

CALIFORNIA DEPARTMENT OF JUSTICE

FINAL STATEMENT OF REASONS

UPDATE OF THE INITIAL STATEMENT OF REASONS

SECTION 820.

Subdivision (a) - The Department amended this definition to include the new definition of “Applicable Controlled Substances.” This amendment is necessary because the definition of “abuse” only relates to specified schedules of controlled substances, not all controlled substances.

Subdivision (d) - In response to the passage of AB 528 and the inclusion of Schedule V in the CURES reporting requirements effective January 1, 2021, the Department added the new subdivision (d), which defines “Applicable Controlled Substance.” The addition of this defined term is necessary because it distinguishes between specific controlled substances versus the more generalized definition of Controlled Substances, and it will include Schedule V Controlled Substances beginning January 1, 2021. The addition of this definition requires the subsequent renumbering of subdivisions (d)-(fff) in this section.

Subdivision (f) - The Department narrowed the scope of this definition so that it no longer includes all research. Bona Fide Research must now have four specified qualities and the final research product may be used for more specified purposes, not just publication in a peer-review journal. This amendment is necessary to ensure that the use of CURES data for Bona Fide Research will have a broader impact than originally proposed.

Subdivision (g) - The Department narrowed the scope of this definition to principal investigator or public health officer. This amendment is necessary to limit access to sensitive health information and to protect patient privacy.

Subdivision (m) - The Department amended this subdivision to replace “administrates” with “administers.” This amendment is necessary to be grammatically correct.

Subdivisions (t) - The Department amended these subdivisions to replace “Schedule II, Schedule III, or Schedule IV Controlled Substances” with the new definition of “Applicable Controlled Substances.” These amendments are necessary because to include Schedule V Controlled Substances beginning January 1, 2021.

Subdivision (u) - The Department amended this definition to replace “a Controlled Substance” with “an Applicable Controlled Substance.” This amendment is necessary because the definition of “Diversion” only relates to specified schedules of controlled substances, not all controlled substances.

Subdivision (v) - The Department amended this definition to replace “a Controlled Substance” with “an Applicable Controlled Substance.” This amendment is necessary because the definition

of “Diversion and Resultant Abuse” only related to specified schedules of controlled substances, not all controlled substances. The Department also nonsubstantively amended this subdivision to add a comma after “or user.” This amendment is necessary to be grammatically correct.

Subdivisions (w), (nn), and (oo) - The Department amended these subdivisions to delete “Schedule II, Schedule III, or Schedule IV.” These amendments are necessary to clarify that these definitions do not include reference to Applicable Controlled Substances, but rather the more general definition of Controlled Substances.

Subdivision (dd) - The Department added subdivision (dd) to define “Interested Party” as a public or private entity, Bona Fide Researcher, or Team Member. This definition modifies the term “Research Requestor.” This amendment is necessary to consolidate references to multiple parties and to clarify which requirements apply collectively to public or private entities, Bona Fide Researchers, and Team Members.

Subdivision (gg) - This subdivision was amended to reference Government Code section 811.2. This amendment is necessary because the statute gives examples of political subdivisions of the state.

Former Subdivision (ccc) - The Department removed the definition of “Research Requestor” and replaced it with “Interested Parties.” The Department further removed all references to this definition in all sections of the proposed regulations. This amendment is necessary to better distinguish Bona Fide Researchers from the collective term “Research Requestors.”

Former Subdivision (ggg) - The Department removed the definition of “Secure Lab” because it removed section 826, subdivision (f)(5), as discussed below. The Department further removed all references to this definition in all sections of the proposed regulations.

Subdivision (kkk) - The Department amended this subdivision to require that individuals who will have access to CURES data obtained for research purposes must first have authorization from the Department’s Research Center. These amendments are necessary to limit who may have access to sensitive health information and to protect patient privacy. The Department further amended this subdivision to replace “Research Requestor” with “Bona Fide Researcher from CURES.” This amendment is necessary because the Department removed the defined term “Research Requestor.”

Subdivision (lll) - The Department nonsubstantively amended this subdivision to add commas after “use of CURES” and “data from CURES.” These amendments are necessary to be grammatically correct.

Subdivision (nnn) - The Department amended this subdivision to replace “Under His or Her Care” with “Under the Practitioner’s Care, and Under the Pharmacist’s Care.” This amendment is necessary to conform to revised statutory language. The Department also nonsubstantively amended this subdivision to replace “means” with “mean.”

Subdivision (ooo)(1)(D) - The Department added this subdivision to provide that, for purposes of accessing CURES data, an emergency room patient will be considered to be under the care of the doctor who oversees or is involved in admitting or providing medical consultation to the patient. This subdivision is necessary to allow for proactive delivery of medical services in an emergency context.

