CALIFORNIA DEPARTMENT OF JUSTICE

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

FINAL STATEMENT OF REASONS

UPDATE OF THE INITIAL STATEMENT OF REASONS

On September 3, 2021, the Department of Justice (Department) published an Initial Statement of Reasons (ISOR) to explain modifications to these regulations as originally proposed and the reasons for those modifications. These regulations were modified as follows:

Article 1. Chapter Definitions

§ 820. Definitions.

Subdivision (h) was amended to replace "section" with "part." This amendment is necessary to correctly cite the document incorporated by reference and to conform to citations of the Code of Federal Regulations elsewhere in these regulations. This subdivision was also amended to make clear that the Code of Federal Regulations part was incorporated by reference in these regulations. This amendment is necessary to ensure the regulations include the most recent laws and regulations.

Subdivision (k) was amended to replace "section" with "part." This amendment is necessary to correctly cite the document incorporated by reference and to conform to citations of the Code of Federal Regulations elsewhere in these regulations. This subdivision was also amended to make clear that the Code of Federal Regulations part was incorporated by reference in these regulations. This amendment is necessary to ensure the regulations are up to date with existing laws and regulations.

Subdivision (p) was amended to replace "section" with "part." This amendment is necessary to correctly cite the document incorporated by reference and to conform to citations of the Code of Federal Regulations elsewhere in these regulations.

Subdivision (w) was non-substantively amended to remove a parenthesis that should have been removed in the 45-day comment period. This amendment is necessary to fix a formatting error.

Subdivision (x) was amended to include that a Delegate Agreement may be between an Authorizing User and one or more Delegates. This amendment is necessary to further specify what a Delegate Agreement is and to help support the newly proposed requirements regarding Delegate Agreements, as specified in Article 2.4, section 824.2. This subdivision was also amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout these regulations.

Subdivision (kkk) was amended to change "any" to "a." This amendment is necessary to correctly reference a change from the previous 45-day public comment period.

Subdivision (xxx) was amended to add "and" before the last item in the list. This amendment is necessary to be grammatically correct.

Subdivision (eeee)(1)(C) was amended to remove language noting incorporation by reference in this chapter since it had already been incorporated in these regulations previously. This amendment is necessary to properly incorporate documents by reference, which had already been incorporated by reference in subdivision (k).

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

§ 821.1. Eligibility for Access to CURES.

Subdivision (e) was amended to specify that if an individual is registered for CURES, is an Out-of-State Prescriber, and is no longer eligible, the individual must not access CURES and must notify CURES prescription drug monitoring program (PDMP) in writing. This amendment is necessary to specify the means in which an Out-of-State Prescriber must notify CURES when that Out-of-State Prescriber is no longer eligible to access CURES. Verbal notifications can be easily lost, but written notifications document compliance with the regulations.

§ 821.2. Procedures to Register for Access to CURES.

Subdivision (c) was amended to replace "application" with "Prescriber Registration Application." This amendment is necessary to reference the defined term in subdivision (a).

Former **s**ubdivision (c)(2)(H)2. was removed to delete the requirement that if an applicant is licensed by the Medical Board of California or the Dental Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board certified. This amendment is necessary because during the public comment period the Department learned that there are a variety of applicants who are licensed by boards other than the Medical Board of California and the Dental Board of California, and these applicants may also have specialties and board certifications. The Department conferred with the Department of Consumer Affairs on this issue, after the 45-day public comment period.

§ 821.4 Restrictions on Accessing Data in CURES.

Subdivision (a)(1)(A) was non-substantively amended to correctly cite the provision, which had been renumbered as a result of changes in the 45-day public comment period.

Article 2.2. Access and Use by Non-DEA Practitioners

§ 822.2. Procedures to Register for Access to CURES.

Former subdivision (c)(2)(H)2. was removed to delete the requirement that if an applicant is licensed by the Medical Board of California, the applicant must provide the applicant's specialty and indicate whether the applicant is board certified. This amendment is necessary because during the public comment period the Department learned that there are a variety of applicants who are licensed by boards other than the Medical Board of California, and these applicants may also have specialties and board certifications.

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

Subdivision (c) is necessary to prohibit the sale of data obtained from CURES. This is consistent with Health and Safety Code (HSC) section 11165, subdivision (c)(2)(A), not HSC section 11165, subdivision (b)(2)(A), as previously misstated in the ISOR.

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

§ 823.1. Eligibility for Access to CURES.

