CALIFORNIA DEPARTMENT OF JUSTICE

TITLE 11. LAW DIVISION 1. ATTORNEY GENERAL CHAPTER 8.5. CONTROLLED SUBSTANCE UTILIZATION REVIEW AND EVALUATION SYSTEM (CURES)

SECOND MODIFIED TEXT OF PROPOSED REGULATIONS

The original text published in the California Code of Regulations has no underline. The initial proposal (noticed on September 3, 2021) is illustrated by <u>single blue underline</u> for proposed additions and <u>single red strikethrough</u> for proposed deletions. Changes made during the first 15-day comment period are illustrated by <u>double light orange underline</u> for proposed additions and <u>double green strikethrough</u> for proposed deletions. Changes made during this second 15-day comment period are illustrated by <u>bold double underline</u> for proposed additions and <u>bold</u> <u>double strikethrough</u> for proposed deletions.

Article 1. Chapter Definitions § 820. Definitions.

- (a) "Abuse" means any use of an Applicable Controlled Substance that is not authorized in its manner of use, purpose, quantity, or user.
- (b) "Aggregated Data" means data that does not include PII and is presented in summary counts, mitigating privacy risks and attempts at re-identification.
- (c) "Animal Patient Entity" means a unique animal patient profile created from dispensation records reported to CURES PDMP for each distinct combination of animal name, animal owner first name, animal owner last name, animal owner date of birth, animal owner gender, and animal owner address, and with which any subsequently reported dispensations that match the same combination of animal patient data are linked. A single animal patient may be associated with multiple Animal Patient Entities due to variations in reported animal name, animal owner first name, animal owner last name, animal owner date of birth, and animal owner address.
- (ed) "Annual Renewal" means the annual process by which a User updates all applicable information contained within that User's CURES profile.
- (de) "Applicable Controlled Substance" means a drug, substance, or immediate precursor that is listed in Health and Safety Code section 11055, 11056, or 11057, or 11058. This definition also

- includes, as of January 1, 2021, a drug, substance, or immediate precursor that is listed in Health and Safety Code section 11058.
- (ef) "Applicant Type" means the type of account for which an applicant is applying for access to CURES, including only the following types: Prescriber, Out-of-State Prescriber, Non-DEA Practitioner, Pharmacist, or Out-of-State Pharmacist, or Delegate.
- (g) "Authorizing User" means a Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User who delegates authority to a Delegate to access data in CURES on behalf of that Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User.
- (h) "Authorized Health Care Provider" means an individual who qualifies as a covered health care provider as defined in 45 Code of Federal Regulations section part 162.103 (10-1-20)

Edition), incorporated by reference in this chapter.

- (fi) "Bona Fide Research" means research that is characterized by all of the following qualities:
 - (1) The identification, evaluation, or resolution of a problem in a research field.
 - (2) The intention to contribute to the knowledge of a research field.
 - (3) The utilization of scientific methods and research methodologies.
 - (4) The reasonable expectation that the final research product may support publication in a peer-reviewed journal, program evaluation and quality improvement, public health surveillance, or policy development.
- (gj) "Bona Fide Researcher" means a principal investigator, or a public health officer, who conducts Bona Fide Research and meets all of the following requirements:
 - (1) Has possession of a Master of Science degree, Master of Arts degree, other master's degree, or higher level degree in a field that conducts research. These fields include, but are not limited to, physical sciences, life sciences, social sciences, and medical sciences.
 - (2) Is research-affiliated with a research entity including, but not limited to, accredited universities, recognized research organizations, or public departments and agencies.
 - (3) Has relevant research experience at an accredited university or college, research entity, or public agency.
- (k) "Business Associate" has the meaning set forth in 45 Code of Federal Regulations-section part 160.103 (10-1-20 Edition), incorporated by reference in this chapter.
- (h/) "Category of Licensure" means the title of the license issued to an individual by that individual's Licensing Board or Out-of-State Licensing Agency Board.

- (im) "Compliant Password" means a password that meets the password security standards as set forth by the application.
- (jn) "Connectivity Fee" means the mandatory, one-time fee paid by an entity operating a HIT System which covers the cost of connecting that HIT System to the Information Exchange Web Service. The Connectivity Fee amount is \$1,500.
- (ko) "Controlled Substance" has the meaning set forth in Health and Safety Code section 11007, unless otherwise specified.
- (p) "Covered Entity" has the meaning set forth in 45 Code of Federal Regulations—section part 160.103.
- (19) "CURES" means the Controlled Substance Utilization Review and Evaluation System.
- (mr) "CURES PDMP" means the Department's program that administers CURES.
- (ns) "DEA" means the United States Drug Enforcement Administration.
- (et) "DEA Number" means the DEA Registration Certificate number issued to an individual by the DEA.
- (pu) "DEA Registration Certificate" means the DEA certificate of registration issued to an individual granting that individual federal authority to handle Ccontrolled Substances.
- (qv) "De-Identified Individual-Level Data" means individually disaggregated data that does not include any PII.
- (rw) "Delegate" means an individual to whom a Prescriber User or Pharmacist User has delegated authority to order Patient Activity Reports from CURES under Business and Professions Code section 209, subdivision (b) means an individual who meets the eligibility requirements of section 824.1, subdivision (a), has entered into an agreement that meets the requirements of section 824.2, subdivision (a), and is at least 18 years of age.
- (x) "Delegate Agreement" means an agreement between—an Authorizing User and one or more

 Delegates and Authorizing User—that meets the requirements of section 824.2, subdivision (a).
- (y) "Delegate Audit Report" means a report generated by CURES of the patient activity searches conducted by an individual who is or was a Delegate-User of an Authorizing User. A Delegate Audit Report includes, as applicable, the search date, search time, Authorizing User first name, Authorizing User last name, Authorizing User State License Number, Delegate-User first name, Delegate-User last name, patient first name, patient last name, patient date of birth, patient

- gender, patient address, patient activity Search Period, search mode, and generated Patient Entities or Animal Patient Entities.
- (z) "Delegate-User" means a Delegate who is registered to access CURES on behalf of an Authorizing User.
- (saa) "Department" means the Department of Justice of the State of California.
- (<u>tbb</u>) "Department Investigative Team" means two or more Law Enforcement Agencies, one of which is the Department, requesting access to CURES, or data from CURES, through the Department, to assist that Department Investigative Team's efforts to control the Diversion and Resultant Abuse of Applicable Controlled Substances.
- (<u>ucc</u>) "Diversion" means any redirection of an Applicable Controlled Substance from a use that is authorized in its manner of use, purpose, quantity, and user, toward any use that is not authorized in its manner of use, purpose, quantity, or user.
- (vdd) "Diversion and Resultant Abuse" means any redirection of an Applicable Controlled Substance from a use that is authorized in its manner of use, purpose, quantity, and user, toward any use that is not authorized in its manner of use, purpose, quantity, or user, and any use of an Applicable Controlled Substance that is not authorized in its manner of use, purpose, quantity, or user, that results, either directly or indirectly, from that redirection.
- (wee) "Health Care Practitioner" means a licensee authorized under Health and Safety Code section 11150 to prescribe, order, administer, furnish, or dispense Controlled Substances, excluding non-prescribing Pharmacists and non-prescribing Out-of-State Pharmacists, or a Non-DEA Practitioner.
- (*ff) "Health Information Technology System" or "HIT System" has the meaning set forth in Health and Safety Code section 11165.1, subdivision (g)(4).
- (ygg) "HIPAA" means the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936 (1996)).
- (zhh) "HIPAA Regulations" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 Code of Federal Regulations parts 160 and 164, as are currently in effect or as later amended.
- (aaii) "Identified Individual-Level Data" means individually disaggregated data that includes the PII of any patient to which that data relates.

- (bbjj) "Information Exchange Web Service" means the method of system integration developed by the Department by which approved Prescriber-Users and Pharmacist-Users may use a qualified HIT System to request data from CURES.
- (eekk) "Institutional DEA Number" means a unique number issued by the DEA to a licensed, eligible institution that handles Controlled Ssubstances.
- (dd/l) "Interested Party" means a public or private entity, Bona Fide Researcher, or Team Member.
- (mm) "Interstate Non-DEA Practitioner" means an individual who meets all of the following requirements:
 - (1) Has a license issued by an Out-of-State Licensing Board that is equivalent to a Non-
 - DEA Practitioner, and is engaged in the professional practice authorized by that license.
 - (2) Does not have a DEA Registration Certificate.
 - (3) Is an authorized user of a PDMP of a state other than California, is in good standing with that PDMP, and is authorized by that PDMP to request data from CURES.
- (eenn) "Interstate Pharmacist," means an Out-of-State Pharmacist who is authorized to:
 - (1) Access the PDMP of a state other than California, and is in good standing with that PDMP.
 - (2) Request data from CURES from that Interstate Pharmacist's PDMP.
- (ffoo) "Interstate Prescriber," means an Out-of-State Prescriber who is authorized to:
 - (1) Access the PDMP of a state other than California, and is in good standing with that PDMP.
 - (2) Request data from CURES from that Interstate Prescriber's PDMP.
- (pp) "Interstate-User" means an Interstate Prescriber, Interstate Non-DEA Practitioner, or Interstate Pharmacist.
- (ggqq) "Law Enforcement Agency" means-any an agency of the United States, the State of California, or a public entity as defined in Government Code section 811.2, authorized to perform any of the following activities:
 - (1) Investigate or conduct an official inquiry into a potential violation of law, including an investigation or official inquiry into the manner, circumstances, or cause of death of a person, if the manner, circumstances, or cause of death might have involved a violation of law.

- (2) Prosecute or otherwise conduct a criminal or civil proceeding arising from an alleged violation of law.
- (3) Supervise criminal offenders post-sentencing.
- (hhrr) "Law Enforcement Official" means a Law Enforcement Agency officer or employee who is designated by that Law Enforcement Agency to access CURES, or request data from CURES, on behalf of that Law Enforcement Agency.
- (HSS) "Law Enforcement-User" means a Law Enforcement Official who is registered for access to CURES.
- (jj) "Licensing Agency" means the California Department of Consumer Affairs or a licensing agency outside of California.
- (kktt) "Licensing Board" means each of the boards and committees established within the California Department of Consumer Affairs and identified in Business and Professions Code section 208, subdivision (d).
- (#uu) "List of Patients" means a List of Patients generated by CURES for whom a Prescriber-User or Pharmacist-User is identified as the prescriber in CURES. A List of Patients includes the Pprescriber DEA Number, Pprescriber last name, prescriber first name, Pprescriber address, and the patient last name, patient first name, patient date of birth, patient gender, animal name, animal owner last name, animal owner first name, animal owner date of birth, animal owner gender, and patient address, as reported to CURES PDMP.
- (vv) "Non-DEA Practitioner" means a California licensee who holds a physician's and surgeon's license and is engaged in the professional practice authorized by that license under the jurisdiction of the applicable Licensing Board, who does not have a DEA Registration Certificate.
- (ww) "Non-DEA Practitioner-User" means a Non-DEA Practitioner who is registered for access to CURES.
- (mmxx) "Out-of-State Licensing Board" means a <u>licensing agency outside of California or a</u> board or committee established by a <u>Licensing Agency other than the California Department of Consumer Affairs</u> licensing agency outside of California.
- (nnyy) "Out-of-State Pharmacist" means any a pharmacist licensed by an Out-of-State Licensing Agency Board in a state or states of the United States other than California, a territory or territories of the United States, or the Commonwealth of Puerto Rico, but not by a Licensing

Board, and authorized under the laws of the Out-of-State Licensing-Agency's Board's jurisdiction to dispense Controlled Substances.

(90ZZ) "Out-of-State Prescriber" means any a prescriber licensed by an Out-of-State Licensing Agency Board in a state or states of the United States other than California, a territory or territories of the United States, or the Commonwealth of Puerto Rico, but not by a Licensing Board, and authorized under the laws of the Out-of-State Licensing Agency's Board's jurisdiction to prescribe Controlled Substances, and who possesses a valid DEA Registration Certificate.

(ppaaa) "Patient Activity Report" means a report generated by CURES of the Controlled Substances history of a patient, as reported to CURES PDMP. The Patient Activity Report includes, as applicable, the patient last name, patient first name, patient middle initial, patient date of birth, patient gender, animal name, animal owner last name, animal owner first name, animal owner middle initial, animal owner date of birth, animal owner gender, patient address, compact status, number of prescriptions, contract provider name, contract provider contact number, contract expiration date, date filled, date sold, drug name, refill number, number of authorized refills, drug strength, drug form, days' supply, quantity, daily morphine milligram equivalency, total morphine milligram equivalency, drug form, drug strength, quantity, days supply, species code, prescription number, refill number, number of authorized refills, payment method, prescriber name, prescriber DEA Number, prescriber city, pharmacy name, pharmacy number, pharmacy license number, pharmacy address, and prescription form serial number of prescriptions, and total number of active prescriptions.

(qqbbb) "Patient Entity" means a unique patient profile created from dispensation records reported to CURES PDMP for each distinct combination of patient first name, patient last name, patient date of birth, patient gender, and patient address, and with which any subsequently reported dispensations that match the same combination of patient information patient data are linked. A single patient may be associated with multiple Patient Entities due to variations in reported patient first name, patient last name, patient date of birth, and patient address.

(rrccc) "Patient Picklist" means a list of Patient Entities or Animal Patient Entities returned to a User when that User submits the search criteria to initiate a Patient Activity Report.

(ssddd) "PDMP" means prescription drug monitoring program.

(tteee) "Peer Review" means subjecting a researcher's scholarly work, research, or ideas to the scrutiny of other researchers in the same field of research for either of the following purposes:

- (1) To ensure that the scholarly work meets the accepted standards of the researcher's discipline.
- (2) To prevent the dissemination of research that is compromised by unwarranted claims, unacceptable interpretations, or personal views.

(wufff) "Personal Identifying Information" or "PII" has the meaning set forth in Penal Code section 530.55, subdivision (b).

(wggg) "Pharmacist" has the meaning set forth in Health and Safety Code section 11024. (hhh) "Pharmacist Serialized Prescription Form Report" means a report generated by CURES that a Pharmacist-User may initiate to determine whether a prescription form serial number has been reported to CURES as lost or stolen, and whether the prescription associated with that prescription form serial number has been reported as filled in CURES. A Pharmacist Serialized Prescription Form Report includes the prescription form serial number, prescription form order type, prescriber last name, prescriber first name, prescriber DEA number, prescriber phone number, prescription form serial number status, and number of serialized prescription forms. (iii) "Pharmacist-User" means a Pharmacist or Out-of-State Pharmacist who is registered to access CURES.

(wwjjj) "Pharmacy History Report" means a report generated by CURES of the Controlled Substances dispensation history of a pharmacy, as reported to CURES PDMP. The A Pharmacy History Report includes the pharmacy name, pharmacy license number, pharmacy address, total number of prescriptions, date filled, date sold, patient last name, patient first name, patient date of birth, patient gender, patient address, species, animal name, date filled, date sold, drug name, refill number, number of authorized refills, drug strength, drug form, days' supply, quantity, daily morphine milligram equivalency, total morphine milligram equivalency, drug form, drug strength, quantity, days supply, prescription number, prescription form serial number, prescription form serial number, and prescriber address.

(xx) "Pharmacist User" means any Pharmacist or Out of State Pharmacist who is registered to access CURES.

(yykkk) "Prescriber" means <u>a</u> any Health Care Practitioner licensed in California who possesses a valid DEA Registration Certificate.

(222[11]) "Prescriber History Report" means a report generated by CURES of the Controlled Substances prescribing history of a prescriber, as reported to CURES PDMP. The A Prescriber History Report includes the prescriber name, prescriber DEA Number, prescriber address, total number of prescriptions, date filled, date sold, patient last name, patient first name, patient date of birth, patient gender, patient address, species, animal name, date filled, date sold, drug name, refill number, number of authorized refills, drug strength, drug form, days' supply, quantity, daily morphine milligram equivalency, total morphine milligram equivalency, prescription number, prescription form serial number, prescription form status, payment method, drug name, drug form, drug strength, quantity, days supply, pharmacy name, pharmacy license number, and pharmacy address, pharmacy number, prescription number, and refill number.

(aaammm) "Prescriber-User" means-any a Prescriber or Out-of-State Prescriber who is registered to access CURES.

(nnn) "Prescription History Report" means a Prescriber History Report, Pharmacy History Report, or Serialized Prescription History Report.

(bbbooo) "Prescription Form Theft or Loss Report" means the Web-form a Prescriber or Pharmacist is required to submit to the Department under Health and Safety Code section 11165.3.

(ppp) "Protected Health Information" has the meaning set forth in 45 Code of Federal Regulations part 160.103.

(eceqqq) "Regulatory Agency" means the Department of Consumer Affairs, and the boards and committees identified in Business and Professions Code section 208, subdivision (d).

(dddrrr) "Regulatory Agency Official" means a Regulatory Agency officer or employee who is designated by that Regulatory Agency to access CURES, or request data from CURES, on behalf of that Regulatory Agency.

(eeesss) "Regulatory Agency-User" means a Regulatory Agency Official who is registered for access to CURES.

(fffttt) "Research Purposes" means analysis on data to conduct a systematic investigation, including research development, testing, or evaluation, which is designed to develop or contribute to generalizable knowledge or education.

(ggguuu) "Search Period" means the requested date range for which CURES is to be searched in relation to a Delegate Audit Report, Patient Activity Report, Prescriber History Report, Pharmacy History Report, Serialized Prescription History Report, Pharmacist Serialized Prescription Form Report, Serialized Prescription Form Report, Prescription Form Theft or Loss Report, or other report generated by CURES.

(hhhvvv) "Security Question Answer" means an answer used to verify the identity of a User when the User resets the User's Compliant Password.

(www) "Serialized Prescription Form Report" means a report generated by CURES that a Regulatory Agency-User or Law Enforcement-User may initiate to determine whether a prescription form serial number has been reported to CURES as lost or stolen, and whether the associated prescription form information has been reported to CURES by the applicable security printer. A Serialized Prescription Form Report includes the prescriber last name, prescriber first name, prescriber DEA Number, prescription form order type, prescription form order delivery date, delivery recipient entity name, delivery recipient last name, delivery recipient first name, starting prescription form serial number, ending prescription form serial number, prescription form production date, prescription form filled status, prescription form serial number status, security printer unique record ID, security printer name, security printer file name, security printer file submission date, security printer file processed date, security printer file validation status, security printer file error code, security printer file error description, and security printer file version number.

