

## California Law Changes for 2012

Provided below are code sections that were added or amended during the 2011 Legislative Session. Unless otherwise indicated, all these provisions go into effect January 1, 2012. Summaries of the changes made to many of the code sections will be provided in the next issue of *The Script*.

(~~Strikeout~~ indicates text that has been removed. Underlined text indicates new or added text.)

## Business and Professions Code

Section 4104 of the Business and Professions Code is amended to read:

(a) Every pharmacy shall have in place procedures for taking action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs.

(b) Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy.

(c) Every pharmacy shall report and provide to the board, within ~~30~~14 days of the receipt or development ~~of thereof~~, the following information with regard to any licensed individual employed by or with the pharmacy:

(1) Any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice.

(2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs.

(3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual.

(5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice.

(6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs.

(d) The report required in subdivision (c) shall include sufficient detail to inform the board of the facts upon which the report is based, including an estimate of the type and quantity of all dangerous drugs involved, the timeframe over which the losses are suspected, and the date of the last controlled substances inventory. Upon request of the board, the pharmacy shall prepare and submit an audit involving the dangerous drugs suspected to be missing.

(e) Anyone making a report authorized or required by this section shall have immunity from any liability, civil or criminal, that might otherwise arise from the making of the report. Any participant shall have the same immunity with respect to participation in any administrative or judicial proceeding resulting from the report.

**Section 4105 of the Business and Professions Code is amended to read:**

(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

~~(f) This section shall become operative on January 1, 2006~~ When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

**Section 4112 of the Business and Professions Code is amended to read:**

(a) Any pharmacy located outside this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, and (4) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful 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 pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist whose license has been revoked by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

~~(h)~~(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

~~(i)~~(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

~~(j)~~(k) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

**Section 4140 of the Business and Professions Code is repealed.**

~~No person shall possess or have under his or her control any hypodermic needle or syringe except when acquired in accordance with this article.~~

**Section 4144 of the Business and Professions Code is amended to read:**

(a) A person may sell or obtain hypodermic needles and hypodermic syringes without a prescription or permit, for uses that the board determines are industrial, and that person shall not be required to comply with Section 4145 or 4146.

(b) This section shall be inoperative until January 1, 2015.

**Section 4144.5 is added to the Business and Professions Code, to read:**

(a) A person may sell or obtain hypodermic needles and hypodermic syringes without a prescription or permit, for uses that the board determines are industrial, and that person shall not be required to comply with Section 4145.5 or 4146.

(b) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

**Section 4145 of the Business and Professions Code is amended to read:**

(a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if one of the following requirements is met:

(1) The person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(2) Pursuant to authorization by a county, with respect to all of the territory within the county, or a city, with respect to the territory within the city, for the period commencing January 1, 2005, and ending December 31, 2018, a pharmacist may furnish or sell 10 or fewer hypodermic needles or syringes at any one time to a person 18 years of age or older if the pharmacist works for a pharmacy that is registered with the Disease Prevention Demonstration Project pursuant to Chapter 13.5 (commencing with Section 121285) of Part 4 of Division 105 of the Health and Safety Code and the pharmacy complies with the provisions of that chapter.

(b) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals,

providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(c) This section shall be inoperative until January 1, 2015.

**Section 4145.5 is added to the Business and Professions Code, to read:**

(a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the person is known to the furnisher and the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish 30 or fewer hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain 30 or fewer hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals, providing that no needle or syringe shall be furnished to a person who is unknown to the furnisher and unable to properly establish his or her identity.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(2) It shall furnish, or make available, mail-back sharps containers authorized by the United States Postal Service that meet applicable state and federal requirements for the transport of medical sharps waste, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(f) A pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

(g) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

**Section 4148 of the Business and Professions Code is amended to read:**

(a) All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption under Section 4143, 4144, or 4145.

(b) This section shall be inoperative until January 1, 2015.

**Section 4148.5 is added to the Business and Professions Code, to read:**

(a) All stocks of hypodermic needles or syringes shall be confiscated if found outside the licensed premises of any person holding a permit under Section 4141 and found not in the possession or under the control of a person entitled to an exemption

under Section 4143, 4144, or 4145.5, or under Section 11364.5, 121349, or 121349.1 of the Health and Safety Code.

(b) This section shall remain in effect only until January 1, 2015, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2015, deletes or extends that date.

**Section 4149.5 is added to the Business and Professions Code, to read:**

(a) Local authorizations related to Sections 4144, 4145, and 4148 of this code and Sections 11364 and 121285 of the Health and Safety Code shall be inoperative until January 1, 2015.

