

## **INITIAL STATEMENT OF REASONS**

### **PROBLEM STATEMENT**

The Controlled Substance Utilization Review and Evaluation System (CURES) database contains information about Schedule II, Schedule III, and Schedule IV Controlled Substance prescriptions dispensed to patients, as reported by those dispensers. The CURES Program is the prescription drug monitoring program for the state of California and is responsible for administering CURES.

Health and Safety Code (H&SC) section 11165, subdivision (a) requires the Department of Justice (the Department) to maintain CURES to assist Health Care Practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of Controlled Substances; to assist Law Enforcement and Regulatory Agencies in their efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances; and for statistical analysis, education, and research.

Senate Bill (SB) 809 (Statutes of 2013, Chapter 400), amended, in part, by Assembly Bill (AB) 679 in 2015, and codified in H&SC section 11165.1, subdivision (a)(1)(A), requires all California licensed pharmacists, upon licensure, and all California licensed Health Care Practitioners authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV Controlled Substances in California, upon receipt of a federal Drug Enforcement Administration (DEA) Registration Certificate, to register for access to CURES.

AB 40 (Statutes of 2017, Chapter 607), chaptered on October 9, 2017, and codified in H&SC section 11165.1, requires the Department to establish a method of system integration whereby approved Health Care Practitioners and Pharmacists may use a qualified health information technology (HIT) system to access information in CURES. The method of system integration developed by the Department pursuant to AB 40 is referred to as the “CURES Information Exchange Web Service.”

In 2018, CURES 2.0 was certified for statewide use by the Department, and, as a result, the SB 482 (Chapter 708, Statutes of 2016) mandate to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II, Schedule III, or Schedule IV Controlled Substance, as stipulated in H&SC section 11165.4, subdivision (a), became effective on October 2, 2018. In addition, AB 1751 (Chapter 478, Statutes of 2018) expressly required the Department to adopt regulations regarding the access and use of the information within CURES.

### **BENEFITS**

The Department anticipates that these regulations will benefit the health, welfare, and safety of California residents because they clarify and make specific the statutes governing the access and use of CURES. As such, these regulations are intended to contribute to safe prescribing and dispensing of Controlled Substances, and to protect the security of the patient information contained within CURES. By clearly detailing the requirements for access and use for each User type, these regulations will provide transparency, empower Users to confidently utilize the

system as a tool to facilitate care, and ensure that the information contained in CURES is used only for statutorily authorized purposes.

Specifically, these regulations codify policies, procedures, requirements, and limitations currently in place for individuals who are statutorily required or permitted to consult CURES in the course of patient care, those who utilize the system in efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances, and those who wish to obtain access to CURES data for Research Purposes or to review their own CURES data. This will provide clarity as to who exactly is eligible for access to CURES and the data contained therein, as well as the strict limitations on how the database and associated data may and may not be used. As such, these regulations will preserve the privacy rights of the individuals whose information is contained within CURES.

## **PURPOSE AND NECESSITY**

### **§ 820. Definitions.**

Subdivisions (a) through (rrr) of these regulations define terms that will be used throughout the chapter. It is necessary for these terms to be defined because many lend themselves to different interpretations within different contexts. Definitions help establish appropriate scope and applicability. This uniformity assists affected parties in understanding their authority and responsibility with respect to CURES and the data it contains.

Subdivision (a) establishes that “Abuse” means any use of a Controlled Substance that is not authorized in its manner of use, purpose, quantity, or user. H&SC section 11165, subdivision (a) establishes CURES to, among other things, assist Law Enforcement and Regulatory Agencies in their efforts to control the Diversion and Resultant Abuse of Controlled Substances. This definition is necessary to ensure that term is universally understood so this intent is realized.

Subdivision (b) establishes that “Aggregated Data” means data that does not include Personal Identifying Information, and is presented in summary counts, mitigating privacy risks and attempts at re-identification. Restrictions on data access are based, in part, on the form of the data at issue. For example, Aggregated Data is the only type of data that may be accessed by a Research Requestor who is not a Bona Fide Researcher, pursuant to Section 826 of these regulations. This definition is necessary to distinguish this type of data from other forms of data.

Subdivision (c) establishes that “Annual Renewal” means the annual process in which a Prescriber-User, Pharmacist-User, Regulatory Agency-User, or Law Enforcement-User updates all applicable information contained within that User’s CURES profile. This definition is necessary to ensure that User profile information is updated on a yearly basis so that it remains current for purposes of communication with the User.

Subdivision (d) establishes that “Applicant Type” means the type of account for which an applicant is applying for access to CURES, including Prescriber, Out-of-State Prescriber, Pharmacist, and Out-of-State Pharmacist. This definition is necessary to provide clarity to a piece of information that is required to be provided by an applicant as a part of registration for access to CURES.

Subdivision (e) establishes that “Bona Fide Research” means research that is characterized by the identification, evaluation, or resolution of a problem in a research field, the intention to contribute to the basic knowledge of a research field, the utilization of scientific methods and research methodologies, or the reasonable expectation that the final research product will be accepted for publication in a peer-reviewed journal. These regulations establish specific requirements related to access to, and use of, CURES data by Bona Fide Researchers. This definition is necessary to clearly articulate the work that must be performed by an individual in order for the term Bona Fide Researcher to apply.

Subdivision (f) establishes that “Bona Fide Researcher” means a principle investigator, team lead, or other individual, who conducts Bona Fide Research, and has possession of a master’s degree, or higher level degree in a field that conducts research, is research-affiliated with a research entity including, but not limited to, accredited universities, recognized research organizations, or public departments and agencies, or has relevant research experience at an accredited university or college, research entity, or public agency. In accordance with H&SC section 11165, subdivision (c)(2)(A), the Department may provide CURES data to public or private entities, as approved by the Department, for educational, Peer Review, statistical, or Research Purposes. This definition is therefore necessary to provide specificity around who qualifies to access CURES data for statutorily authorized Research Purposes. Further, restrictions on data access are based, in part, on the nature of the requesting party, so it is necessary to assign and define relevant researcher categories.

Subdivision (g) establishes that “Category of Licensure” means the title of the license issued to an individual by that individual’s Licensing Board, as defined in subdivision (ii), or Licensing Agency, as defined in subdivision (hh). Sections 821 and 822 of these regulations dictate the information that a Prescriber and Pharmacist, respectively, must provide as part of CURES registration, which includes Category of Licensure. This definition is necessary as it clearly explains what information is required to be submitted for this field as a part of registration, which will reduce the chance of registration denial.

Subdivision (h) establishes that “Compliant Password” means a password that meets application security standards. This definition is necessary because it informs CURES Users of the security requirement that must be met in order to establish a new password in CURES.

Subdivision (i) establishes that “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. This definition is necessary to set the amount of the fee that H&SC section 11165.1, subdivision (a)(1)(H) authorizes the Department to collect and make specific the reasons for which it is being collected. It was necessary to set the Connectivity Fee in the amount of \$1,500 in order to account for the cost associated with the duties performed related to testing and onboarding a HIT System. These processes were calculated as taking an estimated 24.5 hours and that figure was then multiplied by the information technology specialist position rate of \$62 per hour.

Subdivision (j) establishes that “Controlled Substance” has the meaning set forth in H&SC section 11007. This definition is necessary to establish that these regulations use the term as defined in State statute, because federal statute defines it separately. In addition, it is necessary to ensure alignment of this term with how it is statutorily defined to mean a drug, substance, or immediate precursor which is listed in any schedule. This term must be easily understood by the persons affected by these regulations as they read through the text of the regulations.

Subdivision (k) establishes that “CURES” means the Controlled Substance Utilization Review and Evaluation System. This definition is necessary for clarity purposes because Controlled Substance Utilization Review and Evaluation System is used in its acronym form throughout these regulations.

Subdivision (l) establishes that “CURES PDMP” means the Department’s program that administrates CURES. This definition is necessary and was included in these regulations so that the Department’s program that administers CURES could be distinguished from CURES, the system or database. Certain regulations require the User to contact or submit information to the Department’s program that administers CURES (CURES PDMP), rather than through direct submission to the CURES database, making this distinction necessary. Also, CURES PDMP helps distinguish an Interstate Prescriber’s or Interstate Pharmacist’s prescription drug monitoring program, as those terms are used in Section 823 of this chapter. This definition is necessary for clarity purposes because CURES prescription drug monitoring program is used in its acronym form in Sections 824, 827, and 828 of this chapter.

Subdivision (m) establishes that “DEA” means the United States Drug Enforcement Administration. This definition is necessary for clarity purposes because Drug Enforcement Administration is used in its acronym form in Sections 821, 822, 824, 825, and 828 of this chapter, and is part of the defined terms “DEA Number” and “DEA Registration Certificate.”

Subdivision (n) establishes that “DEA Number” means the DEA Registration Certificate number issued to an individual by the DEA. This definition is necessary to provide clarity on a piece of information that is required to be used on the following: Prescriber Registration Application, Annual Renewal, List of Patients, Prescriber History Report, and Prescription Theft or Loss Report, and to authenticate the identity of an authorized Prescriber or Pharmacist when a HIT System is submitting a request.

Subdivision (o) establishes that a “DEA Registration Certificate” means the DEA certificate of registration issued to an individual granting that individual federal authority to handle Controlled Substances. This definition is necessary because a valid DEA Registration Certificate is a requirement for a Prescriber to register for access to CURES. Defining the term DEA Registration Certificate serves to clarify this requirement for Prescriber registrants. Registration for access to CURES requires that a provided DEA Number match the information on an applicant’s DEA Registration Certificate.

Subdivision (p) establishes that “De-Identified Individual-Level Data” means individually disaggregated data that does not include any Personal Identifying Information. Restrictions on data access are based, in part, on the form of the data at issue. As such, this definition is

necessary to distinguish this type of data from other forms of data. This definition is also necessary to clearly explain a type of CURES data that is available to a Research Requestor who is a Bona Fide Researcher, through the process specified in Section 826 of these regulations.

Subdivision (q) establishes that “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 (BPC) section 209, subdivision (b). This definition is necessary because it provides specificity to a permitted role that can be assigned CURES access, with associated use parameters.

Subdivision (r) establishes that “Department” means the State of California Department of Justice. This definition is necessary to specify the State agency that is issuing these regulations and distinguish that it is the California Department of Justice, not the United States Department of Justice.

Subdivision (s) establishes that “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 Schedule II, Schedule III, or Schedule IV Controlled Substances. This term is necessary to specify the conditions under which a team of Law Enforcement Agencies, one of which is the Department, constitute a Department Investigative Team.

Subdivision (t) establishes that “Diversion” means any redirection of a Controlled Substance from a use, purpose, quantity, or user, toward any use that is not authorized in its manner of use, purpose, quantity, or user. H&SC section 11165, subdivision (a) establishes CURES to, among other things, assist Law Enforcement and Regulatory Agencies in their efforts to control the Diversion and Resultant Abuse of Controlled Substances. This definition is necessary to ensure the term is universally understood so this intent is realized.

Subdivision (u) establishes that “Diversion and Resultant Abuse” means any redirection of a 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 a Controlled Substance that is not authorized in its manner of use, purpose, quantity, or user that results, either directly or indirectly, from that redirection. This definition is necessary to ensure the term is universally understood so this intent is realized.

Subdivision (v) establishes that “Health Care Practitioner” means a licensee authorized under H&SC section 11150 to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV Controlled Substances, and does not include non-prescribing Pharmacists or non-prescribing Out-of-State Pharmacists. This definition is necessary to ensure the term is universally understood so this intent is realized.

Subdivision (w) establishes that “Health Information Technology System” or “HIT System” has the meaning set forth in H&SC section 11165.1, subdivision (g)(4). This definition is necessary

for clarity purposes and because the term Health Information Technology System is used in its acronym form throughout these regulations.

Subdivision (x) establishes that “HIPAA” means the Health Insurance Portability and Accountability Act of 1996 (Pub. L. No. 104-191, 110 Stat. 1936 (1996)). This definition is necessary for clarity purposes because Health Insurance Portability and Accountability Act of 1996 is used in its acronym form throughout these regulations.

Subdivision (y) establishes that “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. This definition is necessary for clarity purposes because HIPAA Regulations are referenced throughout these regulations.

Subdivision (z) establishes that “Identified Individual-Level Data” means individually disaggregated data that includes the PII, as defined in subdivision (ss), of any patient to which that data relates. Restrictions on data access are based, in part, on the form of the data at issue. As such, this definition is necessary to distinguish this type of data from other forms of data. This definition is also necessary to clearly explain a type of CURES data that is available to a Research Requestor who is a Bona Fide Researcher, through the process specified in Section 826 of this chapter.

Subdivision (aa) establishes that “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. This definition is necessary for clarity because it is the name of the system integration developed by the Department.

Subdivision (bb) establishes that “Institutional DEA Number” means a unique number issued by the DEA to a licensed, eligible institution that handles Controlled Substances. This definition is necessary because it differentiates an Institutional DEA Number from a DEA Number and provides clarity on a piece of information that is required to be used on a Prescriber Registration Application, if applicable.

Subdivisions (cc) and (dd) establish that the terms “Interstate Pharmacist” and “Interstate Prescriber” mean an Out-of-State Pharmacist and an Out-of-State Prescriber, respectively, who is authorized to access the PDMP, as defined in subdivision (qq), of a state other than California, and is in good standing with, and can request data from, that PDMP.