(xxx) "Serialized Prescription History Report" means a report generated by CURES of the serialized prescription order information associated with specified prescription form serial numbers, as reported to CURES PDMP. A Serialized Prescription History Report includes, as applicable, starting prescription form serial number, ending prescription form serial number, prescription form order type, prescription form order delivery date, prescriber last name, prescriber first name, prescriber DEA Number, total number of prescriptions, patient last name, patient first name, patient date of birth, patient gender, animal name, animal owner last name, animal owner first name, animal owner date of birth, animal owner gender, patient address, date filled, date sold, drug name, refill number, number of authorized refills, drug strength, drug form, days' supply, quantity, daily morphine milligram equivalency, total morphine milligram equivalency, prescriber address, pharmacy name, pharmacy license number, pharmacy address,

prescription form serial number, prescription form serial number status, prescription number, and payment method.

(iiiyyy) "State" means the State of California.

(jjjzzz) "State License Number" means a licensee's professional license number assigned to that licensee by the applicable Licensing <u>Agency Board or Out-of-State Licensing Board</u>.

(kkkaaaa) "Team Member" means any an individual authorized by the Department's Research Center, upon approval of a Data Request Application, to access or analyze data obtained by a Bona Fide Researcher from CURES.

(##bbbb) "Terms and Conditions of CURES" means all restrictions imposed by this chapter on the access and use of CURES, or data from CURES, with which a User must comply. Any violation of these Terms and Conditions of CURES, or any applicable State or federal law or regulation, may result in prosecution.

(mnm_cccc) "Ultimate User" has the meaning set forth in Health and Safety Code section 11030.

(nnn_dddd) "Under the Practitioner's Care," and "Under the Pharmacist's Care," and "Under Their Care," as used in Health and Safety Code section 11165.1, mean Under the Care of.

(ooo_cece) "Under the Care of" when used in this chapter to determine if a patient is Under the Care of a Prescriber-User, Non-DEA Practitioner-User, Pharmacist-User, Interstate Prescriber, or Interstate Pharmacist or Interstate-User, means:

- (1) With respect to a Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner, when any of the following conditions exist:
 - (A) The patient has had a professional medical consultation with the Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner, and has an ongoing provider-patient relationship with that Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner.
 - (B) The patient has an appointment for a professional medical consultation with the Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner.
 - (C) The patient has not had a professional medical consultation with the Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate

Non-DEA Practitioner, but the Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner is part of the patient's "organized health care arrangement," as defined by in 45 Code of Federal Regulations part 160.103—(10-1-19 Edition), incorporated by reference in this ehapter, and the patient has a provider-patient relationship with that Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner.

- (D) The patient presents to an emergency department for treatment and the Prescriber-User, Non-DEA Practitioner-User, or Interstate Prescriber, or Interstate Non-DEA Practitioner is involved in or oversees the intake or professional medical consultation of that patient within the emergency department.
- (2) With respect to a Pharmacist-User or Interstate Pharmacist, when both of the following conditions exist:
 - (A) The patient, or an individual purporting to be a patient, has presented a prescription for a Controlled Substance, or a prescriber has ordered, or appears to have ordered, a prescription on behalf of that patient, to a pharmacy where the Pharmacist-User or Interstate Pharmacist is authorized to dispense Controlled Substances.
 - (B) The Pharmacist-User or Interstate Pharmacist is involved in or oversees the ordering, compounding, filling, dispensing, furnishing, or delivery of the Controlled Substance to that patient, or individual purporting to be a patient.

(pppffff) "User" means-any a type of CURES registrant, including "Prescriber-User," "Non-DEA Practitioner-User," "Pharmacist-User," "Delegate-User," "Regulatory Agency-User," and "Law Enforcement-User."

(qqqggg) "User Search Profile Details Report" means a report generated by CURES that a Regulatory Agency-User may initiate to request the account information User profile details of a Prescriber-User or, Non-DEA Practitioner-User, Pharmacist-User, or Delegate-User in CURES. The User Search includes the following information regarding the Prescriber User or Pharmacist User searched: User ID, Prescriber User or Pharmacist User first name, Prescriber User or Pharmacist User last name, State License Number, Licensing Board, Category of Licensure, and DEA Number A User Profile Details Report includes, as applicable, User first

name, User last name, User ID, User Category of Licensure, User License Number, User DEA

Number, User role, User status, number of Delegate associations, Delegate Agreement effective

date, Delegate Agreement expiration date, and Delegate association status.

(hhhh) "Veterinary Workforce Member" means an employee, volunteer, trainee, or other person whose conduct, in the performance of work for a veterinarian who is a Prescriber-User, is under the direct control of that Prescriber-User.

(rrriiii) "Web-Based Application" means a Department-administered Web site or Web application that is made available for the purposes of accessing data in CURES or maintaining an account to access CURES. Web-Based Application does not include the Information Exchange Web Service or a HIT System.

(jjjj) "Workforce Member" means an employee, volunteer, trainee, or other person whose conduct, in the performance of work for an Authorized Health Care Provider, is under the direct control of that Authorized Health Care Provider.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4 and 11165.6, Health and Safety Code; and Sections 208 and 209, Business and Professions Code.

Article 2.1. Access and Use by Prescribers and Out-of-State Prescribers § 821.1. Eligibility for Access to CURES.

- (a) A Prescriber who possesses a valid DEA Registration Certificate for a practice location in California must register for access to CURES.
- (b) A Prescriber who possesses a valid DEA Registration Certificate for a practice location only in a state or states other than California may register for access to CURES if the Prescriber's Licensing Board expressly permits or requires that the Prescriber register for access to CURES.
- (c) An Out-of-State Prescriber who possesses a valid DEA Registration Certificate for a practice location only in a state or states other than California may register for access to CURES.
- (d) If an individual who is registered for access to CURES as a Prescriber is no longer eligible for access to CURES under this section, the individual must not access CURES.
- (e) If an individual who is registered for access to CURES as an Out-of-State Prescriber is no longer eligible for access to CURES under this section, the individual must not access CURES, and the individual must immediately notify CURES PDMP in writing.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 821.2. Procedures to Register for Access to CURES.

- (a) "Prescriber Registration Application," when used in this section, means the Web-form application developed by the Department, under Health and Safety Code section 11165.1, subdivision (a)(1)(A)(i), for a Prescriber or Out-of-State Prescriber to obtain approval to electronically access—patient information from CURES.
- (b) An applicant must electronically submit the Prescriber Registration Application, located on the CURES Web page of the Department's Web site.
- (c) If the applicant is a Prescriber, to To complete the application Prescriber Registration Application, the applicant must:
 - (1) Provide all of the following applicant information on the Prescriber Registration

 Application If registering for the first time, provide all of the following information to establish an account with the Department:
 - (A) First name at birth.
 - (B) Last name at birth.
 - (C) Mother's maiden name.
 - (D) City of birth.
 - (E) Date of birth.
 - (F) Email address.
 - (G) Email verification code.
 - (2) Provide all of the following applicant information on the Prescriber Registration Application:
 - (A) Applicant Type.
 - (B) Name of Licensing Agency.
 - (C) Email address.
 - (DB) First name.
 - (EC) Last name.
 - 1. The last name must match the information on the applicant's DEA Registration Certificate.

- (FD) Date of birth.
 - 1. <u>If the applicant is a Prescriber</u>, <u>T</u>the date of birth must match the information on record with the applicant's Licensing Board.
- (G) Phone number.
- (H) Phone type.
- (E) Licensing state.
- (F) Social security number or individual taxpayer identification number.
 - 1. <u>If the applicant is a Prescriber</u>, <u>T</u>the social security number or individual taxpayer identification number must match the information on record with the applicant's Licensing Board.
- (JG) Licensing Board or Out-of-State Licensing Board.
- (KH) Category of Licensure.
 - The Category of Licensure must match the information on record with the applicant's Licensing Board or Out-of-State Licensing Board.
 If the applicant is licensed by the Medical Board of California or the
 - Dental Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board-certified.
- (LI) State License Number.
 - 1. The State License Number must match the information on record with the applicant's Licensing Board or Out-of-State Licensing Board.
- (MJ) DEA Number.
 - 1. The DEA Number must match the information on the applicant's DEA Registration Certificate.
 - 2. If the applicant submits an Institutional DEA Number, the applicant must indicate that the DEA Number is an Institutional DEA Number and provide the name of the institution.

(K) Email address.

- 1. The applicant must indicate whether the applicant's email address may be shared in CURES if the applicant is approved for access to CURES.
- (L) Phone number.
 - 1. The applicant must indicate whether the applicant's phone number may be shared in CURES if the applicant is approved for access to CURES.

- (M) Street address and postal code of the applicant's work address.
 - 1. The street address must not be a P.O. Box.
- (3) If the applicant is an Out-of-State Prescriber, the applicant must submit supporting documentation, which must include a photocopy of all of the following:
 - (A) The applicant's government-issued identification card or passport.
 - (B) The applicant's DEA Registration Certificate.
 - (C) The applicant's professional license issued by an Out-of-State Licensing Board.
- (4) If the applicant is an Out-of-State Prescriber, the applicant must submit a notarized acknowledgement verifying both of the following:
 - (A) The applicant has presented to a valid notary public all of the following supporting documentation:
 - 1. The applicant's government-issued identification card or passport.
 - 2. The applicant's DEA Registration Certificate.
 - 3. The applicant's professional license issued by an Out-of-State Licensing Board.
 - (B) The applicant is the individual identified in the supporting documentation presented to the valid notary public.
- (5) Provide a Compliant Password.
- (26) Select security questions and provide Security Question Answers.
- (37) Agree to the Terms and Conditions of CURES.
- (d) If the applicant is an Out-of-State Prescriber, to complete the application the applicant must:
 - (1) Provide all of the following applicant information on the Prescriber Registration Application:
 - (A) Applicant Type.
 - (B) Name of Licensing Agency.
 - (C) Email address.
 - (D) First name.
 - (E) Last name.
 - 1. The last name must match the information on the applicant's DEA Registration Certificate.
 - (F) Date of birth.

- (G) Phone number.
 (H) Phone type.
 (I) Licensing state.
- (J) Out of State Licensing Board.
- (K) Category of Licensure.
- (L) State License Number.
- (M) DEA Number.
 - 1. The DEA Number must match the information on the applicant's DEA Registration Certificate.
 - 2. If the applicant submits an Institutional DEA Number, the applicant must indicate that the DEA number is an Institutional DEA Number.
- (2) Submit supporting documentation, which must include a photocopy of all of the following:
 - (A) The applicant's government issued identification card or passport.
 - (B) The applicant's DEA Registration Certificate.
 - (C) The applicant's professional license issued by a Licensing Agency other than a Licensing Board.
- (3) Submit a notarized acknowledgement verifying both of the following:
 - (A) The applicant has presented to a valid notary public all of the following supporting documentation:
 - 1. The applicant's government issued identification card or passport.
 - 2. The applicant's DEA Registration Certificate.
 - 3. The applicant's professional license issued by a Licensing Agency other than a Licensing Board.
 - (B) The applicant is the individual identified in the supporting documentation presented to the valid notary public.
- (4) Select security questions and provide Security Question Answers.
- (5) Agree to the Terms and Conditions of CURES.
- (e) When an approved applicant accesses CURES for the first time, the approved applicant must:
 - (1) Answer the prompted security questions on the Web-Based Application.
 - (2) Provide a Compliant Password.

- (3) Provide the approved applicant's street address and postal code.
 - (A) The street address must reflect the approved applicant's work address.
 - (B) The street address must not be a P.O. Box.
- (4) If the approved applicant is licensed by the Medical Board of California or the Dental Board of California, the approved applicant must provide the approved applicant's specialty and specify whether the approved applicant is board certified.
- (5) Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code; and Section 209, Business and Professions Code.

§ 821.3. Data Accessible to Prescriber-Users in CURES.

- (a) Subject to the restrictions of section 821.4, a Prescriber-User may-access patient information in CURES through both obtain all of the following:
 - (1) A Patient Activity Report.
 - (A) A Patient Activity Report generated by a Prescriber-User who is a veterinarian will only display reported dispensations for Animal Patient Entities.
 - (2) A List of Patients.
 - (A) A List of Patients generated by a Prescriber-User who is a veterinarian will only display Animal Patient Entities.
 - (3) A Delegate Audit Report.
- (b) A Prescriber-User may access patient information data in CURES for a Search Period not to exceed 24 months from the date of the search.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 821.4. Restrictions on Accessing Patient Information Data in CURES.

- (a) A Prescriber-User must only access-patient information to data in CURES for one or more of the following authorized purposes:
 - (1) Treat To obtain the Controlled Substance history of a patient Under the Care of the Prescriber-User.

- (A) If the patient is Under the Care of the Prescriber-User within the meaning of section 820, subdivision (occeee)(1)(B), but the patient does not have an ongoing provider-patient relationship with the Prescriber-User, the Prescriber-User must not access the patient's information data in CURES earlier than 7-seven days before the appointment for a professional medical consultation with the Prescriber-User.
- (2) <u>To Comply with the Prescriber-User's</u> duty to consult CURES under Health and Safety Code section 11165.4.
- (3) <u>To Oo</u>btain a List of Patients for whom the Prescriber-User is listed as the Prescriber or Out-of-State Prescriber.
- (4) To obtain a Delegate Audit Report of the patient activity searches conducted by an individual who is or was a Delegate-User of the Prescriber-User.
- (b) A Prescriber-User who is a veterinarian must only access patient information of the veterinarian's animal patient. A Prescriber User who is a veterinarian must not access patient information from CURES regarding the animal patient's Ultimate User.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 821.5. Restrictions on Use or Disclosure of <u>Patient Information Data</u> Obtained from CURES.

- (a) A Prescriber-User must not use, disclose, or transfer <u>patient information</u> <u>data</u> obtained from CURES unless the use, disclosure, or transfer is consistent with all of the following:
 - (1) The use, disclosure, or transfer is for the same authorized purpose for which the <u>patient information</u> data was originally requested <u>under section 821.4</u>.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to:
 - (A) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (B) The HIPAA Regulations.
 - (C) Health and Safety Code section 11165, subdivision (c).
- (b) Notwithstanding subdivision (a)(1), a Prescriber-User may disclose or transfer data obtained

from CURES to either of the following:

(1) A Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA

Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist,
or Interstate Pharmacist, if all of the following requirements are met:

(A) The patient whose data is disclosed or transferred is Under the Care of the Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist to whom the data is disclosed or transferred.

- (B) The disclosure or transfer complies with subdivision (a)(2).
- (C) The data was obtained in accordance with the restrictions of section 821.4.

 (2) The Prescriber-User's Licensing Board to document compliance with the law, if both of the following requirements are met:
 - (A) The disclosure or transfer complies with subdivision (a)(2).
 - (B) The data was obtained in accordance with the restrictions of section 821.4.
- (bc) A Prescriber-User must not sell any patient information data obtained from CURES.
- (c) Notwithstanding subdivision (a)(1), a Prescriber may disclose or transfer patient information obtained from CURES to the Prescriber's Licensing Board to document compliance with the law if the disclosure or transfer complies with subdivision (a)(2), and the patient information was obtained in accordance with the restrictions of section 821.4.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 821.6. Procedures for Use of CURES.

- (a) Patient information Data is available in both of the following environments:
 - (1) The Web-Based Application.
 - (2) The Information Exchange Web Service.
- (b) A Compliant Password may be changed in the Web-Based Application. A Prescriber-User must create a Compliant Password every 90 days.
- (c) Procedure to Complete an Annual Renewal.
 - (1) An Annual Renewal may be completed in the Web-Based Application.
 - (2) A Prescriber-User must complete the Annual Renewal every 365 days.

- (3) A Prescriber-User must update the <u>following Prescriber-User's</u> information <u>provided</u> under section 821.2, <u>subdivision (c)(2)</u>, on the Annual Renewal, if applicable:
 - (A) DEA Number.
 - (B) Phone number.
 - (C) Phone type.
 - (D) Street address.
 - 1. The street address must reflect the Prescriber-User's work address.
 - 2. The street address must not be a P.O. Box.
 - (E) Postal code.
 - (F) Email address.
- (4) To submit the Annual Renewal, a Prescriber-User must agree to the Terms and Conditions of CURES.
- (d) Procedure to Request a Patient Activity Report.
 - (1) A Patient Activity Report is available in the Web-Based Application or the Information Exchange Web Service.
 - (2) To request a Patient Activity Report in the Web-Based Application, a Prescriber-User must:
 - (A) Provide search criteria that includes, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - a. If the Prescriber-User is a veterinarian, the patient first name and patient last name must match the Ultimate User of the animal-patient.
 - 2. Patient date of birth.
 - a. If the Prescriber-User is a veterinarian, the patient date of birth must match the Ultimate User of the animal-patient.
 - 3. Search Period.
 - (B) Agree to the Terms and Conditions of CURES.
 - (C) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
 - (3) To request an interstate Patient Activity Report in the Web-Based Application, a Prescriber-User must:
 - (A) Provide search criteria that include, at a minimum, all of the following:

- 1. Patient first name or patient last name.
 - a. If the Prescriber-User is a veterinarian, the first name and last name must match the Ultimate User of the animal-patient.
- 2. Patient date of birth.
 - a. If the Prescriber-User is a veterinarian, the date of birth must match the Ultimate User of animal-patient.
- 3. Search Period.
- 4. State or states in addition to California.
- (B) Agree to the Terms and Conditions of CURES.
- (C) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
- (34) Subject to the requirements of section 82830.3 of this chapter, to request a Patient Activity Report in the Information Exchange Web Service, a Prescriber-User, or an authorized HIT System on behalf of a Prescriber-User, must:
 - (A) Provide search criteria that includes, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.
 - (B) Agree to the Terms and Conditions of CURES.
- (e) Procedure to Request a List of Patients.
 - (1) A List of Patients is available in the Web-Based Application.
 - (2) To request a List of Patients, a Prescriber-User must:
 - (A) Select the Prescriber-User's DEA Number or DEA Numbers.
 - (B) Provide the Search Period.
 - (C) Agree to the Terms and Conditions of CURES.
- (f) Procedure to Submit a Prescription Form Theft or Loss Report.
 - (1) A Prescription Form Theft or Loss Report is available in the Web-Based Application.
 - (2) Each Prescriber-User whose name is printed on a prescription form that is lost or stolen must submit a separate Prescription Form Theft or Loss Report.
 - (3) To submit a Prescription Form Theft or Loss Report, a Prescriber-User must:
 - (A) Provide all of the following information:
 - 1. First name of the reporting Prescriber-User.