(b) Local authorizations related to Sections 4144, 4145, and 4148 of this code and Sections 11364 and 121285 of the Health and Safety Code shall again become operative on January 1, 2015, unless the city, county, or city and county acts to remove the authorization.

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

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

(1) Is at least 18 years of age.

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

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

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

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

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

(6) Has passed ~~a written and practical examination given by the board prior to December 31, 2003, or has passed~~ the North American Pharmacist Licensure Examination and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.

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

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

**Section 4207 of the Business and Professions Code is amended to read:**

(a) Upon receipt of an application for a license and the applicable fee, the board shall make a thorough investigation to determine whether the applicant is qualified for the license being sought. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license that may affect the public welfare.

(b) The board shall not investigate matters connected with the operation of a premises other than those matters solely related to the furnishing of dangerous drugs or dangerous devices that might adversely affect the public welfare.

(c) The board shall deny an application for a license if the applicant does not qualify for the license being sought.

(d) Notwithstanding any other provision of law, the board may request any information it deems necessary to complete the application investigation required by this section, and a request for information that the board deems necessary in carrying out this section in any application or related form devised by the board shall not be required to be adopted by regulation pursuant to the Administrative ~~Procedures~~ Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).

**Section 4324 of the Business and Professions Code is amended to read:**

(a) Every person who signs the name of another, or of a fictitious person, or falsely makes, alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment ~~in the state prison~~ pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in ~~the~~ a county jail for not more than one year.

(b) Every person who has in his or her possession any drugs secured by a forged prescription shall be punished by imprisonment ~~in the state prison~~ pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in the county jail for not more than one year.

## Health and Safety Code

### **Section 11161.5 of the Health and Safety Code is amended to read:**

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

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

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

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

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

(4) (A) The location, names, and titles of the applicant's agent for service of process in this state; all principal corporate officers, if any; ~~and~~ 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, ~~or~~ managing general partner, or of any person described in subparagraph (A).

(5) (A) A signed statement indicating whether the applicant, any principal corporate officers, or officer, any managing general partners have 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 fingerprints the security printer application, fingerprints, and related information to the department.

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

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

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

(1) The applicant, any individual owner, partner, corporate officer, manager, agent, representative, employee, or subcontractor for the applicant, who has direct access, management, or control of controlled substance prescription forms, has been convicted of a crime. A conviction within the meaning of this paragraph means a plea or verdict of guilty or a conviction following a plea of nolo contendere. Any action which a board is permitted to take following the establishment of a conviction may be taken when the time for appeal has elapsed, the judgment of conviction has been affirmed on appeal, or when an order granting probation is made suspending the imposition of sentence, irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

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

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

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

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

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

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

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

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

(g) Before printing any controlled substance prescription forms, a security printer shall verify with the appropriate licensing board that the prescriber possesses a

license and current prescribing privileges which permits the prescribing of controlled substances with the federal Drug Enforcement Administration (DEA).

(h) Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by a means that requires a signature signifying receipt of the package and provision of that signature to the security printer. Controlled substance prescription forms provided in person shall be restricted to established customers. Security printers shall obtain a photo identification from the customer and maintain a log of this information. Controlled substance prescription forms shall be shipped only to the prescriber's address on file and verified with the federal Drug Enforcement Administration or the Medical Board of California.

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

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

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

(l) (1) The department ~~may~~ 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.

**Section 11162.1 of the Health and Safety Code is amended to read:**

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

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

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

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

(4) A feature printed in thermochromic ink.

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

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

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

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~~-number, and address of the prescribing practitioner.

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

(11) The date of origin of the prescription.

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

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

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

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

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

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

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

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

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

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

(d) This section shall become operative on January 1, 2012. Prescription forms not in compliance with this division shall not be valid or accepted after July 1, 20042012.

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

(a) To assist law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds from the Contingent

Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, and the Osteopathic Medical Board of California Contingent Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

(b) The reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds from the Department of Justice. The ~~Department of Justice~~ department may seek and use grant funds to pay the costs incurred from the reporting of controlled substance prescriptions to CURES. Funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor's Fund, or the Osteopathic Medical Board of California Contingent Fund to pay the costs of reporting Schedule III and Schedule IV controlled substance prescriptions to CURES.

(c) 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 persons or public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy or clinic shall provide the following information to the Department of Justice on a weekly basis and in a format specified by the Department of Justice:

(1) Full name, address, and the 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 and license number; federal controlled substance registration number; and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.

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

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

(5) Quantity of the controlled substance dispensed.

(6) ICD-9 (diagnosis code), if available.

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(e) This section shall become operative on January 1, 2005.

