prescribes, orders, administers, or furnishes buprenorphine or other controlled substance containing buprenorphine in the emergency department of a general acute care hospital.
- (4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:
  - (A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.
  - (B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.
  - (C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.
  - (D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.
  - (E) A place of practice, as defined in Section 1658 of the Business and Professions Code.
  - (F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.
- (5) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.
- (6) (A) If all of the following circumstances are satisfied:
  - (i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.
  - (ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.
  - (iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.
  - (B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.
- (7) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.
- (8) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.
- (9) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.
- (d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

- (2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.
- (e) All applicable state and federal privacy laws govern the duties required by this section.
- (f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.
- (g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

(Amended by Stats. 2023, Ch. 144, Sec. 1. (AB 1731) Effective January 1, 2024.)

- 11165.5. (a) The Department of Justice may seek voluntarily contributed private funds from insurers, health care service plans, qualified manufacturers, and other donors for the purpose of supporting CURES. Insurers, health care service plans, qualified manufacturers, and other donors may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (c) of Section 208 of the Business and Professions Code. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.
- (b) For purposes of this section, the following definitions apply:
  - (1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.
  - (2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).
  - (3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers' compensation insurance, as defined in Section 109 of the Insurance Code.
  - (4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

(Added by Stats. 2013, Ch. 400, Sec. 8. (SB 809) Effective January 1, 2014.)

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

(Added by Stats. 2018, Ch. 274, Sec. 1. (AB 2086) Effective January 1, 2019.)

11166. No person shall fill a prescription for a controlled substance after six months has elapsed from the date written on the prescription by the prescriber. No person shall knowingly fill a mutilated or forged or altered prescription for a controlled substance except for the addition of the address of the person for whom the controlled substance is prescribed as provided by paragraph (3) of subdivision (b) of Section 11164.

(Amended by Stats. 2003, Ch. 406, Sec. 19. Effective January 1, 2004.)

- 11167. Notwithstanding subdivision (a) of Section 11164, in an emergency where failure to issue a prescription may result in loss of life or intense suffering, an order for a controlled substance may be dispensed on an oral order, an electronic data transmission order, or a written order not made on a controlled substance form as specified in Section 11162.1, subject to all of the following requirements:
- (a) The order contains all information required by subdivision (a) of Section 11164.
- (b) Any written order is signed and dated by the prescriber in ink, and the pharmacy reduces any oral or electronic data transmission order to hard copy form prior to dispensing the controlled substance.
- (c) The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of Section 11162.1, by the seventh day following the transmission of the initial order; a postmark by the seventh day following transmission of the initial order shall constitute compliance.

- (d) If the prescriber fails to comply with subdivision (c), the pharmacy shall so notify the Department of Justice in writing within 144 hours of the prescriber's failure to do so and shall make and retain a hard copy, readily retrievable record of the prescription, including the date and method of notification of the Department of Justice.
- (e) This section shall become operative on January 1, 2005.

(Amended by Stats. 2012, Ch. 867, Sec. 8. (SB 1144) Effective January 1, 2013.)

11167.5. (a) An order for a controlled substance classified in Schedule II for a patient of a licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice may be dispensed upon an oral or electronically transmitted prescription. If the prescription is transmitted orally, the pharmacist shall, prior to filling the prescription, reduce the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy for this purpose. If the prescription is transmitted electronically, the pharmacist shall, prior to filling the prescription, produce, sign, and date a hard copy prescription. The prescriptions shall contain the date the prescription was orally or electronically transmitted by the prescriber, the name of the person for whom the prescription was authorized, the name and address of the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice in which that person is a patient, the name and quantity of the controlled substance prescribed, the directions for use, and the name, address, category of professional licensure, license number, and federal controlled substance registration number of the prescriber. The original shall be properly endorsed by the pharmacist with the pharmacy's state license number, the name and address of the pharmacy, and the signature of the person who received the controlled substances for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency, or licensed hospice. A licensed skilled nursing facility, a licensed intermediate care facility, a licensed home health agency, or a licensed hospice shall forward to the dispensing pharmacist a copy of any signed telephone orders, chart orders, or related documentation substantiating each oral or electronically transmitted prescription transaction under this section.

(b) This section shall become operative on July 1, 2004.

(Repealed (in Sec. 23) and added by Stats. 2003, Ch. 406, Sec. 24. Effective January 1, 2004. Section operative July 1, 2004, by its own provisions.)

11170. No person shall prescribe, administer, or furnish a controlled substance for himself.

(Repealed and added by Stats. 1972, Ch. 1407.)

**11171.** No person shall prescribe, administer, or furnish a controlled substance except under the conditions and in the manner provided by this division.

(Repealed and added by Stats. 1972, Ch. 1407.)

11172. No person shall antedate or postdate a prescription.

(Repealed and added by Stats. 1972, Ch. 1407.)

- **11173.** (a) No person shall obtain or attempt to obtain controlled substances, or procure or attempt to procure the administration of or prescription for controlled substances, (1) by fraud, deceit, misrepresentation, or subterfuge; or (2) by the concealment of a material fact.
- (b) No person shall make a false statement in any prescription, order, report, or record, required by this division.
- (c) No person shall, for the purpose of obtaining controlled substances, falsely assume the title of, or represent himself to be, a manufacturer, wholesaler, pharmacist, physician, dentist, veterinarian, registered nurse, physician's assistant, or other authorized person.
- (d) No person shall affix any false or forged label to a package or receptacle containing controlled substances.

(Amended by Stats. 1977, Ch. 843.)

<u>11174.</u> No person shall, in connection with the prescribing, furnishing, administering, or dispensing of a controlled substance, give a false name or false address.

(Repealed and added by Stats. 1972, Ch. 1407.)

**11175.** No person shall obtain or possess a prescription that does not comply with this division, nor shall any person obtain a controlled substance by means of a prescription which does not comply with this division or possess a controlled substance obtained by such a prescription.

(Amended by Stats. 1976, Ch. 896.)

<u>11179.</u> A person who fills a prescription shall keep it on file for at least three years from the date of filling it. (*Amended by Stats. 1976, Ch. 896.*)

 $\underline{\textbf{11180.}} \ \ \text{No person shall obtain or possess a controlled substance obtained by a prescription that does not comply with this division.}$ 

(Added by Stats. 1972, Ch. 1407.)