- 2. Last name of the reporting Prescriber-User.
- 3. Address of the reporting Prescriber-User.
- 4. Postal code of the reporting Prescriber-User.
- 5. Phone number of the reporting Prescriber User.
- 6. DEA Number of the reporting Prescriber User.
- 7. Date of theft or loss.
- 8. Principal business.
- 9. Type of theft or loss.
- 10. Name of county in which theft or loss occurred.
- 1. DEA Number or DEA Numbers on the lost or stolen prescription form associated with the reporting Prescriber-User.
- 2. Type of theft or loss.
 - a. If the Prescriber-User indicates the type of theft or loss as "other," the Prescriber-User must provide a description of the type of theft or loss.
 - b. If the Prescriber-User indicates the type of theft or loss as "lost in shipment," the Prescriber-User must provide the name of the shipping company and delivery address.
- 3. Approximate date of theft or loss.
- 4. Description of theft or loss.
- 5. Starting prescription form serial number.
- 6. Prescription form type.
 - a. If the Prescriber-User indicates the form type as "institutional," the Prescriber-User must provide the institution name and indicate whether the Prescriber-User is the designated prescriber. If the Prescriber-User is not the designated prescriber, the Prescriber-User must provide the designated prescriber first name, designated prescriber last name, and designated prescriber DEA Number.
- (B) Indicate whether the theft or loss was reported to a law enforcement agency in the applicable jurisdiction. <u>If the Prescriber-User indicates the theft or loss as reported to a law enforcement agency, the Prescriber-User must provide all of the following:</u>

- 1. Name of the law enforcement agency.
- 2. Report number.
- 3. Name of the county in which the theft or loss was reported.
- 4. Date reported.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 821.7. Delegate Use of CURES.

- (a) Restrictions on Delegate Use of CURES.
 - (1) A Prescriber-User is responsible for the access and use of CURES of each of that Prescriber-User's Delegates.
 - (2) If a Delegate initiates a request to CURES on behalf of a Prescriber-User the request must conform to that Prescriber User's restrictions on accessing patient information under section 821.4.
- (b) Procedures to Register for Access to CURES.
 - (1) "Delegate Registration Application," when used in this section, means the electronic application developed by the Department for a Prescriber-User to designate an individual as a Delegate.
 - (2) A Prescriber User must electronically submit the Delegate Registration Application on the Web-Based Application.
 - (3) A Prescriber-User must provide all of the following information on the Delegate Registration Application:
 - (A) Delegate first name.
 - (B) Delegate last name.
 - (C) Delegate email address.
 - (4) To submit the Delegate Registration Application, a Prescriber-User must agree to the Terms and Conditions of CURES.
 - (5) When a Delegate accesses CURES for the first time, the Delegate must:
 - (A) Provide a Compliant Password.
 - (B) Provide security questions and Security Question Answers.
 - (C) Agree to the Terms and Conditions of CURES.

- (c) Procedures for Use of CURES.
 - (1) A Delegate may access the Web-Based Application.
 - (2) A Delegate must create a Compliant Password every 90 days.
 - (3) Procedure to Complete an Annual Renewal.
 - (A) A Delegate must complete the Annual Renewal every 365 days.
 - (B) A Delegate must update the Delegate's email address on the Annual Renewal, if applicable.
 - (C) To submit the Annual Renewal, a Delegate must agree to the Terms and Conditions of CURES.
 - (4) Procedure to Initiate a Patient Activity Report.
 - (A) To initiate a Patient Activity Report, a Delegate must:
 - 1. Provide search criteria that includes, at a minimum, all of the following:
 - a. Patient first name and patient last name.
 - b. Patient date of birth.
 - c. Search Period.
 - 2. Select the Prescriber-User on whose behalf the Delegate is initiating the Patient Activity Report.
 - 3. Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

Article 2.2. Access and Use by Non-DEA Practitioners § 822.1. Eligibility for Access to CURES.

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- (a) A Non-DEA Practitioner may register for access to CURES.
- (b) If an individual who is registered for access to CURES as a Non-DEA Practitioner is no longer eligible for access to CURES under this section, the individual must not access CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 822.2. Procedures to Register for Access to CURES.

(a) "Non-DEA Practitioner Registration Application," when used in this section, means the Web-

form application developed by the Department, under Health and Safety Code section 11165.1, subdivision (a)(1)(A)(iii), for a Non-DEA Practitioner to obtain approval to electronically access CURES.

- (b) An applicant must electronically submit the Non-DEA Practitioner Registration Application, located on the CURES Web page of the Department's Web site.
- (c) To complete the Non-DEA Practitioner Registration Application, the applicant must:
 - (1) If registering for the first time, provide all of the following information to establish an account with the Department:
 - (A) First name at birth.
 - (B) Last name at birth.
 - (C) Mother's maiden name.
 - (D) City of birth.
 - (E) Date of birth.
 - (F) Email address.
 - (G) Email verification code.
 - (2) Provide all of the following applicant information on the Non-DEA Practitioner Registration Application:
 - (A) Applicant Type.
 - (B) First name.
 - (C) Last name.
 - (D) Date of birth.
 - 1. The date of birth must match the information on record with the applicant's Licensing Board.
 - (E) Licensing state.
 - (F) Social security number or individual taxpayer identification number.
 - 1. The social security number or individual taxpayer identification number must match the information on record with the applicant's Licensing Board.
 - (G) Licensing Board.
 - (H) Category of Licensure.
 - 1. The Category of Licensure must match the information on record with the applicant's Licensing Board.

2. If the applicant is licensed by the Medical Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board-certified.

(I) State License Number.

1. The State License Number must match the information on record with the applicant's Licensing Board.

(J) Email address.

1. The applicant must indicate whether the applicant's email address may be shared in CURES if the applicant is approved for access to CURES.

(K) Phone number.

- 1. The applicant must indicate whether the applicant's phone number may be shared in CURES if the applicant is approved for access to CURES.
- (L) Street address and postal code of the applicant's work address.
 - 1. The street address must not be a P.O. Box.
- (3) Provide a Compliant Password.
- (4) Select security questions and provide Security Question Answers.
- (5) Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code; and Section 209, Business and Professions Code.

§ 822.3. Data Accessible to Non-DEA Practitioner-Users in CURES.

- (a) Subject to the restrictions of section 822.4, a Non-DEA Practitioner-User may obtain both of the following:
 - (1) A Patient Activity Report.
 - (2) A Delegate Audit Report.
- (b) A Non-DEA Practitioner-User may access data in CURES for a Search Period not to exceed 24 months from the date of the search.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 822.4. Restrictions on Accessing Data in CURES.

- (a) A Non-DEA Practitioner-User must only access data in CURES for one or more of the following authorized purposes:
 - (1) To obtain the Controlled Substance history of a patient Under the Care of the Non-DEA Practitioner-User.
 - (A) If the patient is Under the Care of the Non-DEA Practitioner-User within the meaning of section 820, subdivision (eeee)(1)(B), but the patient does not have an ongoing provider-patient relationship with the Non-DEA Practitioner-User, the Non-DEA Practitioner-User must not access the patient's data in CURES earlier than seven days before the appointment for a professional medical consultation with the Non-DEA Practitioner-User.
 - (2) To obtain a Delegate Audit Report of the patient activity searches conducted by an individual who is or was a Delegate-User of the Non-DEA Practitioner-User.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 822.5. Restrictions on Use or Disclosure of Data Obtained from CURES.

- (a) A Non-DEA Practitioner-User must not use, disclose, or transfer data obtained from CURES unless the use, disclosure, or transfer is consistent with all of the following:
 - (1) The use, disclosure, or transfer is for the same authorized purpose for which the data was originally requested under section 822.4.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to:
 - (A) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (B) The HIPAA Regulations.
 - (C) Health and Safety Code section 11165, subdivision (c).
- (b) Notwithstanding subdivision (a)(1), a Non-DEA Practitioner-User may disclose or transfer data obtained from CURES to either of the following:
 - (1) A Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner,

Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate

Pharmacist, if all of the following requirements are met:

- (A) The patient whose data is disclosed or transferred is Under the Care of the Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist to whom the data is disclosed or transferred.
- (B) The disclosure or transfer complies with subdivision (a)(2).
- (C) The data was obtained in accordance with the restrictions of section 822.4.
- (2) The Non-DEA Practitioner-User's Licensing Board to document compliance with the law, if both of the following are met:
 - (A) The disclosure or transfer complies with subdivision (a)(2).
 - (B) The data was obtained in accordance with the restrictions of section 822.4.
- (c) A Non-DEA Practitioner-User must not sell any data obtained from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 822.6. Procedures for Use of CURES.

- (a) Data is available in both of the following environments:
 - (1) The Web-Based Application.
 - (2) The Information Exchange Web Service.
- (b) A Compliant Password may be changed in the Web-Based Application. A Non-DEA Practitioner-User must create a Compliant Password every 90 days.
- (c) Procedure to Complete an Annual Renewal.
 - (1) An Annual Renewal may be completed in the Web-Based Application.
 - (2) A Non-DEA Practitioner-User must complete the Annual Renewal every 365 days.
 - (3) A Non-DEA Practitioner-User must update the Non-DEA Practitioner-User's information provided under section 822.2, subdivision (c)(2), on the Annual Renewal, if applicable.
 - (4) To submit the Annual Renewal, a Non-DEA Practitioner-User must agree to the Terms and Conditions of CURES.
- (d) Procedure to Request a Patient Activity Report.

- (1) A Patient Activity Report is available in the Web-Based Application or the Information Exchange Web Service.
- (2) To request a Patient Activity Report in the Web-Based Application, a Non-DEA Practitioner-User must:
 - (A) Provide search criteria that include, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.
 - (B) Agree to the Terms and Conditions of CURES.
 - (C) Select the applicable Patient Entity or Patient Entities from the

Patient Picklist.

- (3) To request an interstate Patient Activity Report in the Web-Based Application, a Non-DEA Practitioner-User must:
 - (A) Provide search criteria that include, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.
 - 4. State or states in addition to California.
 - (B) Agree to the Terms and Conditions of CURES.
 - (C) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
- (4) Subject to the requirements of section 830.3, to request a Patient Activity Report in the Information Exchange Web Service, a Non-DEA Practitioner-User, or an authorized HIT System on behalf of a Non-DEA Practitioner-User, must:
 - (A) Provide search criteria that include, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

Article 2.23. Access and Use by Pharmacists and Out-of-State Pharmacists § 8223.1. Eligibility for Access to CURES.

- (a) A Pharmacist who possesses a valid California license must register for access to CURES.
- (b) An Out-of-State Pharmacist who possesses a valid pharmacist license only in a state or states other than California may register for access to CURES.
- (c) If an individual who is registered for access to CURES as a Pharmacist is no longer eligible for access to CURES under this section, the individual must not access CURES.
- (d) If an individual who is registered for access to CURES as an Out-of-State Pharmacist is no longer eligible for access to CURES under this section, the individual must not access CURES, and the individual must immediately notify CURES PDMP in writing.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code.

§ 8223.2. Procedures to Register for Access to CURES.

- (a) "Pharmacist Registration Application," when used in this section, means the Web-form application developed by the Department, under Health and Safety Code section 11165.1, subdivision (a)(1)(A)(ii), for a Pharmacist or Out-of-State Pharmacist to obtain approval to electronically access-patient information from CURES.
- (b) An applicant must electronically submit the Pharmacist Registration Application, located on the CURES Web page of the Department's Web site.
- (c) If the applicant is a Pharmacist, to To complete the Pharmacist Registration a Application, the applicant must:
 - (1) Provide all of the following applicant information on the Pharmacist Registration

 Application If registering for the first time, provide all of the following information to establish an account with the Department:
 - (A) First name at birth.
 - (B) Last name at birth.
 - (C) Mother's maiden name.
 - (D) City of birth.
 - (E) Date of birth.
 - (F) Email address.

- (G) Email verification code.
- (2) Provide all of the following applicant information on the Pharmacist Registration Application:
 - (A) Applicant Type.
 - 1. If the applicant is a prescribing Pharmacist, the applicant must indicate whether the applicant is a prescribing Pharmacist.
 - (B) Name of Licensing Agency.
 - (C) Email address.
 - (DB) First name.
 - (EC) Last name.
 - (FD) Date of birth.
 - 1. <u>If the applicant is a Pharmacist</u>, <u>T</u>the date of birth must match the information on record with the California Board of Pharmacy.
 - (G) Phone number.
 - (H) Phone type.
 - (E) Licensing state.
 - (F) Social security number or individual taxpayer identification number.
 - 1. <u>If the applicant is a Pharmacist</u>, <u>T</u>the social security number or individual taxpayer identification number must match the information on record with the California Board of Pharmacy.
 - (G) Licensing Board or Out-of-State Licensing Board.
 - (H) Category of Licensure.
 - 1. The Category of Licensure must match the information on record with the applicant's Licensing Board or Out-of-State Licensing Board.
 - (JI) State License Number.
 - 1. The State License Number must match the information on record with the California Board of Pharmacy or Out-of-State Licensing Board.
 - (J) Email address.
 - 1. The applicant must indicate whether the applicant's email address may be shared in CURES if the applicant is approved for access to CURES.
 - (K) Phone number.

- 1. The applicant must indicate whether the applicant's phone number may be shared in CURES if the applicant is approved for access to CURES.
- (L) Street address and postal code of the applicant's work address.
 - 1. The street address must not be a P.O. Box.
- (3) If the applicant is a prescribing Pharmacist, the applicant must provide the applicant's DEA Number.
 - (A) The DEA Number must match the information on the applicant's DEA Registration Certificate.
 - (B) If the applicant submits an Institutional DEA Number, the applicant must indicate that the DEA Number is an Institutional DEA Number and provide the name of the institution.
- (4) If the applicant is an Out-of-State Pharmacist, the applicant must submit supporting documentation, which must include a photocopy of all of the following:
 - (A) The applicant's government-issued identification card or passport.
 - (B) The applicant's professional license issued by an Out-of-State Licensing Board.
 - (C) If the applicant is a prescribing Pharmacist, the applicant's DEA Registration Certificate.
- (5) If the applicant is an Out-of-State Pharmacist, the applicant must submit a notarized acknowledgement verifying both of the following:
 - (A) The applicant has presented to a valid notary public all of the following supporting documentation:
 - 1. The applicant's government-issued identification card or passport.
 - 2. The applicant's professional license issued by an Out-of-State Licensing Board.
 - 3. If the applicant is a prescribing Pharmacist, the applicant's DEA Registration Certificate.
 - (B) The applicant is the individual identified in the supporting documentation presented to the valid notary public.
- (6) Provide a Compliant Password.
- (27) Select security questions and provide Security Question Answers.

- (38) Agree to the Terms and Conditions of CURES.
- (d) If the applicant is an Out-of-State Pharmacist, to complete the application, the applicant must:
 - (1) Provide all of the following applicant information on the Pharmacist Registration Application:
 - (A) Applicant Type.
 - (B) Name of Licensing Agency.
 - (C) Email address.
 - (D) First name.
 - (E) Last name.
 - (F) Date of birth.
 - (G) Phone number.
 - (H) Phone type.
 - (I) Licensing state.
 - (J) Out of State Licensing Board.
 - (K) Category of Licensure.
 - (L) State License Number.
 - (2) Submit supporting documentation, which must include a photocopy of all of the following:
 - (A) The applicant's government-issued identification card or passport.
 - (B) The applicant's professional license issued by a Licensing Agency other than a Licensing Board.
 - (3) Submit a notarized acknowledgement verifying both of the following:
 - (A) The applicant has presented to a valid notary public all of the following supporting documentation:
 - 1. The applicant's government-issued identification card or passport.
 - 2. The applicant's professional license issued by a Licensing Agency other than a Licensing Board.
 - (B) The applicant is the individual identified in the supporting documentation presented to the valid notary public.
 - (4) Select security questions and provide Security Question Answers.
 - (5) Agree to the Terms and Conditions of CURES.

- (e) When an approved applicant accesses CURES for the first time, the approved applicant must:
 - (1) Answer the prompted security questions on the Web-Based Application.
 - (2) Provide a Compliant Password.
 - (3) Provide the approved applicant's street address and postal code.
 - (A) The street address must reflect the approved applicant's work address.
 - (B) The street address must not be a P.O. Box.
 - (4) Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code; and Section 209, Business and Professions Code.

§ 8223.3. Data Accessible to Pharmacist-Users in CURES.

- (a) Subject to the restrictions of section 8223.4, a Pharmacist-User may access patient information in CURES through both obtain all of the following:
 - (1) A Patient Activity Report.
 - (2) A List of Patients, but only if the Pharmacist-User has a DEA Number associated with that Pharmacist-User's CURES account.
 - (3) A Pharmacist Serialized Prescription Form Report.
 - (4) A Delegate Audit Report.
- (b) A Pharmacist-User may access-patient information data in CURES for a Search Period not to exceed 24 months from the date of the search.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code.

§ 8223.4. Restrictions on Accessing Patient Information Data in CURES.

- (a) A Pharmacist-User must only access-patient information to data in CURES for one or more of the following authorized purposes:
 - (a1) Treat To obtain the Controlled Substance history of a patient Under the Care of the Pharmacist-User.

- (b2) To Oobtain a List of Patients for whom the Pharmacist-User is listed as the prescribing Pharmacist or prescribing Out-of-State Pharmacist.
- (3) To obtain a Pharmacist Serialized Prescription Form Report of the prescription form status associated with a prescription form serial number reported to CURES.
- (4) To obtain a Delegate Audit Report of the patient activity searches conducted by an individual who is or was a Delegate-User of the Pharmacist-User.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code.

§ 8223.5. Restrictions on Use or Disclosure of Patient Information Data Obtained from CURES.