SECTIONS 821(e)(2), 822(e)(2), 823(e)(2), 824(e)(2), 825(e)(2), and 826(d)(8).

Regarding the description of these provisions in the Initial Statement of Reasons, the references to Health and Safety Code section 11165, subdivision (b)(2)(A) should be to Health and Safety Code section 11165, subdivision (c)(2)(A).

SECTION 821.

Subdivision (c)(2) - The Department amended this subdivision to extend the time period a health care practitioner may access CURES data during a search period from 12 months to 24 months. This revision is necessary to balance the need to improve the quality of medical consultations and a patient's privacy interest.

Subdivision (d)(1)(A)(i) - The Department amended this subdivision to extend the time a health care practitioner may access CURES data for an upcoming appointment with a new patient from 24 hours or one business day to seven days before the appointment. This revision is necessary to balance a practitioner's need for flexibility to prepare for new appointments in between existing appointments and a patient's privacy interest.

Subdivision (g)(3)(A) - The Department amended this subdivision to authorize delegate access to the Web-Based Application, but not necessarily restrict access to the Information Exchange Web Service if authorized by statute. This amendment is necessary to accommodate future statutory provisions governing delegate access to CURES data.

SECTION 822.

Subdivision (c)(2) - The Department amended this subdivision to extend the time period a pharmacist may access CURES data during a search period from 12 months to 24 months. This revision is necessary to balance the need to improve the quality of medical consultations and a patient's privacy interest.

Subdivision (g)(3)(A) - The Department amended this subdivision to authorize delegate access to the Web-Based Application, but not necessarily restrict access to the Information Exchange Web Service if authorized by statute. This amendment is necessary to accommodate future statutory provisions governing delegate access to CURES data.

SECTION 823.

Subdivision (b)(2) - The Department amended this subdivision to extend the time period an out-of-state health care practitioner or pharmacist may access CURES data during a search period

from 12 months to 24 months. This amendment is necessary to balance the need to improve the quality of medical consultations and a patient's privacy interest.

Subdivision (c)(1)(A) - The Department amended this subdivision to extend the time an out-of-state health care practitioner may access CURES data for an upcoming appointment with a new patient from 24 hours or one business day to seven days before the appointment. This amendment is necessary to balance a practitioner's need for flexibility to prepare for new appointments in between existing appointments and a patient's privacy interest.

Subdivision (e)(2)(C) – The Department amended this subdivision to add a lead in sentence to make the provision grammatically correct.

SECTION 824.

Subdivision (a)(2) - The Department added this subdivision to require a Regulatory Agency to notify the Department when a Regulatory Agency Official leaves the agency or loses authorization to access CURES data. This subdivision is necessary to ensure that the system may only be accessed by authorized individuals.

Subdivision (b)(3)(C) - The Department amended this subdivision to replace “board-issued identification card” with “Regulatory Agency-issued identification card.” This amendment is necessary because not all regulatory agencies are governed by a board. The Department also amended this subdivision to require the applicant's supervisor, or if required by the applicant's Regulatory Agency, the head of the applicant's Regulatory Agency, to sign the letter supporting access to CURES data. This amendment is necessary to ensure that supporting documentation is authorized by the appropriate designated individual at a Regulatory Agency.

Subdivision (d)(1) - The Department amended this subdivision to replace “Schedule II, Schedule III, or Schedule IV Controlled Substances” with “Applicable Controlled Substances.” This amendment is necessary because it will include Schedule V Controlled Substances beginning January 1, 2021. The Department also amended this subdivision to expand the purposes for which a Regulatory Agency may use CURES data. These amendments are necessary because it will include other statutory functions of the Regulatory Agency not previously included in the regulation.

Subdivisions (d)(2) and (d)(3) - The Department amended these subdivisions to correct a grammatical error.

Subdivision (e)(1)(A) - The Department amended this subdivision to add the exception, “[u]nless otherwise required by law,” to the requirement that the use of the CURES data must be for the same authorized purpose for which the data was originally requested. This amendment is necessary to ensure that a Regulatory Agency is not prevented from complying with applicable state and federal laws that may require the disclosure of information obtained from CURES.

Subdivision (f)(7)(A) – The Department amended this subdivision to replace Regulation Board User with Regulatory Agency User to conform to the terms used in the definition section of the regulations.

SECTION 825.

Subdivision (a)(2) - The Department added this subdivision to require a Law Enforcement Agency to notify the Department when a Law Enforcement Official leaves the agency or loses authorization to access CURES data. This subdivision is necessary to ensure that the system may only be accessed by authorized individuals.