H&SC section 11165, subdivision (h) authorizes the Department to enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a PDMP in another state, for purposes of interstate data sharing of PDMP information. These definitions are necessary to specify the terms used for an Out-of-State Pharmacist and Out-of-State Prescriber accessing CURES through a PDMP pursuant to H&SC section 11165, subdivision (h), as those terms are used to in Section 823 of these regulations wherein the procedures for that access are made specific.

Subdivision (ee) establishes that “Law Enforcement Agency” means any agency of the United States, the State of California, or a political subdivision of the State of California, 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 or cause of a death, if such manner 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; or (3) supervise criminal offenders post-sentencing. This definition is necessary because it describes, for purposes of these regulations, the agencies whose officials qualify to access CURES or request data from CURES.

Subdivision (ff) establishes that “Law Enforcement Official” means an officer or employee of a Law Enforcement Agency who is designated by that agency to access, or request data from, CURES on behalf of that Law Enforcement Agency in connection with that Law Enforcement Agency’s efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. Law Enforcement Officials may obtain data from CURES through direct access or by request to CURES PDMP. This definition is necessary to distinguish between a Law Enforcement Official and a Law Enforcement-User. A Law Enforcement-User is registered for direct access to CURES, while a Law Enforcement Official is a broader category that can encompass both Law Enforcement-Users and officers and employees of a Law Enforcement Agency who are authorized to request data from CURES, but who are not registered for direct access to CURES. This is an important distinction.

Subdivision (gg) establishes that “Law Enforcement-User” means a Law Enforcement Official who is registered for direct access to CURES. This definition is necessary and was included in these regulations so that a Law Enforcement-User could be distinguished from a Prescriber-User, Pharmacist-User, Interstate Prescriber, Interstate Pharmacist, and Regulatory Agency-User, and the access and data use rules that apply to each. This definition is also useful to distinguish Law Enforcement-Users from the broader category of Law Enforcement Officials.

Subdivision (hh) establishes that “Licensing Agency” means the California Department of Consumer Affairs or a Licensing Agency outside of California. This definition is necessary to distinguish an in-state applicant, who is licensed by a board or committee of the California Department of Consumer Affairs, from an out-of-state applicant, who is licensed by a Licensing Agency outside of California. Specified details related to an applicant’s Licensing Agency must be furnished at the time of registration.

Subdivision (ii) establishes that “Licensing Board” means each of the boards and committees established within the California Department of Consumer Affairs and identified in BPC section 208, subdivision (d). This definition is necessary to clarify that these committees and boards must be the entities through which a Prescriber or Pharmacist is licensed.

Subdivision (jj) establishes that a “List of Patients” means a list of patients for whom a Prescriber-User or Pharmacist-User is identified as the prescriber in CURES. A List of Patients includes the Prescriber DEA Number, Prescriber name, Prescriber address, patient last name, patient first name, patient date of birth, patient gender, and patient address. This definition is

necessary to provide clarification around the Prescriber and patient information that is included in the List of Patients accessible in CURES and to define who may access that specific data.

Subdivision (kk) establishes that “Out-of-State Licensing Board” means a board or committee established by a Licensing Agency other than the California Department of Consumer Affairs. This definition is necessary to differentiate an Out-of-State Licensing Board from a Licensing Board. These terms have different applications in the registration requirements and procedures sections.

Subdivision (ll) establishes that an “Out-of-State Pharmacist” is any pharmacist licensed by a Licensing Agency in a state or 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 Licensing Agency’s jurisdiction to dispense Schedule II, Schedule III, or Schedule IV Controlled Substances. This definition is necessary to differentiate between a Pharmacist and an Out-of-State Pharmacist because they have different registration requirements and procedures.

Subdivision (mm) establishes that “Out-of-State Prescriber” means any prescriber licensed in a state or 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 Licensing Agency’s jurisdiction to prescribe Schedule II, Schedule III, or Schedule IV Controlled Substances. This definition is necessary to differentiate between a Prescriber and an Out-of-State Prescriber because they have different registration requirements and procedures.

Subdivision (nn) establishes that “Patient Activity Report” means a report generated by CURES of the Controlled Substances history of a patient. The Patient Activity Report is defined to include, for each prescription dispensed to that patient, the patient last name, patient first name, patient middle initial, patient date of birth, patient gender, patient address, compact status, number of prescriptions, date filled, date sold, drug name, drug form, drug strength, quantity, days supply, species code, prescription number, refill number, number of authorized refills, payment method, prescriber name, prescriber DEA Number, pharmacy name, pharmacy number, and prescription form serial number. This definition is necessary to provide clarification around the patient, Prescriber, and pharmacy information that is included in the Patient Activity Report accessible in CURES by a Prescriber-User, Pharmacist-User, Interstate Prescriber, Interstate Pharmacist, Regulatory Agency Official, including a Regulatory Agency-User, and Law Enforcement Official, including a Law Enforcement-User, as specified in Sections 821 through 825, inclusive.

Subdivision (oo) establishes that “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, and patient address, and with which any subsequently reported dispensations that match the same combination of patient information are linked. This definition is necessary to clarify an intermediary step in the process for generating a Patient Activity Report, because 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.

Subdivision (pp) establishes that “Patient Picklist” means a list of Patient Entities returned to a User when that User submits the search criteria to initiate a Patient Activity Report. This definition is necessary for clarity because it is used throughout these regulations.

Subdivision (qq) establishes that a “PDMP” means a Prescription Drug Monitoring Program. This definition is necessary for clarity purposes because Prescription Drug Monitoring Program is used in its acronym form throughout these regulations.

Subdivision (rr) establishes that “Peer Review” means subjecting a researcher’s scholarly work, research, or ideas to the scrutiny of other researchers in the same field of research either to ensure that the scholarly work meets the accepted standards of the researcher’s discipline, or to prevent the dissemination of research that is compromised by unwarranted claims, unacceptable interpretations, or personal views. This definition is necessary to clarify one of the four purposes for which a Research Requestor is authorized to request data from CURES.

Subdivision (ss) establishes that “Personal Identifying Information” or “PII” has the same meaning as that term is defined in Penal Code section 530.55, subdivision (b). This definition is necessary to define the information that must be protected as a part of the Research Requestor process. Different levels of security and eligibility to access data from CURES exist depending on the type of data being requested (Aggregated Data, De-Identified Individual-Level Data, or Identified Individual-Level Data). More stringent security measures are put in place for data that contains Personal Identifying Information, and is therefore necessary to distinguish what it includes.

Subdivision (tt) establishes that “Pharmacist” has the meaning set forth in H&SC section 11024. This definition is necessary because Pharmacist is one of the main User types in CURES, the term is used throughout the regulations, and it clarifies who constitutes a Pharmacist.

Subdivision (uu) establishes that “Pharmacy History Report” means a report of the Controlled Substances dispensation history of a pharmacy, as reported to CURES PDMP. The Pharmacy History Report includes the pharmacy name, pharmacy license number, date filled, date sold, patient last name, patient first name, patient date of birth, patient gender, drug name, drug form, drug strength, quantity, days supply, prescription number, refill number, prescriber name, and prescriber DEA Number. This definition is necessary to provide clarification around the pharmacy, patient, and prescriber information that is included in the Pharmacy History Report accessible in CURES by a Regulatory Agency Official, including a Regulatory Agency-User, and a Law Enforcement Official, including a Law Enforcement-User, as specified in Sections 824 and 825.

Subdivision (vv) establishes that “Pharmacist-User” means any Pharmacist or Out-of-State Pharmacist who is registered to access CURES. This definition is necessary and was included in these regulations so that a Pharmacist-User could be distinguished from a Prescriber-User, Law Enforcement-User, Interstate Prescriber, Interstate Pharmacist, and Regulatory Agency-User, and the access and data use rules that apply to each.

Subdivision (ww) establishes that “Prescriber” means any Health Care Practitioner licensed in California. This definition is necessary because Prescribers are one of the main User types in CURES, the term is used throughout the regulations, and it clarifies who constitutes a Prescriber.

Subdivision (xx) establishes that “Prescriber History Report” means a report of the Controlled Substances prescribing history of a Prescriber, as reported to CURES PDMP. The Prescriber History Report includes the prescriber name, prescriber DEA Number, date filled, date sold, patient last name, patient first name, patient date of birth, patient gender, patient address, drug name, drug form, drug strength, quantity, days supply, pharmacy name, pharmacy number, prescription number, and refill number. This definition is necessary to provide clarification around the Prescriber, patient, and pharmacy information that is included in the Prescriber History Report accessible in CURES by a Regulatory Agency Official, including a Regulatory Agency-User, and a Law Enforcement Official, including a Law Enforcement-User, as specified in Sections 824 and 825.

Subdivision (yy) establishes that “Prescriber-User” means any Prescriber or Out-of-State Prescriber who is registered to access CURES. This definition is necessary and was included in these regulations so that a Prescriber-User could be distinguished from a Pharmacist-User, Law Enforcement-User, Interstate Prescriber, Interstate Pharmacist, and Regulatory Agency-User, and the access and data use rules that apply to each.

Subdivision (zz) establishes that “Prescription Theft or Loss Report” means the Web-form a Prescriber or Pharmacist is required to submit to the Department under H&SC section 11165.3. This definition is necessary because it specifies the means by which a Prescriber or Pharmacist would comply with the statutory requirements related to reporting the theft or loss of prescription forms.

Subdivision (aaa) establishes that “Regulatory Agency” means the Department of Consumer Affairs, and the boards and committees identified in BPC section 208, subdivision (d). This definition is necessary because it identifies the entities whose qualifying officers and employees are eligible for access to CURES or data from CURES.

Subdivision (bbb) establishes that “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. This definition is necessary to distinguish between a Regulatory Agency Official and a Regulatory Agency-User. A Regulatory Agency-User has direct access to CURES, while a Regulatory Agency Official is a broader category that can encompass both Regulatory Agency-Users and officers and employees of a Regulatory Agency who are authorized to request data from CURES, but who are not registered for direct access to CURES. This is an important distinction.

Subdivision (ccc) establishes that “Regulatory Agency-User” means a Regulatory Agency Official who is registered for access to CURES. This definition is necessary and was included in these regulations so that a Regulatory Agency-User could be distinguished from a Pharmacist-User, Law Enforcement-User, Interstate Prescriber, Interstate Pharmacist, and Prescriber-User,

and the access and data use rules that apply to each. This definition is also useful to distinguish Regulatory Agency-Users from the broader category of Regulatory Agency Officials.

Subdivision (ddd) establishes that “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. This definition is necessary to clearly explain what would constitute one of the four purposes for which a Research Requestor is authorized to request data from CURES.

Subdivision (eee) establishes that “Research Requestor” means a public or private entity, or a Bona Fide Researcher, that requests data from CURES. Restrictions on data access are based, in part, on the nature of the requesting party, so it is necessary to assign and define relevant researcher categories. This definition is necessary because it encompasses both types of permissible research data requestors, and thus provides a descriptive term that helps clarify requirements applicable to all research requests for data from CURES.

Subdivision (fff) establishes that “Search Period” means the requested data range for which CURES is to be searched in relation to a Patient Activity Report, Prescriber History Report, Pharmacy History Report, or other report. A User is required to enter a Search Period to run any of the aforementioned reports. This definition is necessary because it clarifies the meaning of a Search Period relative to such reports.

Subdivision (ggg) establishes that “Secure Lab” means a secure and monitored environment, operated by the Department, where authorized Research Requestors can access and analyze Identified Individual-Level Data. This definition is necessary to explain the physical location to which access to CURES data may be restricted to for a Bona Fide Researcher.

Subdivision (hhh) establishes that “Security Question Answer” means an answer used to verify the identity of a User, as defined in subdivision (ppp), when the User resets the User’s Compliant Password. This definition is necessary to explain the function of a piece of information that is required to be supplied by an applicant during CURES registration.

Subdivision (iii) establishes that “State” means the State of California. This definition is necessary because it specifies the State that is issuing these regulations and distinguishes it from other states. The State of California is used in this abbreviated form throughout these regulations.

Subdivision (jjj) establishes that “State License Number” means a licensee’s professional license number assigned to that licensee by the applicable Licensing Agency. This definition is necessary to provide clarity to a piece of information that is required to be provided by an applicant as a part of registration for access to CURES.

Subdivision (kkk) establishes that “Team Member” means any individual who will access or analyze data from CURES obtained by a Research Requestor. This term is necessary to specify the conditions under which an individual will be considered a Team Member. This definition is also necessary to ensure the term is universally understood so this intent is realized.

Subdivision (lll) establishes that “Terms and Conditions of CURES” means all restrictions imposed by this chapter and the California Uniform Controlled Substances Act (H&SC sections 11000 through 11651, inclusive) on the access and use of CURES, or data from CURES, with which a User must comply, and that any violation of these Terms and Conditions may result in prosecution. This definition is necessary because it simplifies the regulatory and statutory requirements for use of CURES into a single, context-specific term that can be easily understood by the persons affected by these regulations as they read through the text of the regulations.

Subdivision (mmm) establishes that “Ultimate User” has the meaning set forth in H&SC section 11030. This definition is necessary to distinguish an Ultimate User, the animal’s owner, from the animal-patient when the Prescriber-User is a veterinarian.