- (a) A Pharmacist-User must not use, disclose, or transfer <u>patient information</u> <u>data</u> obtained from CURES unless the use, disclosure, or transfer is consistent with all of the following:
 - (1) The use, disclosure, or transfer is for the same authorized purpose for which the <u>patient information</u> data was originally requested <u>under section 823.4</u>.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to:
 - (A) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (B) The HIPAA Regulations.
 - (C) Health and Safety Code section 11165, subdivision (c).
- (b) Notwithstanding subdivision (a)(1), a Pharmacist-User may disclose or transfer data obtained from CURES to either of the following:
 - (1) A Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist, if all of the following requirements are met:
 - (A) The patient whose data is disclosed or transferred is Under the Care of the Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist to whom the data is disclosed or transferred.

- (B) The disclosure or transfer complies with subdivision (a)(2).
- (C) The data was obtained in accordance with the restrictions of section 823.4.
- (2) The Pharmacist-User's Licensing Board to document compliance with the law, if both of the following are met:
 - (A) The disclosure or transfer complies with subdivision (a)(2).
 - (B) The data was obtained in accordance with the restrictions of section 823.4.
- (bc) A Pharmacist-User must not sell any patient information data obtained from CURES.
- (c) Notwithstanding subdivision (a)(1), a Pharmacist may disclose or transfer patient information obtained from CURES to the California Board of Pharmacy to document compliance with the law if the disclosure or transfer complies with subdivision (a)(2) and the patient information was obtained in accordance with the restrictions section 822.4.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code.

§ 8223.6. Procedures for Use of CURES.

- (a) Patient information Data is available in both of the following environments:
 - (1) The Web-Based Application.
 - (2) The Information Exchange Web Service.
- (b) A Compliant Password may be changed in the Web-Based Application. A Pharmacist-User must create a Compliant Password every 90 days.
- (c) Procedure to Complete an Annual Renewal.
 - (1) An Annual Renewal may be completed in the Web-Based Application.
 - (2) A Pharmacist-User must complete the Annual Renewal every 365 days.
 - (3) A Pharmacist-User must update the <u>followingPharmacist-User's</u> information <u>provided</u> under section 823.2, <u>subdivision</u> (c)(2), on the Annual Renewal, if applicable:
 - (A) Phone number.
 - (B) Phone type.
 - (C) Street address.
 - 1. The street address must reflect the Pharmacist-User's work address.
 - 2. The street address must not be a P.O. Box.

- (D) Postal code.
- (E) Email address.
- (4) To submit the Annual Renewal, a Pharmacist-User must agree to the Terms and Conditions of CURES.
- (d) Procedure to Request a Patient Activity Report.
 - (1) A Patient Activity Report is available in the Web-Based Application or the Information Exchange Web Service.
 - (2) To request a Patient Activity Report in the Web-Based Application, a Pharmacist-User must:
 - (A) Provide search criteria that includes, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.
 - (B) Agree to the Terms and Conditions of CURES.
 - (C) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
 - (3) To request an interstate Patient Activity Report in the Web-Based Application, a Pharmacist-User must:
 - (A) Provide search criteria that include, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.
 - 4. State or states in addition to California.
 - (B) Agree to the Terms and Conditions of CURES.
 - (C) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
 - (34) Subject to the requirements of section 82830.3 of this chapter, to request a Patient Activity Report in the Information Exchange Web Service, a Pharmacist-User, or an authorized HIT System on behalf of a Pharmacist-User, must:
 - (A) Provide search criteria that includes, at a minimum, all of the following:
 - 1. Patient first name or patient last name.

- 2. Patient date of birth.
- 3. Search Period.
- (B) Agree to the Terms and Conditions of CURES.
- (e) Procedure to Request a List of Patients.
 - (1) A List of Patients is available in the Web-Based Application.
 - (2) To request a List of Patients, a Pharmacist-User must:
 - (A) Select the Pharmacist-User's DEA Number or DEA Numbers.
 - (B) Provide the Search Period.
 - (C) Agree to the Terms and Conditions of CURES.
- (f) Procedure to Request a Pharmacist Serialized Prescription Form Report.
 - (1) A Pharmacist Serialized Prescription Form Report is available in the Web-Based Application.
 - (2) To request a Pharmacist Serialized Prescription Form Report, a Pharmacist-User must provide a complete prescription form serial number.
- (fg) Procedure to Submit a Prescription Form Theft or Loss Report.

(A) Provide all of the following information:

- (1) A Prescription Form Theft or Loss Report is available in the Web-Based Application.
- (2) Each Pharmacist-User whose name is printed on a prescription form that is lost or stolen must submit a separate Prescription Form Theft or Loss Report.
- (3) To submit a Prescription Form Theft or Loss Report, a Pharmacist-User must:

(11) The vide and of the fellowing information.
1. First name of the reporting Pharmacist User.
2. Last name of the reporting Pharmacist-User.
3. Address of the reporting Pharmacist-User.
4. Postal code of the reporting Pharmacist User.
5. Phone number of the reporting Pharmacist User.
6. DEA Number of the reporting Pharmacist-User.
7. Date of theft or loss.
8. Principal business.
9. Type of theft or loss.
— 10. Name of county in which theft or loss occurred.

- 1. DEA Number or DEA Numbers on the lost or stolen prescription form associated with the reporting Pharmacist-User.
- 2. Type of theft or loss.
 - a. If the Pharmacist-User indicates the type of theft or loss as "other," the Pharmacist-User must provide a description of the type of theft or loss.
 - b. If the Pharmacist-User indicates the type of theft or loss as "lost in shipment," the Pharmacist-User must provide the name of the shipping company and delivery address.
- 3. Approximate date of theft or loss.
- 4. Description of theft or loss.
- 5. Starting prescription form serial number.
- 6. Prescription form type.
 - a. If the Pharmacist-User indicates the form type as "institutional," the Pharmacist-User must provide the institution name and indicate whether the Pharmacist-User is the designated prescriber. If the Pharmacist-User is not the designated prescriber, the Pharmacist-User must provide the designated prescriber first name, designated prescriber last name, and designated prescriber DEA Number.
- (B) Indicate whether the theft or loss was reported to a law enforcement agency in the applicable jurisdiction. If the Pharmacist-User indicates the theft or loss as reported to a law enforcement agency, the Pharmacist-User must provide all of the following:
 - 1. Name of the law enforcement agency.
 - 2. Report number.
 - 3. Name of the county in which the theft or loss was reported.
 - 4. Date reported.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code.

§ 822.7. Delegate Use of CURES.

- (a) Restrictions on Delegate Use of CURES.
 - (1) A Pharmacist-User is responsible for the access and use of CURES of each of that Pharmacist-User's Delegates.
 - (2) If a Delegate initiates a request to CURES on behalf of a Pharmacist-User, the request must conform to that Pharmacist-User's restrictions on accessing patient information under section 822.4.
- (b) Procedures to Register for Access to CURES.
 - (1) "Delegate Registration Application," when used in this section, means the electronic application developed by the Department for a Pharmacist-User to designate an individual as a Delegate.
 - (2) A Pharmacist-User must electronically submit the Delegate Registration Application on the Web-Based Application.
 - (3) A Pharmacist-User must provide all of the following information on the Delegate Registration Application:
 - (A) Delegate first name.
 - (B) Delegate last name.
 - (C) Delegate email address.
 - (4) To submit the Delegate Registration Application, a Pharmacist-User must agree to the Terms and Conditions of CURES.
 - (5) When a Delegate accesses CURES for the first time, the Delegate must:
 - (A) Provide a Compliant Password.
 - (B) Provide security questions and Security Question Answers.
 - (C) Agree to the Terms and Conditions of CURES.
- (c) Procedures for Use of CURES.
 - (1) A Delegate may access the Web Based Application.
 - (2) A Delegate must create a Compliant Password every 90 days.
 - (3) Procedure to Complete an Annual Renewal.
 - (A) A Delegate must complete the Annual Renewal every 365 days.
 - (B) A Delegate must update the Delegate's email address on the Annual Renewal, if applicable.

- (C) To submit the Annual Renewal, a Delegate must agree to the Terms and Conditions of CURES.
- (4) Procedure to Initiate a Patient Activity Report.
 - (A) To initiate a Patient Activity Report, a Delegate must:
 - 1. Provide search criteria that includes, at a minimum, all of the following:
 - a. Patient first name or patient last name.
 - b. Patient date of birth.
 - c. Search Period.
 - 2. Select the Pharmacist User on whose behalf the Delegate is initiating the Patient Activity Report.
 - 3. Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165, 11165.1 and 11165.3, Health and Safety Code; Section 209, Business and Professions Code.

Article 2.4. Access and Use by Delegates

§ 824.1. Eligibility for Access to CURES.

- (a) Subject to the requirements of section 824.2, subdivision (a), an individual to whom authority is delegated by an Authorizing User may access data in CURES as a Delegate for that Authorizing User if the individual to whom authority is delegated qualifies as at least one of the following:
 - (1) A Prescriber, Out-of-State Prescriber, Non-DEA Practitioner, Pharmacist, or Out-of-State Pharmacist, who is under the common control of the same Covered Entity as the Authorizing User.
 - (2) An Authorized Health Care Provider who is under the common control of the same Covered Entity as the Authorizing User.
 - (3) A Workforce Member who needs access to Protected Health Information to carry out the Workforce Member's duties.
 - (4) A Veterinary Workforce Member who needs access to Personal Identifying Information to carry out the Veterinary Workforce Member's duties.
- (b) An Authorizing User must immediately terminate that Authorizing User's delegation of authority to a Delegate under this article, including the ability of that Delegate to access data in

<u>CURES on behalf of that Authorizing User</u> <u>cancellation of the Delegate association with that Delegate under section 824.8, subdivision (c), if any of the following occur:</u>

- (1) The Delegate is no longer eligible under subdivision (a).
- (2) The terms of the Delegate Agreement between the Authorizing User and the Delegate require termination.
- (3) The Delegate Agreement between the Authorizing User and the Delegate is terminated by the Authorizing User or the Delegate prior to the expiration of the term of that Delegate Agreement.
- (4) The Authorizing User becomes aware of any violation by the Delegate of any requirements of this article, including the restrictions on accessing data in CURES under section 824.6, and the requirements on use and disclosure of data obtained from CURES under section 824.7.
- (c) If an Authorizing User terminates that Authorizing User's delegation of authority to a

 Delegate under section 824.1, subdivision (b)(4), the Authorizing User must immediately notify
 the Department and the Authorizing User's Licensing Board or Out-of-State Licensing Board in
 writing of the termination and the basis of the termination. If a Delegate terminated under section
 824.1, subdivision (b)(4), is licensed by a Licensing Board or Out-of-State Licensing Board, the
 Authorizing User must also immediately notify the Delegate's Licensing Board or Out-of-State
 Licensing Board in writing of the termination and the basis of the termination.

 (d) If an Authorizing User's access to CURES is suspended or terminated, the Department must
 suspend any Delegate of the Authorizing User from accessing CURES on behalf of that
 Authorizing User.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.2. Delegate Agreement between Authorizing User and Delegate.

- (a) An Authorizing User must enter into a Delegate Agreement with each Delegate to whom that Authorizing User delegates authority under this article. The Delegate Agreement must meet all of the following requirements:
 - (1) The Delegate Agreement includes, at a minimum, all of the following:

- (A) A statement acknowledging the Authorizing User's understanding of the requirement in section 824.6, subdivision (a).
- (B) A statement acknowledging the Delegate's understanding of, and agreement to comply with, the laws and regulations governing the Delegate's access and use of CURES, including the requirements on accessing data in CURES under section 824.6, and the requirements on use and disclosure of data obtained from CURES under section 824.7.
- (C) A statement acknowledging the Delegate's understanding that the Delegate's access and use of CURES is subject to audit by the Authorizing User.
- (D) A statement acknowledging that the Authorizing User or the Delegate may terminate the Delegate Agreement, in either party's sole discretion, prior to the expiration of the term of that Delegate Agreement.
- (E) An effective date of the delegation of authority, and an expiration date of the delegation of authority, which will establish the term of the Delegate Agreement.
- (2) The Delegate Agreement must only be between one Authorizing User and one

 Delegate—and one Authorizing User, or between one Authorizing User and multiple

 Delegates. This limitation does not prevent an Authorizing User from having multiple

 Delegates, or a Delegate from having multiple Authorizing Users.
- (3) The term of the Delegate Agreement between the <u>Authorizing User and the Delegate</u> and the <u>Authorizing User-must not exceed 12 months from the effective date of that Delegate Agreement.</u>
- (4) The Delegate Agreement may include additional requirements or provisions to which the parties consent, provided those requirements are consistent with the laws and regulations governing the Delegate's access and use of CURES and which, if found to conflict, will be subordinate to the laws and regulations governing the Delegate's access and use of CURES.
- (5) The Delegate Agreement must be signed and dated by the <u>Authorizing User and the Delegate and the Authorizing User.</u>
- (b) If an Authorizing User cancels a Delegate association with a Delegate under section 824.8, subdivision (c), the Delegate Agreement between the Authorizing User and the Delegate will automatically terminate without further action by the Authorizing User.

- (c) If an Authorizing User or a Delegate terminates a Delegate Agreement prior to the expiration of the term of that Delegate Agreement, and the Delegate Agreement is between one Authorizing User and multiple Delegates, the Delegate Agreement will remain in full force and effect as to the remaining Delegates.
- (bd) Upon expiration of the term of a Delegate Agreement between an Authorizing User and a Delegate and an Authorizing User, the Authorizing User's delegation of authority to that Delegate will be automatically terminated, unless the Authorizing User and the Delegate enter into a new Delegate Agreement under this section that takes effect upon expiration of the term of the existing Delegate Agreement.
- (ee) A fully executed copy of any Delegate Agreement between an Authorizing User and a Delegate and an Authorizing User under this section must be retained by both parties for a period of five years from the expiration of the term of that Delegate Agreement. Upon request, the Authorizing User and the Delegate and Authorizing User must provide the Delegate Agreement to the Authorizing User's Licensing Board or Out-of-State Licensing Board, the California Department of Consumer Affairs, or the Department.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.3. Procedures to Register for Access to CURES.

- (a) "Delegate Registration Application," when used in this section, means the Web-form application developed by the Department, under Health and Safety Code section 11165.1, for a Delegate to obtain approval to electronically access CURES.
- (b) An applicant must electronically submit the Delegate Registration Application, located on the CURES Web page of the Department's Web site.
- (c) To complete the Delegate Registration Application, if registering for the first time, the applicant must:
 - (1) Provide all of the following information to establish an account with the Department:
 - (A) First name at birth.
 - (B) Last name at birth.
 - (C) Mother's maiden name.

- (D) City of birth.
- (E) Date of birth.
- (F) Email address.
- (G) Email verification code.
- (2) Provide all of the following applicant information on the Delegate Registration Application:
 - (A) First name.
 - (B) Last name.
 - (C) Email address.
 - (D) Phone number.
 - (E) Street address and postal code of the applicant's work address.
 - 1. The street address must not be a P.O. Box.
- (3) Provide a Compliant Password.
- (4) Select security questions and provide Security Question Answers.
- (5) Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code; and Section 209, Business and Professions Code.

§ 824.4. Procedure to Activate a Delegate Association in CURES.

- (a) A Delegate association may be activated in the Web-Based Application.
- (b) To activate a Delegate association in the Web-Based Application, a Delegate-User must provide the Authorizing User's Delegate association code.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.5. Data Accessible to Delegate-Users in CURES.

(a) Subject to the restrictions of section 824.6, a Delegate-User may obtain a Patient Activity Report.

(1) A Patient Activity Report generated by a Delegate-User whose Authorizing User is a veterinarian will only display reported dispensations for Animal Patient Entities.
 (b) A Delegate-User may access data in CURES for a Search Period not to exceed 24 months from the date of the search.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.6. Restrictions on Accessing Data in CURES.

- (a) An Authorizing User is responsible for all access and use of CURES by a Delegate-User to whom that Authorizing User has delegated authority under this article, including the Delegate-User's compliance with the requirements of this article.
- (b) A Delegate-User must only access data in CURES on behalf of an Authorizing User if all of the following requirements are met:
 - (1) The Delegate-User and the Authorizing User have an active Delegate Agreement.
 - (2) The Delegate-User complies with all requirements of the Delegate Agreement entered into between the <u>Authorizing User and the Delegate and the Authorizing User.</u>
 - (3) The Delegate-User complies with all requirements on accessing data in CURES applicable to the Authorizing User, as follows:
 - (A) If the Authorizing User is a Prescriber-User, the Delegate-User must comply with section 821.4. For purposes of complying with section 821.4, subdivision (a)(1), the patient whose information is being searched must be Under the Care of the Prescriber-User on whose behalf the Delegate-User is accessing that information.
 - (B) If the Authorizing User is a Non-DEA Practitioner-User, the Delegate-User must comply with section 822.4. For purposes of complying with section 822.4, subdivision (a)(1), the patient whose information is being searched must be Under the Care of the Non-DEA Practitioner-User on whose behalf the Delegate-User is accessing that information.
 - (C) If the Authorizing User is a Pharmacist-User, the Delegate-User must comply with section 823.4. For purposes of complying with section 823.4, subdivision

(a)(1), the patient whose information is being searched must be Under the Care of the Pharmacist-User on whose behalf the Delegate-User is accessing that information.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.7. Restrictions on Use or Disclosure of Data Obtained from CURES.

- (a) A Delegate-User must not use, disclose, or transfer data obtained from CURES unless the use, disclosure, or transfer is consistent with all of the following:
 - (1) The use, disclosure, or transfer is for the same authorized purpose for which the data was originally requested under section 824.6, subdivision (b), and the disclosure or transfer is limited to the Authorizing User for whom the data was requested.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to:
 - (A) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (B) The HIPAA Regulations.
 - (C) Health and Safety Code section 11165, subdivision (c).
- (b) A Delegate-User must not sell any data obtained from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.8. Procedures for Use of CURES by Authorizing Users.

- (a) Procedure to Establish a Delegate Association.
 - (1) A Delegate association may be established in the Web-Based Application.
 - (2) To establish a new Delegate association in the Web-Based Application, an Authorizing User must:
 - (A) Verify that the <u>Authorizing User and the Delegate and Authorizing User have</u> entered into a Delegate Agreement.

