

CALIFORNIA DEPARTMENT OF JUSTICE

TITLE 11. LAW

DIVISION 1. ATTORNEY GENERAL

**CHAPTER 8.5. CONTROLLED SUBSTANCE UTILIZATION REVIEW AND
EVALUATION SYSTEM (CURES)**

INITIAL STATEMENT OF REASONS

PROBLEM STATEMENT

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

Health and Safety Code (HSC) section 11165, subdivision (a) requires the Department of Justice (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 HSC 11165.1(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 HSC 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” or “IEWS.”

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

AB 528 (Statutes of 2019, Chapter 677), chaptered on October 9, 2019, and codified in HSC 11165, 11165.1, and 11165.4, requires the Department to permit a licensed physician and surgeon who does not hold a DEA Registration Certificate to submit an application to obtain approval to electronically access information regarding the controlled substance history of a patient under their care based on data contained in the CURES PDMP, which upon approval, shall be released to the physician and surgeon or their delegate. Additionally, upon approval for access to CURES, AB 528 requires the Department to release to the practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner's care based on data contained in CURES. These proposed regulations set forth the requirements and procedures surrounding the AB 528 addition of non-DEA licensed physicians and surgeons and the expansion of delegate functionality.

BENEFITS ANTICIPATED FROM REGULATORY ACTION

The Department anticipates that these regulations will benefit the health, welfare, and safety of California residents because they contribute to safe prescribing and dispensing of Controlled Substances, and protect the security of the data contained within CURES. By clearly detailing the requirements for access and use for each User type including Delegates and Non-DEA Practitioners, these regulations increase transparency, empower Users to confidently access the system as a tool to facilitate care and control the Diversion and Resultant Abuse of Controlled Substances, and ensure that the information contained in CURES is used only for statutorily-authorized purposes. Furthermore, these regulations will improve researcher access to CURES data while maintaining security of the data.

These regulations will provide clarity as to who exactly is eligible for access to CURES and the data contained therein, and supplement 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.

SPECIFIC PURPOSE AND NECESSITY OF EACH AMENDMENT

Article 1. Chapter Definitions

§ 820. Definitions.

New subdivision (c) defines "Animal Patient Entity." This definition is necessary to clarify an intermediary step in the process for generating a Patient Activity Report of an animal patient, because a single animal patient may be associated with multiple Animal Patient Entities due to variations in reported animal owner first name, animal owner last name, animal owner date of birth, and animal owner address. It is also necessary to assist in distinguishing the type of List of Patients and Patient Activity Reports that are accessible by veterinarian Prescriber-Users as provided in proposed section 821.3, subdivision (a). The addition of this definition requires the subsequent renumbering of subdivisions (d)-(hhhh) in this section.

Subdivision (e) (formerly subdivision (d)) was amended to include the applicable citation in HSC 11058 for Schedule V Controlled Substances. This amendment is necessary because it

distinguishes between specific controlled substances versus the more generalized definition of Controlled Substances.

Subdivision (f) (formerly subdivision (e)) was amended to add Non-DEA Practitioner and Delegate to the list of account types that may apply for access to CURES. This amendment is necessary to provide clarity surrounding the information required to be provided by an applicant as a part of registration for access to CURES. Additionally, this amendment is necessary to include the two new user roles authorized to register for access to CURES under AB 528.

New subdivision (g) establishes that “Authorizing User” means any Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User who delegates authority to a Delegate to access data in CURES on behalf of that Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User. This definition is necessary to describe which Users may delegate access to CURES. This definition was added as a result of AB 528 to consolidate Prescriber-Users, Non-DEA Practitioner-Users, and Pharmacist-Users under a single term, as they relate to establishing Delegate Agreements and Delegate associations.

New subdivision (h) establishes that “Authorized Health Care Provider” means any individual who qualifies as a covered health care provider as defined in 45 Code of Federal Regulations part 162.103. This definition was added to provide clarity and consistency between these regulations and the Code of Federal Regulations. This definition is necessary to specify who may qualify as a Delegate under section 824.1, subdivision (a).

New subdivision (k) has the meaning set forth in 45 Code of Federal Regulations part 160.103. This definition was added to provide clarity and consistency between these regulations and the Code of Federal Regulations. This definition is necessary to specify the requirements around an entity operating a HIT System.

Subdivision (l) (formerly subdivision (h)) was amended to replace “Licensing Agency” with “Out-of-State Licensing Board.” This amendment is necessary as the previously defined term “Licensing Agency” was removed to prevent duplication of the defined terms “Licensing Board” and “Out-of-State Licensing Board,” and to clarify what information is required to be submitted for this field as a part of registration, which will reduce the chance of registration denial.

New subdivision (p) establishes that “Covered Entity” has the meaning set forth in 45 Code of Federal Regulations part 160.103. This definition was added to provide clarity and consistency between these regulations and the Code of Federal Regulations. This definition is necessary to specify who may qualify as a Delegate under proposed section 824.1, subdivision (a), and to specify the requirements for an entity operating a HIT System.

Subdivision (u) (formerly subdivision (p)) was amended to replace “Controlled Substances” with “controlled substances.” This amendment is necessary to remove the defined term and instead reference the more generalized term of controlled substances.

Subdivision (w) (formerly subdivision (r)) was amended to establish that “Delegate” means an individual who meets the eligibility requirements of section 824.1, subdivision (a), has entered

into an agreement that meets the requirements of section 824.2, subdivision (a), and is at least 18 years of age. This amendment is necessary because the eligibility requirements of Delegates have changed pursuant to AB 528.

New subdivision (x) establishes that “Delegate Agreement” means an agreement between a Delegate and Authorizing User that meets the requirements of section 824.2. This definition is necessary because it specifies where in the regulations the requirements of a Delegate Agreement between an Authorizing User and a Delegate may be found, in order for a Delegate to be authorized to access data in CURES.

New subdivision (y) establishes that “Delegate Audit Report” means a report generated by CURES of the patient activity searches conducted by an individual who is or was a Delegate-User of an Authorizing User. This definition is necessary to describe the data that is included in the Delegate Audit Report accessible in CURES by an Authorizing User, and a Regulatory Agency Official, including a Regulatory Agency-User, as specified in articles 2.4 and 2.6.

New subdivision (z) establishes that “Delegate-User” means any Delegate who is registered to access CURES on behalf of an Authorizing User. This definition is necessary and was included in these regulations so that a Delegate-User could be distinguished from other types of Users, and the access and data use rules that apply to each.

Subdivision (ee) (formerly subdivision (w)) was amended to exclude a Non-DEA Practitioner from the list of licensees who are authorized under HSC 11150 to prescribe, order, administer, furnish, or dispense Controlled Substances. This amendment is necessary as the term Health Care Practitioner assists in defining Prescriber in subdivision (kkk).

Subdivision (kk) (formerly subdivision (cc)) was amended to replace “Controlled Substances” with “controlled substances.” This amendment is necessary to remove the defined term and instead reference the more generalized term of controlled substances.

New subdivision (mm) defines “Interstate Non-DEA Practitioner.” This definition is necessary to distinguish out-of-state individuals who hold a license equivalent to a Non-DEA Practitioner, and who are in good standing with and authorized to access the PDMP of a state other than California.

Subdivision (nn) (formerly subdivision (ee)) and subdivision (oo) (formerly subdivision (ff)) were non-substantively amended to remove a comma after the defined terms. These amendments are necessary to provide clarity and consistency.

New subdivision (pp) establishes that “Interstate-User” means an Interstate Prescriber, Interstate Non-DEA Practitioner, or Interstate Pharmacist. This definition is necessary because it encompasses all individuals who may request data from CURES from a PDMP, of a state other than California. Moreover, it consolidates the multiple types of individuals outside of California who may access CURES into one word, “Interstate-User,” so that the regulations using this term will be simpler to follow.

Subdivision (qq) (formerly subdivision (gg)) was non-substantively amended to replace “any” with “an.” This amendment is necessary to be grammatically correct.

Former subdivision (jj) was removed, as the Department replaced all references of this term throughout the regulations with “Licensing Board” or “Out-of-State Licensing Board.” This amendment is necessary as this term is no longer applicable with these regulations because the Department more clearly aligned the terms as they apply to California licensed applicants and out-of-state applicants.

Subdivision (uu) (formerly subdivision (ll)) was amended to remove a defined term and instead reference the more generalized term of prescriber. The subdivision was also amended to include animal patient information. The changes are necessary to assist in distinguishing defined terms and to assist in distinguishing the type of List of Patients that are accessible by veterinarian Prescriber-Users as provided in proposed section 821.3, subdivision (a).

New subdivision (vv) establishes that “Non-DEA Practitioner” means a California licensee who holds a physician’s and surgeon’s license and is engaged in the professional practice authorized by that license under the jurisdiction of the applicable Licensing Board, and who does not have a DEA Registration Certificate. This definition is necessary to clarify who qualifies as a Non-DEA Practitioner because this is a new User type in CURES added by AB 528 and therefore this term is used throughout the regulations.

New subdivision (ww) establishes that “Non-DEA Practitioner-User” means a Non-DEA Practitioner who is registered for access to CURES. This definition is necessary to distinguish a Non-DEA Practitioner-User from other types of Users, and the access and data use rules that apply to each.

Subdivision (xx) (formerly subdivision (mm)) was amended to remove the defined term “Licensing Agency” and instead include a licensing agency outside of California or a board or committee established by a licensing agency outside of California. This amendment 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 (yy) (formerly subdivision (nn)) was amended to replace the defined term “Licensing Agency” with “Out-of-State Licensing Board.” This amendment is necessary to differentiate between a Pharmacist and an Out-of-State Pharmacist because both types of applicants have different registration requirements and procedures. This subdivision was also non-substantively amended to replace “any” with “a” to be grammatically correct.

Subdivision (zz) (formerly subdivision (oo)) was amended to replace the defined term “Licensing Agency” with “Out-of-State Licensing Board.” This amendment is necessary to differentiate between a Prescriber and an Out-of-State Prescriber because both types of applicants have different registration requirements and procedures. This subdivision was also non-substantively amended to replace “any” with “a” to be grammatically correct.

Subdivision (aaa) (formerly subdivision (pp)) defines “Patient Activity Report” and was amended to more accurately describe the Controlled Substance history information that is available in a Patient Activity Report generated by CURES. The definition was also amended to include animal patient information. These changes were necessary to assist in distinguishing the information available and the type of Patient Activity Reports that are accessible by veterinarian Prescriber-Users as described in proposed section 821.3, subdivision (a).

Subdivision (bbb) (formerly subdivision (qq)) was amended to add patient gender to the list of information included in a unique patient profile. This amendment is necessary to more accurately describe the data that is included in a Patient Entity in CURES and accessible to specified Users. 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. Additionally, this subdivision was non-substantively amended to replace “patient information” with “patient data.”

Subdivision (ccc) (formerly subdivision (rr)) was amended to include Animal Patient Entities in the list of information returned to a User when that User submits the search criteria to initiate a Patient Activity Report. The change is necessary to assist in distinguishing the type of Patient Activity Reports that are accessible by veterinarian Prescriber-Users as provided in proposed section 821.3, subdivision (a).

New subdivision (hhh) defines “Pharmacist Serialized Prescription Form Report.” This report is available to Pharmacist-Users under proposed section 823.3. The purpose of the report is to notify Pharmacist-Users of the status of a particular prescription form serial number. Serial numbers are used on prescriptions to track the distribution of Controlled Substances. Including this definition is necessary, because allowing this type of report will assist Pharmacist-Users in preventing Diversion and Resultant Abuse.

New subdivision (iii) (formerly subdivision (xx)) was a preexisting definition and was non-substantively moved to be in correct alphabetical order. This addition is necessary to ensure the definitions are in correct alphabetical order. Additionally, this definition was non-substantively amended to remove “any” and replaced it with “a.” This amendment is necessary to directly point at one specific pharmacist in the definition, rather than any type of pharmacist.

Subdivision (jjj) (formerly subdivision (ww)) defines “Pharmacy History Report” and was amended to more accurately describe the Controlled Substance dispensation history information available in a Pharmacy History Report generated by CURES, which may be accessed by Regulatory Agency Officials and Law Enforcement Officials. This change was necessary because describing the dispensation history information available in these reports assists in enforcing Controlled Substance laws and preventing Diversion and Resultant Abuse.

Former subdivision (xx) was non-substantively moved to be new subdivision (iii). This amendment is necessary to ensure the definitions are in correct alphabetical order.

Subdivision (kkk) (formerly subdivision (yy)) was amended to establish that “Prescriber” means a Health Care Practitioner licensed in California who possesses a valid DEA Registration

Certificate. This amendment is necessary to distinguish Prescribers from practitioners who do not possess a valid DEA Registration.

Subdivision (*lll*) (formerly subdivision (*zz*)) defines Prescriber History Report and was amended to more accurately describe the Controlled Substance prescribing history information available in a Prescriber History Report generated by CURES, which may be accessed by Regulatory Agency Officials and Law Enforcement Officials. This change was necessary because describing the prescribing history information available in these reports assists in enforcing Controlled Substance laws and preventing Diversion and Resultant Abuse.

Subdivision (*mmm*) (formerly subdivision (*aaa*)) was non-substantively amended to replace “any” with “a.” This amendment is necessary to be grammatically correct.