Subdivision (nnn) establishes that “Under His or Her Care,” as used in H&SC section 11165.1, means Under the Care of, as defined in subdivision (ooo). This definition is necessary because it connects the circumstances outlined in statute as a condition for a type of CURES access to the term used to detail that statutory requirement throughout these regulations.

Subdivision (ooo) establishes that “Under the Care of,” when used in this chapter to determine if a patient is Under the Care of a Prescriber-User, Pharmacist-User, Interstate Prescriber, or Interstate Pharmacist, means that the delineated conditions must exist between the patient and the Prescriber-User, Pharmacist-User, or Interstate Prescriber or Interstate Pharmacist. This definition is necessary because it provides specificity to the vague language used in statute as a condition of CURES access. Clearly defining the circumstances under which a Prescriber-User, Pharmacist-User, or Interstate Prescriber or Interstate Pharmacist may consider a patient to be Under His or Her Care provides the medical community, regulatory entities, and affected public with a defined standard under which use of CURES is justifiable.

Subdivision (ppp) establishes that “User” means any type of CURES registrant, including Prescriber-User, Pharmacist-User, Delegate, Regulatory Agency-User, and Law Enforcement-User. This definition is necessary because it encompasses all individuals who are registered for direct access to CURES, regardless of Applicant Type, and thus provides a descriptive term that helps clarify requirements applicable to all such Users. Moreover, it simplifies the multiple types of individuals who may access CURES into one word, “User,” so that this term can be easily understood by the persons affected by these regulations.

Subdivision (qqq) establishes that “User Search” means a report generated by CURES that a Regulatory Agency-User may initiate to request the account information of a Prescriber-User or Pharmacist-User in CURES. The User Search includes 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. This definition is necessary because it provides the function of this particular report generated by CURES and details the information that is accessible to a Regulatory Agency through this channel.

Subdivision (rrr) establishes that “Web-Based Application” means any 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; provided, however, Web-Based Application does not include the Information Exchange Web Service or a HIT System. This definition is necessary because it explains the forum through which CURES may be accessed and distinguishes this avenue from access from the Information Exchange Web Service, for which access guidelines are provided in Section 828.

### **§ 821. Prescribers and Out-of-State Prescribers.**

The purpose of subdivisions (a) through (g) is to set forth who within the prescriber community may have access to CURES, the process and requirements for gaining access, and how and for what purposes CURES and the information contained therein must be used. These subdivisions are necessary because, together with the provisions related to the other User types, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES.

The purpose of subdivision (a) is to limit CURES access to Prescribers who possess a valid DEA Registration Certificate and practice within the State or in another state other than California and are permitted CURES access by their Licensing Boards. This subdivision also addresses the eligibility for Out-of-State Prescribers to register for access to CURES when they are licensed in another state other than California and their DEA Number is registered in a state other than California. This subdivision is necessary because there is currently confusion about who within the prescriber community may access CURES, especially when a Prescriber is licensed in California but his or her DEA Number is registered outside of California or a Prescriber is licensed and practices only outside of California. This subdivision is further necessary because granting access to Prescribers who do not meet the eligibility criteria would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

The purpose of subdivision (b) is to set forth the procedures for registration that must be fulfilled by a Prescriber before he or she may be permitted access to CURES and to specify the application information that the Department has determined must be furnished by an applicant. This subdivision is necessary because it makes specific the H&SC section 11165.1, subdivision (a)(1)(A)(i) requirement that a Health Care Practitioner authorized to prescribe, order, administer, furnish, or dispense Controlled Substances pursuant to H&SC section 11150 shall submit an application to obtain approval to electronically access information regarding the Controlled Substance history of a patient that is maintained by the Department.

The purpose of subdivisions (b)(3) and (b)(4) is to differentiate between the information that must be submitted by California licensed Prescribers and Out-of-State Prescribers. This is necessary because there are automated validation tools in place for California Prescribers that cross-reference information on file with the Prescriber's Licensing Board, as well as the DEA. The automated validation tools are not possible for Out-of-State Prescribers due to the fact that CURES does not connect directly with out-of-state licensing boards or Licensing Agencies. As such, additional documentation must be provided in order for an Out-of-State Prescriber to validate his or her identity. This additional documentation includes photocopies of specified documentation related to the applicant's eligibility to access CURES. This documentation, as

well as the required notarized acknowledgement, is necessary because it is the most accurate way to validate the applicant's identity.

It is further necessary to specify that certain application information reported pursuant to subdivisions (b)(3)(A) and (b)(4)(A) must match specified official records or documentation because applications containing information that does not match will be denied when automated validation is applied to those fields.

The requirement that both a State License Number and a DEA Number be provided is necessary to validate whether the prescriber applicant is licensed to practice and prescribe Controlled Substances.

The purpose of subdivisions (b)(3)(C) and (b)(4)(E) is to require an applicant to agree to the Terms and Conditions of CURES prior to use of the system. This is necessary because it ensures that each applicant is aware of the provisions that regulate CURES and actively agrees to abide by them before that individual is allowed to access CURES and the data contained therein.

The purpose of subdivision (b)(5) is to outline the steps that an approved applicant must take when accessing CURES for the first time. This is necessary to clarify the procedures specific to first-time access, thereby avoiding confusion regarding whether the specified steps must be completed when subsequently accessing CURES.

The purpose of subdivision (c) is to explain that a Prescriber-User has access to both a Patient Activity Report and a List of Patients within CURES, and to set the Search Period that a Prescriber-User may access patient information within a 12-month timeframe. This subdivision is necessary to limit the temporal scope of information that a Prescriber-User may access, to only that information which the Department has determined is authorized and is necessary to assist a Prescriber-User in appropriately prescribing to a patient Under His or Her Care. Providing access to a List of Patients is a statutorily authorized activity that enables a Prescriber-User to identify patients to whom that Prescriber is listed as a Prescriber in CURES. Limiting the Search Period to 12 months is necessary to ensure that a Prescriber-User is only permitted access to data for patients currently Under His or Her Care, pursuant to H&SC section 11165.1.

The purpose of subdivision (d) is to set restrictions on access to CURES data for Prescriber-Users by limiting access to only what is necessary to treat a patient Under the Care of the Prescriber-User, to comply with the duty to consult CURES under H&SC section 11165.4, and to view a List of Patients for whom the Prescriber-User is listed as the Prescriber or Out-of-State Prescriber. This subdivision is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

This subdivision also clarifies that a Prescriber-User who is a veterinarian may only access animal-patient information. This clarification is necessary to mitigate confusion surrounding the scope of veterinary authority related to access to CURES data. The Department has been made aware of questions in the prescribing community regarding whether patient information in the context of veterinary care constitutes the Controlled Substance data of the animal-patient, of the owner of the animal-patient (Ultimate User), or of both the owner and the animal-patient. This

clarification is necessary so that both the Users of CURES and the public understand the distinction between an animal-patient and the animal-patient's Ultimate User as those terms relate to CURES.

The purpose of subdivision (e) is to set forth the restrictions on use, disclosure, and transfer of patient information applicable to Prescriber-Users. More specifically, the purpose of subdivision (e)(1) is to explicitly prohibit the use, disclosure, or transfer of CURES patient information unless it is for the same authorized purpose for which the patient information was originally requested and all applicable federal and State laws are complied with. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of CURES patient information provides references to applicable State and federal privacy, confidentiality, and security laws and regulations with which a Prescriber-User must comply. As CURES contains confidential patient information, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

The purpose of subdivision (e)(2) is to prohibit the sale of patient information obtained from CURES, consistent with H&SC section 11165, subdivision (b)(2)(A). This subdivision is necessary because the sale of patient information is an activity that is not for the sole purpose of treating someone, which is the only statutorily authorized use of CURES data for a Prescriber-User. This subdivision clarifies there is no circumstance under which a Prescriber-User should sell patient information.

The purpose of subdivision (e)(3) is to explain that a Prescriber-User is authorized to disclose or transfer CURES patient information to that Prescriber-User's Licensing Board to document compliance with the law. This subdivision is necessary to authorize Prescriber-Users to validate with their Licensing Board(s) that they complied with the duty to consult CURES, as required by H&SC section 11165.4, so long as that disclosure complies with all applicable federal and State laws and regulations, thus substantiating their compliance with the mandate.

The purpose of subdivision (f)(1) is to set forth in which environments patient information is made available: the Web-Based Application and the Information Exchange Web Service. This is necessary because the accessible environments vary by User. It is necessary for all Users to have access to the Web-Based Application, as it is the main way to access CURES. It is further necessary because it clarifies that H&SC section 11165.1, subdivision (a)(1)(D) authorizes a Prescriber-User to also access CURES patient information through the Information Exchange Web Service.

The purpose of subdivision (f)(2) is to specify that a Prescriber-User may only change his or her Compliant Password in the Web-Based Application and is required to create a new Compliant Password every 90 days. It is necessary to clarify that Compliant Passwords can only be changed in the Web-Based Application because Prescriber-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to change a Compliant Password. It is necessary that a User create a new Compliant Password every 90 days because the Department has determined that this timeframe meets the Department's security policy and is consistent with industry standards.

The purpose of subdivision (f)(3) is to set forth the requirement that Users update specified information about themselves annually, clarify that this requirement is applicable to Prescriber-Users, and specify that an Annual Renewal must be made in the Web-Based Application. It is necessary that the specified data elements be updated annually because any or all of them are constantly subject to change. For example, individuals regularly move, which can alter their street address, postal code, phone numbers, or email addresses. It is vital that the Department have up-to-date information for all Users in order to manage CURES, validate that only Users with a current and valid need to access CURES are able to do so, and ensure that the Department is able to contact Users regarding any statutory and/or technical updates to CURES. Lastly, it is necessary to stipulate that Annual Renewals must be processed in the Web-Based Application because Prescriber-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to complete the Annual Renewal.

More specifically, the purpose of subdivision (f)(3)(D) is to require the Prescriber-User to agree to the Terms and Conditions of CURES prior to submitting the required Annual Renewal. This is necessary because it ensures that each Prescriber-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (f)(4) is to explain the procedures that a Prescriber-User must follow in order to request a Patient Activity Report. The purpose of subdivision (f)(4)(A) is to specify that a Patient Activity Report is available in both the Web-Based Application and the Information Exchange Web Service. This is necessary because some functionalities are only available in the Web-Based Application, but a Prescriber-User may access a Patient Activity Report in either environment.

The purpose of subdivision (f)(4)(B) is to explain the procedures that a Prescriber-User must follow in order to request a Patient Activity Report in the Web-Based Application, including the search criteria that must be provided, a requirement to agree to the Terms and Conditions of CURES, and direction to find and generate the Patient Activity Report for the proper patient.

Subdivision (f)(4)(B)(i) is necessary because a Prescriber-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, the Prescriber-User will not be able to complete the search, which is the first step in initiating a Patient Activity Report in the Web-Based Application.

Subdivision (f)(4)(B)(ii) is necessary because it ensures that each Prescriber-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to access a Patient Activity Report.

Subdivision (f)(4)(B)(iii) is necessary because a Prescriber-User must complete these steps in order to successfully submit a search. If this is not done, then the Prescriber-User will not be able to generate a Patient Activity Report.

The purpose of subdivision (f)(4)(C) is to explain the procedures that a Prescriber-User must follow in order to generate and view a Patient Activity Report in the Information Exchange Web Service, including the search criteria that must be provided and a requirement to agree to the Terms and Conditions of CURES, and direction to find and generate the Patient Activity Report for the proper patient.

Subdivision (f)(4)(C)(i) is necessary because a Prescriber-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, then the Prescriber-User will not be able to complete the search, which is the first step in initiating a Patient Activity Report in the Information Exchange Web Service.

Subdivision (f)(4)(C)(ii) is necessary because it ensures that each Prescriber-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (f)(5) is to explain how to access a List of Patients. Subdivision (f)(5)(A) is necessary because it specifies that a Prescriber-User can only request a List of Patients in the Web-Based Application. Prescriber-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to generate a List of Patients.

The purpose of subdivision (f)(5)(B) is to specify the procedures that a Prescriber-User must follow in order to request a List of Patients, including requirements to select the Prescriber-User's DEA Number(s), provide a Search Period, and agree to the Terms and Conditions of CURES. Subdivisions (f)(5)(B)(i) and (f)(5)(B)(ii) are necessary because a Prescriber-User is unable to generate a List of Patients without first completing the steps specified therein.

Subdivision (f)(5)(B)(iii) is necessary because it ensures that each Prescriber-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to request a List of Patients.

The purpose of subdivision (f)(6) is to explain how to submit a Prescription Theft or Loss Report and specify associated requirements. This is necessary to clarify H&SC section 11165.3, which requires an affected Prescriber to report the theft or loss of prescription forms no later than three days after the date of discovery.

More specifically, the purpose of subdivision (f)(6)(A) is to specify that a Prescriber-User can only access a Prescription Theft or Loss Report in the Web-Based Application. This is necessary because Prescriber-Users have access to both environments, but only the Web-Based Application has the technical functionality required to generate and submit a Prescription Theft or Loss Report.

The purpose of subdivision (f)(6)(B) is to specify that each Prescriber-User whose name is printed on a prescription form that is lost or stolen must submit a separate Prescription Theft or

Loss Report. This is necessary because it provides clarity regarding who is required to report the theft or loss of prescription forms pursuant to H&SC section 11165.3.