- (B) Provide Delegate information that includes all of the following:
 - 1. Delegate first name.
 - 2. Delegate last name.
 - 3. Delegate email address.
 - 4. Effective date of the delegation of authority and expiration date of the delegation of authority, which represent the term of the Delegate

 Agreement.
 - a. The term of the Delegate Agreement must not exceed 12 months from the effective date. The effective date and expiration date provided must reflect the effective date and expiration date agreed upon in the written Delegate Agreement. The effective date provided by the Authorizing User under this subdivision may be a past, present, or future date, but the Authorizing User must not provide an effective date that is more than 60 days into the future when establishing a Delegate association.
 - b. An Authorizing User and a Delegate must not have more than one active Delegate Agreement with each other at any given time.

 This restriction does not prohibit an Authorizing User and a Delegate from entering into a new Delegate Agreement that will become active upon expiration of an existing Delegate Agreement to avoid a lapse in the Delegate association.
- (C) Agree to the Terms and Conditions of CURES.
- (b) Procedure to Approve a Delegate Association.
 - (1) A Delegate association may be approved in the Web-Based Application.
 - (2) To approve a new Delegate association in the Web-Based Application an Authorizing User must:
 - (A) Verify that the <u>Authorizing User and the Delegate and Authorizing User have</u> entered into a Delegate Agreement.
 - (B) Provide Delegate information that includes all of the following:
 - 1. Delegate first name.
 - 2. Delegate last name.

3. Effective date of the delegation of authority and expiration date of the delegation of authority, which represent the term of the Delegate Agreement.

a. The term of the Delegate Agreement must not exceed 12 months from the effective date. The effective date and expiration date provided must reflect the effective date and expiration date agreed upon in the written Delegate Agreement.

- (C) Agree to the Terms and Conditions of CURES.
- (c) Procedure to Cancel a Delegate Association.
 - (1) A Delegate association may be cancelled in the Web-Based Application.
 - (2) To cancel a Delegate association in the Web-Based Application an Authorizing User must:
 - (A) Identify the Delegate association.
 - (B) Cancel the Delegate association.
- (d) Procedure to Request a Delegate Audit Report.
 - (1) A Delegate Audit Report is available in the Web-Based Application.
 - (2) To request a Delegate Audit Report in the Web-Based Application, an Authorizing User must:
 - (A) Provide search criteria that include both of the following:
 - 1. First name and last name of the individual who is or was a Delegate-User.
 - 2. Search Period.
 - (B) Select the applicable individual who is or was a Delegate-User from the picklist.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

§ 824.9. Procedures for Use of CURES by Delegate-Users.

(a) A Delegate-User may access the Web-Based Application.

- (b) A Compliant Password may be changed in the Web-Based Application. A Delegate-User must create a Compliant Password every 90 days.
- (c) Procedure to Complete an Annual Renewal.
 - (1) An Annual Renewal may be completed in the Web-Based Application.
 - (2) A Delegate-User must complete the Annual Renewal every 365 days.
 - (3) A Delegate-User must update the Delegate-User's information provided under section
 - 824.3, subdivision (c)(2), on the Annual Renewal, if applicable.
 - (4) To submit the Annual Renewal, a Delegate-User must agree to the Terms and Conditions of CURES.
- (d) Procedure to Request a Patient Activity Report.
 - (1) A Patient Activity Report is available in the Web-Based Application.
 - (2) To request a Patient Activity Report in the Web-Based Application, a Delegate-User must:
 - (A) Identify the Authorizing User on whose behalf the Delegate-User is accessing the Patient Activity Report.
 - (B) Provide search criteria that include, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - a. If the Delegate-User's Authorizing User is a veterinarian, the first name and last name must match the Ultimate User of the animal-patient.
 - 2. Patient date of birth.
 - a. If the Delegate-User's Authorizing User is a veterinarian, the date of birth must match the Ultimate User of the animal-patient.
 - 3. Search Period.
 - (C) Agree to the Terms and Conditions of CURES.
 - (D) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
 - (3) To request an interstate Patient Activity Report in the Web-Based Application, a Delegate-User must:
 - (A) Identify the Authorizing User on whose behalf the Delegate-User is accessing the Patient Activity Report.

- (B) Provide search criteria that include, at a minimum, all of the following:
 - 1. Patient first name or patient last name.
 - a. If the Delegate-User's Authorizing User is a veterinarian, the first name and last name must match the Ultimate User of the animal-patient.
 - 2. Patient date of birth.
 - a. If the Delegate-User's Authorizing User is a veterinarian, the date of birth must match the Ultimate User of animal-patient.
 - 3. Search Period.
 - 4. State or states in addition to California.
- (C) Agree to the Terms and Conditions of CURES.
- (D) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
- (e) Procedure to Request a Delegate Association.
 - (1) A Delegate association may be requested in the Web-Based Application.
 - (2) To request a new Delegate association in the Web-Based Application a Delegate-User must provide all of the following:
 - (A) Authorizing User's licensing state.
 - (B) Authorizing User's Licensing Board or Out-of-State Licensing Board.
 - (C) Authorizing User's Category of Licensure.
 - (D) Authorizing User's State License Number.
 - (E) Effective date of the delegation of authority and expiration date of the delegation of authority, which represent the term of the Delegate Agreement.
 - 1. The term of the Delegate Agreement must not exceed 12 months from the effective date. The effective date and expiration date provided must reflect the effective date and expiration date agreed upon in the written Delegate Agreement.
- (f) Procedure to Cancel a Delegate Association.
 - (1) A Delegate association may be cancelled in the Web-Based Application.
 - (2) To cancel a Delegate association in the Web-Based Application a Delegate-User must:

(A) Identify the Delegate association.

(B) Cancel the Delegate association.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6 and 11190, Health and Safety Code.

Article 2.35. Access and Use by Interstate Prescribers and Interstate Pharmacists Interstate-Users

§ 8235.1. Eligibility for Access to Data from CURES.

- (a) An Interstate Prescriber or Interstate Pharmacist Interstate-User is eligible to request data from CURES through that Interstate Prescriber's or Interstate Pharmacist's Interstate-User's PDMP if all of the following requirements are met:
 - (1) The Interstate Prescriber's or Interstate Pharmacist's Interstate-User's PDMP has entered into a memorandum of understanding with the Department for interstate sharing of data from CURES, and that memorandum of understanding is in effect at the time of the request.
 - (2) The authorized interstate data sharing hub through which the Interstate Prescriber's or Interstate Pharmacist's Interstate-User's PDMP will request data from CURES has entered into a memorandum of understanding with the Department for interstate sharing of data from CURES, and that memorandum of understanding is in effect at the time of the request.
 - (3) The Interstate-User has agreed to the Terms and Conditions of CURES by reviewing and executing an Interstate-User acknowledgement, which must contain, at a minimum the following statement: "All access and use of CURES and data obtained from CURES by Interstate Prescribers, Interstate Pharmacists, or Interstate Non-DEA Practitioners must comply with California Code of Regulations, title 11, chapter 8.5, article 2.5, and all applicable provisions of California Health and Safety Code, division 10, chapter 4. Any violation of the Terms and Conditions of CURES, or any applicable State or federal law or regulation, may result in prosecution. I have read, understand, and agree to the foregoing terms and conditions governing the access and use of CURES and data obtained from CURES."

- (A) The Interstate-User must review and execute an Interstate-User acknowledgment every 365 days.
- (B) A fully executed copy of the Interstate-User acknowledgement must be retained by the Interstate-User for a period of five years from the date of signature.
- (C) Upon request, the Interstate-User must provide the Interstate-User acknowledgment to the Interstate-User's prescription drug monitoring program,

 Out-of-State Licensing Board, or the California Department of Justice.
- (34) The Interstate Prescriber or Interstate Pharmacist Interstate-User complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to:
 - (A) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (B) The HIPAA Regulations.
 - (C) Health and Safety Code section 11165, subdivision (c).
- (45) The Interstate Prescriber's or Interstate Pharmacist's Interstate-User's PDMP complies with all applicable federal and State privacy, confidentiality, and security laws and regulations.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.4, Health and Safety Code.

§ 8235.2. Data Accessible to Interstate Prescribers or Interstate Pharmacists Interstate— Users in CURES.

- (a) Subject to the restrictions of section 8235.3, an Interstate Prescriber or Interstate

 Pharmacist Interstate-User may access patient information in CURES through obtain a Patient Activity Report.
- (b) An Interstate Prescriber or Interstate Pharmacist Interstate-User may access patient information data in CURES for a Search Period not to exceed 24 months from the date of the search.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.4, Health and Safety Code.

§ 8235.3. Restrictions on Accessing Patient Information Data in CURES.

- (a) An Interstate Prescriber or Interstate Pharmacist Interstate-User must only access patient information data in CURES to treat a patient Under the Care of the Interstate Prescriber or Interstate Pharmacist Interstate-User.
 - (1) If the patient is Under the Care of the Interstate Prescriber or Interstate Non-DEA Practitioner within the meaning of section 820, subdivision (acceptable equal) (1)(B), but the patient does not have an ongoing provider-patient relationship with the Interstate Prescriber or Interstate Non-DEA Practitioner, the Interstate Prescriber or Interstate Non-DEA Practitioner must not access the patient's information data in CURES earlier than 7 seven days before the appointment for a professional medical consultation with the Interstate Prescriber or Interstate Non-DEA Practitioner.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.4, Health and Safety Code.

§ 8235.4. Restrictions on Use or Disclosure of <u>Patient Information</u> <u>Data</u> Obtained from CURES.

- (a) An Interstate Prescriber or Interstate Pharmacist Interstate-User must not use, disclose, or transfer patient information data obtained from CURES unless the use, disclosure, or transfer is consistent with all of the following:
 - (1) The use, disclosure, or transfer is for the same authorized purpose for which the patient information data was originally requested under section 825.3.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to:
 - (A) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (B) The HIPAA Regulations.
 - (C) Health and Safety Code section 11165, subdivision (c).

(b) Notwithstanding subdivision (a)(1), an Interstate-User may disclose or transfer data obtained from CURES to the following:

(1) A Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist, if all of the following requirements are met:

(A) The patient whose data is disclosed or transferred is Under the Care of the Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA

Practitioner, Interstate Non-DEA Practitioner, Pharmacist, or Out-of-State

Pharmacist, or Interstate Pharmacist, to whom the data is disclosed or transferred.

- (B) The disclosure or transfer complies with subdivision (a)(2).
- (C) The data was obtained in accordance with the restrictions of section 825.3.
- (bc) An Interstate Prescriber or Interstate Pharmacist Interstate-User must not sell any patient information data obtained from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.4, Health and Safety Code.

§ 8235.5. Procedures for Requesting Patient Information Data from CURES.

- (a) A Patient Activity Report is available through the Interstate Prescriber's or Interstate Pharmacist's an Interstate-User's PDMP.
- (b) To request a Patient Activity Report, an Interstate Prescriber or Interstate Pharmacist

 Interstate-User must provide search criteria that includes, at a minimum, all of the following:
 - (1) Patient first name or patient last name.
 - (2) Patient date of birth.
 - (3) Search Period.
- (c) To request a Patient Activity Report, an Interstate Prescriber or Interstate Pharmacist must agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.4, Health and Safety Code.

Article 2.46. Access and Use by Regulatory Agency Officials § 8246.1. Eligibility to Access CURES or Obtain Data from CURES.

- (a) A Regulatory Agency Official is eligible to access CURES or obtain data from CURES.
- (b) If an individual is no longer eligible to access CURES or obtain data from CURES under this section as a Regulatory Agency Official, the individual must not access CURES or obtain data from CURES.
- (bc) In the event a Regulatory Agency Official is no longer employed by a Regulatory Agency, or is no longer authorized by the Regulatory Agency to access CURES, the Regulatory Agency must notify the Department CURES PDMP in writing. Upon receipt of the Regulatory Agency's written notification, the Department CURES PDMP must terminate the Regulatory Agency Official's access to CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11153, 11153.5, 11165, 11165.4 and 11190, Health and Safety Code.

§ 8246.2. Procedures to Register for Access to CURES.

- (a) "Regulatory Agency Official Registration Application," when used in this section, means the Web-form application developed by the Department for a Regulatory Agency Official to obtain approval to electronically access-data from CURES.
- (b) An applicant must electronically submit the Regulatory Agency Official Registration Application.
- (c) To complete the Regulatory Agency Official Registration application, an applicant must:
 - (1) Contact CURES PDMP to receive an email containing a Web-link to the Regulatory Agency Official Registration Application.
 - (2) Provide all of the following applicant information on the Regulatory Agency Official Registration Application If registering for the first time, provide all of the following information to establish an account with the Department:
 - (A) First name at birth.
 - (B) Last name at birth.
 - (C) Mother's maiden name.
 - (D) City of birth.

- (E) Date of birth.
- (F) Email address.
- (3) Provide all of the following applicant information on the Regulatory Agency Official Registration Application:
 - (A) Email address.
 - (BA) First name.
 - (CB) Last name.
 - (C) Name of Regulatory Agency.
 - (D) Job title.
 - (E) Date of birth.
 - (F) Regulatory Agency.
 - (E) Supervisor first name.
 - (F) Supervisor last name.
 - (G) Supervisor email address.
 - (H) Supervisor phone number.
 - (I) Email address.
 - (GJ) Phone number.
 - (H) Phone type.
 - (K) Street address and postal code of the applicant's work address.
 - 1. The street address must not be a P.O. Box.
- (34) Submit supporting documentation, which must include a photocopy of all of the following:
 - (A) The applicant's Regulatory Agency-issued identification card.
 - (B) A letter on the Regulatory Agency's official letterhead explaining the applicant's need for access to CURES and confirming the applicant's employment by that Regulatory Agency. This letter must be signed by the applicant's supervisor, or if required by the applicant's Regulatory Agency, the head of the applicant's Regulatory Agency.
- (5) Provide a Compliant Password.
- (46) Select security questions and provide Security Question Answers.
- (57) Agree to the Terms and Conditions of CURES.

- (d) When an approved applicant accesses CURES for the first time, the approved applicant must:
 - (1) Answer the prompted security questions on the Web-Based Application.
 - (2) Provide a Compliant Password.
 - (3) Provide the approved applicant's street address and postal code.
 - (A) The street address must reflect the approved applicant's work address.
 - (B) The street address must not be a P.O. Box.
 - (4) Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11153, 11153.5, 11165, 11165.4 and 11190, Health and Safety Code.

§ 8246.3. Data Accessible to Regulatory Agency Officials.

- (a) Subject to the restrictions of section 8246.4, a Regulatory Agency Official may obtain all of the following:
 - (1) A Patient Activity Report.
 - (2) A Prescriber History Report.
 - (3) A Pharmacy History Report.
 - (2) A Prescription History Report.
 - (3) A Serialized Prescription Form Report.
 - (4) A Delegate Audit Report.
 - (5) A User Profile Details Report.
 - (6) A Prescription Form Theft or Loss Report.
 - (47) Any other report generated by CURES available to Regulatory Agency Officials on the Web-Based Application.
- (b) A Regulatory Agency Official may obtain data from CURES for as long as the data is retained in CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11153, 11153.5, 11165, 11165.4 and 11190, Health and Safety Code.

§ 8246.4. Restrictions on Accessing CURES or Data from CURES.

- (a) A Regulatory Agency Official must only access CURES, or obtain data from CURES, on behalf of a Regulatory Agency, to assist the efforts of that Regulatory Agency to control the Diversion and Resultant Abuse of Applicable Controlled Substances, for any one or more of the following authorized purposes:
 - (1) To investigate or evaluate compliance by a licensee with any State or federal law or regulation related to the use, possession, sale, prescribing, ordering, administering, furnishing, or dispensing of any Applicable Controlled Substance, including compliance by a licensee with that licensee's obligation to consult CURES under Health and Safety Code section 11165.4.
 - (2) To investigate or evaluate compliance by a licensee with the applicable standard of practice related to the use, possession, sale, prescribing, ordering, administering, furnishing, or dispensing of any Applicable Controlled Substance.
 - (3) To investigate or evaluate compliance by a dispensing pharmacy, clinic, or other dispenser, with the obligation to report information to the Department under Health and Safety Code section 11165, subdivision (d).
 - (4) To investigate or evaluate compliance by a prescriber, as defined in Business and Profession Code section 4170, with the obligation to report information to the Department under Health and Safety Code section 11190, subdivision (c).
 - (5) To investigate or evaluate compliance by a licensee with the obligation to comply with Health and Safety Code sections 11153 and 11153.5, or any applicable professional standard of care.
 - (6) To investigate or evaluate compliance by a licensee with the terms of a disciplinary probation imposed by a Licensing Board.
 - (7) To use as evidence in a prosecution of a licensee in an administrative disciplinary proceeding.
- (b) A Regulatory Agency Official must not access CURES, or obtain data from CURES, for the purpose of investigating criminal offenses or enforcing criminal law, except as specified in subdivision (c).
- (c) A Regulatory Agency Official who requests access to CURES, or requests data from CURES, for the purpose of investigating criminal offenses or enforcing criminal law must request access

- to CURES, or request data from CURES, as a Law Enforcement Official and comply with all requirements of article 2.57 of this chapter.
- (d) To obtain a Patient Activity Report, a Regulatory Agency Official must provide search criteria that include, at a minimum, both of the following:
 - (1) Patient first name or last name.
 - (2) Search Period.
- (e) To obtain a Prescriber History Report, a Regulatory Agency Official must provide search criteria that include, at a minimum, both of the following:
 - (1) Prescriber first name and Prescriber last name, or DEA Number.
 - (2) Search Period.
- (f) To obtain a Pharmacy History Report, a Regulatory Agency Official must provide search criteria that include, at a minimum, both of the following:
 - (1) Pharmacy name, pharmacy license number, or DEA Number.
 - (2) Search Period.
- (g) To obtain a Serialized Prescription History Report, a Regulatory Agency Official must provide search criteria that include, at a minimum, a starting prescription form serial number.

 (h) To obtain a Serialized Prescription Form Report by prescriber, a Regulatory Agency Official
- must provide search criteria that include all of the following:
 - (1) Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - (2) Date search type.
 - (3) Search Period.
- (i) To obtain a Serialized Prescription Form Report by prescription form serial number, a Regulatory Agency Official must provide search criteria that include, at a minimum, all of the following:
 - (1) A starting prescription form serial number.
 - (2) Date search type.
 - (3) Search Period.
- (j) To obtain a Serialized Prescription Form Report by security printer, a Regulatory Agency Official must provide search criteria that include all of the following:
 - (1) Security printer name.
 - (2) Date search type.