New subdivision (*nnn*) establishes that “Prescription History Report” means a Prescriber History Report, Pharmacy History Report, or Serialized Prescription History Report. This definition is necessary because it encompasses three reports accessible in CURES by a Regulatory Agency Official, including a Regulatory Agency-User, and a Law Enforcement Official, including a Law Enforcement-User. Moreover, it consolidates the three types of reports into one word, “Prescription History Report,” so that the regulations using this term are simpler to follow.

Subdivision (*ooo*) (formerly subdivision (*nnn*)) was amended to correct the name of the report from “Prescription Theft or Loss Report” to “Prescription Form Theft or Loss Report.” This amendment is necessary to specify that this report is for lost or stolen prescription forms and not individual prescriptions.

New subdivision (*ppp*) establishes that “Protected Health Information” has the meaning set forth in 45 Code of Federal Regulations part 160.103. This definition is necessary to define the information a Workforce Member needs to carry out the Workforce Member’s duty as part of the Delegate eligibility requirements and to provide clarity and consistency between these regulations and the Code of Federal Regulations.

Subdivision (*uuu*) (formerly subdivision (*ggg*)) defines Search Period and was amended to apply to four new reports that are now available and may be generated by CURES. This amendment is necessary because a Search Period must be entered before the Department can generate a report containing data from CURES.

Subdivision (*vvv*) (formerly subdivision (*hhh*)) was amended to remove “when the User resets the User’s Compliant Password.” This amendment is necessary because Security Question Answers are also required to be supplied by an applicant during CURES registration.

New subdivision (*www*) establishes that “Serialized Prescription Form Report” means a report generated by CURES that a Regulatory Agency-User or Law Enforcement-User may initiate to determine whether a prescription form serial number has been reported to CURES as lost or stolen, and whether the associated prescription form information has been reported to CURES by the applicable security printer. This change was necessary because these reports are used to enforce Controlled Substance laws and prevent Diversion and Resultant Abuse. They provide an

additional safeguard against fraudulent prescription forms and the improper dispensing of Controlled Substances.

New subdivision (xxx) establishes that “Serialized Prescription History Report” means a report generated by CURES of the serialized prescription order information associated with specified prescription form serial numbers, as reported to CURES PDMP. This change was necessary because these reports are used to enforce Controlled Substance laws and prevent Diversion and Resultant Abuse.

Subdivision (zzz) (formerly subdivision (jjj)) was amended to replace “Licensing Agency” with “Licensing Board or Out-of-State Licensing Board.” This amendment is necessary to differentiate a license number issued by a License Board or an Out-of-State Licensing Board.

Subdivision (aaaa) (formerly subdivision (kkk)) was non-substantively amended to replace “any” with “an.” This amendment is necessary to be grammatically correct.

Subdivision (dddd) (formerly subdivision (nnn)) was amended to add “Under Their Care.” This amendment is necessary to better align this definition with HSC 11165.1. This subdivision was also non-substantively amended to replace “means” with “mean.” This amendment is necessary to be grammatically correct.

Subdivision (eeee) (formerly subdivision (ooo)) was amended to replace “Interstate Prescriber” and “Interstate Pharmacist” with a new defined term “Interstate-User,” and to add “Non-DEA Practitioner-User” to the list of individuals a Patient can be “Under the Care of.” This addition is necessary because Non-DEA Practitioner-Users are a new type of User under AB 528, and the regulation will describe when a patient is “under the care” of the new User. This subdivision was also amended to replace “by” with “in” before “45 Code of Federal Regulations” to be grammatically correct.

Subdivision (ffff) (formerly subdivision (ppp)) was amended to add “Non-DEA Practitioner-User” as a type of CURES registrant and replace “Delegate” with “Delegate-User.” These amendments are necessary to include a new user role in CURES and amend an existing role in CURES. This subdivision was also non-substantively amended to replace “any” with “a” to be grammatically correct.

Subdivision (gggg) (formerly subdivision (qqq)) was amended to replace the defined term “User Search” with “User Profile Details Report.” This change was necessary to use the term report throughout the regulations. Searches are not what are useful, rather reports and the information in those reports are useful, because these reports are used to enforce Controlled Substance laws and prevent Diversion and Resultant Abuse.

New subdivision (hhhh) establishes that “Veterinary Workforce Member” means an employee, volunteer, trainee, or other person whose conduct, in the performance of work for a veterinarian who is a Prescriber-User, is under the direct control of that Prescriber-User. This definition is necessary to define a group of individuals as part of the Delegate eligibility requirements.

New subdivision (jjjj) establishes that “Workforce Member” means an employee, volunteer, trainee, or other person whose conduct, in the performance of work for an Authorized Health Care Provider, is under the direct control of that Authorized Health Care Provider. This definition is necessary to define a group of individuals as part of the Delegate eligibility requirements.

Article 2.1 Access and Use by Prescribers and Out-of-State Prescribers

§ 821.1. Eligibility for Access to CURES.

New subdivision (d) was added to establish that an individual must not access CURES if they no longer meet the eligibility requirements for access. This subdivision is 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.

New subdivision (e) was added to establish that an individual must not access CURES if they no longer meet the eligibility requirements for access and require a notification to CURES PDMP. This subdivision is necessary because granting access to Out-of-State 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 notification requirement is necessary because account cancellation is not an automated process for Out-of-State Prescribers so the CURES PDMP must be notified in order to perform an account update.

§ 821.2. Procedures to Register for Access to CURES.

Subdivision (a) was amended to remove “patient information from.” This amendment is necessary to clarify that a Prescriber Registration Application must be used to obtain approval to access any information in CURES, not just patient information.

Subdivision (c) was amended to reorder and restate the procedures for registration that must be fulfilled by a Prescriber or Out-of-State Prescriber before they may be permitted access to CURES and to reorder and restate the application information that the Department has determined must be furnished by an applicant. The application will now allow registrants to designate whether their email address or phone number may be shared in CURES. These amendments are necessary because the information on the application has been reordered. These amendments are further necessary to allow the Department to obtain consent from registrants before their information is shared in CURES with other registrants to assist in patient treatment. This amendment is further necessary because the Department combined the registration application process for Prescribers and Out-of-State Prescribers. Proposed subdivisions (c)(3) and (c)(4) are a restatement of existing subdivisions (d)(2) and (d)(3).

Former subdivision (d) was removed and incorporated into subdivision (c) because the Department combined the registration application process for Prescribers and Out-of-State Prescribers.

Former subdivision (e) was removed because it is no longer part of the first-time log in process for Prescribers and Out-of-State Prescribers. This amendment is necessary because the information previously required on the first-time log in by a user is now included in the registration application.

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

Subdivision (a) was amended to remove and replace “access patient information in CURES through both.” This amendment is necessary because a Prescriber-User has access to other information in CURES, not just patient information.

New subdivisions (a)(1)(A) and (a)(2)(A) were added to clarify that a Prescriber-User who is a veterinarian may only access reports containing animal patient data. 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 data in the context of veterinary care constitutes as 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 further 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. These subdivisions are further necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

New subdivision (a)(3) was added to include a new report Prescriber-Users have available in CURES. Under AB 528, a Delegate will be authorized to access Patient Activity Reports on behalf of their Authorizing User. This subdivision is further necessary to provide a report to an Authorizing User to ensure that information contained within CURES by their Delegate is used solely for the purposes for which it is intended.

Subdivision (b) was amended to replace “patient information” with “data in CURES.” This amendment is necessary because Prescriber-Users have access to more than just patient information. Patient Activity Reports also contain prescriber and pharmacy information.

§ 821.4. Restrictions on Accessing Data in CURES.

This section title was amended to replace “Patient Information” with “Data.” This amendment is necessary because CURES data includes more than “patient information.”

Subdivision (a) was amended to replace “patient information to” with “data in CURES for one or more of the following authorized purposes.” This amendment is necessary to clarify the information available to Prescriber-Users.

Subdivision (a)(1) was amended to replace “treat” with “[t]o obtain the Controlled Substance history of.” This amendment is necessary to better align with the language used in HSC 11165.1. The Department also non-substantively amended subdivision (a)(1)(A) to replace

subdivision (ooo)(1)(B) with subdivision (eeee)(1)(B) to reference the correct citation in the regulations.

Subdivision (a)(1)(A) was amended to replace “information” with “data” for consistency. This subdivision was also amended to replace numerical “7” with the word “seven” to better align with the California Style Manual. Additionally, this subdivision was non-substantively amended to replace subdivision (ooo)(1)(B) with subdivision (eeee)(1)(B) to reference the correct citation in the regulations.

Subdivision (a)(2) was amended to replace “[c]omply” with “[t]o comply” and to add “Prescriber-User’s.” These amendments are necessary to keep parallel construction in the regulation and to more accurately describe whose duty it is to consult CURES under HSC 11165.4.

Subdivision (a)(3) was amended to replace “[o]btain” with “[t]o obtain.” This amendment is necessary to keep parallel construction in the regulation.

New subdivision (a)(4) was added to include a new report available to Prescriber-Users in CURES and to allow a Prescriber-User to access CURES to obtain an audit on the Prescriber-User’s Delegate. This subdivision is necessary to clarify when a Prescriber-User may audit an individual who is or was an associated Delegate-User, and to ensure that information contained within CURES by their Delegate is used solely for the purposes for which it is intended.

Former subdivision (b) was removed and incorporated into section 821.3, subdivision (a), to clarify that a Prescriber-User who is a veterinarian may only access animal patient data. 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 data 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 further 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.

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

This section title was amended to replace “Patient Information” with “Data.” This amendment is necessary because CURES data includes other types of protected information, not just “patient information.”

Subdivision (a) was amended to replace all references of “patient information” with “data.” This amendment is necessary Prescriber-Users may access other types of CURES data, not just patient information. Subdivision (a)(1) was also amended to reference the relevant citation in the regulations regarding the Restrictions on Accessing Data in CURES. Referencing section 821.4 in subdivision (a)(1) is necessary because it protects patient privacy by narrowing the scope of use and disclosure of data from CURES and provides references to applicable federal and State and privacy, confidentiality, and security laws and regulations with which a Prescriber-User must

comply. CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

New subdivision (b) was added to explain that a Prescriber-User is authorized to disclose or transfer CURES data to a Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist so long as all of the specified requirements are met, and to that Prescriber-User's Licensing Board to document compliance with the law. This change is necessary to clarify that subdivision (a)(1) does not prohibit a health care registrant from disclosing CURES data to another health care registrant, provided that the patient whose information being disclosed is Under the Care of both registrants, the transfer of the data complies with all applicable federal and State laws and regulations, and the data being transferred was properly obtained. The addition of this subdivision requires the subsequent renumbering of subdivision (c) in this section.

Subdivision (c) (formerly subdivision (b)) was amended to replace "patient information" with "data." This amendment is necessary to because Prescriber-Users have access to more than just patient information. Patient Activity Reports also contain prescriber and pharmacy information.

Former subdivision (c) was removed and added to subdivision (b) to ensure that data obtained from CURES is disclosed or transferred under the authorized purposes specified in these regulations. This amendment is necessary because CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

§ 821.6. Procedures for Use of CURES.

Subdivision (a) was amended to replace "patient information" with "data." This amendment is necessary because Prescriber-Users have access to other types of protected information in CURES, not just patient information.

Subdivision (c)(3) requires Prescriber-Users to update specified information about themselves annually. 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. This subdivision was amended to replace the itemized list of specific contact information that must be updated with a reference to the Prescriber-User's application information in section 821.2, subdivision (c)(2). This change is necessary in the event that other types of Prescriber-User information, not just contact information, requires updating.

Subdivision (d) explains 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. Subdivision (d)(2)(A)1.a. was added to clarify that a Prescriber-User who is a veterinarian may only access animal patient data. However, the Prescriber-User must provide the search criteria matching the patient first name, patient last name, and date of birth of the

Ultimate User of the animal patient. 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 data 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 further 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. This subdivision is further necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended. Furthermore, this subdivision was amended to replace "includes" with "include." This amendment is necessary to be grammatically correct.

New subdivision (d)(3), including (d)(3)(A)2.a., was added to explain the procedures that a Prescriber-User must follow in order to request an interstate Patient Activity Report. The purpose of subdivision (d)(3) is to specify that an interstate Patient Activity Report is available in the Web-Based Application. This is necessary because Prescriber-Users may access patient data in more than one environment; however, an interstate Patient Activity Report is only available in the Web-Based Application. This subdivision is further necessary to specify that a Prescriber-User may request data from a state or states other than California. Furthermore, this subdivision was added to explain the procedures that a Prescriber-User must follow in order to request an interstate Patient Activity Report in the Web-Based Application, including the search criteria that must be provided.

Subdivision (d)(3)(B) 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 an interstate Patient Activity Report. Subdivision (d)(3)(C) 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 an interstate Patient Activity Report. The authority to generate an interstate Patient Activity Report is provided in HSC 11165(h). The addition of this subdivision requires the subsequent renumbering of subdivision (d)(4) in this section.

Subdivision (d)(4) (formerly subdivision (d)(3)) was non-substantively amended to replace section 828.3 with section 830.3 to reference the correct citation in the regulations.