The purpose of subdivision (f)(6)(C) is to specify the information that must be provided within a Prescription Theft or Loss Report. This is necessary because all listed data elements must be included in order for a Prescription Theft or Loss Report to be submitted, as required by H&SC section 11165.3. The required information also aides in investigating and auditing the loss or theft of prescription forms, which are closely regulated by Law Enforcement Officials and Regulatory Agency Officials.

The purpose of subdivision (g) is to set forth the process and requirements for Delegates to gain access to CURES, the CURES report that they may initiate on behalf of an associated Prescriber-User(s), and how and for what purposes CURES and the information contained therein may be used. A Prescriber-User may have multiple Delegates and a Delegate may support multiple Prescriber-Users. These subdivisions are necessary because, together with the provisions related to the other User types, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

The purpose of subdivision (g)(1) is to set restrictions on access to CURES for Delegates by stipulating that 1) a Prescriber-User is responsible for overseeing the access and use of CURES for his or her Delegates and 2) a Delegate-initiated request must conform to the CURES access restrictions applicable to the Prescriber-User on whose behalf the request is initiated. This subdivision is necessary to advise a Prescriber-User that he or she is responsible for the conduct of any individual for whom he or she requests access to CURES and to ensure that information contained within CURES is used solely for the purposes for which it is intended.

The purpose of subdivision (g)(2) is to set forth the procedures for registration that must be fulfilled by a Prescriber-User who is seeking to designate a Delegate before he or she may be permitted access to CURES and to specify the application information that the Department has determined must be furnished by an applicant. This subdivision is necessary because it differentiates between the information that must be submitted by the various User types in conjunction with an application for access to CURES.

The purpose of subdivisions (g)(2)(D) is to require a Prescriber-User to agree to the Terms and Conditions of CURES in order to submit an application to designate an individual as his or her Delegate. This is necessary because it ensures that each Prescriber-User is aware of the provisions that regulate CURES and actively agrees to abide by them before being allowed to designate a Delegate.

The purpose of subdivision (g)(2)(E) is to outline the steps that a Delegate must take when accessing CURES for the first time. This is necessary to clarify the procedures specific to first-time access, thereby avoiding confusion regarding whether the specified steps must be completed when subsequently accessing CURES.

The purpose of subdivision (g)(3)(A) is to set forth the environment in which a Delegate may access CURES: the Web-Based Application. This is necessary because the accessible environments vary by User type. It is necessary for all Users to have access to the Web-Based Application, as it is the main way to access CURES; however, a Delegate does not have access to the Information Exchange Web Service.

The purpose of subdivision (g)(3)(B) is to specify that a Delegate must create a new Compliant Password every 90 days. It is necessary that a User create a new Compliant Password every 90 days because the Department has determined that this timeframe meets the Department's security policy and is consistent with industry standards.

The purpose of subdivision (g)(3)(C) is to set forth the requirement that Users update specified information about themselves annually and clarify that this requirement is applicable to Delegates. It is necessary that an email address be updated annually because it can change at any time. It is vital that the Department have up-to-date information for all Users in order to manage CURES, validate that only Users with a valid need to access CURES are able to do so, and ensure that the Department is able to contact Users regarding any statutory and/or technical updates to CURES.

More specifically, the purpose of subdivision (g)(3)(C)(iii) is to require a Delegate to agree to the Terms and Conditions of CURES prior to submitting the required Annual Renewal. This is necessary because it ensures that each Delegate is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (g)(3)(D) is to explain the procedures that a Delegate must follow in order to initiate a Patient Activity Report, including the search criteria that must be provided, a requirement to agree to the Terms and Conditions of CURES, and direction to initiate the Patient Activity Report for the appropriate Prescriber-User.

Subdivision (g)(3)(D)(i)(a.) is necessary because a Delegate must enter all of the data elements listed in order to successfully submit a search. If any of the data elements are absent, then the Delegate will not be able to submit the search, which is the first step in initiating a Patient Activity Report.

Subdivision (g)(3)(D)(i)(c.) is necessary because it ensures that each Delegate is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to initiate a Patient Activity Report on behalf of a Prescriber-User.

## **§ 822. Pharmacists and Out-of-State Pharmacists.**

The purpose of subdivisions (a) through (g) is to set forth who within the Pharmacist community may have access to CURES, the process and requirements for gaining access, and how and for what purposes CURES and the information contained therein must be used. These subdivisions

are necessary because, together with the provisions related to the other Users, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES.

The purpose of subdivision (a) is to limit CURES access to Pharmacists who possess a valid pharmacist license. This subdivision is necessary because granting access to Pharmacists who do not meet the eligibility criteria would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

The purpose of subdivision (b) is to set forth the procedures for registration that must be fulfilled by a Pharmacist before he or she may be permitted access to CURES and to specify the application information that the Department has determined must be furnished by an applicant. This subdivision is necessary because it makes specific the H&SC section 11165.1, subdivision (a)(1)(A)(ii) requirement that a Pharmacist shall submit an application to obtain approval to electronically access information regarding the Controlled Substance history of a patient that is maintained by the Department.

The purpose of subdivisions (b)(3) and (b)(4) is to differentiate between the information that must be submitted by California licensed Pharmacists and Out-of-State Pharmacists. This is necessary because there are automated validation tools in place for California Pharmacists that cross-reference information on file with the applicant's Licensing Board. The automated validation tools are not possible for Out-of-State Pharmacists because CURES does not connect directly with out-of-state licensing boards or Licensing Agencies. As such, additional documentation must be provided in order for an Out-of-State Pharmacist to validate his or her identity. This additional documentation includes photocopies of specified documentation related to the applicant's eligibility to access CURES. This documentation, as well as the required notarized acknowledgement, is necessary because it is the most accurate way to validate the applicant's identity.

It is further necessary to specify that certain application information reported pursuant to subdivision (b)(3)(A) must match specified official records or documentation because applications containing information that does not match will be denied when automated validation is applied to those fields.

The purpose of subdivisions (b)(3)(C) and (b)(4)(E) is to require an applicant to agree to the Terms and Conditions of CURES prior to use of the system. This is necessary because it ensures that each applicant is aware of the provisions that regulate CURES and actively agrees to abide by them before the individual is allowed to access CURES and the data contained therein.

The purpose of subdivision (b)(5) is to outline the steps that an approved applicant must take when accessing CURES for the first time. This is necessary to clarify the procedures specific to first-time access, thereby avoiding confusion regarding whether the specified steps must be completed when subsequently accessing CURES.

The purpose of subdivision (c) is to explain that a Pharmacist-User has access to both a Patient Activity Report and a List of Patients within CURES, and to set the Search Period a Pharmacist-

User may access patient information within to a 12-month timeframe. This subdivision is necessary to limit the scope of information that a Pharmacist-User may access to only that information which the Department has determined is authorized by statute and is necessary to assist a Pharmacist-User in appropriately dispensing to a patient Under His or Her Care. Providing access to a List of Patients is a statutorily authorized audit activity that enables a Pharmacist-User who has a DEA Number associated with his or her CURES account to identify patients to whom that Pharmacist is listed as a prescribing Pharmacist in CURES. It is important to distinguish between a Pharmacist-User who has a DEA Number and one who does not. Pharmacists who have a DEA Number are able to prescribe medications, while those that do not have a DEA Number are not. Limiting the Search Period to 12 months is necessary to ensure that a Pharmacist-User is only permitted access to data for patients currently Under His or Her Care, pursuant to H&SC section 11165.1.

The purpose of subdivision (d) is to set restrictions on access to CURES data for Pharmacist-Users by limiting access to only what is necessary to treat a patient Under the Care of the Pharmacist-User, to comply with the duty to consult CURES under H&SC section 11165.4, and to obtain a List of Patients for whom the Pharmacist-User is listed as the prescribing Pharmacist or prescribing Out-of-State Pharmacist. This subdivision is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

The purpose of subdivision (e) is to set forth the restrictions on use, disclosure, and transfer of patient information applicable to Pharmacist-Users. More specifically, the purpose of subdivision (e)(1) is to explicitly prohibit the use, disclosure, or transfer of CURES patient information unless it is for the same authorized purpose for which the patient information was originally requested and all applicable federal and State laws are complied with. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of CURES patient information, and because it provides references to applicable State and federal privacy, confidentiality, and security laws with which a Pharmacist-User must comply. As CURES contains confidential patient information, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

The purpose of subdivision (e)(2) is to prohibit the sale of patient information obtained from CURES, consistent with H&SC section 11165, subdivision (b)(2)(A). This subdivision is necessary because the sale of patient information is an activity that is not for the sole purpose of treating someone, which is the only statutorily authorized use of CURES data for a Pharmacist-User. This subdivision clarifies there is no circumstance under which a Pharmacist-User should sell patient information.

The purpose of subdivision (e)(3) is to explain that a Pharmacist-User is authorized to disclose or transfer CURES patient information to that Pharmacist-User's Licensing Board to document compliance with the law. This subdivision is necessary to authorize Pharmacist-Users to validate with their Licensing Board that they complied with the duty to consult CURES, as required by H&SC section 11165.4, so long as that disclosure complies with all applicable federal and State laws and regulations, thus substantiating their compliance with the mandate.

The purpose of subdivision (f)(1) is to set forth in which environments patient information is made available: the Web-Based Application and the Information Exchange Web Service. This is necessary because the accessible environments vary by User. It is necessary for all Users to have access to the Web-Based Application, as it is the main way to access CURES. It is further necessary because it clarifies that H&SC section 11165.1, subdivision (a)(1)(D) authorizes a Pharmacist -User to also access CURES patient information through the Information Exchange Web Service.

The purpose of subdivision (f)(2) is to specify that a Pharmacist-User may only change his or her Compliant Password in the Web-Based Application and is required to create a new Compliant Password every 90 days. It is necessary to clarify that Compliant Passwords can only be changed in the Web-Based Application because Pharmacist-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to change a Compliant Password. It is necessary that a User create a new Compliant Password every 90 days because the Department has determined that this timeframe meets the Department's security policy and is consistent with industry standards.

The purpose of subdivision (f)(3) is to set forth the requirement that Users update specified information about themselves annually, clarify that this requirement is applicable to Pharmacist-Users, and specify that an Annual Renewal must be made in the Web-Based Application. It is necessary that the specified data elements be updated annually because any or all of them are constantly subject to change. For example, individuals regularly move, which can alter their street address, postal code, phone numbers, or email addresses. It is vital that the Department have up-to-date information for all Users in order to manage CURES, validate that only Users with a current and valid need to access CURES are able to do so, and ensure that the Department is able to contact Users regarding any statutory and/or technical updates to CURES. Lastly, it is necessary to stipulate that Annual Renewals must be processed in the Web-Based Application because Pharmacist-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to complete the Annual Renewal.

More specifically, the purpose of subdivision (f)(3)(D) is to require the Pharmacist-User to agree to the Terms and Conditions of CURES prior to submitting the required Annual Renewal. This is necessary because it ensures that each Pharmacist-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (f)(4) is to explain the procedures that a Pharmacist-User must follow in order to request a Patient Activity Report. The purpose of subdivision (f)(4)(A) is to specify that a Patient Activity Report is available in both the Web-Based Application and the Information Exchange Web Service. This is necessary because some functionalities are only available in the Web-Based Application, but a Pharmacist-User may access a Patient Activity Report in either environment.

The purpose of subdivision (f)(4)(B) is to explain the procedures that a Pharmacist-User must follow in order to request a Patient Activity Report in the Web-Based Application, including the

search criteria that must be provided, a requirement to agree to the Terms and Conditions of CURES, and direction to find and generate the Patient Activity Report for the proper patient.

Subdivision (f)(4)(B)(i) is necessary because a Pharmacist-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, the Pharmacist-User will not be able to complete the search, which is the first step in initiating a Patient Activity Report in the Web-Based Application.

Subdivision (f)(4)(B)(ii) is necessary because it ensures that each Pharmacist-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to access a Patient Activity Report.

Subdivision (f)(4)(B)(iii) is necessary because a Pharmacist-User must complete these steps in order to successfully submit a search. If this is not done, then the Pharmacist-User will not be able to generate a Patient Activity Report.

The purpose of subdivision (f)(4)(C) is to explain the procedures that a Pharmacist-User must follow in order to generate and view a Patient Activity Report in the Information Exchange Web Service, including the search criteria that must be provided and a requirement to agree to the Terms and Conditions of CURES, and direction to find and generate the Patient Activity Report for the proper patient.

Subdivision (f)(4)(C)(i) is necessary because a Pharmacist-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, then the Pharmacist-User will not be able to complete the search, which is the first step in initiating a Patient Activity Report in the Information Exchange Web Service.

Subdivision (f)(4)(C)(ii) is necessary because it ensures that each Pharmacist-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (f)(5) is to explain how to access a List of Patients. Subdivision (f)(5)(A) is necessary because it specifies that a Pharmacist-User can only request a List of Patients in the Web-Based Application, so long as there is a DEA Number associated with the Pharmacist-User's CURES account. Pharmacist-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to generate a List of Patients.