- (3) Search Period.
- (k) To obtain a Delegate Audit Report, a Regulatory Agency Official must provide search criteria that include, at a minimum, all of the following:
 - (1) Licensing Board.
 - (2) Category of Licensure.
 - (3) State License Number.
 - (4) Search Period.
- (*l*) To obtain a User Profile Details Report, a Regulatory Agency Official must provide search criteria that include, at a minimum, all of the following:
 - (1) Licensing Board.
 - (2) Category of Licensure.
 - (3) State License Number.
- (m) To obtain a Prescription Form Theft or Loss Report by Prescriber or Pharmacist, a Regulatory Agency Official must provide search criteria that include, at a minimum, all of the following:
 - (1) First name and last name of the Prescriber or Pharmacist, or DEA Number of the Prescriber or Pharmacist, or Category of Licensure of the Prescriber or Pharmacist.
 - (2) Date search type.
 - (3) Search Period.
- (n) To obtain a Prescription Form Theft or Loss Report by prescription form serial number, a Regulatory Agency Official must provide search criteria that include, at a minimum, all of the following:
 - (1) A starting prescription form serial number.
 - (2) Date search type.
 - (3) Search Period.
- (o) To obtain a Prescription Form Theft or Loss Report by theft or loss details, a Regulatory Agency Official must provide search criteria that include, at a minimum, all of the following:
 - (1) Reporter type, or type of theft or loss, or city theft or loss occurred, or county theft or loss occurred, or current report status.
 - (2) Date search type.
 - (3) Search Period.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11153, 11153.5, 11165, 11165.4 and 11190, Health and Safety Code.

§ 8246.5. Restrictions on Use or Disclosure of Data Obtained from CURES.

- (a) A Regulatory Agency—User Official must not use, disclose, or transfer data obtained from CURES unless the use, disclosure, or transfer is consistent with both of the following:
 - (1) Unless otherwise required by law, the use, disclosure, or transfer is for the same authorized purpose for which the information was originally requested <u>under section</u> 826.4.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to, the California Uniform Controlled Substances Act, including Health and Safety Code section 11165.
- (b) A Regulatory Agency—User Official must not sell any data obtained from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11153, 11153.5, 11165, 11165.4 and 11190, Health and Safety Code.

§ 8246.6. Procedures for Use of CURES.

- (a) Subject to the restrictions of this section, a Regulatory Agency-User must only access the Web-Based Application.
- (b) A Regulatory Agency-User must create a Compliant Password every 90 days.
- (c) Procedure to Complete an Annual Renewal.
 - (1) A Regulatory Agency-User must complete the Annual Renewal every 365 days.
 - (2) A Regulatory Agency-User must update the <u>following Regulatory Agency-User's</u> information <u>provided under section 826.2</u>, <u>subdivision (c)(2)</u>, on the Annual Renewal, if applicable:
 - (A) Job title.
 - (B) Phone number.
 - (C) Phone type.

- (D) Supervisor first name.
- (E) Supervisor last name.
- (F) Supervisor phone number.
- (G) Supervisor phone type.
- (H) Street address.
 - 1. The street address must reflect the Regulatory Agency User's work address.
 - 2. The street address must not be a P.O. Box.
- (I) Postal code.
- (J) Email address.
- (3) To submit the Annual Renewal, a Regulatory Agency-User must agree to the Terms and Conditions of CURES.
- (d) Procedure to Request a Patient Activity Report.
 - (1) To request a Patient Activity Report, a Regulatory Agency-User must:
 - (A) Provide search criteria that includes, at a minimum, both of the following:
 - 1. Patient first name or patient last name.
 - 2. Search Period.
 - (B) Agree to the Terms and Conditions of CURES.
 - (C) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
- (e) Procedure to Request a Prescriber Prescription History Report.
 - (1) To request a Prescription History Report, a Regulatory Agency-User must indicate the Prescription History Report type and complete the applicable procedure, as follows:
 - (1)(A) To request a Prescriber History Report, a Regulatory Agency-User must:
 - (A)1. Provide search criteria that includes, at a minimum, both of the following:
 - 4<u>a</u>. Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - 2b. Search Period.
 - (B)2. Agree to the Terms and Conditions of CURES.
 - (C)3. Select the applicable Prescriber from the picklist.

- (f) Procedure to Request a Pharmacy History Report.
 - (1)(B) To request a Pharmacy History Report, a Regulatory Agency-User must: (A)1. Provide search criteria that includes, at a minimum, both of the following:
 - a. Pharmacy name-or, pharmacy license number, or DEA Number.
 - b. Search Period.
 - (B) 2. Agree to the Terms and Conditions of CURES.
 - (C)3. Select the applicable pharmacy from the picklist.
 - (C) To request a Serialized Prescription History Report, a Regulatory Agency-User must:
 - 1. Provide search criteria that include, at a minimum, a starting prescription form serial number.
 - 2. Agree to the Terms and Conditions of CURES.
- (f) Procedure to Request a Serialized Prescription Form Report.
 - (1) To request a Serialized Prescription Form Report, a Regulatory Agency-User must:
 - (A) Indicate the Serialized Prescription Form Report type and complete the applicable procedure, as follows:
 - 1. To request a Serialized Prescription Form Report by prescriber, a

 Regulatory Agency-User must provide search criteria that include all of
 the following:
 - a. Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - b. Date search type.
 - c. Search Period.
 - 2. To request a Serialized Prescription Form Report by prescription form serial number, a Regulatory Agency-User must provide search criteria that include, at a minimum, all of the following:
 - <u>a.</u> A starting prescription form serial number.
 - b. Date search type.
 - c. Search Period.

- 3. To request a Serialized Prescription Form Report by security printer, a Regulatory Agency-User must provide search criteria that include all of the following:
 - a. Security printer name.
 - b. Date search type.
 - c. Search Period.
- (g) Procedure to Request a Delegate Audit Report.
 - (1) To request a Delegate Audit Report, a Regulatory Agency-User must:
 - (A) Provide search criteria that include all of the following:
 - 1. Licensing Board.
 - 2. Category of Licensure.
 - 3. State License Number.
 - 4. Search Period.
 - (B) Select the applicable Authorizing User from the picklist.
- (gh) Procedure to <u>Initiate Request</u> a User <u>Search Profile Details Report</u>.
 - (1) To <u>initiate</u> request a User <u>Search Profile Details Report</u>, the Regulatory Agency-User must:
 - (A) Provide search criteria that includes, at a minimum, both all of the following:
 - 1. Licensing Board.
 - 2. Category of Licensure.
 - 3. State License Number.
 - 1. Prescriber State License Number.
 - 2. Prescriber Licensing Board.
 - (B) Submit the search criteria.
- (i) Procedure to Request a Prescription Form Theft or Loss Report.
 - (1) To request a Prescription Form Theft or Loss Report, a Regulatory Agency-User must:
 - (A) Indicate the Prescription Form Theft or Loss Report type and complete the applicable procedure, as follows:

1. To request a Prescription Form Theft or Loss Report by Prescriber or Pharmacist, a Regulatory Agency-User must provide search criteria that include, at a minimum, all of the following:

a. First name and last name of the Prescriber or Pharmacist, DEA

Number of the Prescriber or Pharmacist, or Category of Licensure

of the Prescriber or Pharmacist.

- b. Date search type.
- c. Search Period.
- 2. To request a Prescription Form Theft or Loss Report by prescription form serial number, a Regulatory Agency-User must provide search criteria that include, at a minimum, all of the following:
 - a. A starting prescription form serial number.
 - b. Date search type.
 - c. Search Period.
- 3. To request a Prescription Form Theft or Loss Report by theft or loss details, a Regulatory Agency-User must provide search criteria that include, at a minimum, all of the following:
 - a. Report type, type of theft or loss, city theft or loss occurred, county theft or loss occurred, or current report status.
 - b. Date search type.
 - c. Search Period.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11153, 11153.5, 11165, 11165.4 and 11190, Health and Safety Code.

Article 2.57. Access and Use by Law Enforcement Officials § 8257.1. Eligibility to Access CURES or Obtain Data from CURES.

(a) A Law Enforcement Official is eligible to access CURES or obtain data from CURES.

(b) If an individual is no longer eligible to access CURES or obtain data from CURES under this section as a Law Enforcement—Agency Official, the individual must not access CURES or obtain data from CURES.

(bc) In the event a Law Enforcement Official is no longer employed by a Law Enforcement Agency, or is no longer authorized by the Law Enforcement Agency to access CURES, the Law Enforcement Agency must notify the Department CURES PDMP in writing. Upon receipt of the Law Enforcement Agency's written notification, the Department CURES PDMP must terminate the Law Enforcement Agency Official's access to CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code.

§ 8257.2. Procedures to Register for Access to CURES.

- (a) "Law Enforcement Official Registration Application," when used in this section, means the Web-form application developed by the Department for a Law Enforcement Official to obtain approval to electronically access—data from CURES.
- (b) An applicant must electronically submit the Law Enforcement Official Registration Application.
- (c) To complete the <u>Law Enforcement Official Registration</u> <u>a</u>Application, an applicant must:
 - (1) Contact CURES PDMP to receive an email containing a Web-link to the Law Enforcement Official Registration Application.
 - (2) Provide all of the following applicant information on the Law Enforcement Official Registration Application If registering for the first time, provide all of the following information to establish an account with the Department:
 - (A) First name at birth.
 - (B) Last name at birth.
 - (C) Mother's maiden name.
 - (D) City of birth.
 - (E) Date of birth.
 - (F) Email address.
 - (3) Provide all of the following applicant information on the Law Enforcement Official Registration Application:
 - (A) Email address.
 - (BA) First name.

- (CB) Last name.
- (DC) Agency name.
- (ED) Badge number or identification number.
- (FE) Job title Rank.
- (GF) Classification.
- (H) Phone number.
- (I) Phone type.
- (JG) Supervisor first name.
- (KH) Supervisor last name.
- (LI) Supervisor rank.
- (J) Supervisor email address.
- (MK) Supervisor phone number.
- (N) Supervisor phone type.
- (L) Email address.
- (M) Phone number.
- (N) Street address and postal code of the applicant's work address.
 - 1. The street address must not be a P.O. Box.
- (34) Submit supporting documentation, which must include a photocopy of all of the following:
 - (A) The applicant's agency-issued identification card.
 - (B) A letter on the Law Enforcement Agency's official letterhead, signed by the applicant's supervisor, explaining the applicant's need for access to CURES and confirming the applicant's employment by that Law Enforcement Agency.
- (5) Provide a Compliant Password.
- (46) Select security questions and provide Security Question Answers.
- (57) Agree to the Terms and Conditions of CURES.
- (d) When an approved applicant accesses CURES for the first time, the approved applicant must:
 - (1) Answer the prompted security questions on the Web-Based Application.
 - (2) Provide a Compliant Password.
 - (3) Provide the approved applicant's street address and postal code.
 - (A) The street address must reflect the approved applicant's work address.

- (B) The street address must not be a P.O. Box.
- (4) Agree to the Terms and Conditions of CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code.

§ 8257.3. Data Accessible to a Law Enforcement Official.

- (a) Subject to the restrictions of section 82<u>57</u>.4, a Law Enforcement Official may obtain all of the following:
 - (1) A Patient Activity Report.
 - (2) A Prescription History Report.
 - (2) A Prescriber History Report.
 - (3) A Pharmacy History Report.
 - (3) A Serialized Prescription Form Report.
 - (4) A Prescription Form Theft or Loss Report.
 - (45) Any other report generated by CURES available to Law Enforcement Officials on the Web-Based Application.
- (b) A Law Enforcement Official may obtain data from CURES for as long as the data is retained in CURES.
- (c) Notwithstanding subdivision (a), a Law Enforcement Official acting in the capacity of a coroner or medical examiner, or a Law Enforcement Official directly assisting an individual acting in the capacity of a coroner or medical examiner, is prohibited from obtaining a Prescriber History Report or a Pharmacy History Report from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code.

§ 8257.4. Restrictions on Accessing CURES or Data from CURES.

(a) A Law Enforcement Official must only access CURES, or request data from CURES, on behalf of a Law Enforcement Agency, to assist the efforts of that Law Enforcement Agency to control the Diversion and Resultant Abuse of Applicable Controlled Substances, in connection with an investigation or prosecution of a violation or possible violation of law related to the use, possession, sale, prescribing, ordering, administering, furnishing, or dispensing of any Applicable Controlled Substance.

- (b) To obtain a Prescriber History Report or a Pharmacy History Report, a Law Enforcement Official must indicate whether the request is for a civil or criminal investigation and provide both all of the following:
 - (1) Case number.
 - (2) Violation code or crime code.
 - (3) Search criteria that include, at a minimum, both of the following:
 - (A) Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - (B) Search Period.
- (c) To obtain a Pharmacy History Report, a Law Enforcement Official must indicate whether the request is for a civil or criminal investigation and provide all of the following:
 - (1) Case number.
 - (2) Violation code or crime code.
 - (3) Search criteria that include, at a minimum, both of the following:
 - (A) Pharmacy name, pharmacy license number, or DEA Number.
 - (B) Search Period.
- (d) To obtain a Serialized Prescription History Report, a Law Enforcement Official must indicate whether the request is for a civil or criminal investigation and provide all of the following:
 - (1) Case number.
 - (2) Violation code or crime code.
- (a) Search criteria that include, at a minimum, a starting prescription form serial number.

 (b) To obtain a Serialized Prescription Form Report by prescriber, a Law Enforcement Official must provide search criteria that include all of the following:
 - (1) Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - (2) Date search type.
 - (3) Search Period.
- (f) To obtain a Serialized Prescription Form Report by prescription form serial number, a Law Enforcement Official must provide search criteria that include, at a minimum, all of the following:

- (1) A starting prescription form serial number.
- (2) Date search type.
- (3) Search Period.
- (g) To obtain a Serialized Prescription Form Report by security printer, a Law Enforcement Official must provide search criteria that include all of the following:
 - (1) Security printer name.
 - (2) Date search type.
 - (3) Search Period.
- (h) To obtain a Prescription Form Theft or Loss Report by Prescriber or Pharmacist, a Law Enforcement Official must provide search criteria that include, at a minimum, all of the following:
 - (1) First name and last name of the Prescriber or Pharmacist, DEA Number of the Prescriber or Pharmacist, or Category of Licensure of the Prescriber or Pharmacist.
 - (2) Date search type.
 - (3) Search Period.
- (i) To obtain a Prescription Form Theft or Loss Report by prescription form serial number, a Law Enforcement Official must provide search criteria that include, at a minimum, all of the following:
 - (1) A starting prescription form serial number.
 - (2) Date search type.
 - (3) Search Period.
- (j) To obtain a Prescription Form Theft or Loss Report by theft or loss details, a Law Enforcement Official must provide search criteria that include, at a minimum, all of the following:
 - (1) Reporter type, type of theft or loss, city theft or loss occurred, county theft or loss occurred, or current report status.
 - (2) Date search type.
 - (3) Search Period.
- (ek) To obtain a Patient Activity Report, a Law Enforcement Official must <u>indicate whether the</u> request is for a civil or criminal investigation and provide all of the following:
 - (1) Case number.

- (2) Violation code or crime code.
 - (A) If the Law Enforcement Official is acting in the capacity of a coroner or medical examiner, or the Law Enforcement Official is directly assisting an individual acting in the capacity of a coroner or medical examiner, and the subject of the search is deceased, the Law Enforcement Official is not required to provide a violation code or a crime code.
- (3) Search warrant or court order.
- (4) Search criteria that include, at a minimum, all of the following:
 - (A) Patient first name and patient last name.
 - (B) Patient date of birth.
 - (C) Search Period.
- (d/) Notwithstanding subdivision (ek) or any other regulation in this chapter, a Law Enforcement Official is not eligible for direct electronic access to a Patient Activity Report in connection with investigating or prosecuting a possible violation of civil law; however, a Law Enforcement Official may request a Patient Activity Report in connection with investigating or prosecuting a possible violation of civil law through written submission to CURES PDMP for manual processing.
- (em) Notwithstanding subdivision (ek)(3), a Law Enforcement Official is not required to provide a search warrant or a court order to obtain a Patient Activity Report under any of the following circumstances:
 - (1) The Law Enforcement Official provides CURES or CURES PDMP with a federal grand jury subpoena.
 - (2) The Law Enforcement Official provides CURES PDMP with a subpoena that meets all of the following requirements:
 - (A) The request is from a federal, State, or local prosecutor.
 - (B) The records requested are of the named defendant in the case.
 - (C) The request identifies the court in which the case is filed and the court case number.
 - (D) The records requested are to be delivered to the court.

- (3) The Law Enforcement Official provides CURES PDMP with an administrative subpoena issued under 21 United-States-Code-Section 876 of the Controlled Substances Act.
- (4) The Law Enforcement Official provides CURES PDMP with a federal civil subpoena.
- (54) The Law Enforcement Official is an officer or employee of the Department's DivisionBureau of Medi-Cal Fraud and Elder Abuse, or the Department of Health Care Services, and provides CURES or CURES PDMP with both of the following:
 - (A) A Medi-Cal beneficiary status report indicating that the individual whose information is to be searched was a Medi-Cal beneficiary, or an applicant to the Medi-Cal program, during the applicable Search Period.
 - (B) An affidavit produced on the Law Enforcement Agency's official letterhead that includes all of the following:
 - 1. A statement to the effect that the Law Enforcement Official is conducting or assisting an investigation, prosecution, or civil or criminal proceeding, related to one or both of the following:
 - a. Administration of the Medi-Cal plan within the meaning of 42

 Code of Federal Regulations \square part 431.302(d).
 - b. Activities consistent with the duties and responsibilities of the Medicaid Fraud Control Unit as set forth in 42 Code of Federal Regulations §part 1007.11.
 - 2. Medi-Cal beneficiary first name and Medi-Cal beneficiary last name.
 - 3. Medi-Cal beneficiary date of birth.
 - 4. Search Period.
 - 5. Requesting Law Enforcement Official's signature and job title.
- (65) The Law Enforcement Official provides CURES or CURES PDMP with a copy of an individual's death certificate or a memorandum produced on Law Enforcement Agency's official letterhead that includes all of the following:
 - (A) A statement attesting that the subject of the search is deceased.
 - (B) A statement attesting that the search is related to an open Law Enforcement Agency investigation or a coroner or medical examiner case.
 - (C) Decedent first name and decedent last name.