Subdivision (d)(4)(A) was amended to replace "includes" with "include." This amendment is necessary to be grammatically correct

Subdivision (d)(4)(B) was removed because the language was redundant in these regulations. Prescriber-Users who request a Patient Activity Report in the Information Exchange Web Service already agree to the Terms and Conditions of CURES through a memorandum of understanding previously entered into, and do not need to do so when submitting the request.

Subdivision (f) was amended to revise the fields that must be completed in a Prescription Form Theft or Loss Report. This subdivision implements HSC 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. The added fields are necessary to give a more accurate and detailed picture of a loss or theft, which will assist law enforcement and help prevent Diversion and Resultant Abuse. Furthermore, this subdivision was amended to correct the name of the report from “Prescription Theft or Loss Report” to “Prescription Form Theft or Loss Report.” This amendment is necessary to specify that this report is for lost or stolen prescription forms and not individual prescriptions.

§ 821.7. Delegate Use of CURES.

The Department removed this section in its entirety. This amendment is necessary because AB 528 created an expanded Delegate-User role, which is outlined in Article 2.4 Access and Use by Delegates.

Article 2.2 Access and Use by Non-DEA Practitioners

The addition of this article requires the subsequent renumbering of these regulations.

The purpose of sections 822.1 through 822.6 are to set forth who within the licensed physician and surgeon 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.

Article 2.2 is very similar to Article 2.1 governing access and use of CURES data by Prescriber-Users, and Article 2.3 governing access and use of CURES data by Pharmacist-Users.

§ 822.1. Eligibility for Access to CURES.

The addition of this section requires the subsequent renumbering of these regulations.

New subdivision (a) was added to limit CURES access to Non-DEA Practitioners who practice within the state and are permitted CURES access by their Licensing Board. This subdivision is necessary because there is currently confusion about who within the licensed physician and surgeon community may access CURES. This subdivision is further necessary because granting access to Non-DEA Practitioners who do not meet the eligibility criteria would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

New subdivision (b) was added to establish that an individual must not access CURES if they no longer meet the eligibility requirements for access. This subdivision is necessary because granting access to Non-DEA Practitioners who do not meet the eligibility criteria would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

§ 822.2. Procedures to Register for Access to CURES.

New subdivision (a) was added to set forth the procedures for registration that must be fulfilled by a Non-DEA Practitioner before they may be permitted access to CURES and to specify the application information that the Department has determined must be furnished by an applicant. This new subdivision is necessary because AB 528 added a new type of User who may access CURES. The Non-DEA Practitioner Registration Application is identical to the Prescriber Registration Application as described in proposed section 821.2, except that it does not require the applicant to provide a DEA number. Upon approval, the Department shall release to the physician and surgeon or their delegate the electronic history of Controlled Substances dispensed to a patient under their care based on data contained in the CURES PDMP.

New subdivision (b) was added to clarify that the Non-DEA Practitioner Registration Application must be electronically submitted in the Web-Based Application. This subdivision is necessary to clarify where the Non-DEA Practitioner Registration Application must be submitted for Non-DEA Practitioners to successfully register for access to CURES.

New subdivision (c) was added to set forth the information that must be submitted by a Non-DEA Practitioner in order to obtain approval for access to CURES. It is necessary to establish the information required for submission of a Non-DEA Registration Application, because there are automated validation tools in place for Non-DEA Practitioners that cross-reference information on file with the Non-DEA Practitioner's Licensing Board. This subdivision 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 (c)(2) 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 a State License Number be provided is necessary to validate whether the applicant is licensed to practice in California. The purpose of subdivisions (c)(5) 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.

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

New subdivision (a) was added to explain that a Non-DEA Practitioner-User has access to both a Patient Activity Report and a Delegate Audit Report within CURES. This subdivision is necessary to clarify which reports are available to a Non-DEA Practitioner-User in CURES.

New subdivision (b) was added to establish a 24-month timeframe for the Search Period that a Non-DEA Practitioner-User may access data. This subdivision is necessary to limit the temporal scope of information that a Non-DEA Practitioner-User may access, to only that information which the Department has determined is authorized and is necessary to assist a Non-DEA Practitioner-User in appropriately prescribing to a patient Under the Care of the Non-DEA Practitioner. This search period is already applicable to other Users, including Prescriber-Users as set forth in Section 821.3, subdivision (b). Limiting the Search Period to 24 months is necessary to ensure that a Non-DEA Practitioner-User is only permitted access to data for

patients currently Under the Care of the Non-DEA Practitioner pursuant to HSC 11165.1. Furthermore, this revision is necessary to permit access to more information for Non-DEA Practitioner-Users, which may improve the quality of medical consultations that utilize information from CURES, while still balancing patient privacy.

§ 822.4. Restrictions on Accessing Data in CURES.

New subdivisions (a) and (a)(1) were added to restrict access to CURES data for Non-DEA Practitioner-Users to only what is necessary to treat a patient Under the Care of that Non-DEA Practitioner-User. These subdivisions are necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

New subdivision (a)(2) was added to include a new report available to Non-DEA Practitioner-Users in CURES and to allow a Non-DEA Practitioner-User to access CURES to obtain an audit on the Non-DEA Practitioner-User's Delegate. This subdivision is necessary to clarify when a Non-DEA Practitioner-User may audit an individual who is or was an associated Delegate-User, and to ensure that information contained within CURES by their Delegate is used solely for the purposes for which it is intended.

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

New section 822.5 is very similar to section 821.5, governing use of CURES data by Prescriber-Users, and section 823.5, governing use of CURES data by Pharmacist-Users, both sections as amended by this rulemaking action.

New subdivision (a) was added to set forth the restrictions on use, disclosure, and transfer of data applicable to Non-DEA Practitioner-Users. This subdivision explicitly prohibits the use, disclosure, or transfer of CURES data unless it is for the same authorized purpose for which the data was originally requested and requires compliance with all applicable federal and State laws. This subdivision is necessary because it protects patient privacy by narrowing the scope of use and disclosure of data from CURES and provides references to applicable federal and State privacy, confidentiality, and security laws and regulations. CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

New subdivision (b) was added to explain that a Non-DEA Practitioner-User is authorized to disclose or transfer CURES data to a Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist so long as all of the specified requirements are met, and to that Non-DEA Practitioner-User's Licensing Board to document compliance with the law. This change is necessary to clarify that subdivision (a)(1) does not prohibit a health care registrant from disclosing CURES data to another health care registrant, provided that the patient whose information being disclosed is Under the Care of both registrants, the transfer of the data complies with all applicable federal and State laws and regulations, and the data being transferred was properly obtained.

New subdivision (c) was added to clarify that a Non-DEA Practitioner-User must not sell any data obtained from CURES. This subdivision is necessary to prohibit the sale of data obtained from CURES, consistent with HSC 11165(b)(2)(A). This subdivision clarifies there is no circumstance under which a Non-DEA Practitioner-User should sell data. CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

§ 822.6. Procedures for Use of CURES.

New section 822.6 is very similar to section 821.6, governing procedures to use CURES data by Prescriber-Users, and section 823.6, governing procedures to use CURES data by Pharmacist-Users, both sections as amended by this rulemaking action.

New subdivision (a) was added to set forth in which environments data is made available: the Web-Based Application and IEWS. This subdivision 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 HSC 11165.1(a)(1)(D) authorizes a Non-DEA Practitioner-User to also access CURES data through IEWS.

New subdivision (b) was added to specify that a Non-DEA Practitioner-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. This subdivision is necessary to clarify that Compliant Passwords can only be changed in the Web-Based Application because Non-DEA Practitioner-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.

New subdivision (c) was added to set forth the requirement that Non-DEA Practitioner-Users update specified information about themselves annually and specify that an Annual Renewal must be made in the Web-Based Application. This subdivision is necessary because any or all of the data elements are 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. Lastly, it is necessary to stipulate that Annual Renewals be processed in the Web-Based Application because Non-DEA Practitioner-Users have access to both environments, but only the Web-Based Application has the technical functionality necessary to complete the Annual Renewal. The purpose of subdivision (c)(4) is to require the Non-DEA Practitioner-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 Non-DEA Practitioner-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.

New subdivisions (d) and (d)(1) were added to explain the procedures that a Non-DEA Practitioner-User must follow in order to request a Patient Activity Report. These subdivisions are necessary to specify that a Patient Activity Report is available in both the Web-Based Application and the IEWS. Furthermore, these subdivisions are necessary because some functionalities are only available in the Web-Based Application, but a Non-DEA Practitioner-User may access a Patient Activity Report in either environment.

New subdivision (d)(2) was added to explain the procedures that a Non-DEA Practitioner-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 instructions on how to search and generate a Patient Activity Report for the proper patient. This subdivision is necessary because a Non-DEA Practitioner-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 Non-DEA Practitioner-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. This subdivision is further necessary to advise the Non-DEA Practitioner-User of the Terms and Conditions of CURES.

New subdivision (d)(3) was added to explain the procedures that a Non-DEA Practitioner-User must follow in order to request an interstate Patient Activity Report and to specify that an interstate Patient Activity Report is available in the Web-Based Application. This subdivision is necessary because Non-DEA Practitioner-Users may access patient data in more than one environment; however, an interstate Patient Activity Report is only available in the Web-Based Application. This subdivision is further necessary to specify that a Non-DEA Practitioner-User may request data from a state or states other than California. Furthermore, this subdivision was added to explain the procedures that a Non-DEA Practitioner-User must follow in order to request an interstate Patient Activity Report in the Web-Based Application, including the search criteria that must be provided. Subdivision (d)(3)(B) is necessary because it ensures that each Non-DEA Practitioner-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 an interstate Patient Activity Report. Subdivision (d)(3)(C) is necessary because a Non-DEA Practitioner-User must complete these steps in order to successfully submit a search. If this is not done, then the Non-DEA Practitioner-User will not be able to generate an interstate Patient Activity Report. The authority to generate an interstate Patient Activity Report is provided in HSC 11165(h).

New subdivision (d)(4) was added to explain the procedures that a Non-DEA Practitioner-User must follow in order to generate and view a Patient Activity Report in the IEWS, 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 (d)(4)(A) was added to explain the data elements that must be listed to request a Patient Activity Report. This subdivision is necessary because a Non-DEA Practitioner-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 Non-DEA Practitioner-User will not be able to complete the search, which is the first step in initiating a Patient Activity Report in the IEWS.

Article 2.3 Access and Use by Pharmacists and Out-of-State Pharmacists

§ 823.1. Eligibility for Access to CURES.

New subdivision (c) was added to establish that an individual must not access CURES if they no longer meet the eligibility requirements for access. 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.

New subdivision (d) was added to establish that an individual must not access CURES if they no longer meet the eligibility requirements for access. This subdivision is necessary because granting access to Out-of-State 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. This subdivision is further necessary because account cancellation is not an automated process for Out-of-State Pharmacists so the CURES PDMP must be notified in order to perform an account update.

§ 823.2. Procedures to Register for Access to CURES.

Subdivision (a) was amended to remove “patient information from.” This amendment is necessary to clarify that a Pharmacist Registration Application must be used to obtain approval to access any information in CURES, not just patient information.

Subdivision (c) was amended to reorder and restate the procedures for registration that must be fulfilled by a Pharmacist or Out-of-State Pharmacist before they may be permitted access to CURES and to reorder and restate the application information that the Department has determined must be furnished by an applicant. The application will now allow registrants to designate whether their email address or phone number may be shared in CURES. The amendments are necessary because the information on the application has been reordered. These amendments are further necessary to allow the Department to obtain consent from registrants before their information is shared in CURES with other registrants to assist in patient treatment. . This amendment is further necessary because the Department combined the registration application process for Pharmacists and Out-of-State Pharmacists. Proposed subdivisions (c)(3) and (c)(4) are a restatement of existing subdivisions (d)(2) and (d)(3).

Former subdivision (d) was removed from this subdivision and added to subdivision (c) because the Department combined the registration application process for Pharmacists and Out-of-State Pharmacists.

Former subdivision (e) was removed because it is no longer part of the first-time log in process for Pharmacists and Out-of-State Pharmacists. This amendment is necessary because the information previously required on the first-time log in by a user is now included in the registration application.

The Authority and Reference section was non-substantively amended to delete a space before “[r]eference.”

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

Subdivision (a) was amended to replace “access patient information in CURES through both” with “obtain all.” This amendment is necessary because a Pharmacist-User may access other types of protected information in CURES, not just patient information. This subdivision was also non-substantively amended to replace “section 822.4” with “section 823.4” to reference the correct citation in the regulations.

Subdivision (a)(3) was added to include a new report Pharmacist-Users have available in CURES. This subdivision is necessary to assist Pharmacist-Users in determining whether a prescription form serial number has been reported as lost or stolen in CURES, and whether the prescription associated with that prescription form serial number has been reported as filled in CURES. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

Subdivision (a)(4) was added to include a new report Pharmacist-Users have available in CURES. Under AB 528, a Delegate will be authorized to access Patient Activity Reports on behalf of their Authorizing User. This subdivision is further necessary to provide a report to an Authorizing User to ensure that information contained within CURES by their Delegate is used solely for the purposes for which it is intended.

Subdivision (b) was amended to replace “patient information” with “data in CURES.” This amendment is necessary because Pharmacist-Users have access to other information in CURES, not just patient information.