Subdivision (d) was amended to specify that if an individual is registered for CURES and is an Out-of-State Pharmacist, the individual must not access CURES and must notify CURES PDMP in writing. This amendment is necessary to specify the means in which an Out-of-State Pharmacist must notify CURES when that Out-of-State Prescriber is no longer eligible to access CURES. Verbal notifications can be easily lost, but written notifications document compliance with the regulations.

Article 2.4. Access and Use by Delegates

§ 824.1. Eligibility for Access to CURES.

Subdivision (b) was amended to be more prescriptive. There is a specific process established under section 824.8, subdivision (c), to terminate the ability of a Delegate to access CURES on behalf of an Authorizing User. This amendment is necessary to clarify the process that Authorizing Users must comply with to satisfy this requirement.

§ 824.2. Delegate Agreement Between Authorizing User and Delegate.

Subdivision (a)(2) was amended to specify that a Delegate Agreement may be between one Authorizing User and one Delegate or between one Authorizing User and multiple Delegates. This amendment is necessary to reduce the administrative workload for Authorizing Users when establishing a Delegate Agreement and allow Authorizing Users flexibility in creating a Delegate Agreement either with a Delegate or Delegates. This subdivision was also amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

Subdivision (a)(3) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

Subdivision (a)(5) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

New subdivision (b) was added to specify that if an Authorizing User cancels a Delegate association with a Delegate, the Delegate Agreement between the Authorizing User and that Delegate will automatically terminate. This amendment is necessary to specify that if a Delegate association is cancelled in the system that cancellation will translate over to the Delegate Agreement.

New subdivision (c) was added to specify that if an Authorizing User or a Delegate cancels a Delegate Agreement prior to the expiration of the term of that Delegate Agreement, and the Delegate Agreement is between one Authorizing User and multiple Delegates, the Delegate Agreement will remain active for the remaining Delegates. This amendment is necessary because an Authorizing User may have one Delegate Agreement with multiple Delegates, and if one of those Delegates is removed, this new provision will prevent the entire Delegate Agreement from no longer being valid for all Delegates specified on that Delegate Agreement. The addition of this subdivision requires the subsequent renumbering of subdivisions (d)-(e) in this section.

Subdivision (d) (formerly subdivision (b)) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

Subdivision (e) (formerly subdivision (c)) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

§ 824.6. Restrictions on Accessing Data in CURES.

Subdivision (b)(1) was non-substantively amended to include "the" before "Authorizing User." This amendment is necessary for consistency.

Subdivision (b)(2) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

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

Subdivision (b), as previously noted in the ISOR, is necessary to prohibit the sale of data obtained from CURES. This is consistent with HSC section 11165, subdivision (c)(2)(A), not HSC section 11165, subdivision (b)(2)(A), as previously misstated in the ISOR.

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

Subdivision (a)(2)(A) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

Subdivision (b)(2)(A) was amended to switch the order of Authorizing User and Delegate. This amendment is necessary to be consistent throughout the regulations.

Article 2.5. Access and Use by Interstate-Users

§ 825.1 Eligibility for Access to Data from CURES.

In subdivision (a)(3)(B), the Department reaffirms that the text language was correct in that the acknowledgement be retained for five years from the date of signature, or execution, and not expiration as stated in the ISOR.

§ 825.3 Restrictions on Accessing Data in CURES.

Subdivision (a)(1) was amended to replace subdivision (dddd)(1)(B) with subdivision (eeee)(1)(B) to reference the correct citation in the regulations.

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

Subdivision (b)(1)(A) was amended to include Interstate Prescriber, Interstate Non-DEA Practitioner, and Interstate Pharmacist. This amendment is necessary to specify, among other requirements, that an Interstate-User may disclose or transfer the data of a patient so long as that patient is Under the Care of a Prescriber, Out-of-State Prescriber, Interstate Prescriber, Non-DEA Practitioner, Interstate Non-DEA Practitioner, Pharmacist, Out-of-State Pharmacist, or Interstate Pharmacist, to whom the data is disclosed or transferred. This was also necessary for consistency in the regulations regarding who can disclose and transfer the data.

Article 2.6. Access and Use by Regulatory Agency Officials

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

Subdivision (c) was amended to specify that if an individual is registered for CURES, is a Regulatory Agency Official and is no longer eligible to access CURES, the individual must not access CURES and the Regulatory Agency must notify CURES PDMP in writing. Verbal notifications can be easily lost, but written notifications document compliance with the regulations. Additionally, this subdivision was amended to specify that upon receipt of the Regulatory Agency's written notification, CURES PDMP must terminate the Regulatory Agency Official's access to CURES. There is no automated process in place for the Department to verify whether Regulatory Agency-Users are still eligible to access CURES, since Regulatory Agency-User account statuses are not dependent of an associated State License Number. This amendment is necessary to limit access to sensitive health information to individuals who are no longer eligible to access CURES and to specify the means in which a Regulatory Agency must notify CURES when that Regulatory Agency Official is no longer eligible to access CURES.