The purpose of subdivision (f)(5)(B) is to specify the procedures that a Pharmacist-User must follow in order to request a List of Patients, including requirements to select the Pharmacist-User's DEA Number(s), provide a Search Period, and agree to the Terms and Conditions of CURES. Subdivisions (f)(5)(B)(i) and (f)(5)(B)(ii) are necessary because a Prescriber-User is unable to generate a List of Patients without first completing the steps specified therein.

Subdivision (f)(5)(B)(iii) is necessary because it ensures that each Pharmacist-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to request a List of Patients.

The purpose of subdivision (f)(6) is to explain how to submit a Prescription Theft or Loss Report and specify associated requirements. This is necessary to clarify H&SC section 11165.3, which requires an affected prescriber to report the theft or loss of prescription forms no later than three days after the date of discovery.

More specifically, the purpose of subdivision (f)(6)(A) is to specify that a Pharmacist-User can only access a Prescription Theft or Loss Report in the Web-Based Application. This is necessary because Pharmacist-Users have access to both environments, but only the Web-Based Application has the technical functionality required to generate and submit a Prescription Theft or Loss Report.

The purpose of subdivision (f)(6)(B) is to specify that each Pharmacist-User whose name is printed on a prescription form that is lost or stolen must submit a separate Prescription Theft or Loss Report. This is necessary because it provides clarity regarding who is required to report the theft or loss of prescription forms pursuant to H&SC section 11165.3.

The purpose of subdivision (f)(6)(C) is to specify the information that must be provided within a Prescription Theft or Loss Report. This is necessary because all listed data elements must be included in order for a Prescription Theft or Loss Report to be submitted, as required by H&SC section 11165.3. The required information also aides in investigating and auditing the loss or theft of prescription forms, which are closely regulated by Law Enforcement Officials and Regulatory Agency Officials.

The purpose of subdivision (g) is to set forth the process and requirements for Delegates to gain access to CURES, the CURES report that they may initiate on behalf of an associated Pharmacist-User(s), and how and for what purposes CURES and the information contained therein may be used. A Pharmacist-User may have multiple Delegates and a Delegate may support multiple Pharmacist-Users. These subdivisions are necessary because, together with the provisions related to the other Users, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

The purpose of subdivision (g)(1) is to set restrictions on access to CURES for Delegates by stipulating that 1) a Pharmacist-User is responsible for overseeing the access and use of CURES for his or her Delegates and 2) a Delegate-initiated request must conform to the CURES access restrictions applicable to the Pharmacist-User on whose behalf the request is initiated. This subdivision is necessary to advise a Pharmacist-User that he or she is responsible for the conduct of any individual for whom he or she requests access to CURES and to ensure that information contained within CURES is used solely for the purposes for which it is intended.

The purpose of subdivision (g)(2) is to set forth the procedures for registration that must be fulfilled by a Pharmacist-User who is seeking to designate a Delegate before he or she may be permitted access to CURES and to specify the application information that the Department has determined must be furnished by an applicant. This subdivision is necessary because it differentiates between the information that must be submitted by the various User types in conjunction with an application for access to CURES.

The purpose of subdivision (g)(2)(D) is to require a Pharmacist-User to agree to the Terms and Conditions of CURES in order to submit an application to designate an individual as his or her Delegate. This is necessary because it ensures that each Pharmacist-User is aware of the provisions that regulate CURES and actively agrees to abide by them before being allowed to designate a Delegate.

The purpose of subdivision (g)(2)(E) is to outline the steps that a Delegate must take when accessing CURES for the first time. This is necessary to clarify the procedures specific to first-time access, thereby avoiding confusion regarding whether the specified steps must be completed when subsequently accessing CURES.

The purpose of subdivision (g)(3)(A) is to set forth the environment in which a Delegate may access CURES: the Web-Based Application. This is necessary because the accessible environments vary by User type. It is necessary for all Users to have access to the Web-Based Application, as it is the main way to access CURES; however, a Delegate does not have access to the Information Exchange Web Service.

The purpose of subdivision (g)(3)(B) is to specify that a Delegate must create a new Compliant Password every 90 days. It is necessary that a User create a new Compliant Password every 90 days because the Department has determined that this timeframe meets the Department's security policy and is consistent with industry standards.

The purpose of subdivision (g)(3)(C) is to set forth the requirement that Users update specified information about themselves annually and clarify that this requirement is applicable to Delegates. It is necessary that an email address be updated annually because it can change at any time. It is vital that the Department have up-to-date information for all Users in order to manage CURES, verify that only Users with a valid need to access CURES are able to do so, and ensure that the Department is able to contact Users regarding any statutory and/or technical updates to CURES.

More specifically, the purpose of subdivision (g)(3)(C)(iii) is to require a Delegate to agree to the Terms and Conditions of CURES prior to submitting the required Annual Renewal. This is necessary because it ensures that each Delegate is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (g)(3)(D) is to explain the procedures that a Delegate must follow in order to initiate a Patient Activity Report, including the search criteria that must be provided, a

requirement to agree to the Terms and Conditions of CURES, and direction to initiate the Patient Activity Report for the appropriate Pharmacist-User.

Subdivision (g)(3)(D)(i)(a.) is necessary because a Delegate must enter all of the data elements listed in order to successfully submit a search. If any of the data elements are absent, then the Delegate will not be able to submit the search, which is the first step in initiating a Patient Activity Report.

Subdivision (g)(3)(D)(i)(c.) is necessary because it ensures that each Delegate is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to initiate a Patient Activity Report on behalf of a Pharmacist-User.

### **§ 823. Interstate Prescribers and Interstate Pharmacists.**

The purpose of subdivisions (a) through (e) is to set forth who within the Interstate Prescriber and Interstate Pharmacist community may have access to CURES pursuant to H&SC section 11165, subdivision (h), the process and requirements for gaining access, and how and for what purposes CURES and the information contained therein must be used. These subdivisions are necessary because, together with the provisions related to the other User types, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

The purpose of subdivision (a) is to limit CURES access to Interstate Prescribers and Interstate Pharmacists whose PDMP and authorized interstate data sharing hub have both entered into a memorandum of understanding (MOU) with the Department for interstate sharing of CURES data and the Interstate Prescriber or Interstate Pharmacist's PDMP comply with all applicable federal and State laws and regulations. This subdivision is necessary to make specific the provisions of H&SC 11165, subdivision (h). This subdivision is further necessary because granting access to Interstate Prescribers or Interstate Pharmacists who do not meet the eligibility criteria would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

The purpose of subdivision (b) is to explain that an Interstate Prescriber or Interstate Pharmacist has access to Patient Activity Report information within CURES and sets the Search Period that an Interstate Prescriber or Interstate Pharmacist may access patient data within a 12-month timeframe. This subdivision is necessary to limit the scope of information that an Interstate Prescriber or Interstate Pharmacist may access to only that information which the Department has determined is authorized and is necessary to assist an Interstate Prescriber or Interstate Pharmacist in appropriately prescribing or dispensing to a patient Under His or Her Care. Limiting the Search Period to 12 months is necessary to ensure that an Interstate Prescriber or Interstate Pharmacist is only permitted access to data for patients currently under their care, pursuant to H&SC section 11165.1.

The purpose of subdivision (c) is to set restrictions on access to CURES data for Interstate Prescribers or Interstate Pharmacists by limiting access to only what is necessary to treat a

patient Under the Care of the Interstate Prescriber or Interstate Pharmacist. Subdivision (c) also stipulates that, for a patient who is Under the Care of the Interstate Prescriber but does not have an ongoing provider-patient relationship, the Interstate Prescriber may only access the patient's information in CURES within 24 hours or the previous business day before the appointment for a professional medical consultation. This subdivision is necessary to ensure information contained within CURES is used solely for the purposes for which it is intended and to clarify that the restriction stipulated in H&SC section 11165.4, subdivision (a)(2) is applicable to all Interstate Prescribers or Interstate Pharmacists.

The purpose of subdivision (d) is to set forth the restrictions on use, disclosure, and transfer of patient information applicable to Interstate Prescribers or Interstate Pharmacists. More specifically, the purpose of subdivision (d)(1) is to explicitly prohibit the use, disclosure, or transfer of CURES patient information unless it is for the same authorized purpose for which the patient information was originally requested and all applicable federal and State laws are complied with. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of CURES patient data, and provides references to applicable State and federal privacy, confidentiality, and security laws and regulations with which an Interstate Prescriber or Interstate Pharmacist must comply. As CURES contains confidential patient information, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

The purpose of subdivision (d)(2) is to prohibit the sale of patient information obtained from CURES, consistent with H&SC section 11165, subdivision (b)(2)(A). This subdivision is necessary because the sale of patient information is an activity that is not for the sole purpose of treating someone, which is the only statutorily authorized use of CURES data for an Interstate Prescriber or Interstate Pharmacist. This subdivision clarifies that there is no circumstance under which an Interstate Prescriber or Interstate Pharmacist could sell patient information.

The purpose of subdivision (e) is to specify the CURES data and report that Interstate Prescribers or Interstate Pharmacists may access. This subdivision is necessary to clarify H&SC section 11165, subdivision (h), which authorizes CURES data sharing across state lines through an approved interstate data-sharing hub.

#### **§ 824. Regulatory Agencies.**

The purpose of subdivisions (a) through (f) is to set forth who within a Regulatory Agency may have access to CURES, the process and requirements for gaining access, and how and for what purposes CURES and the information contained therein may be used. These subdivisions are necessary because, together with the provisions related to the other User types, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

The purpose of subdivision (a) is to establish appropriate restrictions on CURES access for Regulatory Agencies. This subdivision is necessary because Regulatory Agency Officials require access to CURES in order to support their efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. It is also necessary

because granting access to officers or employees within a Regulatory Agency who do not meet the eligibility criterion would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES. It is further necessary because it specifies that access to CURES is granted to Regulatory Agency Officials on an individual basis.

The purpose of subdivision (b) is to set forth the procedures for registration that must be fulfilled by a Regulatory Agency Official before he or she may be permitted access to CURES and to specify the application and application information that the Department has determined must be furnished by an applicant. This subdivision is necessary because it specifies how the Department makes CURES available for the electronic monitoring of prescribing and dispensing of Schedule II, Schedule III, and Schedule IV Controlled Substances to Regulatory Agency Officials in their efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances.

More specifically, the purpose of subdivision (b)(3)(C) is to stipulate the required method by which the Department will validate the identity of the applicant. This is necessary because the Department does not have an alternative method by which to validate that the applicant meets the eligibility requirement for access to CURES. It provides verification that the applicant is, in fact, applying as an officer or employee of a Regulatory Agency and justification as to why the Regulatory Agency Official requires access to CURES.

The purpose of subdivision (b)(3)(E) is to require an applicant to agree to the Terms and Conditions of CURES prior to use of the system. This is necessary because it ensures that each applicant is aware of the provisions that regulate CURES and actively agrees to abide by them before the individual is allowed to access CURES and the data contained therein.

The purpose of subdivision (b)(4) is to outline the steps that an approved applicant must take when accessing CURES for the first time. This is necessary to clarify the procedures specific to first-time access, thereby avoiding confusion regarding whether the specified steps must be completed when subsequently accessing CURES.

The purpose of subdivision (c) is to explain that a Regulatory Agency Official has access to a Patient Activity Report, a Prescriber History Report, a Pharmacy History Report, and any other report generated by CURES available to Regulatory Agency Officials via the Web-Based Application, and to provide that a Regulatory Agency Official may access patient data from CURES for as long as the data is retained in CURES. This subdivision is necessary to limit the scope of information that a Regulatory Agency Official may access to only that information which the Department has determined is necessary to support a Regulatory Agency Official's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. A Regulatory Agency is responsible for the regulation of its licensees for the duration of the licensee's tenure; thus, it is necessary to allow Regulatory Agency Officials access to CURES data, without limiting queries to a specified Search Period.

The purpose of subdivision (d) is to set restrictions on access to CURES data for Regulatory Agency Officials, accessing CURES on behalf of a Regulatory Agency, by limiting access to only what is necessary to assist a Regulatory Agency's efforts to control the Diversion and

Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. This subdivision is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended. The reasons outlined in subdivisions (d)(1)(A) through (d)(1)(F), inclusive, are based on a Regulatory Agency's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances.

More specifically, the purpose of subdivisions (d)(2) and (d)(3) is to prohibit a Regulatory Agency Official from accessing CURES or the data therein in order to enforce or investigate a suspected violation of any criminal law, unless specified criteria are met. This is necessary in order to clarify the circumstances by which a Regulatory Agency Official may access CURES or the data therein in order to enforce or investigate a suspected violation of any criminal law. It is further necessary to explicitly outline the restrictions or procedures with which a Regulatory Agency Official must comply in order to access CURES or the data therein in order to enforce or investigate a suspected violation of any criminal law.

The purpose of subdivision (e) is to set forth the restrictions on use, disclosure, and transfer of patient information applicable to Regulatory Agency Officials. More specifically, the purpose of subdivision (e)(1) is to explicitly prohibit the use, disclosure, or transfer of CURES patient information unless it is for the authorized purpose for which the patient information was originally requested and complies with all applicable laws and regulations. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of CURES patient data, and because it provides reference to the main State law pertaining to Controlled Substances. As CURES contains confidential patient information, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

The purpose of subdivision (e)(2) is to prohibit the sale of patient information obtained from the CURES, consistent with H&SC section 11165(b)(2)(A). This subdivision is necessary because the sale of patient information is an activity that does not support a Regulatory Agency Official's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. This subdivision clarifies that there is no circumstance under which a Regulatory Agency Official could sell CURES data.