§ 823.4. Restrictions on Accessing Data in CURES.

This section title was amended to replace “Patient Information” with “Data.” This amendment is necessary because Pharmacist-Users have access to other types of protected information in CURES, not just patient information.

Subdivision (a) was amended to replace “patient information to” with “data in CURES for one or more of the following authorized purposes.” This amendment is necessary because Pharmacist-Users have access to other types of protected information in CURES, not just patient information.

Subdivision (a)(1) (formerly subdivision (a)) was amended to replace “treat” with “[t]o obtain the Controlled Substance history of.” This amendment is necessary to better align with the language used in HSC 11165.1.

Subdivision (a)(2) (formerly subdivision (b)) was amended to replace “[o]btain” with “[t]o obtain.” This amendment is necessary to keep parallel construction in the regulation.

New subdivision (a)(3) was added to include a new report available to Pharmacist-Users in CURES. This subdivision is necessary to clarify when a Pharmacist-User may initiate a request to determine if a prescription form serial number has been reported as lost or stolen in CURES, and whether the prescription associated with that prescription form serial number has been reported as filled in CURES. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

New subdivision (a)(4) was added to include a new report available to Pharmacist-Users in CURES and to allow a Pharmacist-User to access CURES to obtain an audit on the Pharmacist-User's Delegate. This subdivision is necessary to clarify when a Pharmacist-User may audit an individual who is or was an associated Delegate-User, and to ensure that information contained within CURES by their Delegate is used solely for the purposes for which it is intended.

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

This section title was amended to replace "Patient Information" with "Data." This amendment is necessary because Pharmacist-Users have access to other types of protected information in CURES, not just patient information.

Subdivision (a) was amended to replace all references of "patient information" with "data." These amendments are necessary because Pharmacist-Users have access to other types of protected information in CURES, not just patient information. The Department also non-substantively amended subdivision (a)(1) to reference the relevant citation in the regulations regarding the Restrictions on Accessing Data in CURES.

New subdivision (b) was added to explain that a Pharmacist-User is authorized to disclose or transfer CURES data to a Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist so long as all of the specified requirements are met, and to that Pharmacist-User's Licensing Board to document compliance with the law. This change is necessary to clarify that subdivision (a)(1) does not prohibit a health care registrant from disclosing CURES data to another health care registrant, provided that the patient whose information being disclosed is Under the Care of both registrants, the transfer of the data complies with all applicable federal and State laws and regulations, and the data being transferred was properly obtained. The addition of this subdivision requires the subsequent renumbering of this section.

Subdivision (c) (formerly subdivision (b)) was amended to replace "patient information" with "data." This amendment is necessary because Pharmacist-Users have access to other types of protected information in CURES, not just patient information.

Former subdivision (c) was removed and added to subdivision (b)(2) to provide clarity surrounding the disclosure and transfer of data in CURES. As CURES contains confidential data, it is vital to safeguard it, thereby protecting the privacy of the individuals to whom the information pertains.

§ 823.6. Procedures for Use of CURES.

Subdivision (a) was amended to replace “patient information” with “data.” This amendment is necessary because Pharmacist Users have access to other types of protected information in CURES, not just patient information.

Subdivision (c)(3) requires Pharmacist-Users to update specified information about themselves annually. 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. This subdivision was amended to replace the itemized list of specific contact information that must be updated with a reference to the Pharmacist-User’s application information in section 823.2, subdivision (c)(2). This change is necessary in the event that other types of Pharmacist-User information, not just contact information, requires updating.

Subdivision (d)(2)(A) was amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

New subdivision (d)(3) was added to explain the procedures that a Pharmacist-User must follow in order to request an interstate Patient Activity Report. The purpose of subdivision (d)(3) is to specify that an interstate Patient Activity Report is available in the Web-Based Application. This is necessary because some functionalities are only available in the Web-Based Application, but a Pharmacist-User may only access an interstate Patient Activity Report in the Web-Based Application. This subdivision is further necessary to specify that a Pharmacist-User may request data from a state or states other than California. Furthermore, this subdivision was added to explain the procedures that a Pharmacist-User must follow in order to request an interstate Patient Activity Report in the Web-Based Application, including the search criteria that must be provided. Subdivision (d)(3)(B) 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 an interstate Patient Activity Report. Subdivision (d)(3)(C) is necessary because a Prescriber-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 an interstate Patient Activity Report. The authority to generate an interstate Patient Activity Report is provided in HSC 11165(h). The addition of this subdivision requires the subsequent renumbering of subdivision (d)(4) in this section.

Subdivision (d)(4) was non-substantively amended to reference the correct citation in the regulations. This amendment is necessary to provide clarity to the Pharmacist-User. Furthermore, subdivision (d)(4)(A) was amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

Subdivision (d)(4)(B) was removed because the language was redundant in these regulations. Pharmacist-Users who request a Patient Activity Report in the Information Exchange Web

Service already agree to the Terms and Conditions of CURES through a memorandum of understanding previously entered into, and do not need to do so when submitting the request.

New subdivision (f) was added to include a new report available to Pharmacist-Users in CURES and the procedures required to request a Pharmacist Serialized Prescription Form Report. This subdivision is necessary to clarify the information Pharmacist-Users are required to provide in order to determine if a prescription form serial number has been reported as lost or stolen in CURES, and whether the prescription associated with that prescription form serial number has been reported as filled in CURES. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance. The addition of this subdivision requires the subsequent renumbering of this section.

Subdivision (g) (formerly subdivision (f)) was amended to revise the fields that must be completed in a Prescription Form Theft or Loss Report. This subdivision implements HSC 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. The added fields are necessary to give a more accurate and detailed picture of a loss or theft, which will assist law enforcement and help prevent Diversion and Resultant Abuse. Furthermore, this subdivision was amended to correct the name of the report from “Prescription Theft or Loss Report” to “Prescription Form Theft or Loss Report.” This amendment is necessary to specify that this report is for lost or stolen prescription forms and not individual prescriptions.

§ 823.7. Delegate Use of CURES.

The Department removed this section in its entirety. This amendment is necessary because AB 528 created an expanded Delegate-User role which is outlined in Article 2.4 Access and Use by Delegates.

Article 2.4 Access and Use by Delegates

The purpose of sections 824.1 through 824.9 are to set forth who may have access to CURES as a Delegate, the process and requirements for gaining access as a Delegate, 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.

§ 824.1. Eligibility for Access to CURES.

New subdivision (a) was added to limit CURES access to an individual to whom authority is delegated by an Authorizing User and permit access to data in CURES as a Delegate for that Authorizing User if the individual to whom authority is delegated meets the specified eligibility requirements. This subdivision is necessary because there may be confusion about who may qualify as a Delegate to access CURES on behalf of an Authorizing User. This subdivision is further 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.

New subdivision (b) was added to specify the instances in which an Authorizing User must terminate that Authorizing User's the delegation of authority to a Delegate under this article, including the ability of that Delegate to access data in CURES on behalf of that Authorizing User. This subdivision is 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.

New subdivision (c) was added to specify the requirement that an Authorizing User must immediately notify the Department and the Authorizing User's Licensing Board or Out-of-State Licensing Board in writing of the termination and the basis of the termination of a Delegate. Additionally, this subdivision sets forth the requirement that if a Delegate terminated under section 824.1, subdivision (b)(4), is licensed by a Licensing Board or Out-of-State Licensing Board, the Authorizing User must also immediately notify the Delegate's Licensing Board or Out-of-State Licensing Board in writing of the termination and the basis of the termination. This subdivision is 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.

New subdivision (d) was added to set forth the requirement that if an Authorizing User's access to CURES is suspended or terminated, the Department must suspend any Delegate of the Authorizing User from accessing CURES on behalf of that Authorizing User. This subdivision is necessary because a Delegate's access to CURES is based off the Authorizing User's access to CURES. Therefore, a Delegate, whose Authorizing User does not meet the eligibility criteria to access CURES, will not be authorized to access CURES on behalf of that Authorizing User.

§ 824.2. Delegate Agreement between Authorizing User and Delegate.

New subdivision (a) was added to set forth the requirement that an Authorizing User must enter into a Delegate Agreement with each Delegate to whom that Authorizing User delegates authority under this article. The Delegate Agreement must meet all of the specified requirements set forth in subdivision (a)(1). A Delegate Agreement is necessary to help ensure that both the Authorizing User and Delegate understand and have agreed to their respective responsibilities—including the Authorizing User's responsibility for the Delegate, and the Delegate's accountability to the Authorizing User—and that the Authorizing User and Delegate are aware of the access and use requirements of CURES. Without a Delegate Agreement, a Delegate will not be authorized to access CURES on behalf of that Authorizing User.

New subdivision (a)(1) was added to specify the minimum requirements of the Delegate Agreement. These subdivisions are necessary to set forth the requirements of a Delegate Agreement and to ensure that the information contained in CURES is used in accordance with these regulations. The minimum requirements reflect the requirements established in the regulations for each party. These are only minimum requirements because the parties to a Delegate Agreement may include additional requirements, in their discretion, so long as such

requirements do not conflict with these regulations. Setting forth minimum requirements for a Delegate Agreement is necessary to help ensure that both the Authorizing User and Delegate understand and have agreed to their respective responsibilities.

New subdivision (a)(2) was added to establish that a Delegate Agreement must only be between one Delegate and one Authorizing User. This subdivision is necessary to specify that a Delegate Agreement must be entered into on an individual basis. Authorizing Users may have multiple Delegates, and Delegates may be associated with multiple Authorizing Users, so long as each Delegate and Authorizing User have entered into a Delegate Agreement.

New subdivision (a)(3) was added to specify that a Delegate Agreement between the Delegate and the Authorizing User must not exceed 12 months from the effective date of that Delegate Agreement. This subdivision is necessary to limit the temporal scope of a Delegate Agreement between a Delegate and an Authorizing User. The Department consulted with the Department of Consumer Affairs and its boards and committees and 12 months as the maximum duration of a Delegate Agreement was the recommendation from the participating members of the Department of Consumer Affairs. This is to ensure an Authorizing User and Delegate are aware of any changes in the laws and regulations governing the access and use of CURES.

New subdivision (a)(4) permits additional requirements or provisions in a Delegate Agreement, provided those requirements are consistent with the laws and regulations governing the Delegate's access and use of CURES and which, if found to conflict, will be subordinate to the laws and regulations governing the Delegate's access and use of CURES. This subdivision is necessary to allow a range of flexibility when an Authorizing User and Delegate are establishing a Delegate Agreement, so long as the additional requirements or provisions are consistent with the laws and regulations surrounding the Delegates access and use of CURES.

New subdivision (a)(5) was added to set the requirement that the Delegate Agreement must be signed and dated by the Delegate and the Authorizing User. This subdivision is necessary to establish an executed Delegate Agreement in order for the Authorizing User to create an association in CURES with that Delegate.

New subdivision (b) was added to set forth the requirement that if a Delegate Agreement expires and the Authorizing User and Delegate do not enter into a new agreement, the Delegate will not be authorized to access CURES on behalf of that Authorizing User. This subdivision is necessary because authorizing individuals to access CURES, who do not meet the requirements set forth in this article, would pose an unnecessary risk to the privacy of those individuals whose information is contained within CURES.

New subdivision (c) was added to set forth the requirement that a fully executed copy of any Delegate Agreement between a Delegate and an Authorizing User under this section be retained by both parties for a period of five years from the expiration of the term of that Delegate Agreement. This subdivision also specifies that upon request, the Delegate and Authorizing User must provide the Delegate Agreement to the Authorizing User's Licensing Board or Out-of-State Licensing Board, the California Department of Consumer Affairs, or the Department. This subdivision is necessary to ensure that Authorizing Users and Delegates are following the requirements set forth in these regulations.

§ 824.3. Procedures to Register for Access to CURES.

New subdivision (a) was added to set forth the procedures for registration that must be fulfilled by a Delegate before they may be permitted access to CURES and to specify the application information that the Department has determined must be furnished by an applicant. This new subdivision is necessary because AB 528 expanded Delegate access to CURES and implements the requirement that the Department shall release to an Authorizing User or their Delegate the electronic history of Controlled Substances dispensed to a patient under the care of the Authorizing User based on data contained in the CURES PDMP.

New subdivision (b) was added to clarify that the Delegate Registration Application must be electronically submitted in the Web-Based Application. This subdivision is necessary to clarify where the Delegate Registration Application must be submitted for Delegates to successfully register for access to CURES.

New subdivision (c) was added to set forth the information on the Delegate Registration Application that must be submitted by a Delegate in order to obtain approval for access to CURES. The purpose of subdivisions (c)(5) 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.

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

New subdivision (a) was added to clarify that the Delegate association must be activated in the Web-Based Application. This subdivision is necessary to clarify where the Delegate association must be activated in order for a Delegate to successfully be associated with an Authorizing User.

New subdivision (b) was added to specify that a Delegate-User must provide the Authorizing User's association verification code to activate a new Delegate association in the Web-Based Application. This subdivision is necessary to outline the procedure for a Delegate to successfully be associated with an Authorizing User.

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

New subdivision (a) was added to explain that a Delegate-User has access to a Patient Activity Report within CURES. This subdivision is necessary to clarify the report available to a Delegate-User in CURES.