- (D) Decedent date of birth.
- (E) Search Period.
- (F) Requesting Law Enforcement Official's signature and job title.
- (76) The Law Enforcement Official is an officer or employee of the Department and has written approval from the Attorney General to access CURES, or request data from CURES, on behalf of the Department, for limited purposes and use consistent with Section 13 of Article V of the Constitution, related to the Attorney General's investigative authority. In addition to the restrictions of section 8257.5, access to CURES or data from CURES, and the use or disclosure of data obtained from CURES, by the Law Enforcement Officials of the Department may be subject to additional restrictions as determined by the Department.
- (87) The Law Enforcement Official is an officer or employee of a Law Enforcement Agency that is a member of a Department Investigative Team. In addition to the restrictions of section 8257.5, access to CURES or data from CURES, and the use or disclosure of data obtained from CURES, by Department Investigative Team members may be subject to additional restrictions as determined by the Department.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code.

§ 8257.5. Restrictions on Use or Disclosure of Data Obtained from CURES.

- (a) A Law Enforcement—User Official must not use, disclose, or transfer data obtained from CURES unless the use, disclosure, or transfer is consistent with both of the following:
 - (1) Unless otherwise required by law, the use, disclosure, or transfer is for the same authorized purpose for which the information was originally requested <u>under section</u> 827.4.
 - (2) The use, disclosure, or transfer complies with all applicable federal and State privacy, confidentiality, and security laws and regulations, including, but not limited to, the California Uniform Controlled Substances Act, including Health and Safety Code section 11165.
- (b) A Law Enforcement—User Official must not sell any data obtained from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code.

§ 8257.6. Procedures for Use of CURES.

- (a) Subject to the restrictions of this section, a Law Enforcement-User must only access the Web-Based Application.
- (b) A Law Enforcement-User must create a Compliant Password every 90 days.
- (c) Procedure to Complete an Annual Renewal.
 - (1) A Law Enforcement-User must complete the Annual Renewal every 365 days.
 - (2) A Law Enforcement-User must update the <u>following Law Enforcement-User's</u> information <u>provided under section 827.2</u>, <u>subdivision (c)(2)</u>, on the Annual Renewal, if applicable:
 - (A) Job title.
 - (B) Badge number or identification number.
 - (C) Classification.
 - (D) Phone number.
 - (E) Phone type.
 - (F) Supervisor first name.
 - (G) Supervisor last name.
 - (H) Supervisor job title.
 - (I) Supervisor phone number.
 - (J) Supervisor phone type.
 - (K) Street address.
 - 1. The street address must reflect the Law Enforcement User's work address.
 - 2. The street address must not be a P.O. Box.
 - (L) Postal code.
 - (M) Email address.
 - (3) To submit the Annual Renewal, a Law Enforcement-User must agree to the Terms and Conditions of CURES.

- (d) Procedure to Request a Patient Activity Report.
 - (1) To request a Patient Activity Report, a Law Enforcement-User must:
 - (A) Indicate whether the search is for a civil or criminal investigation.
 - 1. If the search is for a civil investigation, the Law Enforcement-User must submit a request to CURES PDMP for manual processing that meets the requirements of section 827.4, subdivision (k).
 - 2. If the search is for a criminal investigation, the Law Enforcement-User may complete the request in accordance with the requirements of section 827.6, subdivision (d)(1)(B).
 - (AB) Provide a search authorization that includes all of the following:
 - 1. Case number.
 - 2. Violation code or crime code, unless otherwise specified in section 8257.4, subdivision (c)(2)(A).
 - 3. Search warrant, court order, or documentation of an approved exception specified in section 8257.4, subdivision (em).
 - a. Unless otherwise approved in writing by the Department, a Law Enforcement-User must submit to CURES PDMP, for manual processing, an approved exception that meets the requirements of section 827.4, subdivision (m)(2).
 - a. Unless otherwise approved in writing by the Department, a Law Enforcement User is prohibited from submitting the following approved exceptions to authorize a search in the Web-Based Application; these approved exceptions must be submitted to CURES PDMP for manual processing:
 - i. A subpoena that meets the requirements of section 825.4, subdivision (e)(2) of this chapter.
 - ii. An administrative subpoena that meets the requirements of section 825.4, subdivision (e)(3) of this chapter.
 - 4. Supporting document type.
 - (B) Indicate whether the search authorization is for a civil or criminal investigation.

- (C) Certify and submit the search authorization for pre-approval by CURES PDMP.
- (D) <u>If the search authorization is approved by CURES PDMP</u>, <u>Pprovide search criteria that includes</u>, at a minimum, all of the following:
 - 1. Patient first name and patient last name.
 - 2. Patient date of birth.
 - 3. Search Period.
- (E) Agree to the Terms and Conditions of CURES.
- (F) Select the applicable Patient Entity or Patient Entities from the Patient Picklist.
- (e) Procedure to Request a <u>Prescriber Prescription</u> History Report.
 - (1) To request a Prescriber Prescription History Report, a Law Enforcement-User must:
 - (A) Indicate whether the search is for a civil or criminal investigation.
 - (AB) Provide a search authorization that includes both of the following:
 - 1. Case number.
 - 2. Violation code or crime code.
 - (B) Indicate whether the search authorization is for a civil or criminal investigation.
 - (C) Certify and submit the search authorization.
 - (D) Indicate the Prescription History Report type and complete the applicable procedure as follows:
 - 1. To request a Prescriber History Report, a Law Enforcement-User must:
 - (D)a. Provide search criteria that includes, at a minimum, both of the following:
 - 4.(i) Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - 2.(ii) Search Period.
 - (E)b. Agree to Terms and Conditions of CURES.
 - (F)c. Select the applicable Prescriber from the picklist.
- (f) Procedure to Request a Pharmacy History Report.

- (1)2. To request a Pharmacy History Report, a Law Enforcement-User must:
- (A) Provide a search authorization that includes both of the following:
 - 1. Case number.
 - 2. Violation code or crime code.
- (B) Indicate whether the search authorization is for a civil or criminal investigation.
- (C) Certify and submit the search authorization.
 - (D)a. Provide search criteria that includes, at a minimum, both of the following:
 - 1.(i) Pharmacy name or pharmacy license number, or DEA Number.
 - 2.(ii) Search Period.
 - (E)b. Agree to the Terms and Conditions of CURES.
 - (F)c. Select the applicable pharmacy from the picklist.
 - 3. To request a Serialized Prescription History Report, a Law Enforcement-User must:
 - a. Provide search criteria that include, at a minimum, a starting prescription form serial number.
 - b. Agree to the Terms and Conditions of CURES.
- (f) Procedure to request a Serialized Prescription Form Report.
 - (1) To request a Serialized Prescription Form Report, a Law Enforcement-User must:

 (A) Indicate the Serialized Prescription Form Report type and complete the applicable procedure as follows:
 - 1. To request a Serialized Prescription Form Report by prescriber, a Law Enforcement-User must provide search criteria that include all of the following:
 - a. Prescriber first name and Prescriber last name, or Prescriber DEA Number.
 - b. Date search type.
 - c. Search Period.

- 2. To request a Serialized Prescription Form Report by prescription form serial number, a Law Enforcement-User must provide search criteria that include all of the following:
 - **a.** A starting prescription serial number.
 - b. Date search type.
 - c. Search Period.
- 3. To request a Serialized Prescription Form Report by security printer, a Law Enforcement-User must provide search criteria that include all of the following:
 - a. Security printer name.
 - b. Date search type.
 - c. Search Period.
- (g) Procedure to Request a Prescription Form Theft or Loss Report.
 - (1) To request a Prescription Form Theft or Loss Report, a Law Enforcement-User must:

 (A) Indicate the Prescription Form Theft or Loss Report type and complete the applicable procedure, as follows:
 - 1. To request a Prescription Form Theft or Loss Report by Prescriber or Pharmacist, a Law Enforcement-User must provide search criteria that include, at a minimum, all of the following:
 - a. First name and last name of the Prescriber or Pharmacist, DEA

 Number of the Prescriber or Pharmacist, or Category of Licensure
 of the Prescriber or Pharmacist.
 - b. Date search type.
 - c. Search Period.
 - 2. To request a Prescription Form Theft or Loss Report by prescription form serial number, a Law Enforcement-User must provide search criteria that include, at a minimum, all of the following:
 - <u>a.</u> A starting prescription form serial number.
 - b. Date search type.
 - c. Search Period.

- 3. To request a Prescription Form Theft or Loss Report by theft or loss details, a Law Enforcement-User must provide search criteria that include, at a minimum, all of the following:
 - <u>a.</u> Reporter type, type of theft or loss, city theft or loss occurred, county theft or loss occurred, or current report status.
 - b. Date search type.
 - c. Search Period.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code.

Article 3. Research

§ 8268.1. Eligibility for Access to Data from CURES.

- (a) A public or private entity is eligible to obtain data from CURES, subject to the limitations specified in section 8268.2.
- (b) A Bona Fide Researcher is eligible to obtain data from CURES.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code; and Section 1798.24, Civil Code.

§ 8268.2. Data Accessible to Bona Fide Researchers or Public or Private Entities.

- (a) Subject to the restrictions of this section, a public or private entity that is not a Bona Fide Researcher is limited to obtaining Aggregated Data from CURES.
- (b) Subject to the restrictions of this section, a Bona Fide Researcher may obtain all of the following data from CURES:
 - (1) Aggregated Data.
 - (2) De-Identified Individual-Level Data.
 - (3) Identified Individual-Level Data.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code; and Section 1798.24, Civil Code.

§ 8268.3. Restrictions on Accessing Data from CURES.

A public or private entity, or a Bona Fide Researcher, must only obtain data from CURES for educational purposes, Peer Review purposes, statistical purposes, or Research Purposes.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code; and Section 1798.24, Civil Code.

§ 8268.4. Restrictions on Use or Disclosure of Data Obtained from CURES.

- (a) An Interested Party must only use data from CURES to support the educational purposes, Peer Review purposes, statistical purposes, or Research Purposes, as specified in the Written Request for Aggregated Data, defined in section 8268.5, subdivision (a), or Data Request Application, defined in section 8268.6, subdivision (a).
- (b) For Identified Individual-Level Data or De-Identified Individual-Level Data, a Bona Fide Researcher must only obtain data from CURES during the access period defined in the Bona Fide Researcher's Data Request Application.
- (c) To protect patient confidentiality and to confirm that data from CURES obtained in accordance with this section is used for the purposes for which it was requested, the Bona Fide Researcher must provide to the Department's Research Center, for review and comment, sufficiently in advance of any publication or dissemination, a complete draft of any report, evaluation, or other document, and the final publication. This requirement is not applicable if the Bona Fide Researcher only obtains Aggregated Data.
- (d) An Interested Party must not disclose, transfer, or disseminate data from CURES, unless expressly authorized by this section or approved in writing by the Department's Research Center.
- (e) A Bona Fide Researcher must not disclose or disseminate any data or documents identifying any individual, including, but not limited to, a patient, Prescriber, Out-of-State Prescriber, Pharmacist, or Out-of-State Pharmacist, except to the Department's Research Center, absent the written consent of that identified individual, unless approved in writing by the Department's Research Center.

- (f) A Bona Fide Researcher must aggregate Identified Individual-Level Data or De-Identified Individual-Level Data from CURES before it is published to ensure that it does not create a risk of identifying individuals.
- (g) An Interested Party must not release, disclose, or disseminate data or documents from CURES in any form if there is a reasonable possibility that an individual, including, but not limited to, a patient, Prescriber, Out-of-State Prescriber, Pharmacist, or Out-of-State Pharmacist, can be directly or indirectly identified from the information released, unless approved in writing by the Department's Research Center. Data from CURES is considered to have a reasonable possibility of indirectly identifying an individual, including, but not limited to, a patient, Prescriber, Out-of-State Prescriber, Pharmacist, or Out-of-State Pharmacist, if it includes:
 - (1) Any of the following identifying information:
 - (A) Name.
 - (B) Date of birth.
 - (C) Race.
 - (D) Gender.
 - (E) Income.
 - (F) Ethnicity.
 - (G) Age.
 - (H) Health conditions.
 - (I) Use of a drug abuse treatment facility.
 - (J) Pregnancy.
 - (K) HIPAA identifiers <u>under 45 Code of Federal Regulations part 164.514</u>, <u>subdivision (b)(2)(i), (10-1-20 Edition), incorporated by reference in</u> **this chapter,** including, but not limited to, any of the following:
 - 1. Phone number.
 - 2. Email address.
 - 3. Social security number.
 - 4. Driver's license number.
 - 5. PII or any other personal information, if that information, either alone or in combination with other factors, including geographic area, creates a risk of indirectly identifying that individual, including, but not limited to, a

patient, Prescriber, Out-of-State Prescriber, Pharmacist, or Out-of-State Pharmacist.

- 6. Geographical units of fewer than 20,000 people.
- (2) Rates, frequencies, other tabulations, or combined factors, including geographic information other than state and county-level information, and social stratification information, including gender, race, and economics, which result in the reporting of data for fewer than 2910 individuals.
- (h) If the Department's Research Center determines that any publication, dissemination, disclosure, or release of data from CURES or analyses could compromise the identity of any individual, Prescriber, Out-of-State Prescriber, Pharmacist, or Out-of-State Pharmacist, the Interested Party must not publish, disseminate, disclose, or release, that publication, dissemination, or disclosure containing any data from CURES.
- (i) An Interested Party must not re-identify or attempt to re-identify De-Identified Individual-Level Data or Aggregated Data from CURES.
- (i) An Interested Party must not sell any data from CURES.
- (jk) An Interested Party must not disclose or transfer data from CURES in a legal proceeding or in response to a subpoena in the absence of a court order. An Interested Party must give immediate notice to the Department's Research Center of any subpoena or other legal proceeding in which the disclosure of data from CURES is requested.
- (kl) A public or private entity, or a Bona Fide Researcher, must notify the Department's Research Center when the project, as specified in the applicable Data Request Application or Written Request for Aggregated Data, has been completed. All restrictions imposed in this section regarding use or disclosure of data from CURES survive the completion of the project. (lm) A Team Member is limited to accessing or analyzing data obtained by a Bona Fide Researcher.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code; and Section 1798.24, Civil Code.

§ 8268.5. Procedures for Requesting Aggregated Data from CURES.

- (a) "Written Request for Aggregated Data," when used in this section, means the written request a public or private entity, or a Bona Fide Researcher, must submit to obtain approval to receive Aggregated Data from CURES.
- (b) A public or private entity, or a Bona Fide Researcher, must electronically submit a complete Written Request for Aggregated Data to the Department's Research Center.
- (c) To complete a Written Request for Aggregated Data, a public or private entity, or a Bona Fide Researcher, must provide all of the following information in the Written Request for Aggregated Data:
 - (1) Designation as a new request or a modified request.
 - (2) Date of request.
 - (3) Name, phone number, and email address of the public or private entity, or the Bona Fide Researcher.
 - (4) Address, city, state, and postal code of the public or private entity, or the Bona Fide Researcher.
 - (5) Name of the public agency or research body with which the public or private entity, or the Bona Fide Researcher, is affiliated.
 - (6) Project title.
 - (7) Project outline that describes all of the following:
 - (A) The purposes and objectives of the project or report.
 - (B) How the requested data will be used to support the educational purposes, Peer Review purposes, statistical purposes, or Research Purposes, of the project.
 - (C) The expected benefits of the project.
 - (D) The proposed project design and methodology, including, but not limited to, a detailed description of the requested Aggregated Data from CURES.
 - (E) If applicable, any information pertaining to other formal project approvals, including institutional review board approvals for the academic community.
 - (8) Signature of the public or private entity's authorized representative, or of the Bona Fide Researcher, and the date of signature of the public or private entity's authorized representative, or of the Bona Fide Researcher, acknowledging the restrictions on use or disclosure of data from CURES, as specified in section 8268.4.

(d) If the Written Request for Aggregated Data is approved, the Department's Research Center will securely transfer the requested Aggregated Data to the public or private entity, or the Bona Fide Researcher.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code; and Section 1798.24, Civil Code.

§ 8268.6. Procedures for Requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES.

- (a) "Data Request Application," when used in this section, means the application developed by the Department's Research Center for a Bona Fide Researcher to obtain approval to receive Identified Individual-Level Data or De-Identified Individual-Level Data from CURES.
- (b) A Bona Fide Researcher must electronically submit a completed Data Request Application to the Department's Research Center.
- (c) To complete the Data Request Application, a Bona Fide Researcher must provide all of the following information on the Data Request Application:
 - (1) Designation as a new request or a modified request.
 - (2) Date of request.
 - (3) Name, phone number, and email address of the Bona Fide Researcher.
 - (4) Address, city, state, and postal code of the Bona Fide Researcher.
 - (5) Name of the public agency or research body with which the Bona Fide Researcher is affiliated.
 - (6) Name, phone number, and email address of the public agency's or research body's information security officer or IT manager.
 - (7) Project title.
 - (8) Date of anticipated completion of the project or the report.
 - (9) List of information for each Team Member that includes all of the following:
 - (A) Name of Team Member.
 - (B) The physical location from which the Team Member will access individual-level data from CURES.
 - (C) Whether the Team Member is part of the data analysis team.

- (D) Whether the Team Member is part of the IT team.
- (10) Signature of the Bona Fide Researcher, and date of signature of the Bona Fide Researcher.
- (11) Completed Data Request Application checklist that includes all of the following:
 - (A) Project outline that describes all of the following:
 - 1. The purposes and objectives of the project or report.
 - 2. How the requested data will be used to support the educational purposes, Peer Review purposes, statistical purposes, or Research Purposes, of the project.
 - 3. The expected benefits of the project.
 - 4. If applicable, the funding source of the project or report, including all of the following:
 - a. Whether the funding source is a public or private grant.
 - b. The grant period.
 - c. The grant expiration date.
 - 5. Proposed project design and methodology, including, but not limited to:
 - a. Where the data analysis will be conducted.
 - b. A detailed description of the requested individual-level data from CURES.
 - 6. Security measures, compliant with NIST Special Publication 800171, Revision 2, Protecting Controlled Unclassified Information in
 Nonfederal Systems and Organizations (February 2020),
 incorporated by reference in this chapter, that the Bona Fide
 Researcher has in place to prevent theunauthorized access of hard copies or electronic files containing Identified Individual-Level Data or DeIdentified Individual-Level Data from CURES, including, but not limited
 - a. Encryption methods.

to:

- b. Anti-virus software.
- c. Network security.
- d. Physical storage location of the data.
- e. Risks or confidentiality issues related to the storage location.