§ 826.6. Procedures for Use of CURES.

Subdivision (f)(1)(A)2.a. was non-substantively amended to indicate this is a new subdivision from the 45-day public comment period.

Article 2.7. Access and Use by Law Enforcement Officials

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

Subdivisions (b) and (c) were non-substantively amended to remove the term "Agency." These amendments are necessary to correspond with the defined term in the regulations.

Subdivision (c) was amended to specify that if an individual is registered for CURES and is a Law Enforcement Official, the individual must not access CURES and the Law Enforcement Agency must notify CURES PDMP in writing. Verbal notifications can be easily lost, but written notifications document compliance with the regulations. Additionally, this subdivision was amended to specify that upon receipt of the Law Enforcement Agency's written notification, CURES PDMP must terminate the Law Enforcement Official's access to CURES. There is no automated process in place for the Department to verify whether Law Enforcement-Users are still eligible to access CURES, since Law Enforcement-User account statuses are not dependent of an associated State License Number. This amendment is necessary to limit access to sensitive health information to individuals who are no longer eligible to access CURES and to specify the means in which a Law Enforcement Agency must notify CURES when that Law Enforcement Official is no longer eligible to access CURES.

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

Subdivision (m)(4) was amended to replace "Bureau" with "Division." This amendment is necessary to reference the correct Law Enforcement Agency.

§ 827.6. Procedures for Use of CURES.

Subdivision (d)(1)(B)2. was non-substantively amended to replace the reference to "section 827.4, subdivision (c)(2)(A)" to the correct reference of "section 827.4, subdivision (k)(2)(A)." This amendment is necessary because of renumbering and to reference the correct citation in the regulations.

Subdivision (e)(1)(D)2.a.(i) was non-substantively amended to indicate the addition of a comma, which is necessary for grammar.

Subdivision (e)(1)(D)2.b. and c. were non-substantively amended to indicate the appropriate subdivisions that were previously deleted.

Subdivision (f)(1)(A)2.a. and (g)(1)(A)2.a. were non-substantively amended to indicate these are new subdivisions from the 45-day public comment period.

Article 3. Research

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

Subdivision (g)(1)(K) was amended to incorporate 45 Code of Federal Regulations part 164.514, subdivision (b)(2)(i), by reference in these regulations. This amendment is necessary to ensure the regulations include the most recent laws and regulations.

Subdivision (g)(2) was amended to change the deletion of "2" to "20" to correctly reference previous text in the regulations. The number "20" was changed to "10" in the previous 45-day public comment period. This amendment is necessary to clearly indicate the previous text and suggested changes so that the researchers know their obligations and requirements under these regulations.

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

Subdivision (c)(11)(A)6. was amended to specify that the security measures be compliant with the National Institute of Standards and Technology (NIST) Special Publication 800-171, Revision 2, Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations (February 2020). This subdivision was also amended to incorporate this document by reference in these regulations. This amendment 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 to also ensure those security measures are consistent with information outlined in the NIST Special Publication 800-171. The Department chose to require that the security measures be compliant with NIST 800-171 because it is a well-known publication and the security measures will ensure that the data is protected.

Subdivision (c)(11)(A)6 and (c)(11)(C) were also non-substantively amended to add a space between "the unauthorized" and "from CURES."

Subdivision (c)(11)(H)1. was non-substantively amended to include the form number for the CURES 0001, and to correctly reference the entire form title as, "Consent for Use of Personal Information from CURES form." This amendment is necessary so that the Bona Fide Researchers clearly know what form to use, when required in this section.

The Department revised the Department of Justice (DOJ) Consent for Use of Personal Information from CURES form (CURES 0001) that is incorporated by reference in subdivision (c)(11)(H)1. to conform the introductory regulatory citation to the regulations and to state, "A Bona Fide Researcher is required to submit the completed form with any Data Request Application for Identified Individual-Level Data under California Code Regulations, title 11, section 828.6, subdivision (c)(11)(H)1." This revision is necessary to specify that the DOJ Consent for Use of Personal Information from CURES form is only required for requests of Identified Individual-Level Data from CURES under Civil Code section 1798.24, subdivision (b).