New subdivision (b) was added to establish a 24-month timeframe for the Search Period that a Delegate-User may access data. This subdivision is necessary to limit the temporal scope of information that a Delegate-User may access, to only that information which the Department has determined is authorized and is necessary for a Delegate-User when accessing CURES on behalf of an Authorizing User, which may improve the quality of medical consultations that utilize

information from CURES, while still balancing patient privacy. Furthermore, a Delegate-User is granted the same Search Period as their Authorizing User.

§ 824.6. Restrictions on Accessing Data in CURES.

New subdivision (a) was added to specify that an Authorizing User is responsible for all access and use of CURES by a Delegate-User to whom that Authorizing User has delegated authority under this article, including the Delegate-User's compliance with the requirements of this article. This subdivision is necessary because CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

New subdivision (b) was added to set forth all of the requirements that must be met in order for a Delegate to access data in CURES on behalf of an Authorizing User. Additionally, this subdivision specifies that the Delegate-User and Authorizing User must have an active Delegate Agreement, the Delegate-User must comply with all requirements of the Delegate Agreement, and the Delegate-User must comply with all requirements on accessing data in CURES applicable to the Authorizing User. Furthermore, subdivisions (b)(3)(A) through (b)(3)(C) specify the applicable requirements on accessing data in CURES as they relate to the different types of Authorizing Users. These subdivisions are necessary to set forth a Delegate-User's restrictions on accessing data in CURES in relation to the applicable Authorizing User.

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

New subdivision (a) was added to set forth the restrictions on use, disclosure, and transfer of data applicable to Delegate-Users. This subdivision is necessary to explicitly prohibit the use, disclosure, or transfer of CURES data unless it is for the same authorized purpose for which the data was originally requested and the transfer is limited to the Authorizing User for whom the data was requested, and that 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 data from CURES and provides references to applicable federal and State privacy, confidentiality, and security laws and regulations with which a Delegate-User must comply. CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

New subdivision (b) was added to clarify that a Delegate-User must not sell any data obtained from CURES. This subdivision is necessary to prohibit the sale of data obtained from CURES, consistent with HSC 11165(b)(2)(A). This subdivision clarifies there is no circumstance under which a Delegate-User should sell data. CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

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

New subdivision (a) was added to explain the procedures that an Authorizing User must follow in order to establish a Delegate association in CURES. The purpose of subdivision (a)(1) is to specify that a Delegate association must be established in the Web-Based Application. This subdivision is necessary because some functionalities are only available in the Web-Based

Application, and in order to request to be associated with a Delegate, the Authorizing User must initiate this in the Web-Based Application. Furthermore, this subdivision was added to explain the procedures that an Authorizing User must follow in order to establish a new Delegate association in the Web-Based Application, including the information that must be provided. Subdivision (a)(2)(B)4.a. specifies the maximum term of a Delegate Agreement and the procedures on establishing a new Delegate Agreement, setting the requirement that the effective date provided by the Authorizing User under this subdivision may be a past, present, or future date, but the Authorizing User must not provide an effective date that is more than 60 days into the future when establishing a Delegate association. Subdivision (a)(2)(B)4.b. was added to set the requirement that an Authorizing User and a Delegate must not have more than one Delegate Agreement with each other at any given time, but does not prohibit the Authorizing User and Delegate from entering not a new Delegate Agreement that will become active upon expiration of the previous agreement. The purpose of subdivision (a)(2)(C) is to require the Authorizing User to agree to the Terms and Conditions of CURES prior to submitting the Delegate association. This is necessary because it ensures that each Authorizing 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.

New subdivision (b) was added to explain the procedures that an Authorizing User must follow in order to approve a Delegate association in CURES. The purpose of subdivision (b)(1) is to specify that a Delegate association must be approved in the Web-Based Application. This subdivision is necessary because some functionalities are only available in the Web-Based Application, and in order to approve an association with a Delegate, the Authorizing User must initiate this in the Web-Based Application. Furthermore, this subdivision was added to explain the procedures that an Authorizing User must follow in order to approve a new Delegate association, including the information that must be provided. The purpose of subdivision (b)(2)(C) is to require the Authorizing User to agree to the Terms and Conditions of CURES prior to approving a Delegate association. This is necessary because it ensures that each Authorizing 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.

New subdivision (c) was added to explain the procedures that an Authorizing User must follow in order to cancel a Delegate association in CURES. Additionally, this subdivision was added to explain the procedures that an Authorizing User must follow in order to cancel a Delegate association, including the information that must be provided. The purpose of subdivision (c)(1) is to specify that a Delegate association cancellation must be made in the Web-Based Application. This is necessary because some functionalities are only available in the Web-Based Application, and in order to cancel an association with a Delegate User, the Authorizing User must complete this in the Web-Based Application.

New subdivision (d) was added to include a report available to Authorizing Users in CURES and to provide the search criteria required for when an Authorizing User may access CURES to obtain an audit on the Authorizing User's Delegates. Additionally, this subdivision was added to explain the procedures that an Authorizing User must follow in order to request a Delegate Audit

Report, including the information that must be provided. This subdivision is necessary to ensure that information contained within CURES by an Authorizing User's Delegate is used solely for the purposes for which it is intended.

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

New subdivision (a) was added to set forth the environment that a Delegate-User may access CURES via the Web-Based Application. This subdivision is necessary because all Users need access to the Web-Based Application, as it is the main way to access CURES.

New subdivision (b) was added to specify that a Delegate-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. This subdivision is necessary to clarify that Compliant Passwords can only be changed in the Web-Based Application because Delegate-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.

New subdivision (c) was added to set forth the requirement that Delegate-Users update specified information about themselves annually, and specify that an Annual Renewal must be made in the Web-Based Application. This subdivision is necessary because data elements are 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. Lastly, it is necessary to stipulate that Annual Renewals be processed in the Web-Based Application. The purpose of subdivision (c)(4) is to require the Delegate-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 Delegate-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.

New subdivisions (d) through (d)(2) were added to explain the procedures that a Delegate-User must follow in order to request a Patient Activity Report. Subdivision (d)(1) is necessary to specify that a Patient Activity Report is available in the Web-Based Application. Subdivision (d)(2) is necessary to explain the procedures that a Delegate-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.

New subdivision (d)(2)(A) was added to set the requirement that a Delegate-User must indicate the Authorizing User on whose behalf the search is being ran. This subdivision is necessary because an Authorizing User is responsible for a Delegates access and to ensure that information contained within CURES is used solely for the purposes for which it is intended.

New subdivision (d)(2)(B) was added to explain the data elements that must be listed to request a Patient Activity Report. This subdivision is necessary because a Delegate-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 Delegate-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.

New subdivision (d)(2)(C) was added to require that a Delegate-User agree to the Terms and Conditions of CURES in order to request a Patient Activity Report. This subdivision is necessary because it ensures that each Delegate-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.

New subdivision (d)(2)(D) was added to require that a Delegate-User select the applicable Patient Entity or Patient Entities from the Patient Picklist. This subdivision is necessary because a Delegate-User must complete these steps in order to successfully submit a search. If this is not done, then the Delegate-User will not be able to generate a Patient Activity Report as the system will not be able to determine which Patient Entity or Patient Entities to search for if none are provided.

Subdivision (d)(3) was added to explain the procedures that a Delegate-User must follow in order to request an interstate Patient Activity Report. The purpose of subdivision (d)(3) is to specify that an interstate Patient Activity Report is available in the Web-Based Application. This is necessary because some functionalities are only available in the Web-Based Application, but a Delegate-User may only access an interstate Patient Activity Report in the Web-Based Application. This subdivision is further necessary to specify that a Delegate-User may request data from a state or states other than California. Furthermore, this subdivision was added to explain the procedures that a Delegate-User must follow in order to request an interstate Patient Activity Report in the Web-Based Application, including the search criteria that must be provided. Subdivision (d)(3)(C) is necessary because it ensures that each Delegate-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 an interstate Patient Activity Report. Subdivision (d)(3)(D) is necessary because a Delegate-User must complete these steps in order to successfully submit a search. If this is not done, then the Delegate-User will not be able to generate an interstate Patient Activity Report. The authority to generate an interstate Patient Activity Report is provided in HSC 11165(h).

New subdivision (e) was added to explain the procedures that a Delegate-User must follow in order to request a Delegate association in CURES. The purpose of subdivision (e)(1) is to specify that a Delegate association request must be made in the Web-Based Application. This subdivision is necessary because some functionalities are only available in the Web-Based Application, and in order to request to be associated with an Authorizing User, the Delegate-User must initiate this in the Web-Based Application. Furthermore, this subdivision was added to explain the procedures that a Delegate-User must follow in order to request a new Delegate association in the Web-Based Application, including the information that must be provided.

New subdivision (f) was added to explain the procedures that a Delegate-User must follow in order to cancel a Delegate association in CURES. The purpose of subdivision (f)(1) is to specify that a Delegate association cancellation must be made in the Web-Based Application. This subdivision is necessary because some functionalities are only available in the Web-Based Application, and in order to cancel an association with an Authorizing User, the Delegate-User must complete this in the Web-Based Application. Furthermore, this subdivision was added to explain the procedures that a Delegate-User must follow in order to cancel a Delegate association in the Web-Based Application, including the information that must be provided.

Article 2.5. Access and Use by Interstate-Users

This article title was amended to replace “Interstate Prescribers and Interstate Pharmacists” with “Interstate-Users.” This amendment is necessary because the Department added the defined term “Interstate-Users” to section 820.

§ 825.1. Eligibility for Access to Data from CURES.

Subdivision (a), including (a)(1) and (a)(2), was amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” This amendment is necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists.

New subdivision (a)(3) was added to specify that an Interstate-User must agree to the Terms and Conditions of CURES by reviewing and executing an Interstate-user acknowledgment. This subdivision is necessary to set forth the requirements of an Interstate-User acknowledgement and to ensure that the information contained in CURES is used in accordance with these regulations. An Interstate-User acknowledgement is necessary to protect the data in CURES by ensuring Interstate-Users understand and agree to the laws and regulations governing access and use of CURES and data obtained from CURES.

New subdivision (a)(3)(A) was added to specify that an Interstate-User must review and execute an Interstate acknowledgement every 365 days. This subdivision is necessary to ensure that an Interstate-User is aware of any changes in the laws and regulations governing the access and use of CURES.

New subdivision (a)(3)(B) was added to set forth the requirement that a fully executed copy of the Interstate-User acknowledgement be retained by an Interstate-User for a period of five years from the expiration of the term of that Interstate-User acknowledgement. This subdivision is necessary to ensure that Interstate-Users are following the other requirements set forth in these regulations.

New subdivision (a)(3)(C) was added to specify that upon request, the Interstate-User must provide the Interstate-User acknowledgement to the Interstate-User’s PDMP, Out-of-State Licensing Board, or the California Department of Justice. This subdivision is necessary to ensure that Interstate-Users are following the other requirements set forth in these regulations.

Subdivision (a)(4) (formerly subdivision (a)(3)) and subdivision (a)(5) (formerly subdivision (a)(4)) were amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” This amendment is necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists.

§ 825.2. Data Accessible to Interstate-Users in CURES.

This section title was amended to replace “Interstate Prescribers and Interstate Pharmacists” with “Interstate-Users.” This amendment is necessary because the Department added the defined term “Interstate-Users” to section 820.

Subdivisions (a) and (b) were amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” This amendment is necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists.

Subdivisions (a) and (b) were also amended to remove and replace references to patient information. This amendment is necessary because the Patient Activity Reports that Interstate-Users may access contain not only patient information, but also prescriber and pharmacy information.

Subdivision (a) was also non-substantively amended to replace “section 823.3” with “section 825.3” to reference the correct citation in the regulations.

§ 825.3. Restrictions on Accessing Data in CURES.

This section title was amended to replace “Patient Information” with “Data.” This amendment is necessary because the Patient Activity Reports Interstate-Users may access contain not only patient information, but also prescriber and pharmacy information.

Subdivision (a) was amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” This amendment is necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists. This subdivision was also amended to replace “patient information” with “data in CURES.” This amendment is necessary because the Patient Activity Reports Interstate-Users may access contain not only patient information, but also prescriber and pharmacy information. This amendment is necessary because CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

Subdivision (a)(1) was amended to add references to Interstate Non-DEA Practitioner. This amendment is necessary to clearly define the circumstances under which an Interstate Non-DEA

Practitioner may consider a patient to be Under the Care of the Interstate Non-DEA Practitioner. Furthermore, this subdivision was non-substantively amended to replace “section 820 subdivision (ooo)” with “section 820, subdivision (cccc)” to reference the correct citation in the regulations. This subdivision was further amended to replace “information” with “data.” This amendment is necessary to clarify the information available to Interstate-Users. This subdivision was further amended to replace numerical “7” with the word “seven” to better align with the California Style Manual. These amendments are necessary to be stylistically correct.

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

This section title was amended to replace “Patient Information” with “Data.” This amendment is necessary because the Patient Activity Reports Interstate-Users may access contain not only patient information, but also prescriber and pharmacy information.