The purpose of subdivision (f)(1) is to specify that a Regulatory Agency-User may access the Web-Based Application. This is necessary to distinguish the Web-Based Application from the Information Exchange Web Service, which a Regulatory Agency-User may not access.

The purpose of subdivision (f)(2) is to specify that a Regulatory Agency-User must create a new Compliant Password every 90 days. It is necessary that a User create a new Compliant Password every 90 days because the Department has determined that this timeframe meets the Department's security policy and is consistent with industry standards.

The purpose of subdivision (f)(3) is to set forth the requirement that Users update specified information about themselves annually and clarify that this requirement is applicable to Regulatory Agency-Users. It is necessary that the specified data elements be updated annually because any or all of them are constantly subject to change. It is vital that the Department have up-to-date information for all Users in order to manage CURES, validate that only Users with a

current and valid need to access CURES are able to do so, and ensure that the Department is able to contact Users regarding any statutory and/or technical updates to CURES.

More specifically, the purpose of subdivision (f)(3)(C) is to require the Regulatory Agency-User to agree to the Terms and Conditions of CURES prior to submitting the required Annual Renewal. This is necessary because it ensures that each Regulatory Agency-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (f)(4)(A) is to explain the procedures that a Regulatory Agency-User must follow in order to request a Patient Activity Report, including the search criteria that must be provided, a requirement to agree to the Terms and Conditions of CURES, and direction to find and generate the Patient Activity Report for the proper patient.

Subdivision (f)(4)(A)(i) is necessary because a Regulatory Agency-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, then the Regulatory Agency-User will not be able to complete the search, which is the first step in initiating a Patient Activity Report.

Subdivision (f)(4)(A)(ii) is necessary because it ensures that each Regulatory Agency-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to access a Patient Activity Report.

Subdivision (f)(4)(A)(iii) is necessary because a Regulatory Agency-User must complete these steps in order to successfully complete a search. If this is not done, then the Regulatory Agency-User will not be able to generate a Patient Activity Report.

The purpose of subdivisions (f)(5) and (f)(6) is to explain how a Regulatory Agency-User may access a Prescriber History Report and a Pharmacy History Report, respectively, including requirements to provide search criteria and Search Period, agree to the Terms and Conditions of CURES, and select the applicable Prescriber and pharmacy, respectively.

Subdivisions (f)(5)(A)(i) and (f)(6)(A)(i) are necessary because a Regulatory Agency-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, then the Regulatory Agency-User will not be able to complete the search, which is the first step in requesting a Prescriber History Report and Pharmacy History Report, respectively.

Subdivisions (f)(5)(A)(ii) and (f)(6)(A)(ii) are necessary because they ensure that each Regulatory Agency-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to access a Prescriber History Report and Pharmacy History Report, respectively.

Subdivisions (f)(5)(A)(iii) and (f)(6)(A)(iii) are necessary because a Regulatory Agency-User must complete the specified steps in order to successfully complete a search. If this is not done, then the Regulatory Agency-User will not be able to generate a Prescriber History Report and Pharmacy History Report, respectively.

The purpose of subdivision (f)(7)(A) is to explain the procedures that a Regulatory Agency-User must follow in order to initiate a User Search, including the search criteria that must be provided and direction to find and generate the User Search. This is necessary because a Regulatory Agency-User must provide all of the search criteria information and complete the specified steps in order to successfully initiate a User Search. If this is not done, then the Regulatory Agency-User will not be able to generate or view a User Search.

### **§ 825. Law Enforcement.**

The purpose of subdivisions (a) through (f) is to set forth who within the law enforcement community may have access to CURES, the process and requirements for gaining access, and how and for what purposes CURES and the information contained therein may be used. These subdivisions are necessary because, together with the provisions related to the other User types, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

The purpose of subdivision (a) is to establish appropriate restrictions for CURES access to Law Enforcement Agencies. This subdivision is necessary to clarify the role and access provisions of Law Enforcement Officials as noted in H&SC section 11165, subdivision (a). It is also necessary because granting access to individuals who do not meet the eligibility criteria would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES. It is further necessary because it specifies that access to CURES is granted to Law Enforcement Officials on an individual basis.

The purpose of subdivision (b) is to set forth the procedures for registration that must be fulfilled by a Law Enforcement Official before he or she may be permitted access to CURES and to specify the application and application information that the Department has determined must be furnished by an applicant. This subdivision is necessary because it specifies how the Department makes CURES available for the electronic monitoring of prescribing and dispensing of schedule II, Schedule III, and Schedule IV Controlled Substances to Law Enforcement Officials in their efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances.

More specifically, the purpose of subdivision (b)(3)(C) is to stipulate the required method by which the Department will validate the identity of the applicant. This is necessary because the Department does not have an alternative method by which to validate that the applicant meets the eligibility requirement for access to CURES. It provides verification that the applicant is, in fact, applying as an officer or employee of a Law Enforcement Agency and justification as to why the Law Enforcement Official requires access to CURES.

The purpose of subdivision (b)(3)(E) is to require an applicant to agree to the Terms and Conditions of CURES prior to use of the system. This is necessary because it ensures that each applicant is aware of the provisions that regulate CURES and actively agrees to abide by them before the individual is allowed to access CURES and the data contained therein.

The purpose of subdivision (b)(4) is to outline the steps that an approved applicant must take when accessing CURES for the first time. This is necessary to clarify the procedures specific to first-time access, thereby avoiding confusion regarding whether the specified steps must be completed when subsequently accessing CURES.

The purpose of subdivision (c) is to explain that a Law Enforcement Official has access to a Patient Activity Report, a Prescriber History Report, a Pharmacy History Report, and any other report generated by CURES available to Law Enforcement Officials via the Web-Based Application, and to provide that a Law Enforcement Official may access patient data from CURES for as long as the data is retained in CURES. This subdivision is necessary to limit the scope of information that a Law Enforcement Official may access to only that information which the Department has determined is necessary to support a Law Enforcement Official's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. A Law Enforcement Agency is responsible for investigating suspected civil and criminal violations of statutory and regulatory provisions related to Controlled Substances and CURES. As such, it is necessary to allow Law Enforcement Officials access to CURES data, without limiting queries to a specified Search Period.

The purpose of subdivision (c)(3) is to prohibit a coroner, medical examiner, or officer or employee of a Law Enforcement Agency directly assisting a coroner or medical examiner from obtaining a Prescriber History Report or a Pharmacy History Report. This subdivision is necessary because the Department has determined that the noted individuals do not require access to these reports in order to perform their duties.

The purpose of subdivision (d)(1) is to set restrictions on access to CURES data for Law Enforcement Officials by limiting access to only what is necessary to assist a Law Enforcement Agency's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. This subdivision is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

The purpose of subdivision (d)(2) is to require a Law Enforcement Official to provide both a case number and a violation code or crime code in order to obtain a Prescriber History Report or a Pharmacy History Report. The purpose of subdivision (d)(3) is to require a Law Enforcement Official to provide a case number, a violation code or crime code, and a search warrant or court order in order to obtain a Patient Activity Report. These subdivisions are necessary to provide additional safeguards in accessing CURES data. Because CURES contains patient information, it is necessary to ensure that Law Enforcement Officials cannot access it outside of their statutorily-mandated duties related to CURES.

The purpose of subdivision (d)(4) is to prohibit a Law Enforcement Official from direct electronic access to a Patient Activity Report in connection with investigating or prosecuting a

possible violation of civil law. This section is necessary to clarify that the process through which a Law Enforcement Official may request a Patient Activity Report in connection with investigating or prosecuting a possible violation of civil law is through written submission to CURES PDMP for manual processing.

The purpose of subdivision (d)(5) is to outline the circumstances under which a Law Enforcement Official is not required to provide a search warrant or a court order to obtain a Patient Activity Report. Subdivisions (d)(5)(A) through (d)(5)(D), inclusive, outline the types of subpoenas that call for the release of patient data within CURES for the purposes of investigating or prosecuting violations of law. Subdivision (d)(5)(E) provides an exemption to the search warrant or court order rule for Law Enforcement Officials who are an officer or employee of specified departments and provide CURES or CURES PDMP with a Medi-Cal beneficiary report, as delineated. Subdivision (d)(5)(F) allows a Law Enforcement Official to provide a copy of an individual's death certificate or memorandum containing specified statements and information in lieu of a search warrant or a court order. Subdivision (d)(5)(G) provides an exemption to the search warrant or court order rule for a Law Enforcement Official who is an officer or employee of the Department and who has written approval from the Attorney General to access CURES, or request data from CURES, on behalf of the Department. Lastly, subdivision (d)(5)(H) provides an exemption to the search warrant or court order rule for a Law Enforcement Official who is an officer or employee of a Law Enforcement Agency that is a member of a Department Investigative Team. These subdivisions, which are based on circumstances that the Department has encountered, are necessary because they delineate the mechanisms other than a search warrant or a court order that call for the release of CURES data.

The purpose of subdivision (e) is to set forth the restrictions on use, disclosure, and transfer of patient information applicable to Law Enforcement Officials. More specifically, the purpose of subdivision (e)(1) is to explicitly prohibit the use, disclosure, or transfer of CURES patient information unless it is for the same authorized purpose for which the patient information was originally requested and complies with applicable laws and regulations. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of CURES patient data, and because it provides reference to the State law with which the use or disclosure must comply. As CURES contains confidential patient information, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

The purpose of subdivision (e)(2) is to prohibit the sale of patient information obtained from the CURES, consistent with H&SC section 11165, subdivision (b)(2)(A). This subdivision is necessary because the sale of patient information is an activity that does not support a Law Enforcement Official's efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances. This subdivision clarifies that there is no circumstance under which a Law Enforcement Official could sell CURES data.

The purpose of subdivision (f)(1) is to specify that a Law Enforcement-User may access the Web-Based Application. This is necessary to distinguish the Web-Based Application from the Information Exchange Web Service, which a Law Enforcement-User may not access.

The purpose of subdivision (f)(2) is to specify that a Law Enforcement-User must create a new Compliant Password every 90 days. It is necessary that a User create a new Compliant Password every 90 days because the Department has determined that this timeframe meets the Department's security policy and is consistent with industry standards.

The purpose of subdivision (f)(3) is to set forth the requirement that Users update specified information about themselves annually and clarify that this requirement is applicable to Law Enforcement-Users. It is necessary that the specified data elements be updated annually because any or all of them are constantly subject to change. It is vital that the Department have up-to-date information for all Users in order to manage CURES, validate that only Users with a current and valid need to access CURES are able to do so, and ensure that the Department is able to contact Users regarding any statutory and/or technical updates to CURES.

More specifically, the purpose of subdivision (f)(3)(C) is to require the Law Enforcement-User to agree to the Terms and Conditions of CURES prior to submitting the required Annual Renewal. This is necessary because it ensures that each Law Enforcement-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to continue accessing CURES and the data contained therein.

The purpose of subdivision (f)(4)(A) is to explain the procedures that a Law Enforcement-User must follow in order to request a Patient Activity Report, including search authorization and search criteria that must be provided, a requirement to agree to the Terms and Conditions of CURES, and direction to find and generate the Patient Activity Report for the proper patient.

Subdivision (f)(4)(A)(i) is necessary because, as provided in subdivision (d)(3), a Law Enforcement-User must provide a case number, violation code or crime code, and a search warrant, court order, or approved exception in order to request a Patient Activity Report. If one or more of these documents is absent, then the Law Enforcement-User will not be able to complete the search needed to initiate a Patient Activity Report.

More specifically, subdivision (f)(4)(A)(i)(c)(1.) is necessary because the specified approved exemption documents must be manually processed by the Department.

Subdivision (f)(4)(A)(iv) is necessary because a Law Enforcement-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, then the Law Enforcement-User will not be able to complete the search needed to initiate a Patient Activity Report.

Subdivision (f)(4)(A)(v) is necessary because it ensures that each Law Enforcement-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to access a Patient Activity Report.

Subdivision (f)(4)(A)(vi) is necessary because a Law Enforcement-User must complete these steps in order to successfully complete a search. If this is not done, then the Law Enforcement-User will not be able to generate a Patient Activity Report.

The purpose of subdivisions (f)(5) and (f)(6) is to explain how a Law Enforcement-User may request a Prescriber History Report and a Pharmacy History Report, respectively, including requirements to provide search authorization, search criteria, and Search Period, agree to the Terms and Conditions of CURES, and select the applicable Prescriber and pharmacy, respectively.

Subdivisions (f)(5)(A)(i) and (f)(6)(A)(i) are necessary because, as provided in subdivision (d)(2), a Law Enforcement-User must provide a case number and a violation code or crime code in order to request a Prescriber History Report or Pharmacy History Report, respectively. If one or more of these elements are absent, then the Law Enforcement-User will not be able to complete the search needed to initiate a Prescriber History Report or Pharmacy History Report, respectively.

Subdivisions (f)(5)(A)(iv) and (f)(6)(A)(iv) are necessary because a Law Enforcement-User must enter all of the data elements listed in order to successfully complete a search. If any of the data elements are absent, then the Law Enforcement-User will not be able to complete the search, which is the first step in initiating a Prescriber History Report or Pharmacy History Report, respectively.