Subdivision (c)(11)(H)2. was amended to specify that if the Bona Fide Researcher has met all other application and security requirements pursuant to these regulations and would be approved by the Department's Research Center, the Department's Research Center will provide written documentation to the Bona Fide Researcher to allow the Committee for the Protection of Human

Subjects to review the Bona Fide Researcher's application. This amendment is necessary so that the Bona Fide Researcher knows under what conditions the Department's Research Center will provide them with written documentation to allow the Committee for the Protection of Human Subjects to review their application.

Subdivision (d) was non-substantively amended to include the correct form numbers for the following documents incorporated by reference: DOJRC 0003 Researcher Confidentiality and Non-Disclosure Agreement, DOJRC 0002 Researcher Data Access User Agreement, and the DOJRC 0001 Security Variance Form for Data Access Non-Compliance of Security Requirements.

The Department also revised the forms that are incorporated by reference in this subdivision. The Department revised the DOJRC Security Variance Form for Data Access Non-Compliance of Security Requirements (DOJRC 0001) (Orig. 07/2021) to delete "should be" in the introductory paragraph. This was necessary so that requestors understand their obligation to completely fill out the form and not leave any blanks in order for it to be processed. On page 2, paragraph 3, the Department added language to make clear that if compliance would take longer than one year, then a renewal would be required. Relatedly, the Department revised language in the last box on page 3. The changes on page 3 also make clear that compliance could occur, for example in three months from the form being submitted, or for one year and then a renewal would be required. These changes were necessary to make clear that the Department would not allow non-compliance for longer than one year and that compliance should occur as soon as possible, regardless of the one-year limit. Selecting a year aligns with other form submissions at the Department and helps protect the CURES information by prohibiting researchers from being out of compliance with security requirements indefinitely, and without any tracking or oversight.

The Department revised page 3 of the DOJRC Researcher Data Access User Agreement (DOJRC 0002) (Orig. 07/2021). To make clear that the form was being used to confirm compliance with the security requirements listed on page 2, the Department added a cross-reference at the top of page 3. This was necessary for the requestors to know what the requirements are to comply with so that they can confirm compliance. This is also necessary to protect the CURES information by setting forth security requirements. The Department also deleted the requirement to confirm compliance with an email client. This was necessary because the email client information was not a security requirement, but what client was being used could help the Department know what security was already in place by that email client. Because compliance with the security requirements exists without needing to know the particular email client, the Department deleted this entry on the form. The Department revised the web browser requirements to make clear the security requirements that the requestors must comply with. This was necessary to protect the CURES information by ensuring the web browsers are secure.

The Department revised paragraph 3.d. on page 2 of the DOJRC Researcher Confidentiality and Non-Disclosure Agreement (DOJRC 0003) (Orig. 07/2021). The Department deleted two instances of "should" and replaced those instances with "must." This was necessary to make clear the requirements of the requestors when there is a security incident or breach. This change was also necessary to protect the CURES information and ensure that steps are taken when there is a security incident or breach. The Department also made a non-substantive change for

grammar and syntax to delete "the DOJRC." This was necessary for the sentence to read correctly, and for the Information Security Officer to know who to contact.

Subdivision (f) was non-substantively amended to clearly indicate the numbering of this subdivision.

Article 4. Information Practices Act Requests

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

This section was non-substantively amended to remove all hyphens from "CURES 101" and "CURES 201." These amendments are necessary to correctly reference the form numbers for the CURES 101 Information Practices Act Individual Request Form and the CURES 201 Information Practices Act Representative Request Form, incorporated by reference.

The Information Practices Act Individual Request Form (CURES 101) was amended to include "Street" before "Address" in Section A. Request for CURES Personal Records. This document was also amended to include "Date," "Year," "City," and "State" in Section B. Verification. These amendments are necessary to clearly identify the proposed changes in this form.

The Information Practices Act Representative Request Form (CURES 201) was amended to include "Street" before "Address" in Section B. Request for Prescription History Information in CURES. This document was also amended to include "Date," "Year," "City," and "State" in Section C. Verification. These amendments are necessary to clearly identify the proposed changes in this form.

Article 5. Information Exchange Web Service

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

Subdivision (c)(2) was non-substantively amended to include the correct form number for the CURES 0002 CURES Information Exchange Web Service Onboarding Questionnaire which is necessary to assist in identifying the correct form. The CURES Information Exchange Web Service Onboarding Questionnaire was amended to remove the application package checklist statement. This amendment is necessary because this checklist is not a requirement of the regulations or application package. The CURES Information Exchange Web Service Onboarding Questionnaire was further amended to add "Patient Activity Report" before the first reference of "PAR" in paragraph 7. This amendment is necessary so that those using this form know what the acronym PAR stands for.