Subdivision (a) was amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” This amendment is necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists. This subdivision was also amended to replace all references of “patient information” with “data” because the Patient Activity Reports that Interstate-Users may access contain not only patient information, but also prescriber and pharmacy information. Subdivision (a)(1) was also amended to reference the relevant citation in the regulations regarding the Restrictions on Accessing Data in CURES. Referencing section 825.3 in subdivision (a)(1) is necessary because it protects patient privacy by narrowing the scope of use and disclosure of data from CURES and provides references to applicable federal and State privacy, confidentiality, and security laws and regulations with which an Interstate-User must comply. CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains.

New subdivision (b) was added to explain that an Interstate-User is authorized to disclose or transfer CURES data to other Users so long as all of the specified requirements are met. This change is necessary to clarify that subdivision (a)(1) does not prohibit a health care registrant from disclosing CURES data to another health care registrant, provided that the patient whose information being disclosed is Under the Care of both registrants, the transfer of the data complies with all applicable federal and state laws and regulations, and the data being transferred was properly obtained. The addition of this subdivision requires the subsequent renumbering of subdivision (c) in this section.

Subdivision (c) (formerly subdivision (b)) was amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” This amendment is necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists. This subdivision was also amended to replace all references of “patient information” with “data” to clarify Interstate-Users must not sell any data from CURES.

§ 825.5. Procedures for Requesting Data from CURES.

This section title was amended to replace “Patient Information” with “Data.” This amendment is necessary because the Patient Activity Reports Interstate-Users may access contain not only patient information, but also prescriber and pharmacy information. .

Subdivisions (a) and (b) were amended to replace “Interstate Prescriber and Interstate Pharmacist” with “Interstate-User.” These amendments are necessary because the Department added “Interstate-User” as a definition to consolidate references to multiple parties and to clarify which requirements apply collectively to Interstate Prescribers, Interstate Non-DEA Practitioners, and Interstate Pharmacists. Subdivision (b) was additionally amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

Subdivision (c) was removed because Interstate-Users who request a Patient Activity Report through their PDMP have agreed to the Terms and Conditions of CURES through the Interstate-User acknowledgment.

Article 2.6. Access and Use by Regulatory Agency Officials

§ 826.1. Eligibility to Access CURES or Obtain Data from CURES.

New subdivision (b) was added to establish that an individual must not access CURES if they no longer meet the eligibility requirements for access. This subdivision is necessary because granting access to Regulatory Agency Officials 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 addition of this subdivision requires the subsequent renumbering of subdivision (c) in this section.

Subdivision (c) (formerly subdivision (b)) was amended to replace “the Department” with “CURES PDMP.” This amendment is necessary to clarify the appropriate entity to whom the Regulatory Agency must notify when a Regulatory Agency Official is no longer employed by a Regulatory Agency, or is no longer authorized by the Regulatory Agency to access CURES.

§ 826.2. Procedures to Register for Access to CURES.

Subdivision (a) was amended to remove “data from.” This amendment is necessary to provide clarity that a Regulatory Agency Official Registration Application is the Web-form application developed by the Department to obtain approval to access CURES.

Subdivision (c) was amended to reorder and restate the procedures for registration that must be fulfilled by a Regulatory Agency Official before they may be permitted access to CURES and to reorder and restate the application information that the Department has determined must be furnished by an applicant. These revisions are necessary to better align the regulations with the Regulatory Agency Registration Application in CURES.

Former subdivision (d) was removed because it is no longer part of the first-time log in process for Regulatory Agency Officials. This amendment is necessary because the information previously required on the first-time log in by a user is now included in the registration application.

§ 826.3. Data Accessible to Regulatory Agency Officials.

Subdivision (a) was non-substantively amended to replace “section 824.4” with “section 826.4” to reference the correct citation in the regulations.

New subdivision (a)(2) was added to include the new term Prescription History Report. This revision is necessary to consolidate three reports available to Regulatory Agency Officials, into one report name. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(7) in this section.

New subdivision (a)(3) was added to include a new report Regulatory Agency Officials have available in CURES. This subdivision is necessary to assist Regulatory Agency-Users in determining whether a prescription form serial number has been reported to CURES as lost or stolen, and whether the associated prescription form information has been reported to CURES by the applicable security printer. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(7) in this section.

New subdivision (a)(4) was added to include a new report Regulatory Agency Officials have available in CURES. Under AB 528, a Delegate will be authorized to access Patient Activity Reports on behalf of their Authorizing User. This subdivision is further necessary to provide a report to a Regulatory Agency-User to ensure that information contained within CURES by a Delegate on behalf of an Authorizing User is used solely for the purposes for which it is intended. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(7) in this section.

New subdivision (a)(5) was added to include a report Regulatory Agency Officials have available in CURES. This report is necessary to provide a Regulatory Agency-User the ability to request the account information of a Prescriber-User, Non-DEA Practitioner-User, Pharmacist-User, or Delegate-User in CURES, for regulatory oversight purposes. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(7) in this section.

New subdivision (a)(6) was added to include a report Regulatory Agency Officials have available in CURES. This subdivision is necessary to assist Regulatory Agency-Users in determining whether a prescription form has been reported to CURES as lost or stolen. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(7) in this section.

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

Subdivision (a) was amended to replace “any” with “one or more.” This amendment is necessary to authorize a Regulatory Agency Official to access CURES for one or more of the authorized purposes outlined in subdivisions (a)(1) through (a)(7).

Subdivision (c) was non-substantively amended to replace “article 2.5” with “article 2.7” to reference the correct citation in the regulations.

New subdivisions (d) through (o) were added to better specify the restrictions on accessing CURES or data from CURES and the information that must be provided, as applicable, by a Regulatory Agency Official when submitting a request to CURES PDMP. These subdivisions are necessary because a Regulatory Agency Official must provide all of the search criteria information and complete the specified steps in order to successfully request specified reports. They are also necessary to establish that the requirements for submitting a request to CURES PDMP are the same requirements as submitting a request to CURES.

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

Subdivision (a) was amended to replace “Regulatory Agency-User” with “Regulatory Agency Official.” This amendment is necessary to cover both scenarios, through CURES or from CURES PDMP, in which a Regulatory Agency Official may access CURES or obtain data from CURES.

Subdivision (a)(1) was amended to include an internal citation to the applicable section in the regulations. This amendment is necessary to clarify which requirements apply to the restrictions on use or disclosures of data obtained from CURES. Furthermore, this amendment is necessary to ensure that a Regulatory Agency Official is complying with applicable requirements of federal and State laws that may require the disclosure of information obtained from CURES.

Subdivision (b) was amended to replace “Regulatory Agency-User” with “Regulatory Agency Official.” This amendment is necessary to cover both scenarios, through CURES or from CURES PDMP, in which a Regulatory Agency Official may access CURES or obtain data from CURES.

§ 826.6. Procedures for Use of CURES.

Subdivision (c)(2) requires Regulatory-Agency Users to update specified information about themselves annually. 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. This subdivision was amended to replace the itemized list of specific contact information that must be updated with a reference to the Regulatory Agency-User’s application information in section 826.2, subdivision (c)(2). This change is necessary in the event that other types of Regulatory Agency-User information, not just contact information, requires updating.

Subdivision (d)(1)(A) was amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

Subdivision (e) was amended to replace “Prescriber History Report” with “Prescription History Report.” This amendment is necessary because this subdivision was revised to include the three reports accessible in CURES by a Regulatory Agency-User and the procedures required to request a Prescription History Report.

New subdivision (e)(1) was added to specify the information that must be provided by a Regulatory Agency-User when submitting a request for a Prescription History Report to CURES, including the requirement that the Regulatory Agency-User must indicate the report type and the search criteria that must be provided for each report. The addition of this subdivision requires the subsequent renumbering of this subdivision.

Subdivision (e)(1)(A)1. was amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

Former subdivision (f) was removed because the Department created the term “Prescription History Report” to include a Pharmacy History Report and added the procedures to request a Pharmacy History Report to subdivision (e)(1)(A)2. The addition of this subdivision requires the subsequent renumbering of this subdivision.

Subdivision (e)(1)(A)2.a. was amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

Subdivision (e)(1)(A)2.a.(i) (formerly subdivision (e)(1)(A)1.) was amended to include “DEA Number” as search criteria when a Regulatory Agency-User is requesting a Pharmacy History Report. This amendment is necessary to allow Regulatory Agency-Users to search by the pharmacy DEA Number to assist the efforts of that Regulatory Agency-User on behalf of a Regulatory Agency to control the Diversion and Resultant Abuse of Applicable Controlled Substances.

New subdivision (e)(1)(A)3 was added to include a new report available to Regulatory Agency-Users in CURES and the procedures required to request a Serialized Prescription History Report. This subdivision is necessary to clarify the information Regulatory Agency-Users are required to provide in order to determine the serialized prescription order information associated with specified prescription form serial numbers, as reported to CURES PDMP. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

New subdivision (f) was added to include a new report available to Regulatory Agency-Users in CURES and to provide the search criteria required for when a Regulatory Agency-User may access CURES to obtain a Serialized Prescription Form Report. Date search type is to specify that the Regulatory Agency-User may search by the date the file was submitted or the date the order was delivered. This subdivision is necessary to clarify the information Regulatory Agency-Users are required to provide in order to determine whether a prescription form serial

number has been reported to CURES as lost or stolen, and whether the associated prescription form information has been reported to CURES by the applicable security printer. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance. The addition of this subdivision requires the subsequent renumbering of this section.

New subdivision (g) was added to include a new report available to Regulatory Agency-Users in CURES and to provide the search criteria required for when a Regulatory Agency-User may access CURES to obtain an audit on the Authorizing User's Delegates. This subdivision is necessary to ensure that information contained within CURES by an Authorizing User's Delegate is used solely for the purposes for which it is intended. This amendment is also necessary because a Regulatory Agency-User may only search by an Authorizing User licensed by that Regulatory Agency-User's Licensing Board.

Subdivision (h) (formerly subdivision (g)) was amended to replace "Initiate" with "Request." This subdivision was also amended to replace "User Search" with "User Profile Details Report." This amendment is necessary because the regulations have changed the name of this report.

Subdivision (h)(1)(A) (formerly subdivision (g)(1)(A)) was amended to replace "at a minimum, both" with "all." This amendment is necessary to clarify that all the search criteria is required by the Regulatory Agency-User when requesting a User Profile Details Report. This subdivision was also amended to add "Category of Licensure" as a search criterion. This information is necessary to successfully request the User Profile Details Report. This subdivision was also amended to replace "includes" with "include." This amendment is necessary to be grammatically correct. Subdivision (h)(1)(B) was removed as redundant.

New subdivision (i) was added to include a new report available to Regulatory Agency-Users in CURES and to provide the search criteria required for when a Regulatory Agency-User may access CURES to obtain a Prescription Form Theft or Loss Report. Date search type is to specify that the Regulatory Agency-User may search by the date the theft or loss was reported, of the date of the theft or loss. This subdivision is necessary to clarify the information Regulatory Agency-Users are required to provide in order to determine whether a prescription form serial number has been reported to CURES as lost or stolen. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

Article 2.7. Access and Use by Law Enforcement Officials

§ 827.1. Eligibility to Access CURES or Obtain Data from CURES.

New subdivision (b) was added and is necessary because granting access to Law Enforcement Officials 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 addition of this subdivision requires the subsequent renumbering of subdivision (c) in this section.

Subdivision (c) (formerly subdivision (b)) was amended to replace “the Department” with “CURES PDMP.” This amendment is necessary to clarify the appropriate entity to whom a Law Enforcement Agency must notify when a Law Enforcement Official is no longer employed by a Law Enforcement Agency or is no longer authorized by the Law Enforcement Agency to access CURES.

§ 827.2. Procedures to Register for Access to CURES.

Subdivision (a) was amended to remove “data from.” This amendment is necessary to clarify that a Law Enforcement Official Registration Application is the Web-form application developed by the Department to obtain approval to access CURES.

Subdivision (c) was amended to reorder and restate procedures for registration that must be fulfilled by a Law Enforcement Official on the Law Enforcement Official Registration Application before they may be permitted access to CURES and to reorder and restate the application information that the Department has determined must be furnished by an applicant. These revisions are necessary to better align the regulations with the Regulatory Agency Registration Application in CURES.

Former subdivision (d) was removed because it is no longer part of the first-time log in process for Law Enforcement Officials. This amendment is necessary because the information previously required on the first-time log in by a user is now included in the registration application.

§ 827.3. Data Accessible to a Law Enforcement Official.

Subdivision (a) was non-substantively amended to replace “section 825.4” with “section 827.4” to reference the correct citation in the regulations.

New subdivision (a)(2) was added to include the new term Prescription History Report. This revision is necessary to consolidate three reports available to Law Enforcement Officials, into one report name. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(5) in this section.

New subdivision (a)(3) was added to include a new report Law Enforcement-Users have available in CURES. This subdivision is necessary to assist Law Enforcement-Users in determining whether a prescription form serial number has been reported to CURES as lost or stolen, and whether the associated prescription form information has been reported to CURES by the applicable security printer. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(5) in this section.

New subdivision (a)(4) was added to include a report Law Enforcement-Users have available in CURES. This subdivision is necessary to assist Law Enforcement-Users in determining whether a prescription form has been reported to CURES as lost or stolen. Additionally, this report

provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance. The addition of this subdivision requires the subsequent renumbering of subdivision (a)(5) in this section.