Subdivisions (f)(5)(A)(v) and (f)(6)(A)(v) are necessary because they ensure that each Law Enforcement-User is aware of the provisions that regulate CURES, specifically any statutory and/or regulatory updates to CURES, and actively agrees to abide by them before the individual is allowed to access a Prescriber History Report or Pharmacy History Report, respectively.

Subdivisions (f)(5)(A)(vi) and (f)(6)(A)(vi) are necessary because a Law Enforcement-User must complete the specified steps in order to successfully complete a search. If this is not done, then the Law Enforcement-User will not be able to generate a Prescriber History Report and Pharmacy History Report, respectively.

## **§ 826. Research Requestors.**

The purpose of subdivisions (a) through (f) is to set forth who within the academic and researcher community may obtain data from CURES, the process and requirements for gaining access, and how and for what purposes CURES data may be used. These subdivisions are necessary because, together with the provisions related to Users, they protect the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

The purpose of subdivision (a) is to limit access to CURES data to Research Requestors who are public or private entities or Bona Fide Researchers. This subdivision is necessary because H&SC section 11165, subdivision (a) requires CURES to be maintained for, among other things, statistical analysis, education, and Research Purposes. It is further necessary because releasing

CURES data to individuals who do not meet the Research Requestor eligibility criterion would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

The purpose of subdivision (b) is to explain that a Research Requestor who is a Bona Fide Researcher may obtain Aggregated Data, De-Identified Individual-Level Data, and Identified Individual-Level Data from CURES, while a Research Requestor who is not a Bona Fide Researcher may only obtain Aggregated Data. This subdivision is necessary to limit the scope of information that a Research Requestor may obtain to only that information which the Department has determined is appropriate for each Research Requestor type. A Bona Fide Researcher is an individual who conducts Bona Fide Research and meets one of the following requirements: possesses a master's degree in a field that conducts research, is research-affiliated with a research entity, or has relevant research experience. It is therefore necessary and appropriate to allow a Research Requestor who is a Bona Fide Researcher to obtain a broader variety of CURES data than what is available to Research Requestor who is not a Bona Fide Researcher.

The purpose of subdivision (c) is to set restrictions on access to CURES data for Research Requestors by limiting access to only what is necessary to support educational purposes, Peer Review purposes, statistical purposes, or Research Purposes. This subdivision is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

The purpose of subdivision (d) is to set forth the restrictions on use or disclosure of patient information applicable to Research Requestors. More specifically, the purpose of subdivision (d)(1) is to narrow the authorized scope of use of CURES data for a Research Requestor to only those educational, Peer Review, statistical, or Research Purposes specified in the Data Request Application or Written Request for Aggregated Data. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of CURES patient data. As CURES contains confidential patient information, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

The purpose of subdivision (d)(2) is to prohibit the accessing of patient information obtained from the CURES outside of the access period defined in the Research Requestor's Data Request Application. This subdivision is necessary because it protects patient privacy by ensuring CURES patient data is only used by a Research Requestor for those statutorily authorized purposes and within the timeline of the project for which it was requested.

The purpose of subdivision (d)(3) is to require a Research Requestor to provide to the Department, for review and comment, a complete draft of any report, evaluation, or other document, and the final publication, sufficiently in advance of any publication or dissemination. This subdivision is necessary to protect patient confidentiality by ensuring the Department has the opportunity to confirm that data from CURES is used only for the purposes for which it was requested and no PII is included.

The purpose of subdivision (d)(4) is to prohibit the disclosure and dissemination of CURES data or documents identifying any individual, except to the Department, absent the written consent of that identified individual, unless approved in writing by the Department. This is necessary to protect the privacy of individuals whose identifying information is contained in CURES, which includes patients, Prescribers, Out-of-State Prescribers, Pharmacists, and Out-of-State Pharmacists.

The purpose of subdivision (d)(5) is to specify that a Research Requestor must aggregate both Identified Individual-Level Data and De-Identified Individual-Level Data from CURES before publishing it. This is necessary because it ensures that the publication of the data will not create a risk of identifying individuals whose data was included within the scope of the project, thus protecting their privacy and confidentiality.

The purpose of subdivision (d)(6) is to prohibit a Research Requestor from releasing, disclosing, or disseminating CURES data if doing so could result in an individual being directly or indirectly identified from the information released. It further outlines the data elements and circumstances whose inclusion could lead to direct or indirect identification. This is necessary to protect the privacy of individuals whose information is contained in CURES.

The purpose of subdivision (d)(7) is to specify that the Department has the authority to prohibit a Research Requestor from publishing, disseminating, or disclosing any data from CURES if the Department determines that publication, dissemination, disclosure, or release of that data could compromise the identity of any individual, Prescriber, Out-of-State Prescriber, Pharmacist, or Out-of-State Pharmacist. This is necessary to protect the privacy of individuals whose identifying information is contained in CURES, which includes patients, Prescribers, Out-of-State Prescribers, Pharmacists, and Out-of-State Pharmacists.

The purpose of subdivision (d)(8) is to prohibit the sale of patient information obtained from the CURES, consistent with H&SC section 11165, subdivision (b)(2)(A). This subdivision is necessary because the sale of patient information is an activity that is not for the sole purpose of education, Peer Review, statistical analysis, or research, which is the only statutorily authorized use of CURES data for a Research Requestor. This subdivision clarifies that there is no circumstance under which a Research Requestor could sell patient data.

The purpose of subdivision (d)(9) is to specify that the transfer, disclosure, or dissemination of data from CURES to any third party is prohibited unless it is approved in writing by the Department. This subdivision is necessary to protect patient confidentiality, as well as the privacy of other individuals whose identifying information is contained in CURES, by ensuring the Department has the opportunity to confirm that data from CURES is being used only for the purposes for which it was requested and by only those entities authorized to access that data.

The purpose of subdivision (d)(10) is to specify that a court order is required before a Research Requestor can disclose or transfer data from CURES in a legal proceeding or in response to a subpoena, and that immediate notice must be given to the Department when such a request is made. This section is necessary because CURES contains confidential patient information that must be safeguarded.

The purpose of subdivision (d)(11) is to specify the notification requirement that a Research Requestor must comply with when the project specified in the Research Requestor's Data Request Application or Written Request for Aggregated Data has been completed, and to specify continuing restrictions on use or disclosure. This subdivision is necessary because it protects patient privacy by ensuring CURES patient data is only used by a Research Requestor for those statutorily authorized purposes for which it was requested and approved for use, and is not used inappropriately after a project ends. This subdivision is further necessary because it is important for Research Requestors to notify the Department when a project is completed to subsequently begin the closeout process for the project.

The purpose of subdivision (e) is to set forth the procedures that a Research Requestor must follow, and the information that a Research Requestor must submit, when requesting Aggregated Data from CURES. More specifically, the purpose of subdivision (e)(1) is to specify that the written request a Research Requestor must submit to obtain approval is referred to as a Written Request for Aggregated Data throughout these regulations. This subdivision is necessary to provide clarity as to the requirements for requesting Aggregated Data from CURES. The Department receives many requests for CURES data and there is currently confusion regarding how to submit them and what information needs to be included. This subdivision will help eliminate that confusion.

The purpose of subdivision (e)(2) is to specify that a Written Request for Aggregated Data must be submitted electronically to the Department's Research Center. The subdivision is necessary because it clarifies in what manner and to whom a Written Request for Aggregated must be submitted so that a Research Requestor has a clear understanding of how this type of CURES data may be obtained if it is being requested for those statutorily authorized purposes.

The purpose of subdivision (e)(3) is to set forth the information that must be provided by a Research Requestor in a Written Request for Aggregated Data. This subdivision is necessary because it provides clarity to the request for Aggregated Data process, setting clear guidelines for a Research Requestor to follow if they wish to access this data, as authorized by H&SC section 11165, subdivision (c)(2)(A). The Department must validate that the applicant meets the eligibility requirements for access to CURES data and has determined that this information is necessary for that validation. It provides verification that the applicant is, in fact, applying as a Research Requestor, justification as to why the Research Requestor requires access to CURES, and ensures the security of CURES data.

More specifically, the purpose of (e)(3)(G) is to require a Research Requestor to include a project outline as a part of a Written Request for Aggregated Data. This is necessary because it enables the Department to determine whether the project for which the Aggregated Data is being requested will be used to support educational, Peer Review, statistical, or Research Purposes, which are the only purposes for which Research Requestors may obtain CURES data. As such, it is necessary to protect the privacy of the individuals whose information is contained within CURES.

The purpose of subdivision (f) is to set forth the procedures that a Research Requestor must follow when requesting either Identified Individual-Level Data or De-Identified Individual-Level Data from CURES. More specifically, the purpose of subdivisions (f)(1) and (2) are to specify that the Data Request Application must be submitted electronically to the Department's Research Center before a Research Requestor can be approved to access either Identified Individual-Level Data or De-Identified Individual-Level Data from CURES. These subdivisions are necessary to provide clarity as to the requirements for requesting Identified Individual-Level Data or De-Identified Individual-Level data from CURES. The Department receives many requests for CURES data and there is currently confusion regarding how to submit them and what information needs to be included. These subdivisions will help eliminate that confusion.

The purpose of subdivision (f)(3) is to set forth the application information that the Department has determined must be furnished by a Research Requestor in order to determine whether either Identified Individual-Level Data or De-Identified Individual-Level Data from CURES may be released. This is necessary because it provides clarity to the Data Request Application process setting clear guidelines for a Research Requestor to follow if they wish to access this data, as authorized by H&SC section 11165, subdivision (c)(2)(A). The Department must validate that the applicant meets the eligibility requirements for access to CURES data and has determined that this information is necessary for that validation. It provides verification that the applicant is, in fact, applying as a Research Requestor, justification as to why the Research Requestor requires access to CURES, and ensures the security of CURES data. The name, phone number, and email address of the public agency's or research body's information security officer or IT manager is necessary to provide the Department with a point of contact in the event that there is a breach of information that may contain any data from CURES.

More specifically, the purpose of subdivision (f)(3)(I) is to require a Research Requestor to include in his or her Data Request Application a list of information pertaining to each member of the project team. This subdivision is necessary because it further ensures the confidentiality of CURES data. Presumably, any or all of the Team Members would have access to any CURES data provided to the Research Requestor, so it is necessary for the Department to ensure that it is aware of everyone with access to CURES data.

The purpose of subdivision (f)(3)(K) is to make specific the form and information that must be provided by a Research Requestor as part of the Data Request Application checklist when requesting Identified Individual-Level Data and De-Identified Individual-Level Data from CURES. This subdivision is necessary because it ensures that the Department has the information that it has deemed necessary to verify that the CURES data being requested is for the sole purpose of education, Peer Review, statistical analysis, or research, which is the only statutorily authorized use of CURES data for a Research Requestor. A detailed project outline, curriculum vitae, relevant research materials, and copy of the institutional review board approval and any other documentation, are necessary to authenticate the validity of the research project and the identity of the Research Requestor. It is further necessary to provide an Institutional Review Board approval because it is required to comply with federal regulations that govern research projects involving human subjects.

Requiring the submission of security measures the Research Requestor has in place and a completed Department data security checklist that includes the public agency's or research body's information technology contact is necessary to provide the Department with information regarding the security measures in place to protect any data received by the Research Requestor, and a point of contact in the event that there is a breach of information that may contain any data from CURES.

The purpose of (f)(3)(K)(vii) is to require a Bona Fide Researcher to include within the Data Request Application written verification of compliance with Civil Code (CC) section 1798.24, subdivision (t) or 1798.24, subdivision (b). CC section 1798.24, subdivision (t) authorizes the disclosure of personal information in a manner that would link the information to the individual to whom it pertains if that information is disclosed to a nonprofit entity conducting scientific research and the request has been approved by the Committee for the Protection of Human Subjects for the California Health and Human Services Agency or an institutional review board, as specified. CC section 1798.24, subdivision (b) authorizes a State agency to disclose personal information if it receives prior written voluntary consent of each individual to whom the information pertains, as specified. This is necessary to clarify the applicability of the specified statutory requirements and how they may be satisfied for purposes of requesting and obtaining CURES data.

Further, the purpose of (f)(3)(K)(vii)(b.)(1.) is to set forth the disclosures that must be included in each written consent obtained for the purposes of satisfying CC section 1798.24, subdivision (b). This is necessary because it ensures that the Research Requestor is fully explaining the individuals' rights and for what purpose the information will be used.

The purpose of (f)(3)(K)(vii)(b.)(2.) is to require a Research Requestor to notify the Department if an individual withdraws consent to obtain the individual's Identified Individual-Level Data from CURES. Its purpose is also to specify that a Research Requestor in this circumstance may retain any of the individual's data that was collected under the previous consent. This is necessary to provide clarity for a Research Requestor and an individual who has provided consent under CC section 1798.24, subdivision (b).

The purpose of (f)(3)(K)(viii) is to require a Research Requestor and all associated Team Members to include a certification of human subjects protection training in a Data Request Application. This is necessary because human subjects protection training is a requirement adopted from federal policy that deals with the ethics surrounding studies involving human subjects.

The purpose of subdivision (f)(4) is to require a Research Requestor whose request for access to De-Identified Individual-Level Data has been approved to submit notarized verification of identity to the Department. This is necessary to enable the Department to verify the identities of the individuals who will have access to CURES data.

