

CALIFORNIA DEPARTMENT OF JUSTICE

TITLE 11. LAW

DIVISION 1. ATTORNEY GENERAL

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

UPDATED INFORMATIVE DIGEST

Applicable Laws:

Since the filing of the Notice of Proposed Rulemaking Action on September 3, 2021, Assembly Bill (AB) 527 (Statutes of 2021, Chapter 618) was passed and signed into law, amending California Health and Safety Code (HSC) section 11165 of the enabling statute. AB 527 specified that the University of California shall be provided access to identifiable data for research purposes if the requirements of Civil Code section 1798.24, subdivision (t), are satisfied. Business and Professions Code section 208 was amended in AB 1534 (Statutes of 2021, Chapter 630) to add “California” before “State Board of Optometry”. Civil Code section 1798.24 was amended in AB 172 (Statutes of 2021, Chapter 696) to revise subdivision (t) regarding disclosures relating to the Cradle-to-Career Data System Act.

Effects of the Proposed Rulemaking:

On September 3, 2021, the Department of Justice (Department) published the Notice of Proposed Rulemaking Action which included an Informative Digest. Following the Notice of Proposed Rulemaking Action, the regulations text was modified on December 15, 2021 and once more on May 26, 2022. Two additional non-substantive changes were made for spacing in section 828.6, subdivision (c)(11)(A)6 and (C). The modifications are described below:

Article 1 was amended to remove a parenthesis that should have been removed in the 45-day comment period, to include that a Delegate Agreement may be between an Authorizing User and one or more Delegates, and to switch the order of Authorizing User and Delegate. Article 1 was also amended to properly cite the Code of Federal Regulations part and edition, which was incorporated by reference in these regulations. Article 1 was further amended to address grammatical changes and to fix formatting changes from the previous 45-day public comment period.

Article 2.1 was amended to reference the correct registration application for Prescribers applying for access to CURES, and to fix formatting changes from the previous 45-day public comment period.

Articles 2.1, 2.3, 2.6, and 2.7 were amended to include the requirement that if an individual is registered for CURES and is an Out-of-State Prescriber, Out-of-State Pharmacist, Regulatory Agency Official, or Law Enforcement Official, and the individual is no longer eligible to access the individual must not access CURES and the individual or the applicable Regulatory Agency or Law Enforcement Agency must notify CURES prescription drug monitoring program in

writing to protect patient privacy, by not granting access to individuals who are no longer eligible.

Articles 2.1 and 2.2 were also amended 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.

Article 2.4 was amended to add a period after the Article and include "the" before "Authorizing User." This article was also 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 article was also amended to include the requirement that a Delegate Agreement may be between one Authorizing User and one Delegate or between one Authorizing User and multiple Delegates, 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, and 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. Furthermore, this article was amended to switch the order of Authorizing User and Delegate.

Article 2.5 was amended to reference the correct defined term citation, and to add Interstate Prescriber, Interstate Non-DEA Practitioner, and Interstate Pharmacist to the disclosure and transfer requirements.

Article 2.6 was non-substantively amended to fix formatting inconsistencies throughout.

Article 2.7 was amended to replace "Bureau" with "Division." Additionally, the word "Agency" was deleted in two places to conform to the defined term "Law Enforcement Official," and had no regulatory effect. This article was non-substantively amended to update the citation in section 827.6(d)(1)(B)2. to reference the correct and renumbered regulation citation, section 827.4(k)(2)(A), and was non-substantively amended to fix formatting inconsistencies, such as numbering, throughout.

Article 3 was amended to properly cite the Code of Federal Regulations part and edition, which was incorporated by reference in these regulations. Article 3 was amended by indicating the correct text of the regulations as "20" and not "2," which was being deleted and replaced by "10." This Article was further amended to state 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." The Department also specified that the required security measures in place must be compliant with NIST SP 800-171, which was incorporated by reference.

Form numbers were added to the text for the documents incorporated by reference in this Article and the title of CURES 0001 was revised to be accurate. CURES 0001 was amended to conform

the introductory regulatory citation to the regulations and 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.” DOJRC 0001 was revised to make completion of all fields mandatory, clarify how long the exception will be valid, and specify when renewals must be submitted. DOJRC 0002 was updated to clarify the security requirements for web browsers and remove the email client requirements. DOJRC 0003 was updated to change both references of “should” to “must” and correct some grammar.

Article 4 was amended to remove the hyphen in the form numbers throughout this article. The two forms incorporated by reference in Article 4 were amended to include “Street” before “Address” and “Date,” “Year,” “City,” and “State” in the relevant sections of each form.

Article 5 was amended to add the form number for CURES 0002 and update the revision date to November 2021 in the text of the regulations and on the document incorporated by reference. Page 5 of CURES 0002 was also amended to change “pick-list” to “picklist,” and page 8 was amended to add “Memorandum of Understanding,” “(,” and “)” to the first reference of “MOU.” Page 2 of CURES 0002 was amended to remove reference to the checklist and page 6 was amended to add “Patient Activity Report,” “(,” and “)” to the first reference of “PAR.” Article 5 was also amended to include “or” between two listed sections.