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

New subdivisions (b) through (k) were added and amended to better specify the restrictions on accessing CURES or data from CURES and the information that must be provided, as applicable, by a Law Enforcement Official when submitting a request to CURES PDMP. These subdivisions are necessary because a Law Enforcement Official must provide all of the search criteria information and complete the specified steps in order to successfully request specified reports. They are also necessary to establish that the requirements for submitting a request to CURES PDMP are the same requirements as submitting a request to CURES. The addition of subdivision (c) through (j) require the subsequent renumbering in this section.

Former subdivision (e)(4) was removed because a Law Enforcement Official is no longer authorized to provide a federal civil subpoena in lieu of a search warrant or court order to obtain a Patient Activity Report. The removal of this subdivision is necessary to protect the privacy of the individual's information being requested by a Law Enforcement Official, under these circumstances.

Subdivision (m)(5)(B) (formerly subdivision (e)(6)(B)) was amended to correct the word "coroner" instead of "corner." This was necessary to describe what types of investigations needed to be included in the statement.

Subdivision (m)(6) (formerly subdivision (e)(7)) was non-substantively amended to replace "section 825.5" with "section 827.5" to reference the correct citation in the regulations.

Subdivision (m)(7) (formerly subdivision (e)(8)) was non-substantively amended to replace "section 825.5" with "section 827.5" to reference the correct citation in the regulations.

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

Subdivision (a) was amended to replace "Law Enforcement-User" with "Law Enforcement Official." This amendment is necessary to cover both scenarios, through CURES or from CURES PDMP, in which a Law Enforcement Official may access CURES or obtain data from CURES.

Subdivision (a)(1) was amended to include an internal citation to the applicable section in the regulations. This amendment is necessary to clarify which requirements apply to the restrictions on use or disclosures of data obtained from CURES. Furthermore, this amendment is necessary to ensure that a Law Enforcement Official is complying with applicable requirements of federal and State laws that may require the disclosure of information obtained from CURES.

Subdivision (b) was amended to replace "Law Enforcement-User" with "Law Enforcement Official." This amendment is necessary to cover both scenarios, through CURES or from

CURES PDMP, in which a Law Enforcement Official may access CURES or obtain data from CURES.

§ 827.6. Procedures for Use of CURES.

Subdivision (c)(2) requires Law Enforcement-Users to update specified information about themselves annually. 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. This subdivision was amended to replace the itemized list of specific contact information that must be updated with a reference to the Law Enforcement-User's application information in section 827.2, subdivision (c)(2). This change is necessary in the event that other types of Law Enforcement-User information, not just contact information, requires updating.

New subdivision (d)(1)(A) was added to specify the requirement that a Law Enforcement-User must indicate whether the search is for a civil or criminal investigation. This subdivision is necessary because a Law Enforcement-User must provide all of the requirements listed in order to initiate a search. If a Law Enforcement-User does not indicate whether the search is for a civil or criminal investigation, the Law Enforcement-User will not be able to proceed in requesting a Patient Activity Report. Furthermore, this subdivision is necessary to advise the Law Enforcement-User of the applicable procedures when the search is being conducted to support a civil or criminal investigation. The addition of this subdivision requires the subsequent renumbering of this subdivision.

Subdivision (d)(1)(B)2. was non-substantively amended to replace "section 825.4" with "section 827.4" and "827.4, subdivision (m)" to reference the correct citations in the regulations.

Subdivision (d)(1)(B)3. was non-substantively amended to replace "section 825.4, subdivision (e)" with "section 827.4, subdivision (m)" to reference the correct citation in the regulations. Additionally, former subdivision (d)(1)(B)3.a. was moved and amended to remove reference to administrative subpoenas. CURES PDMP previously required that two types of requests for CURES data must only be submitted to CURES PDMP for manual processing. The first were administrative subpoenas. Because administrative subpoenas are often civil, and civil subpoenas must be submitted to CURES PDMP for manual processing, the Department required that all administrative subpoenas be submitted directly to CURES PDMP for evaluation and manual processing. However, the system will now require a Law Enforcement-User to indicate whether a request is for a civil or criminal investigation. Only if the administrative subpoena is for a civil investigation must the request be submitted to CURES PDMP for manual processing in accordance with the requirements of section 827.4 subdivision (l). The second type of subpoena that must be submitted to CURES PDMP for manual processing is a subpoena that meets the requirements of section 827.4 subdivision (m)(2), because the responsive records must be sent directly to the court, and not to the Law Enforcement-User. This requires the Law Enforcement-User to provide the supporting documentation to CURES PDMP for manual processing. This requirement remains in the current regulations.

New subdivision (d)(1)(B)4. was added to include the requirement that the Law Enforcement-User must indicate the type of supporting documentation that is being submitted with a request for a Patient Activity Report. This subdivision is necessary to assist the pre-approval process of a submitted search authorization by CURES PDMP, in order for a Law Enforcement-User to complete a Patient Activity Report search. Furthermore, this subdivision is necessary because CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains, and it is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

Subdivision (d)(1)(C) was amended to clarify that once a search authorization for a Patient Activity Report is submitted by a Law Enforcement-User, the request must be approved by CURES PDMP before the Law Enforcement-User is able to perform a Patient Activity Report search in CURES. This subdivision is necessary because CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains, and it is necessary to ensure that information contained within CURES is used solely for the purposes for which it is intended.

Subdivision (d)(1)(D) was amended to clarify that once CURES PDMP approves a Law Enforcement-User's request for a Patient Activity Report, the Law Enforcement-User will be able to conduct the search in CURES. Furthermore, this subdivision is necessary because a Law Enforcement-User must provide all the requirements listed in order to initiate a search. Additionally, this subdivision was amended to replace "includes" with "include." This amendment is necessary to be grammatically correct.

Subdivision (e) was amended to replace "Prescriber History Report" with "Prescription History Report." This amendment is necessary because this subdivision was revised to include the three reports accessible in CURES by a Law Enforcement-User and the procedures required to request a Prescription History Report.

New subdivision (e)(1) was amended to replace "Prescriber" with "Prescription." This subdivision is necessary to specify the information that must be provided by a Law Enforcement-User when submitting a request for a Prescription History Report to CURES. The addition of subdivision (e)(1)(A) requires the subsequent renumbering of this subdivision.

Former subdivision (e)(1)(A) was renumbered as subdivision (e)(1)(B). This is a non-substantive change.

New subdivision (e)(1)(D) was added to explain the procedures a Law Enforcement-User must follow in order to request a Prescription History Report in the Web-Based Application, including the search criteria that must be provided for each type of report.

Subdivision (e)(1)(D)1.a. was amended to replace "includes" with "include." This amendment is necessary to be grammatically correct.

Former subdivision (f) was removed because the Department created the term "Prescription History Report" to include a Pharmacy History Report and added the applicable procedures to

request a Pharmacy History Report to subdivision (e)(1)(D)2. The addition of this subdivision requires the subsequent renumbering of this subdivision.

Former subdivision (f)(1)(A)-(C) was deleted because Law Enforcement-Users no longer needed to provide a search authorization to request a Pharmacy History Report. This was necessary to reduce overly restrictive requirements for Law Enforcement-Users to access the reports in order to assist the Law Enforcement-Users in accessing the reports more quickly.

Subdivision (e)(1)(D)2.a. was amended to replace “includes” with “include.” This amendment is necessary to be grammatically correct.

Subdivision (e)(1)(D)2.a.(i) was amended to include “DEA Number” as search criteria when a Law Enforcement-User is requesting a Pharmacy History Report. This amendment is necessary to allow Law Enforcement-Users to search by the pharmacy DEA Number to assist the efforts of that Law Enforcement-User on behalf of a Law Enforcement Agency to control the Diversion and Resultant Abuse of Applicable Controlled Substances.

New subdivision (e)(1)(D)3. was added to include a new report available to Law Enforcement-Users in CURES and the procedures required to request a Serialized Prescription History Report. This subdivision is necessary to clarify the information Law Enforcement-Users are required to provide in order to determine the serialized prescription order information associated with specified prescription form serial numbers, as reported to CURES PDMP. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

New subdivision (f) was added to include a new report available to Law Enforcement-Users in CURES and to provide the search criteria required for when a Law Enforcement-User may access CURES to obtain a Serialized Prescription Form Report. Date search type is to specify that the Law Enforcement-User may search by the date the file was submitted or the date the order was delivered. This subdivision is necessary to clarify the information Law Enforcement-Users are required to provide in order to determine whether a prescription form serial number has been reported to CURES as lost or stolen, and whether the associated prescription form information has been reported to CURES by the applicable security printer. Additionally, this report provides an additional safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

New subdivision (g) was added to include a new report available to Law Enforcement-Users in CURES and to provide the search criteria required for when a Law Enforcement-User may access CURES to obtain a Prescription Form Theft or Loss Report. Reporter type means that the Law Enforcement-User may search by the individual who submitted the theft or loss report. Reporter type include Prescriber, Pharmacist, or security printer. Date search type is to specify that the Law Enforcement-User may search by the date the theft or loss was reported, of the date of the theft or loss. This subdivision is necessary to clarify the information Law Enforcement-Users are required to provide in order to determine whether a prescription form serial number has been reported to CURES as lost or stolen. Additionally, this report provides an additional

safeguard to prevent fraudulent prescription forms and the improper dispensing of a Controlled Substance.

Article 3. Research

§ 828.1. Eligibility for Access to Data from CURES.

Subdivision (a) was non-substantively amended to replace “section 826.2” with “section 828.2” to reference the correct citation in the regulations.

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

Subdivision (a) was non-substantively amended to replace “section 826.5” with “section 828.5” and “section 826.6” with “section 828.6” to reference the correct citation in the regulations.

Subdivision (g)(1)(K) was non-substantively amended to reference the applicable Code of Federal Regulations citation. This amendment is necessary to provide clarity and consistency between these regulations and the Code of Federal Regulations

Subdivision (g)(2) provides the indirect identifiers that are not unique to an individual in the CURES database but can be used in combination with other information about that individual to identify them. In accordance with best practices and recommendations designed to avoid the disclosure of information that can indirectly identify an individual, subdivision (g)(2) has been amended to revise the minimum number of individuals in certain categories from 2 to 10, that may be used for disclosure purposes. (See Statewide Longitudinal Data Systems (SLDS) Technical Brief 3: Statistical Methods for Protecting Personally Identifiable Information in Aggregate Reporting (NCES 2011-603)).

New subdivision (i) was added to set the requirement that an Interested Party must not re-identify or attempt to re-identify De-Identified Individual-Level Data or Aggregated Data from CURES. This amendment is necessary because CURES contains confidential data that must be safeguarded, thereby protecting the privacy of the individuals to whom the information pertains. The addition of this definition requires the subsequent renumbering of subdivisions (j)-(m) in this section.

§ 828.5. Procedures for Requesting Aggregated Data from CURES.

Subdivision (c)(8) was non-substantively amended to replace “section 826.4” with “section 828.4” to reference the correct citation in the regulations.

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

Subdivision (c)(11)(C) was non-substantively amended to replace “section 826.4” with “section 828.4” to reference the correct citation in the regulations.

New subdivision (c)(11)(D) was added to specify that a completed Data Request Application checklist must include a security acknowledgement that includes the name, the signature, and the date of signature of the public agency's or research body's information security officer or IT manager. This subdivision is necessary to provide the Department with information regarding the security measures in place to protect any data received by the Bona Fide Researcher, and a point of contact in the event that there is a breach of information that may contain any data from CURES. The addition of this subdivision requires the subsequent renumbering of this subdivision.

Subdivision (c)(11)(E) (formerly subdivision (c)(11)(D)) was amended to clarify that the completed Data Request Application checklist must include a completed Data Request Application supplemental security requirements acknowledgement. This subdivision is necessary to provide the Department with information regarding the security measures in place to protect any data received by the Bona Fide Researcher, and a point of contact in the event that there is a breach of information that may contain any data from CURES.

Former subdivision (c)(11)(G) has been deleted. This deletion is necessary because the Department has modified its implementation of Civil Code section 1798.24, subdivision (b) of the Information Practices Act (IPA), which authorizes a state agency to release an individual's personal information maintained by the state agency if the individual consents to the disclosure. The Department has replaced the requirements in this subdivision with a new consent form incorporated by reference in new subdivision (c)(11)(H)1.

New subdivision (c)(11)(H) was amended to allow Bona Fide Researcher access to Identified Individual-Level Data if the researcher complies with either of two IPA disclosure exceptions—Civil Code section 1798.24, subdivision (b), or subdivision (t). This subdivision is necessary to allow researchers access to sensitive data for important public policy research but also to protect the privacy rights of individuals whose personal and sensitive health information is maintained by the Department in the CURES database.

New subdivision (c)(11)(H)1. implements the IPA disclosure exception in Civil Code section 1798.24, subdivision (b), which authorizes a state agency to release an individual's personal information maintained by the state agency if the individual consents to the disclosure. This subdivision incorporates by reference a consent form that must be completed by the research subject before the Department will disclose the individual's CURES data to a Bona Fide Researcher. It also allows an individual to withdraw consent at any time. This subdivision is necessary to protect the privacy rights of individuals whose personal and sensitive health information is maintained by the Department in the CURES database. A uniform consent form applicable to all Bona Fide Researchers will help ensure compliance and promote efficiency in the disclosure process. The proposed content of the consent form is necessary to ensure that an individual is aware of the circumstances surrounding the consent.