Subdivision (d) was amended to change the revision date of the DOJ CURES Information Exchange Web Service Overview to November 2021. The revision date was updated throughout the DOJ CURES Information Exchange Web Service Overview, incorporated by reference. Page 5 of the DOJ CURES Information Exchange Web Service Overview was amended to change "pick-list" to "picklist." This amendment is necessary to be grammatically correct. The DOJ CURES Information Exchange Web Service Overview was further amended to add

"Memorandum of Understanding" before the first reference of "MOU." This amendment is necessary so that those relying on this form know what the acronym MOU stands for.

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

Subdivision (d) was amended to add "or" before the last item in the list. This amendment is necessary to be grammatically correct.

LOCAL MANDATE DETERMINATION

The proposed regulations do not impose any mandate on local agencies or school districts.

SUMMARY OF COMMENTS AND DEPARTMENT RESPONSES

The Department noticed the public on September 3, 2021, of the text of the proposed regulations and Initial Statement of Reasons. In addition to receiving written comments, the Department held a virtual public hearing on October 20, 2021. From September 3, 2021, through October 19, 2021, the Department received four written comments.

In December 2021, the Department revised the proposed regulations to implement several of the changes proposed during the initial 45-day public comment period. The Text of Proposed Regulations was modified on December 15, 2021, resulting in an additional 15-day public comment period that concluded on January 3, 2022. The Department received seven written comments during this modification period. The Second Modifications to the Proposed Regulations was modified on May 26, 2022, resulting in an additional 15-day comment period that concluded on June 12, 2022. The Department received one comment during this modification period.

Attachment A is a summary of all comments (written and oral) submitted during the 45-day public comment period, first 15-day public comment period, second 15-day public comment period, the public hearing, and the Department's responses. Attachment B is a comment index of the commenters and identifies (by number) the comment(s) made by each person.

ALTERNATIVES THAT WOULD LESSEN ADVERSE ECONOMIC IMPACT ON SMALL BUSINESS

No alternatives were proposed to the Department that would lessen any adverse economic impact on small business.

ALTERNATIVES DETERMINATION

The Department has determined that no alternative it considered or that was otherwise identified and brought to its attention would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective as and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

DOCUMENTS INCORPORATED BY REFERENCE

1. CURES 0001 - DOJ Consent for Use of Personal Information from CURES, July 2021, (see subdivision (c)(11)(H)1. of section 828.6).
2. CURES 0002 - DOJ CURES Information Exchange Web Service Onboarding Questionnaire, July 2021, (see subdivision (c)(2) of section 830.2).
3. DOJ CURES Information Exchange Web Service Overview, November 2021, (see subdivision (d) of section 830.2).
4. CURES 101 - Information Practices Act Individual Request Form, July 2021, (see subdivision (a) of section 829.2).
5. CURES 201 - Information Practices Act Representative Request Form, July 2021, (see subdivision (b) of section 829.2).
6. DOJRC 0001 - DOJ Research Center (DOJRC) Security Variance Form for Data Access Non-Compliance of Security Requirements, July 2021, (see subdivision (d) of section 828.6).
7. DOJRC 0002 - DOJRC Researcher Data Access User Agreement, July 2021, (see subdivision (d) of section 828.6).
8. DOJRC 0003 - DOJRC Researcher Confidentiality and Non-Disclosure (CND) Agreement, July 2021, (see subdivision (d) of section 828.6).
9. NIST Special Publication 800-171 - Protecting Controlled Unclassified Information in Nonfederal Systems and Organizations, February 2020.
10. 45 Code of Federal Regulations part 160.103 (10-1-20 Edition).
11. 45 Code of Federal Regulations part 162.103 (10-1-20 Edition).
12. 45 Code of Federal Regulations part 164.514, subdivision (b)(2)(i), (10-1-20 Edition).

The above documents are incorporated by reference because it would be cumbersome, unduly expensive, or otherwise impractical to publish the forms in the California Code of Regulations. During the rulemaking proceeding, the forms were made available upon request, and were available for viewing on the Department's website.

NON-DUPLICATION

Some of the regulations may repeat or rephrase in whole or in part a state or federal statute or regulation. This was necessary to satisfy the clarity standard in Government Code section 11349.1, subdivision (a)(3).