



AB-528 Controlled substances: CURES database. (2019-2020)

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Assembly Bill No. 528

CHAPTER 677

An act to amend Section 209 of the Business and Professions Code, and to amend, repeal, and add Sections 11164.1, 11165, 11165.1, and 11165.4 of the Health and Safety Code, relating to controlled substances.

[Approved by Governor October 09, 2019. Filed with Secretary of State October 09, 2019.]

LEGISLATIVE COUNSEL'S DIGEST

AB 528, Low. Controlled substances: CURES database.

(1) Existing law classifies certain controlled substances into Schedules I to V, inclusive. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance. Existing law requires a dispensing pharmacy, clinic, or other dispenser to report specified information to the department as soon as reasonably possible, but no more than 7 days after a controlled substance is dispensed.

This bill, on and after January 1, 2021, would require a dispensing pharmacy, clinic, or other dispenser to instead report the information required by the CURES database no more than one working day after a controlled substance is released to a patient or a patient's representative, except as specified. The bill would similarly require the dispensing of a controlled substance included on Schedule V to be reported to the department using the CURES database. The bill would make conforming changes to related provisions.

(2) Existing law requires a health care practitioner authorized to prescribe, order, administer, furnish, or dispense controlled substances included on Schedule II, Schedule III, or Schedule IV, and a pharmacist upon licensure, to submit an application to obtain approval to electronically access information in the CURES database.

This bill, on and after a specified date, would permit a licensed physician and surgeon who does not hold a DEA registration to submit an application to obtain approval to electronically access information in the CURES database.

(3) Existing law requires an authorized health care practitioner to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every 4 months thereafter if the controlled substance remains part of the treatment of the patient.

This bill, on and after a specified date, would instead require the authorized health care practitioner to consult the CURES database to review the patient's controlled substance history at least once every 6 months after the first time the substance is prescribed and the prescriber renews the prescription, except as specified. The bill would also establish a review and documentation requirement, as set forth, for a health care practitioner who receives the CURES database information from another authorized user, as specified.

(4) Existing law requires the Department of Justice and other specified entities to identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES database to delegate their authority to order reports from the CURES database.

This bill would instead require those entities to identify necessary procedures to enable those practitioners with access to the CURES database to delegate their authority to access reports from the CURES database.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. It is the intent of the Legislature that state laws regarding the operation and use of prescription drug monitoring programs continue to empower health care-oriented technology solutions to the opioid crisis.

SEC. 2. Section 209 of the Business and Professions Code is amended to read:

209. The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that they are applying for licensure or renewing their license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to access reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

SEC. 3. Section 11164.1 of the Health and Safety Code is amended to read:

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) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances 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) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers 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 remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 4. Section 11164.1 is added to the Health and Safety Code, to read:

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 III, 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.

SEC. 5. Section 11165 of the Health and Safety Code is amended to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, if patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The Department of Justice shall, no later than July 1, 2020, adopt regulations regarding the access and use of the information within CURES. The Department of Justice shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

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

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, and respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility, if provided.

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

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

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

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

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The Department of Justice may enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the Department of Justice pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the Department of Justice for interstate data sharing of prescription drug monitoring program information.

(3) Any agreement entered into by the Department of Justice for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if the authorized user is registered and in good standing with that state's prescription drug monitoring program.

(5) The Department of Justice shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

(i) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 6. Section 11165 is added to the Health and Safety Code, to read:

11165. (a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The department 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. 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.

(k) This section shall become operative on January 1, 2021.

SEC. 7. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that pharmacist the

electronic history of controlled substances dispensed to an individual under the pharmacist's care based on data contained in the CURES PDMP.

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

- (i) Materially falsifying an application to access information contained in the CURES database.
- (ii) Failing to maintain effective controls for access to the patient activity report.
- (iii) Having their federal DEA registration suspended or revoked.
- (iv) Violating a law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.
- (v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

- (I) The date of the query.
- (II) The time of the query.
- (III) The first and last name of the patient queried.
- (IV) The date of birth of the patient queried.
- (V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV 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, or Schedule IV 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, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

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

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

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

(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.

SEC. 8. Section 11165.1 is added to the Health and Safety Code, to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, 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.

(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 query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and

the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

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

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, 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.

SEC. 9. Section 11165.4 of the Health and Safety Code is amended to read:

11165.4. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if 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 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 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 four months thereafter if the substance remains part of the treatment of the patient.

(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 obtain a patient's controlled substance history 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 while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities 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.

(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 a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-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.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (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 five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.

(6) 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 any cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) 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 five-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) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) 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.

(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.

SEC. 10. Section 11165.4 is added to the Health and Safety Code, to read:

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 a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) 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.