New subdivision (c)(11)(H)2. implements the IPA disclosure exception in Civil Code section 1798.24, subdivision (t), which authorizes a state agency to release an individual's personal information maintained by the state agency to certain entities upon approval of the Committee for the Protection of Human Subjects (CPHS) for the California Health and Human Services

Agency (CHHSA) or an institutional review board. This discretionary exception was considered by the Department but ultimately rejected during the rulemaking proceeding for the 2020 CURES regulations. After further evaluation, the Department has determined that researcher access to CURES data as authorized by this discretionary exception poses minimal risks to privacy interests. This new subdivision will allow researchers greater access to sensitive data for important public policy research but also continue to protect the privacy rights of individuals whose personal and sensitive health information is maintained by the Department in the CURES database.

New subdivision (d) was added to provide a mechanism for researchers to access CURES data remotely. It specifies that if a Bona Fide Researcher requests remote access authorization, the Bona Fide Researcher and each applicable Team Member must complete and submit a Researcher Confidentiality and Non-Disclosure (CND) Agreement and a Researcher Data Access User Agreement, both of which are incorporated by reference in the regulation. If the Bona Fide Researcher or any Team Member is unable to meet the security requirements of the Researcher Data Access User Agreement, the subdivision authorizes that Bona Fide Researcher or Team Member to submit a Security Variance Form for Data Access Non-Compliance of Security Requirements, incorporated by reference in the regulation, for consideration by Department's Research Center. This new subdivision is necessary as the state transitions to a post-pandemic work environment where a significant percentage of employees, including researchers, continue to work from home, which may require remote access to CURES to complete a research project. This new subdivision will allow researchers greater access to sensitive data for important public policy research but also continue to protect the privacy rights of individuals whose personal and sensitive health information is maintained by the Department in the CURES database.

Subdivision (e) (formerly subdivision (d)) was amended to add the new forms incorporated by reference in new subdivision (d) to the Data Request Application Package. This change is necessary to ensure that all required material has been submitted to the Department before it releases CURES data.

Subdivision (f) (formerly subdivision (e)) was amended to add the new forms incorporated by reference in new subdivision (d) to the project renewal request. This change is necessary to ensure that all required material has been submitted to the Department before it approves a project renewal request.

Article 4. Information Practices Act Requests

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

Subdivisions (a) and (b) were non-substantively amended to update the format of the date associated with the document incorporated by reference.

Subdivision (c) was amended to include the two new Users in CURES who are authorized to access an individual's data in CURES and to specify that all audit history results, including those of the new users, will be released to the individual upon request. This change is necessary

because Non-DEA Practitioner-Users and Delegate-Users are two new type of Users who now have access to CURES data under AB 528.

Article 5. Information Exchange Web Service

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

This subdivision was amended to reference the newly defined terms “Covered Entity” and “Business Associate.” These amendments are necessary to provide clarity and consistency between these regulations and the Code of Federal Regulations.

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

Subdivision (c)(2) was amended to reference the most updated revision date of the DOJ CURES Information Exchange Web Service Onboarding Questionnaire, incorporated by reference in the regulation. The DOJ CURES Information Exchange Web Service Onboarding Questionnaire was updated to rephrase some of the language and include the full reference for prior acronyms. This was necessary to reduce confusing terms and phrasing to allow those filling out the questionnaire to provide accurate responses. New language was also added to urge responders to contact their HIT System contact. This was necessary to encourage those filling out the questionnaire to ask individuals with necessary information, to assist in providing accurate responses. The form was also revised to indicate whether the organization intends to perform interstate searches via the Information Exchange Web Service. This revision was necessary to include because of the expanding role of interstate users and searches. The form also added discussion of users in the first year and growth of users. These questions were necessary to provide the Department with more information on how many users and intended users would be using the service. This form was also amended to remove the requirements to provide the Internet Protocol (IP) Address or range of IP Addresses or Network for Test Environment whitelisting and IP Address or range of IP Addresses or Network for Production Environment whitelisting. These requirements were removed from this form because both requirements have been replaced with a different information technology process.

Subdivision (d) was amended to reference the most updated revision date of the CURES Information Exchange Web Service Overview, incorporated by reference in the regulation. Figures 1 and 2 of The Information Exchange Web Service Overview were updated to include the most current workflows for HIT Systems to follow when submitting queries through the Information Exchange Web Service (IEWS). The document was also updated to specify that the Department is moving away from IP Address whitelisting in the IEWS to a more secure alternative—mutual authentication. Language was added regarding access security, mutual authentication, and required certificates. These changes were necessary because with mutual authentication, HIT Systems will be authenticated by their client certificates and will also verify that they are talking to the right server by authenticating the server certificate. This change is necessary to better protect the IEWS from cyber-attacks. The form was also updated to change the levels of layers of security from three to two, which was necessary based on the changes for the workflow, IP address requirements, and mutual authentication requirements.

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

Subdivisions (a) through (c) were amended to include Non-DEA Practitioner-Users and to reference the relevant citation in the regulations. These amendments are necessary because, with the inclusion of Non-DEA Practitioners being authorized to access CURES under AB 528, Non-DEA Practitioner-Users are now authorized to access data from CURES via the CURES IEWS.

Subdivision (c)(5) was amended to include that a HIT System must only identify one authorized Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User for each request and the individual identified in the request must be the intended recipient of the data. This amendment is necessary to prevent unauthorized access to protected information in CURES.

New subdivisions (c)(5)(A) through (c)(5)(C) were added to clarify the specified requirements for a HIT system to authenticate an authorized Prescriber-User, Non-DEA Practitioner-User, or Pharmacist-User for each request. These subdivisions are necessary because each specified user requires different information to be authenticated by the HIT System.

Former subdivisions (c)(5)(A) and (c)(5)(B) were removed because the requirements for the authentication of the identity of the Prescriber-User and Pharmacist-User by the HIT System have been revised and moved into new subdivision (c)(5).

Subdivision (d) was amended to include Non-DEA Practitioner-Users. This amendment is necessary because, with the inclusion of Non-DEA Practitioners being authorized to access CURES under AB 528, Non-DEA Practitioner-Users are now authorized to access data from CURES via the CURES IEWS. Additionally, this subdivision has been revised to replace “patient information” with “data in CURES” because Prescriber-Users, Non-DEA Practitioner Users, and Pharmacist-Users have access to other protected information in CURES, not just patient information. Furthermore, this subdivision was non-substantively amended to add “section 822.4” to include the new citation for Non-DEA Practitioners, and to replace the previous citation of “section 822.4” with “section 823.4” to reference the correct citation in the regulations for Pharmacist-Users.

ECONOMIC IMPACT ASSESSMENT/ANALYSIS

The Department concludes:

(1) It is unlikely that the proposal would create or eliminate jobs within the state. This determination is based on the fact that this proposed action makes specific the requirements pertaining to licensed Health Care Practitioners, Non-DEA Practitioners, Pharmacists, and Delegates. For example, it is possible that Health Care 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.

Estimated economic impacts were calculated by conducting outreach with affected stakeholders to determine the scale of projected impacts. Where relevant and appropriate, the Department analyzed instances of prior stakeholder engagement and recent historical data and trends to determine projected economic impacts that businesses or individuals may incur to comply with this regulation over its lifetime. For example, the Department conducted outreach with HIT Systems in order to determine the estimated economic impact, in the form of time and resources, which a HIT System may incur to comply with this regulation. Furthermore, costs that a California Licensee, such as a Prescriber, Pharmacist, or Non-DEA Practitioner, may incur to comply with this regulation for the first year are estimated for each individual, as opposed to each individual's respective business. This helps differentiate the costs that a HIT Systems or California licensee may incur to comply with this regulation. This regulation results in a nominal economic impact to Out-of-State Prescribers and Out-of-State Pharmacists, which was excluded because it strictly impacted out-of-state businesses and individuals.

Estimated Costs to HIT Systems: The Department currently has 41 HIT System businesses connected to the Information Exchange Web Service (IEWS); however, for cost estimating purposes, the Department has rounded that number to 50.

For each HIT System business that would need to make system updates in order to continue to be connected to the IEWS, the Department anticipates that it would take as few as 20 hours and as many as 76 hours to make the additional changes necessary to meet the Department's revised technology requirements. The Department determined the average salary of a Web Services Engineer to be \$108,987, or \$54.49 hourly. As such, the Department estimates that HIT Systems would incur costs of approximately \$54,500 to \$207,100.

Initial Estimated Costs to Prescribers/Non-DEA Practitioners:

The Department estimates that as few as 55,107 and as many as 110,213 prescribers/practitioners would enter into Delegate Agreements each year. For each Prescriber/Non-DEA Practitioner who enters into a Delegate Agreement, there would be a corresponding Delegate. Furthermore, the Department believes many medical practices will have a Medical Practice Administrator assist the Prescriber/Non-DEA Practitioner in drafting the Delegate Agreement. Because the Prescriber/Non-DEA Practitioner, the Delegate, and, if applicable, the Medical Practice Administrator each play a role in completing the Delegate Agreement, the Department separately estimated the amount of time needed by each to complete the Delegate Agreement. Lastly, the Department believes a Delegate will primarily be classified as a medical assistant. The Department determined the average salary of a Prescriber/Non-DEA Practitioner to be \$147,478, or \$73.74 hourly. The Department arrived at this estimate by averaging the salaries of physicians and surgeons, optometrists, dentists, veterinarians, physician assistants, registered nurses, and nurse practitioners, and determined the average salary of a medical assistant to be \$40,348, or \$20.17 hourly, and the average salary of a Medical Practice Administrator to be \$88,043, or \$44.02 hourly.

Because medical practices vary broadly, the Department determined for the low economic impact basis that a Prescriber/Non-DEA Practitioner, Delegate, and Medical Practice

Administrator would be needed to complete the Delegate Agreement. As the basis for estimating the high economic impact, only a Prescriber/Non-DEA Practitioner and Delegate would be needed to complete the Delegate Agreement. The Department made this determination because not all medical practices may have Medical Practice Administrators available to draft the Delegate Agreement, which would in turn require additional time from the Prescriber/Non-DEA Practitioner to complete the Delegate Agreement.

Initial Estimated Costs to Pharmacists:

The Department estimates that as few as 11,711 and as many as 23,421 Pharmacists would enter into Delegate Agreements each year. For each Pharmacist who enters into a Delegate Agreement, there would be a corresponding Delegate. Furthermore, the Department believes many medical practices will have a Medical Practice Administrator assist the Pharmacist in drafting the Delegate Agreement. Because the Pharmacist, the Delegate, and, if applicable, the Medical Practice Administrator each play a role in completing the Delegate Agreement, the Department separately estimated the amount of time needed by each to complete the Delegate Agreement. The Department determined the average salary of a Pharmacist to be \$126,839, or \$63.42 hourly.

Because medical practices vary broadly, the Department determined for the low economic impact basis that a Pharmacist, Delegate, and Medical Practice Administrator, would be needed to complete the Delegate Agreement. As the basis for estimating the high economic impact, only a Pharmacist and Delegate would be needed to complete the Delegate Agreement. The Department made this determination because not all medical practices may have Medical Practice Administrators available to draft the Delegate Agreement, which would in turn requires additional time from the Pharmacist to complete the Delegate Agreement.

(2) It is unlikely that the proposal would create new businesses or eliminate existing businesses within the state for the reason identified above.

(3) It is unlikely that the proposal would result in the expansion of businesses currently doing business within the state for the reason identified above.

The Department also concludes that:

(1) The proposal would benefit the health and welfare 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.

(2) The proposal would make specific the statutes governing the access and use of CURES, which would not have a discernible impact on worker safety. 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 or control the Diversion and Resultant Abuse of Controlled Substances, and ensure that the information

contained in CURES is used only for statutorily authorized purposes. Users may become more aware of their prescribing practices as they learn to navigate CURES and become familiar with the requirements set forth in these regulations.

(3) The proposal would benefit the state's environment because these regulations 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 all across the state of California, and to protect the security of the data contained within CURES. When users are aware of what is being prescribed, that could result in less Controlled Substances in the community. Less Controlled Substances in the community will also decrease the improper disposal of Controlled Substances into the environment, for instance, by being improperly flushed down the toilet or drain and entering the water systems.

TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDIES, REPORTS, OR DOCUMENTS

Statewide Longitudinal Data Systems (SLDS) Technical Brief 3: Statistical Methods for Protecting Personally Identifiable Information in Aggregate Reporting (NCES 2011-603).

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

The Department has made an initial determination that the proposed action would not have a significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

This determination is based on the fact that 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.

REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESS

The Department finds that no reasonable alternatives were presented to, or considered by, the Department that would lessen any adverse impact on small business.

REASONABLE ALTERNATIVES TO THE PROPOSED ACTION AND THE AGENCY'S REASON FOR REJECTING THOSE ALTERNATIVES

The Department finds that no alternatives were presented to, or considered by, the Department that would be more effective in carrying out the purpose of these proposed regulations or would be as effective and less burdensome to affected private persons than these proposed regulations.

Performance Standard as Alternative:

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 data, and adherence to statute.