- f. Whether the data is stored on a device with an internet connection.
- g. Any software protection on the device on which the data is stored.
- h. Whether hard copies of the data will be stored.
- i. If Identified Individual-Level Data is requested, how the Bona Fide Researcher will ensure the elimination of individual identifiers from subject records or publications when the project is completed.
- 7. Whether the Bona Fide Researcher is capable of transferring data over a secure file transfer protocol.
- 8. If applicable, any information pertaining to other formal project approvals, including institutional review board approvals for the academic community.
- (B) Curriculum vitae of the Bona Fide Researcher.
- (C) Signature of the Bona Fide Researcher, and the date of signature of the Bona Fide Researcher, acknowledging the restrictions on use or disclosure of data from CURES, as specified in section 8268.4.
- (D) Completed Data Request Application security requirements acknowledgement that includes all of the following:
 - 1. The name, the signature, and the date of signature of the public agency's or research body's information security officer or IT manager.
- (DE) Completed Data Request Application <u>supplemental</u> security <u>checklistrequirements acknowledgement</u> that includes all of the following:
 - 1. The name of the public agency or research body.
 - 2. The name, position, signature, and date of signature, of the public agency's or research body's information security officer or IT manager.
- (EF) Any relevant research materials, including, but not limited to:
 - 1. Proposals.
 - 2. Endorsements.
 - 3. Questionnaires.
- (FG) Copy of the institutional review board approval and all documentation

submitted as part of that review and approval process, including the application number and expiration date. This requirement is not applicable if the Bona Fide Researcher is a public health officer, acting in the capacity of a public health officer, and is requesting De-Identified Individual-Level Data. This approval must demonstrate that the institutional review board is aware of, and has considered, relevant federal and State laws and regulations regarding the general use of human subjects, and specifically the use of human subjects who are incarcerated, minors, or otherwise vulnerable populations.

(G) If the Bona Fide Researcher is requesting Identified Individual Level Data, the Bona Fide Researcher must provide the prior written voluntary consent of any individual for whom Identified Individual-Level Data is being requested on the Data Request Application, in accordance with the requirements of this section and Civil Code section 1798.24, subdivision (b). Identified Individual-Level Data may be disclosed under Civil Code section 1798.24, subdivision (b), only with the prior written voluntary consent of the individual to whom the data pertains. The individual's written consent must be retained for at least as long as the individual's Identified Individual-Level Data is retained by the Bona Fide Researcher. The Bona Fide Researcher must obtain an individual's written consent not more than 30 days before obtaining that individual's Identified Individual Level Data from CURES, or within the time limit agreed to by the individual in the individual's written consent. A Bona Fide Researcher must not obtain an individual's Identified Individual-Level Data from CURES outside of that 30 days, or the time limit agreed to by the individual in the individual's written consent, unless the individual has provided a renewed written voluntary consent.

1. Each individual written consent must certify, in addition to any other requirements, all of the following:

a. That the consent is voluntary.

b. That the individual understands the individual's identity will never be revealed.

e. That the individual understands the individual may withdraw consent at any time.

- d. The principle purpose or purposes for which the information is to be used.
- e. The period of time, including start and end dates, during which the individual's Identified Individual Level Data from CURES will be acquired.
- f. The individual's right of access to records containing that individual's PII that was acquired, or is possessed, under the Data Request Application.
- 2. If any individual withdraws consent to obtain that individual's Identified Individual Level Data from CURES, the Bona Fide Researcher must immediately notify the Department's Research Center of that withdrawal of consent. If consent is withdrawn, the Bona Fide Researcher may retain any of that individual's Identified Individual-Level Data that was already collected from CURES under any previous consent.

(H) If the Bona Fide Researcher is requesting Identified Individual-Level Data, the Bona Fide Researcher must comply with Civil Code section 1798.24, subdivision (b), or Civil Code section 1798.24, subdivision (t).

1. To comply with Civil Code section 1798.24, subdivision (b), for purposes of this article, the Bona Fide Researcher must provide a signed CURES 0001 Consent for Use of Personal Information from CURES Form-form (Orig. 07/2021), incorporated by reference in this chapter, for each individual for whom Identified Individual-Level Data is being requested on the Data Request Application. Each signed Consent for Use of Personal Information from CURES Form-form must be retained for at least as long as each consenting individual's Identified Individual-Level Data is retained by the Bona Fide Researcher. The Bona Fide Researcher must obtain a signed Consent for Use of Personal Information from CURES Form-form from each individual not more than 30 days before obtaining the individual's Identified Individual-Level Data from CURES, or within the time limit agreed to by the individual in the individual's signed Consent for Use of Personal Information from CURES Form-form. A Bona Fide Researcher must not obtain an individual's Identified

Individual-Level Data from CURES outside of that 30 days, or the time limit agreed to by the individual in the individual's signed Consent for Use or Personal Information from CURES Form on unless the individual has provided a renewed Consent for Use of Personal Information from CURES Form form. If any individual withdraws consent to obtain that individual's Identified Individual-Level Data from CURES, the Bona Fide Researcher must immediately notify the Department's Research Center of that withdrawal of consent.

2. To comply with Civil Code section 1798.24, subdivision (t), for purposes of this article, the Bona Fide Researcher must obtain formal approval for the use of Identified Individual-Level Data, in accordance with the requirements of Civil Code section 1798.24, subdivision (t), by the Committee for the Protection of Human Subjects for the California Health and Human Services Agency or the Bona Fide Researcher's institutional review board, if that institutional review board has a written agreement with the Committee for the Protection of Human Subjects for that institutional review board to provide the data security approvals required by Civil Code section 1798.24, subdivision (t). The Bona Fide Researcher may first submit its application to the Department's Research Center. If the Bona Fide Researcher has met all other application and security requirements pursuant to these regulations and would

Department's Research Center willmay provide written documentation to the Bona Fide Researcher to allow the Committee for the Protection of Human Subjects to review the Bona Fide Researcher's application. The Bona Fide Researcher must provide written verification to the Department's Research Center of formal approvals by the Committee for the Protection of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), for the request of Identified Individual-Level Data from CURES. The written verification must include the review and determination by the Committee for the Protection

be approved by the Department's Research Center, tThe

of Human Subjects or the Bona Fide Researcher's institutional review board, if operating under a written agreement under Civil Code section 1798.24, subdivision (t), that the data security approvals required by Civil Code section 1798.24, subdivision (t), have been satisfied.

(HI) Certification of human subjects protection training for the Bona Fide Researcher and all Team Members.

(d) If the Bona Fide Researcher requests remote access authorization, the Bona Fide Researcher and each applicable Team Member must complete and submit a **DOJRC 0003** Researcher Confidentiality and Non-Disclosure Agreement (Orig. 07/2021), incorporated by reference in this chapter, and a **DOJRC 0002** Researcher Data Access User Agreement (Orig. 07/2021), incorporated by reference in this chapter. If the Bona Fide Researcher or any Team Member is unable to meet the security requirements of the Researcher Data Access User Agreement, that Bona Fide Researcher or Team Member may submit a **DOJRC 0001** Security Variance Form for Data Access Non-Compliance of Security Requirements (Orig. 07/2021), incorporated by reference in this chapter, for consideration by the Department's Research Center. (de) If the Data Request Application is approved, the Bona Fide Researcher and all Team Members must complete and submit a notarized identification verification. After the all notarized identification verifications, applicable Researcher Confidentiality and Non-Disclosure Agreements, applicable Researcher Data Access User Agreements, and applicable Security Variance Form for Data Access Non-Compliance of Security Requirements are is received and approved, the Department's Research Center will securely transfer the requested De-Identified Individual-Level Data or Identified Individual-Level Data to the Bona Fide Researcher. (ef) The Bona Fide Researcher must complete the Department's Research Center renewal process during the 90 days before the expiration date of the approved Data Request Application. The Department's Research Center will notify the Bona Fide Researcher to submit a project renewal before the expiration date of the approved Data Request Application. A Bona Fide Researcher must submit all of the following:

(1) A <u>written project</u> renewal-<u>must be submitted in writing</u>, on the Bona Fide Researcher's official letterhead, to the Department's Research Center, <u>and that</u> includes all of the following information:

(1-A) Any personnel changes and updated contact information, including removal or addition of the Bona Fide Researcher or other Team Members.

- (2B) Any technology changes to the location or procedures around where the individual-level data from CURES is stored or accessed.
- (3C) Any environmental changes to the location or procedures around where the individual-level data from CURES is stored or accessed.
- (4<u>D</u>) The name and contact information of the public agency's or research body's information security officer or IT manager.
- (5E) If applicable, a copy of the institutional review board approval and all documentation submitted as part of that review and approval process, including the application number and expiration date.
- (6<u>F</u>) A certification of human subjects protection training for the Bona Fide Researcher and all Team Members.
- (2) If continued remote access authorization is requested, renewed Researcher

 Confidentiality and Non-Disclosure Agreements and Researcher Data Access User

 Agreements for the Bona Fide Researcher and each Team Member. If the Bona Fide

 Researcher or any Team Member is unable to meet the security requirements of the

 Researcher Data Access User Agreement, that Bona Fide Researcher or Team Member

 may submit a Security Variance Form for consideration by the Department's Research

 Center.
- (fg) When the Bona Fide Researcher has concluded a research project or report, in accordance with the restrictions on use or disclosure of data from CURES, as specified in section 8268.4, the Bona Fide Researcher must submit to the Department's Research Center, in writing, a signed and dated certificate of data destruction confirming all of the following:
 - (1) The project name and project number.
 - (2) The type of data to be destroyed.
 - (3) The name of the Bona Fide Researcher.
 - (4) All confidential information received from the Department's Research Center has been sanitized using one or more of the approved destruction methods listed in National Institute of Standards and Technology (NIST) Special Publication 800-88, Revision 1, Guidelines for Media Sanitation (December 2014).
 - (5) The date that all electronic files containing Identified Individual-Level Data or De-Identified Individual-Level Data from CURES were destroyed.

- (6) The name of the witness or witnesses.
- (7) The position of the witness or witnesses in the research team.
- (8) Acknowledgement by the Bona Fide Researcher that failure to comply with the data destruction protocols required by this section may result in an audit of the project associated with the Identified Individual-Level Data or De-Identified Individual-Level Data from CURES.
- (9) A description of the items disposed of or destroyed.
- (10) An explanation of the method of destruction used.
- (gh) National Institute of Standards and Technology (NIST) Special Publication 800-88, Revision 1, Guidelines for Media Sanitation (December 2014) is incorporated by reference in this chapter.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 11165, Health and Safety Code; and Section 1798.24, Civil Code.

Article 4. Information Practices Act Requests

§ 8272.1. Eligibility to Obtain Prescription History Information from CURES.

- (a) An individual may obtain that individual's prescription history information retained in CURES from CURES PDMP.
- (b) In accordance with subdivisions (b)(1) and (b)(2), an authorized personal representative, on behalf of an individual, may obtain that individual's prescription history information retained in CURES from CURES PDMP.
 - (1) If the individual to whom the information pertains is deceased, the requesting authorized personal representative must provide evidence to CURES PDMP that the requesting authorized personal representative is the court-appointed executor or authorized representative of the decedent or the decedent's estate.
 - (2) If the individual to whom the information pertains is a minor, an adult who has been placed under conservatorship, or an incapacitated individual who has been appointed a health care agent under Division 4 of the California Probate Code, the requesting authorized personal representative must provide evidence to CURES PDMP that the

requesting authorized personal representative is the parental or court-appointed guardian of the minor, the court-appointed conservator, or an authorized health care agent.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 1798.24, Civil Code; and Section 11165, Health and Safety Code.

§ 8272.2. Procedures for Requesting Prescription History Information from CURES.

- (a) An individual must complete and submit the CURES=101 Information Practices Act Individual Request Form (Rev. 07/202109/2019), incorporated by reference in this chapter, to receive that individual's prescription history information retained in CURES from CURES PDMP.
- (b) An authorized personal representative must complete and submit the CURES=201 Information Practices Act Representative Request Form (Rev. 07/202109/2019), incorporated by reference in this chapter, to receive the prescription history information retained in CURES from CURES PDMP for the individual represented by that authorized personal representative.
- (c) To receive audit history information, which identifies the Prescriber-Users or, Non-DEA Practitioner-Users, Pharmacist-Users, or Delegate-Users who have accessed the individual's or represented individual's prescription history information retained in CURES, the individual or authorized personal representative must request the individual's or represented individual's audit history information, in writing, on the CURES=101 Information Practices Act Individual Request Form or CURES=201 Information Practices Act Representative Request Form, respectively.
- (d) A hard copy of the completed CURES-_101 Information Practices Act Individual Request Form or CURES-_201 Information Practices Act Representative Request Form must be submitted to CURES PDMP by mail.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Section 1798.24, Civil Code; and Section 11165, Health and Safety Code.

Article 5. Information Exchange Web Service

§ 82830.1. Eligibility for Integration with the Information Exchange Web Service.

An entity operating a HIT System must be a "eCovered eEntity" or "bBusiness aAssociate," as those terms are defined in the HIPAA Regulations, with respect to any data from CURES the HIT System may receive through the Information Exchange Web Service.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.1, Health and Safety Code.

§ 82830.2. Procedures for Integration with the Information Exchange Web Service.

- (a) "Integration Application Package," when used in this section, means the application package developed by the Department for an entity operating a HIT System to request system integration with CURES.
- (b) An entity operating a HIT System must submit a hard-copy of a completed Integration Application Package to CURES PDMP by mail.
- (c) An entity operating a HIT System must provide all of the following information in the Integration Application Package:
 - (1) A signed memorandum of understanding.
 - (2) A completed <u>CURES 0002</u> CURES Information Exchange Web Service Onboarding Questionnaire (<u>July 2021 December 2019</u>), incorporated by reference in this chapter.
 - (3) A Connectivity Fee check made payable to the "California Department of Justice."
- (d) An entity operating a HIT System must comply with the technical specifications identified in the CURES Information Exchange Web Service Overview (November 2021 July 2021 December 2019), incorporated by reference in this chapter.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.1, Health and Safety Code.

§ 82830.3. Requirements for HIT System Use of the Information Exchange Web Service.

(a) In accordance with Health and Safety Code section 11165.1, subdivision (a)(1)(E)(i), an entity that operates a HIT System is prohibited from using or disclosing data from CURES received through the Information Exchange Web Service for any purpose other than delivering the data from CURES to the authorized Prescriber-User-or, Non-DEA Practitioner-User, or

Pharmacist-User identified in <u>section 830.3</u>, subdivision (c)(35)(E), 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.

- (b) In accordance with Health and Safety Code section 11165.1, subdivision (a)(1)(E)(ii), and in the manner described in <u>section 830.3</u>, subdivision (c)(35)(E), a HIT System must authenticate the identity of the authorized Prescriber-User-or, Non-DEA Practitioner-User, or Pharmacist-User initiating a request, or on whose behalf the HIT System is initiating a request, to the Information Exchange Web Service.
- (c) In accordance with Health and Safety Code section 11165.1, subdivision (a)(1)(E)(ii), a HIT System, on behalf of an authorized Prescriber-User-or, Non-DEA Practitioner-User, or Pharmacist-User, must submit all of the following information to the Information Exchange Web Service with each request for a Patient Activity Report:
 - (1) The date and time of the search.
 - (2) Patient first name and patient last name.
 - (3) Patient date of birth.
 - (4) Search Period.
 - (5) The identification of the authorized Prescriber-User-or, Non-DEA Practitioner-User, or Pharmacist-User for whom the HIT System is submitting a request. A HIT System must only identify one authorized Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User for each request. The Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User whose identity is submitted must be the intended recipient of the data.
 - (A) To authenticate the identity of the authorized Prescriber-User, a HIT System must submit the Prescriber-User's first name, Prescriber-User's last name, Prescriber-User's State License Number, and Prescriber-User's national provider identifier number.
 - (B) To authenticate the identity of the authorized Non-DEA Practitioner-User, a
 HIT System must submit the Non-DEA Practitioner-User's first name, Non-DEA
 Practitioner-User's last name, Non-DEA Practitioner-User's State License
 Number, and Non-DEA Practitioner-User's national provider identifier number.
 (C) To authenticate the identity of the authorized Pharmacist-User, a HIT System
 must submit the Pharmacist-User's first name, Pharmacist-User's last name,

<u>Pharmacist-User's State License Number, and Pharmacist-User's pharmacy</u> business name.

- (A) To authenticate the identity of the authorized Prescriber-User or Pharmacist-User, a HIT System must submit all of the following information for each request:
 - 1. The first name and last name of the authorized Prescriber User or Pharmacist User.
 - 2. The DEA Number of the authorized Prescriber-User or the State License Number of the authorized Pharmacist-User.
- (B) A HIT System must only identify one authorized Prescriber User or Pharmacist User for each request.
- (d) If a HIT System uses predefined criteria to trigger an automated request to CURES on behalf of an authorized Prescriber-User or, Non-DEA Practitioner-User, or Pharmacist-User, the request must conform to that Prescriber-User's or, Non-DEA Practitioner-User's, or Pharmacist-User's restrictions on accessing patient information data in CURES under section 821.4 or, section 822.4, or section 822.4, or section 822.4, or section 822.4, respectively.
- (e) In accordance with Health and Safety Code section 11165.1, subdivision (a)(1)(E)(iii), a HIT System must comply with applicable patient privacy and information security requirements of federal and State laws and regulations, including, but not limited to:
 - (1) The Confidentiality of Medical Information Act (Part 2.6 (commencing with section 56) of Division 1 of the Civil Code).
 - (2) The HIPAA Regulations.
 - (3) The California Uniform Controlled Substances Act, including Health and Safety Code sections 11165 and 11165.1.
- (f) In accordance with Health and Safety Code section 11165.1, subdivision (a)(1)(E)(iv), an entity that operates a HIT System must maintain an active memorandum of understanding with the Department.

Note: Authority cited: Section 11165, Health and Safety Code. Reference: Sections 11165 and 11165.1, Health and Safety Code.