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

(a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist may ~~make a written request for~~ provide a notarized application developed by the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient maintained within the Department of Justice, and the department may release to that practitioner or pharmacist, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

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

(i) Materially falsifying an application for a subscriber.

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

(iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(B) Any authorized subscriber shall notify the Department of Justice within 10 days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist, pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

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

~~(b)~~ (c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice 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.

~~(c)~~ (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 of Justice pursuant to this section shall be considered 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 prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

**Section 11165.2 is added to the Health and Safety Code, to read:**

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.

**Section 11165.3 is added to the Health and Safety Code, to read:**

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 Bureau of Narcotic Enforcement 1175 Reporting Theft/Loss Form or may be reported by the authorized subscriber through the CURES Prescription Drug Monitoring Program.

**Section 121349 of the Health and Safety Code is amended to read:**

(a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to ~~attempt to~~ reduce the spread of HIV infection and ~~blood-borne~~ 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 and county~~ city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health department, or upon the action of the city council and the mayor of a city without a health department.

(c) In order to reduce the spread of HIV infection, viral hepatitis, and other potentially deadly bloodborne infections, the State Department of Public Health may, notwithstanding any other law, authorize entities that provide services set forth in paragraph (1) of subdivision (d), and that have sufficient staff and capacity to provide the services described in Section 121349.1, as determined by the department, to apply for authorization under this chapter to provide hypodermic needle and syringe exchange services consistent with state standards in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Authorization shall be made after consultation with the local health officer and local law enforcement leadership, and after a period of public comment, as described in subdivision (e). In making the determination, the department shall balance the concerns of law enforcement with the public health benefits. The authorization shall not be for more than two years. Before the end of the two-year period, the department may reauthorize the program in consultation with the local health officer and local law enforcement leadership.

(d) In order for an entity to be authorized to conduct a project pursuant to this chapter, its application to the department shall demonstrate that the entity complies with all of the following minimum standards:

(1) The entity provides, directly or through referral, all of the following services:

(A) Drug abuse treatment services.

(B) HIV or hepatitis screening.

(C) Hepatitis A and hepatitis B vaccination.

(D) Screening for sexually transmitted infections.

(E) Housing services for the homeless, for victims of domestic violence, or other similar housing services.

(F) Services related to provision of education and materials for the reduction of sexual risk behaviors, including, but not limited to, the distribution of condoms.

(2) The entity has the capacity to commence needle and syringe exchange services within three months of authorization.

(3) The entity has adequate funding to do all of the following at reasonably projected program participation levels:

(A) Provide needles and syringe exchange services for all of its participants.

(B) Provide HIV and viral hepatitis prevention education services for all of its participants.

(C) Provide for the safe recovery and disposal of used syringes and sharps waste from all of its participants.

(4) The entity has the capacity, and an established plan, to collect evaluative data in order to assess program impact, including, but not limited to, all of the following:

(A) The total number of persons served.

(B) The total number of syringes and needles distributed, recovered, and disposed of.

(C) The total numbers and types of referrals to drug treatment and other services.

(e) If the application is provisionally deemed appropriate by the department, the department shall, at least 90 days prior to approval of the application, provide for a period of public comment as follows:

(1) Post on the department's Internet Web site the name of the applicant, the nature of the services, and the location where the applying entity will provide the services.

(2) Send a written and an e-mail notice to the local health officer of the affected jurisdiction.

(3) Send a written and an e-mail notice to the chief of police, the sheriff, or both, as appropriate, of the jurisdictions in which the program will operate.

(f) The department shall establish and maintain on its Internet Web site the address and contact information of programs providing hypodermic needle and syringe exchange services pursuant to this chapter.

(g) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

(h) This section shall become inoperative on January 1, 2019, and as of that date is repealed.

**Section 121349 is added to the Health and Safety Code, to read:**

(a) The Legislature finds and declares that scientific data from needle exchange programs in the United States and in Europe have shown that the exchange of used hypodermic needles and syringes for clean hypodermic needles and syringes does not increase drug use in the population, can serve as an important bridge to treatment and recovery from drug abuse, and can curtail the spread of human immunodeficiency virus (HIV) infection among the intravenous drug user population.

(b) In order to reduce the spread of HIV infection and bloodborne hepatitis among the intravenous drug user population within California, the Legislature hereby authorizes a clean needle and syringe exchange project pursuant to this chapter in any city, county, or city and county upon the action of a county board of supervisors and the local health officer or health commission of that county, or upon the action of the city council, the mayor, and the local health officer of a city with a health

department, or upon the action of the city council and the mayor of a city without a health department.

(c) The authorization provided under this section shall only be for a clean needle and syringe exchange project as described in Section 121349.1.