Subdivision (b)(3)(C)(ii) - The Department amended this subdivision to require that a letter supporting an applicant’s access to CURES data be signed by the applicant’s supervisor. This amendment is necessary to ensure that an applicant has been authorized by their supervisor to access CURES data.

Subdivision (c)(3) - The Department amended this subdivision to expand the restriction to prescriber or pharmacy history reports that applies to coroners and medical examiners to include anyone acting in the capacity of a coroner or medical examiner, and to use the defined term, “Law Enforcement Official.” This amendment is necessary to ensure that this subdivision is more narrowly tailored and applies only to individuals under the correct circumstances. For example, in some jurisdictions the sheriff also serves as the coroner, and this change is necessary to clarify that the restriction would only apply when the sheriff is acting in the capacity of the coroner.

Subdivision (d)(1) - The Department amended this subdivision to replace “Schedule II, Schedule III, or Schedule IV Controlled Substances” with “Applicable Controlled Substances.” This amendment is necessary because it will include Schedule V Controlled Substances beginning January 1, 2021.

Subdivision (d)(3)(b)(i) - The Department amended this subdivision to expand the exception to providing a violation or crime code to access patient activity reports that applies to coroners and medical examiners to include anyone acting in the capacity of a coroner or medical examiner, and to use the defined term, “Law Enforcement Official.” This amendment is necessary to ensure that this subdivision is more narrowly tailored and applies only to individuals under the correct circumstances. For example, in some jurisdictions the sheriff also serves as the coroner, and this change is necessary to clarify that the restriction would only apply when the sheriff is acting in the capacity of the coroner.

Subdivision (d)(5)(E) - The Department amended this section to narrow one of the exceptions to the requirement of obtaining a search warrant or court order for a patient activity report. As originally proposed, specified state Law Enforcement Officials could access CURES data without a search warrant or court order by providing a Medi-Cal beneficiary status report. The Department has amended this exception to delete explanatory language with no legal effect and has added subdivision (d)(5)(E)(ii) to require that the law enforcement official provide an affidavit meeting specified requirements to the effect that the Law Enforcement Official is

investigating Medi-Cal fraud. The amendment is necessary to balance the lawful disclosure of CURES data for law enforcement purposes with a patient's interest in privacy.

Subdivision (e)(1)(A) - The Department amended this subdivision to add the exception, "unless otherwise required by law," to the requirement that the use of the CURES data must be for the same authorized purpose for which the data was originally requested. This amendment is necessary to ensure that a Law Enforcement Agency is not prevented from complying with applicable state and federal laws that may require the disclosure of information obtained from CURES.

Subdivision (f)(4) - This subdivision was amended to specify that when requesting a patient activity report without a search warrant or court order, the requestor must provide documentation, not just a verbal representation, that an exception applies. This amendment is necessary to ensure that appropriate documentation is provided and to maintain a record of compliance with the regulations. This subdivision was also amended to specify that when requesting a patient activity report, the requestor must provide both the patient's first name and last name, not just one or the other. This amendment is necessary to ensure that Law Enforcement Officials provide additional information to narrow the scope of a search and to further protect patient privacy.

SECTION 826.

The Department amended the title of this section from "Research Requestor" to "Research." This amendment is necessary because the Department removed all references to Research Requestor in all sections of the proposed regulations.

The Department amended this section in several places to delete the collective term "Research Requestor" and replace it with the individual term "Bona Fide Researcher", the collective term "Interested Party," or with the words "public or private entity, or Bona Fide Researcher." The amendments recalibrate and place more restrictions on access to CURES data for research purposes by public and private entities, Bona Fide Researchers, and Team Members. These amendments are necessary to place additional limitations on access to the sensitive health information within the CURES database for research purpose and to protect patient privacy. The Department also amended this section in several places to replace "the Department" with "the Department's Research Center." These amendments are necessary to identify the specific unit within the Department that oversees research requests, which is separate from the unit that oversees the CURES database.

Subdivision (d)(3) - The Department amended the requirement that a Bona Fide Researcher must first provide a complete draft of any report to the Department before final publication by providing an exception for Aggregated Data. This amendment is necessary because a researcher's use of Aggregated Data poses minimal risk to a patient's privacy interest. The Department also nonsubstantively amended this subdivision to remove the comma after "CURES" and "section." This amendment is necessary to be grammatically correct.

Subdivisions (d)(4), (d)(5), and Former Subdivision (d)(9) - The Department amended these subdivisions to address conflicting language regarding the disclosure of CURES data by a researcher to third parties. These amendments are necessary to resolve any ambiguities created by the originally proposed language.