The purpose of subdivision (f)(5) is to specify that a Bona Fide Researcher whose request for access to Identified Individual-Level Data has been approved may have his or her access restricted to the Department's Secure Lab. Further, the purpose is to set forth the requirement

that a Bona Fide Researcher pass a fingerprint criminal history background check through the Department prior to being granted access to the Department's Secure Lab, and set forth the method by which the Department will notify the Research Requestor of his or her approval. This is necessary to validate the identity of the Bona Fide Researcher and ensure that he or she have no disqualifying criminal history.

The purpose of subdivision (f)(6) is to set forth the requirement that a Research Requestor complete the Department's renewal process and the information that must be provided therein. This information includes changes to Team Members and associated contact information, technology or environmental changes to the location or procedures around where the CURES data is stored or accessed, the name and contact information of the public agency's or research body's information security officer or IT manager, a copy of the institutional review board approval, and a certification of human subjects protection training for all Team Members.

Subdivision (f)(6)(A) is necessary because it is vital for the Department to have up-to-date information for all individuals who have access to CURES data in order to ensure the security of the data and that the Department is able to contact those individuals regarding any statutory or regulatory updates to CURES.

Subdivision (f)(6)(B) and (f)(6)(C) are necessary because the storage and transfer of CURES data must be in compliance with the Department security policies. This includes where and how the requestor is housing the data. It is further necessary that any technology or location changes from what the Research Requestor was originally approved for be reported to the Department to ensure compliance.

Subdivision (f)(6)(D) is necessary to maintain the most up-to-date information from the Research Requestor at all times. This is also important when it affects the transfer and storage of CURES data.

Subdivision (f)(6)(E) is necessary because it allows the Department to ensure that the Research Requestor is still eligible to receive CURES data.

Subdivision (f)(6)(F) is necessary because Human Subjects Protection Training is a requirement adopted from federal policy that deals with the ethics surrounding studies involving human subjects. It is further necessary that each member of the research team complete this training if he or she will be handling data from CURES.

The purpose of subdivision (f)(7) is to require a Research Requestor to submit a certification of destruction when he or she has completed a research project or report and set forth the information that must be included therein. This is necessary in order to ensure that CURES data is used solely for the purposes for which it was approved and is destroyed after that purpose is achieved. Failure to ensure appropriate destruction of CURES data could pose an unnecessary risk to the privacy of those individuals whose information was disclosed.

## **§ 827. Individual Requestors.**

The purpose of this regulation is to specify that an individual may request a copy of his or her own CURES records and an authorized personal representative may obtain the CURES records of an individual whom he or she represents. This regulation is necessary because it clarifies the requirements and process for an individual to obtain his or her CURES records in accordance with CC section 1798.24.

More specifically, the purpose of subdivisions (a)(2)(A) and (a)(2)(B) is to set forth the requirements that must be met for an authorized personal representative to request the CURES data of an individual who is deceased, a minor, an adult who has been placed under conservatorship, or an incapacitated individual. This is necessary to ensure patient privacy and confirm that the authorized personal representative is the appropriate requestor on behalf of the individual.

The purpose of subdivision (b)(1) is to set forth the form that must be used by an individual seeking a copy of his or her own CURES data. This subdivision is necessary to provide clarity as to the requirements for requesting one's own CURES data. The Department receives many requests from individuals seeking their own CURES data and there is currently confusion regarding how to submit the requests and what information needs to be included. This subdivision will eliminate that confusion.

The purpose of subdivision (b)(2) is to set forth the form that must be used by an authorized personal representative seeking a copy of the CURES data for the individual he or she is representing. The purpose of subdivision (b)(3) is to further specify that such an authorized personal representative seeking audit history information, as specified, pertaining to the CURES data of the individual he or she is representing must specifically note that request on the request form. These subdivisions are necessary to provide clarity as to the requirements for an authorized personal representative seeking a copy of the CURES data for his or her client. The Department receives many such requests and there is currently confusion regarding how to submit the requests and what information needs to be included. These subdivisions will eliminate that confusion.

The purpose of subdivision (b)(4) is to require a completed request for an individual's own CURES data or a completed request from an authorized personal representative for the CURES data of his or her client to be submitted in hard copy via mail. This subdivision is necessary to help ensure the validity of the notarization which helps to secure patient privacy.

#### **§ 828. Information Exchange Web Service.**

The purpose of subdivision (a) is to limit those entities operating a HIT System who may receive CURES data through the Information Exchange Web Service to covered entities or business associates. This subdivision is necessary to ensure that patient information accessed or transferred by an entity operating a HIT System is governed by HIPAA. It is further necessary because the Department may not impose additional burdens upon an entity operating a HIT System that is a covered entity or business associate.

The purpose of subdivision (b) is to make specific the procedures that must be taken by an entity operating a HIT System prior to integration with the Information Exchange Web Service being permitted. This subdivision is necessary because it provides clarity to the requirements that the Department has set for an entity seeking access to CURES pursuant to the H&SC section 11165.1, subdivision (a)(1)(E) and protects the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

More specifically, the purpose of (b)(1) is to title the application package for requesting system integration with CURES the Integration Application Package. This subdivision is necessary because it clarifies the meaning of a title used throughout this section.

The purpose of (b)(2) is to set forth the requirement that a hard copy of an Integration Application Package be submitted by mail. This is necessary for the Department to authenticate that a received Integration Application Package is an original package that contains all necessary documents.

The purpose (b)(3) is to make specific the information that must be included within an Integration Application Package, which includes a signed MOU, a completed Onboarding Questionnaire, and a Connectivity Fee check made payable to the Department. This is necessary to clarify H&SC section 11165, subdivisions (a)(1)(D) through (a)(1)(I). The statute specifies that a HIT System is required to enter into an MOU with the DOJ and pay a reasonable fee for effectuating integration with CURES; however, further clarification is needed as to how and when to submit the items.

The purpose of (b)(4) is to make specific the technical specifications that an entity operating a HIT System must comply with, by incorporating the CURES Information Exchange Web Service Overview by reference. This is necessary because it ensures that a HIT System understands and meets the technical and security standards that the Department has determined are necessary to ensure the protection of CURES data being accessed.

The purpose of subdivision (c) is to set forth the requirement for use and access that an entity operating a HIT System must comply with when using the Information Exchange Web Service. This subdivision is necessary because it provides clarity to the requirements that the Department has set for an entity when accessing and using CURES pursuant to the H&SC section 11165.1, subdivision (a)(1)(E) and protects the privacy of those California residents whose information is contained within CURES by narrowing the scope of, and conditions for, access and use of CURES data.

In particular, the purpose of subdivision (c)(1) is to prohibit a HIT System from using or disclosing CURES data for any purpose other than delivering the data to the authorized Prescriber or Pharmacist who initiated the request, or on whose behalf a HIT System initiated the request, or performing data processing activities that may be necessary to enable the delivery. This subdivision is necessary because it clarifies the certification required by H&SC section 11165.1, subdivision (a)(1)(E)(i).

The purpose of subdivision (c)(2) is to require a HIT System to authenticate the identity of the authorized Prescriber or Pharmacist initiating a request, or on whose behalf the HIT System is initiating a request, to the Information Exchange Web Service. This subdivision is necessary because it clarifies the certification required by H&SC section 11165.1, subdivision (a)(1)(E)(ii). The statute requires a HIT System to certify that it will authenticate the identity of an authorized Health Care Practitioner or Pharmacist initiating queries to CURES; however, it does not expressly require a HIT System to do so.

The purpose of subdivision (c)(3) is stipulate the information that must be submitted with each request for a Patient Activity Report and to make specific the H&SC section 11165.1, subdivision (a)(1)(E)(ii) requirement that a HIT System must authenticate the identity of a User initiating requests, or a HIT System initiating requests on the User's behalf, to the CURES database by detailing the Prescriber or Pharmacist information that must be submitted for each request. H&SC section 11165.1, subdivision (a)(1)(E)(ii) stipulates that the date and time of a request, the patient's first and last name, the patient's date of birth, and the identification of the User for whom the system is making the request must be submitted by a HIT System as part of this request. This subdivision is necessary because in setting forth these requirements, it additionally requires the Search Period to be submitted and clarifies for an entity operating a HIT System that authentication of the identity of the authorized Prescriber or Pharmacist requires submission of the first and last name of the Prescriber or Pharmacist and their DEA Number or license number, respectively. This section is also necessary because it clarifies that only one authorized Prescriber or Pharmacist may be identified for each request.

The purpose of subdivision (c)(4) is to specify that an automated request to CURES on behalf of a Prescriber or Pharmacist must conform to the access restrictions of that User type. This subdivision is necessary to ensure that the scope of information that a Prescriber-User or Pharmacist-User may access through the Information Exchange Web Service is still limited to only that information which the Department has determined is authorized by statute and is necessary to assist a Prescriber-User or Pharmacist-User in appropriately prescribing to a patient under their care.

The purpose of subdivision (c)(5) is to set forth the View Notification requirement with which a HIT System must comply that confirms receipt of the data from CURES by the authorized Prescriber or Pharmacist who requested it. This subdivision is necessary because it ensures the security of CURES data by putting a process in place that verifies that the authorized requestor is also the recipient of the responsive patient information, and it clarifies that a requestor receiving and opening responsive data constitutes receipt of CURES data. This subdivision is also necessary because it creates an audit trail to assist Regulatory Agencies in ensuring that their licensees are adhering to the requirement to consult CURES, as outlined in H&SC section 11165.4, subdivision(a).

The purpose of subdivision (c)(6) is to make specific the H&SC section 11165, subdivision (a)(1)(E)(iii) requirement that a HIT System comply with applicable patient privacy and information security requirements of State and federal law. This subdivision is necessary because it clarifies that the HIPAA Regulations fall within the scope of this requirement; thus, it ensures that patient privacy laws are followed when CURES data is accessed by a HIT System.

The purpose of subdivision (c)(7) is to make specific the H&SC section 11165, subdivision (a)(1)(E)(iv) requirement that an entity must enter into an MOU with the Department that solely addresses the technical specifications of the HIT System, by requiring that an entity maintain an active MOU with the Department. This subdivision is necessary to specify that only an entity operating a HIT System who has an active MOU with the Department may remain integrated with the Information Exchange Web Service.

### **ECONOMIC IMPACT ASSESSMENT**

Because CURES and the reporting mandates are engendered by the authorizing statutes, not the proposed regulations, their economic impact is appropriately excluded from this assessment. The economic impacts relevant to this assessment are exclusively those which would not occur but for the proposed regulations.

#### **Creation or Elimination of Jobs within the State of California**

The Department has determined that these regulations will not have a significant impact on the creation or elimination of jobs within the State of California. This determination is based on the fact that this proposed action only codifies requirements pertaining to existing licensed Health Care Practitioners and Pharmacists. For example, it is possible that Practitioners or Pharmacists could choose to contract with a HIT System to effectuate any modifications necessary to meet the requirements for integration with CURES; however, it is not possible for the Department to anticipate how many practitioners or pharmacists would choose to do so or the extent of the modifications required.

#### **Creation of New Businesses or the Elimination of Existing Businesses within the State of California**

For the reason identified above, the Department determined that these regulations will not create new businesses or eliminate existing businesses within the State of California.

#### **Expansion of Businesses Currently Doing Business within the State of California**

For the reason identified above, the Department determined that these regulations will not expand existing businesses within the State of California.

#### **Benefits to the Public**

The Department has determined that the proposed regulatory action will protect the privacy of California residents by establishing policies and responsibilities for those who access and use CURES, or data from CURES. This will enable the Department to ensure that all Users are adhering to policies and procedures necessary to protect the information contained in CURES.

The benefits of the proposed regulations are further detailed in the “BENEFITS” section of this document, located on page one.

**TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR DOCUMENTS.**

None.

**EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS**

The Department has determined that these regulations would not have a significant, statewide, adverse economic impact on businesses because these regulations only codify requirements pertaining to existing licensed Health Care Practitioners and Pharmacists. HIT Systems and interstate data sharing hubs currently doing business within the State may provide new services or generate additional revenue as a result of these regulations.

The Department analyzed instances of prior stakeholder engagement and recent historical data and trends to determine projected economic impacts that businesses may incur to comply with this regulation over its lifetime. Impacts on certain businesses were considered, but ultimately excluded from the economic impact analysis because they were determined to be imposed by statute and not these regulations. It was therefore determined that the regulations have no economic impact on the following businesses: hospitals, pharmacies, veterinary practices, dental practices, and other health care institutions. This is because the isolated economic impacts to these businesses that are attributable to this regulation, rather than the underlying statutes, are nominal, if existent. If a hospital was determined to have a measureable economic impact from this regulation, it was captured and quantified as a HIT System for purposes of these calculations.

The Department also considered the economic impact associated with the Connectivity Fee for a HIT System. However, this impact would not result in an adverse economic impact because the cost of this one-time fee is nominal in proportion to the scale of businesses engaging with this regulation.

**REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES**

No other reasonable alternatives were presented to, or considered by, the Department that would be either more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome.

The Department made every effort to consider performance standards where possible. The areas where specific actions are prescribed are necessary to ensure consistency, security of patient information, and adherence to statute.

**DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS**

The Department determines that these regulations are not duplicative, nor do they pose a conflict with federal regulations.