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

**Section 121349.1 of the Health and Safety Code is amended to read:**

~~A city and county, or a~~

(a) The State Department of Public Health or a city, county, or a city and county with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of ~~Health Services~~Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Secretary of Health and Human Services, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and ~~blood-borne~~bloodborne hepatitis infection among injection drug users. ~~Providers~~Staff and volunteers participating in an exchange project authorized by the state, county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for ~~possession of needles or syringes during participation in an exchange project.~~

violation of any law related to the possession, furnishing, or transfer of hypodermic needles or syringes during participation in an exchange project. Program participants shall not be subject to criminal prosecution for possession of needles or syringes acquired from an authorized needle and syringe exchange project entity.

(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed

**Section 121349.1 is added to the Health and Safety Code, to read:**

(a) A city, county, or a city and county, with or without a health department, that acts to authorize a clean needle and syringe exchange project pursuant to this chapter shall, in consultation with the State Department of Public Health, authorize the exchange of clean hypodermic needles and syringes, as recommended by the United States Public Health Service, subject to the availability of funding, as part of a network of comprehensive services, including treatment services, to combat the spread of HIV and bloodborne hepatitis infection among injection drug users.

Providers participating in an exchange project authorized by the county, city, or city and county pursuant to this chapter shall not be subject to criminal prosecution for possession of needles or syringes during participation in an exchange project.

(b) This section shall become operative on January 1, 2019.

**Section 121349.2 of the Health and Safety Code is amended to read:**

(a) Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on an annual-a biennial basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare of clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed.

**Section 121349.2 is added to the Health and Safety Code, to read:**

(a) Local government, local public health officials, and law enforcement shall be given the opportunity to comment on clean needle and syringe exchange programs on an annual basis. The public shall be given the opportunity to provide input to local leaders to ensure that any potential adverse impacts on the public welfare from clean needle and syringe exchange programs are addressed and mitigated.

(b) This section shall become operative on January 1, 2019.

**Section 121349.3 of the Health and Safety Code is amended to read:**

(a) The health officer of the participating jurisdiction shall present annually-biennially at an open meeting of the board of supervisors or city council a report detailing the status of clean needle and syringe exchange programs-programs, including, but not limited to, relevant statistics on blood-borne-bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual-biennial meeting. The notice to the public shall be sufficient to assure-ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate.

. For hypodermic needle and syringe exchange services authorized by the State Department of Public Health, a biennial report shall be provided by the department to the local health officer based on the reports to the department from service providers within the jurisdiction of that local health officer.

(b) This section shall become inoperative on January 1, 2019, and as of that date is repealed.

**Section 121349.3 is added to the Health and Safety Code, to read:**

(a) The health officer of the participating jurisdiction shall present, annually at an open meeting of the board of supervisors or city council, a report detailing the status of clean needle and syringe exchange programs, including, but not limited to, relevant statistics on bloodborne infections associated with needle sharing activity and the use of public funds for these programs. Law enforcement, administrators of alcohol and drug treatment programs, other stakeholders, and the public shall be afforded ample opportunity to comment at this annual meeting. The notice to the public shall be sufficient to ensure adequate participation in the meeting by the public. This meeting shall be noticed in accordance with all state and local open meeting laws and ordinances, and as local officials deem appropriate.

(b) This section shall become operative on January 1, 2019.

## Civil Code

**Section 56.101 of the Civil Code is amended to read:**

(a) Every provider of health care, health care service plan, pharmaceutical company, or contractor who creates, maintains, preserves, stores, abandons, destroys, or disposes of medical ~~records-information~~ shall do so in a manner that preserves the confidentiality of the information contained therein. Any provider of health care, health care service plan, pharmaceutical company, or contractor who negligently creates, maintains, preserves, stores, abandons, destroys, or disposes of medical ~~records-information~~ shall be subject to the remedies and penalties provided under subdivisions (b) and (c) of Section 56.36.

(b) (1) An electronic health record system or electronic medical record system shall do the following:

(A) Protect and preserve the integrity of electronic medical information.

(B) Automatically record and preserve any change or deletion of any electronically stored medical information. The record of any change or deletion shall include the identity of the person who accessed and changed the medical information, the date and time the medical information was accessed, and the change that was made to the medical information.

(2) A patient's right to access or receive a copy of his or her electronic medical records upon request shall be consistent with applicable state and federal laws governing patient access to, and the use and disclosures of, medical information.

(c) This section shall apply to an "electronic medical record" or "electronic health record" that meets the definition of "electronic health record," as that term is defined in Section 17921(5) of Title 42 of the United States Code.