Subdivision (d)(7) - The Department amended this subdivision to expand the list of identifying information that is subject to its disclosure prohibition, including name, date of birth, phone number, email address, social security number, driver's license number, PII, and geographical units of fewer than 20,000 people. These amendments are necessary to further protect the privacy of individuals whose personal information can be found in the CURES database.

Subdivision (d)(11) - The Department amended this subdivision to replace "Research Requestor's" with "applicable." This amendment is necessary because the Department removed all references to Research Requestor in all sections of the proposed regulations.

Subdivision (d)(12) - The Department added this subdivision to limit access to CURES data by a Team Member. Team Members may no longer request CURES data directly from the Department, but may only access data that has been obtained by a Bona Fide Researcher. This subdivision is necessary to protect the privacy of individuals whose personal information and sensitive health information appears in the CURES database.

Subdivision (e)(3) - The Department amended this subdivision to replace "Aggregated data" with "Aggregated Data." This amendment is necessary to accurately reference the defined term "Aggregated Data."

Subdivision (e)(3)(H) - The Department amended this subdivision to replace references of "Research Requestor" with "public or private entity's authorized representative, or of the Bona Fide Researcher." This amendment is necessary because the Department removed all references to Research Requestor in all sections of the proposed regulations.

Subdivision (f)(3)(K)(iv) - The Department amended this subdivision to replace "Department data" with "Data Request Application." This amendment is necessary to accurately reference the definition of "Data Request Application" in subdivision (f)(1).

Subdivision (f)(3)(K)(vi) – The Department has amended this subdivision to narrow the exception to the requirement that a Bona Fide Researcher must provide a copy of an approval from an institutional review board for access to Individual-Level CURES data. The exception for a Bona Fide Researcher who is a public health officer now only applies to De-Identified Individual-Level Data, and not Identified Individual-Level Data. This amendment is necessary to protect the privacy of individuals whose personal and sensitive health information appears in the CURES database.

Subdivision (f)(3)(K)(vii) - The Department amended this subdivision to delete an exception permitting researcher access to Identified Individual-Level Data as described under subdivision (t) of Civil Code section 1798.24. This amendment is necessary to protect the privacy of individuals whose personal and sensitive health information appears in the CURES database.

The Department also amended this subdivision to reword and amend an exception permitting researcher access to Identified Individual-Level Data as described in subdivision (b) of Civil Code section 1798.24, which permits a state agency to provide personal information of an individual with the prior written voluntary consent of the individual. The Department reworded the exception to more closely align with the statute, and amended the exception to require that the voluntary written consent include a certification as specified. These amendments are necessary to protect the privacy of individuals whose personal and sensitive health information appears in the CURES database.

Subdivision (f)(4) - The Department amended this subdivision to expand the requirement that Bona Fide Researchers and Team Members submit a notarized identification verification upon approval of a Data Request Application. This requirement now applies to requests for both Identified Individual-Level Data, and De-Identified Individual-Level Data, not just De-Identified Individual-Level Data. This amendment is necessary because the Department removed the requirement that access to Identified Individual-Level Data is restricted to a secure lab of the Department, as described below. Verifying the identities of researchers who will have access to Identified Individual-Level Data and De-Identified Individual-Level Data helps protect the privacy of individuals whose personal and sensitive health information appears in the CURES database.

Former Subdivision (f)(5) - The Department removed this subdivision to delete the requirements that researcher access to Identified Individual-Level Data be restricted to the Department's Secure Lab, and that a Bona Fide Researcher pass a fingerprint criminal history background check. The Department made these deletions in conjunction with the deletion of the exception permitting researcher access to Identified Individual-Level Data as described under subdivision (t) of Civil Code section 1798.24 in subdivision (f)(3)(K)(vi). The Department supported the added layer of protection of CURES data when researchers were able to access Identified Individual-Level Data without the consent of the individual as originally proposed. As amended, these regulations will only allow researcher access to Identified Individual-Level Data with the consent of the individual, and therefore the added layer of protection is no longer necessary.

Subdivision (f)(5) - The Department amended this subdivision to add a requirement that the Department notify the Bona Fide Researcher to submit a project renewal before expiration of the Data Request Application. This amendment is necessary for the Department's efficient monitoring of research requests.

Subdivision (f)(6)(H) - The Department amended this subdivision to specify that the data destruction protocols referenced are the protocols outlined in section 826 of these regulations rather than any other destruction protocols the Department follows. This amendment is necessary for clarity purposes.

Subdivision (f)(7) – The Department added this subdivision to expressly incorporate by reference National Institute of Standards and Technology (NIST) Special Publication 800-88, Revision 1, Guidelines for Media Sanitization, December 2014. The Department chose this guideline to protect patient privacy because it is a widely used data sanitization standard that the Department applies in similar programs.

SECTION 827.

Subdivision (b) – This provision incorporates by reference two forms—CURES-101 and CURES-201. Both form require a notarized signature and includes a certificate of acknowledgment for a notary to sign under penalty of perjury consistent with the form in Civil Code section 1189.

SECTION 828.

Subdivision (b)(3) – Regarding the description of this provision in the Initial Statement of Reasons, references to Health and Safety Code section 11165, subdivision (a)(1)(D)-(I) should be Health and Safety Code section 11165.1, subdivision (a)(1)(D)-(I).

Subdivision (b)(3)(B) - The Department amended this subdivision to change the revision date of the CURES Information Exchange Web Service Onboarding Questionnaire to December 2019. Page 5 of the questionnaire document was revised to remove subdivision (1) of the “Additional Information” section. This amendment is necessary to formally remove the View Notification requirement and to clarify that a HIT System will not need to submit a View Notification to the Department. The Department determined that the View Notification requirement was not necessary as the existing audit functionality in the CURES IEWS is appropriate and sufficient. This change required the subsequent renumbering of subdivisions (2) through (9). The Department also amended the document to delete references to a checklist, and an annual maintenance fee. The amendments are necessary because the checklist is voluntary, and the Department is not collecting an annual maintenance fee at this time.

Subdivision (b)(4) - The Department amended this subdivision to change the revision date of the CURES Information Exchange Web Service Overview to December 2019. Page 2 of the overview document was amended to remove “[v]iew notification, confirming the health care practitioner or pharmacist who initiated the query, or on whose behalf the HIT system initiated the query, viewed the responsive data, if any.” The Department further amended the overview document to remove the “Audit Patient Activity Report” section on page 5. These amendments are necessary to formally remove the View Notification requirement and to clarify that a HIT System will not need to submit a View Notification to the Department. The Department determined that the View Notification requirement was not necessary as the existing audit functionality in the CURES IEWS is appropriate and sufficient.

Former Subdivision (c)(5) - The Department removed this subdivision to delete the requirement that a HIT System submit a View Notification to the Department. The Department determined that the View Notification requirement was not necessary as the existing audit functionality in the CURES IEWS is appropriate and sufficient. The removal of subdivision (c)(5) requires the renumbering of subdivisions (c)(6) and (c)(7) to subdivisions (c)(5) and (c)(6), respectively.

Subdivision (c)(6) - The Department amended this subdivision to replace “11165” with “11165.1.” This amendment is necessary to cite the correct Health and Safety Code section. Regarding the description of this provision in the Initial Statement of Reasons, references to

Health and Safety Code section 11165, subdivision (a)(1)(E)(iv) should be to Health and Safety Code section 11165.1, subdivision (a)(1)(E)(iv).

LOCAL MANDATE DETERMINATION

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

SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE PERIOD OF October 4, 2019, THROUGH NOVEMBER 19, 2019.

The Department received 63 different comments from 11 persons. Attachment A (83 pages) is a summary of the comments submitted during the 45-day comment period and the Department's responses. Attachment B is a list (2 pages) of the commenters, in alphabetical order by organization name of the commenter, and identifies (by number) the comments made by each person.

COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC

The modified text was made available to the public for comment from January 16, 2020, through January 31, 2020. The Department received 27 different comments from 9 persons. Attachment A (beginning on page 55 of 83) contains a summary of the comments submitted during the 15-day comment period and the Department's responses. Attachment B (2 pages) identifies (by number) the comments made.

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 regulations are proposed, would be as effective as and less burdensome to affected private persons than the adopted regulations, 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. National Institute of Standards and Technology (NIST) Special Publication 800-88, Revision 1, Guidelines for Media Sanitization, December 2014, (see subdivision (f)(7) of section 826).
2. CURES-101 Information Practices Act Individual Request Form, September 2019, (see subdivision (b) of section 827).

3. CURES-201 Information Practices Act Representative Request Form, September 2019, (see subdivision (b) of section 827).
4. CURES Information Exchange Web Service Overview, December 2019, (see subdivision (b)(4) of section 828).
5. CURES Information Exchange Web Service Onboarding Questionnaire, December 2019, (see subdivision (b)(4) of section 828).
6. 45 CFR Part. 160.103 (10-1-2019 Edition)

The above forms 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).