

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

NOTICE OF PROPOSED RULEMAKING

Notice published September 3, 2021

The Department of Justice (Department) proposes to adopt new sections 822.1 through 822.6, and 824.1 through 824.9; amend sections 820 and 821.1 through 821.6, sections 822.1 through 822.6 (renumbered as 823.1 through 823.6), 823.1 through 823.5 (renumbered as 825.1 through 825.5), 824.1 through 824.6 (renumbered as 826.1 through 826.6), 825.1 through 825.6 (renumbered as 827.1 through 827.6), 826.1 through 826.6 (renumbered as 828.1 through 828.6), 827.1 and 827.2 (renumbered as 829.1 and 829.2), 828.1 through 828.3 (renumbered as 830.1 through 830.3); and repeal sections 821.7 and 822.7 of Title 11, Division 1, Chapter 8.5 of the California Code of Regulations (CCR) concerning the Controlled Substance Utilization Review and Evaluation System (CURES).

PUBLIC HEARING

The Department will hold a virtual public hearing to provide all interested persons an opportunity to present statements or arguments, either orally or in writing, with respect to the proposed regulations, as follows:

Wednesday, October 20, 2021 from 9:00 a.m. – 1:00 p.m.

Online via BlueJeans

<https://bluejeans.com/254579643/8261>

Participant Passcode: 8261

JOIN MEETING HERE

(NOTE: You will be prompted to join via the BlueJeans app if you have it installed.
You may also join via browser without installing the app.)

OR

Dial: (408) 317-9254

Meeting ID: 254 579 643

The Department requests but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

WRITTEN COMMENT PERIOD

Any interested person or their authorized representative may submit written comments relevant to the proposed regulatory action. The written comment period closes on October 19, 2021 at 5:00 p.m. Only written comments received by that time will be considered. Please submit written comments to:

California Department of Justice
Justice Data and Investigative Services Bureau
Attn: Haylee James
P.O. Box 160447
Sacramento, CA 95816-0608
(916) 210-3180
CURESregulations@doj.ca.gov

NOTE: Written and oral comments, attachments, and associated contact information (e.g., address, phone, email, etc.) become part of the public record and can be released to the public upon request.

AUTHORITY AND REFERENCE

Authority: Section 11165, Health and Safety Code.

Reference: Sections 11030, 11165, 11165.1, 11165.3, 11165.4, 11165.6, and 11190, Health and Safety Code; and Sections 208 and 209, Business and Professions Code; and Section 1798.24, Civil Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of Existing Laws and Regulations:

CURES is a database of Schedule II, III, IV, and V controlled substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement. The purpose of CURES is to reduce prescription drug abuse and diversion without affecting legitimate medical practice or patient care.

CURES was first established in 1996 by Assembly Bill (AB) 3042 (Statutes of 1996, Chapter 738). AB 3042 effectuated a Controlled Substances Prescription Advisory Council recommendation that the Department develop a “technologically sophisticated data monitoring system to collect as much data as is needed and provide easy access to the data collected for educational, law enforcement, regulatory, and research purposes.” CURES was initially a provisional pilot project; the program collected Schedule II prescription data for law enforcement to identify cases of Diversion.¹ In 2002, AB 2655 (Statutes of 2002, Chapter 345) extended the pilot and authorized licensed health care professionals to request CURES data for prescriptions dispensed to their patients.

¹ Capitalized terms are defined in existing and proposed CURES regulations in Chapter 8.5 of the CCR.

In 2003, Senate Bill (SB) 151 (Statutes of 2003, Chapter 406) made CURES a permanent program. This bill enacted a number of other significant reforms to state laws governing the prescribing of Controlled Substances, intending to “increase patient access to appropriate pain medication and prevent the diversion of controlled substances for illicit use.” SB 151 replaced the triplicate prescription form requirement for Schedule II Controlled Substances with a new requirement that these prescriptions be issued on a special form obtained from an approved security printer. This bill also added Schedule III Controlled Substance data to CURES. In 2006, AB 2986 (Statutes of 2006, Chapter 286) added Schedule IV Controlled Substances.

In 2013, SB 809 (Statutes of 2013, Chapter 400) established a funding mechanism for CURES and called for an update of the database. New system features under SB 809 included the ability for a new “streamlined application and approval process” to replace the previous paper-based registration process and for licensees to delegate their authority to initiate a CURES query to an assistant. The bill also required all licensees authorized to prescribe, order, administer, furnish, or dispense substances to register for the system by 2016.

The improved database, which would come to be called “CURES 2.0,” featured a new user interface and the ability to automatically alert prescribers of patterns indicative of at-risk patient behavior. The new CURES 2.0 also allowed prescribers to flag exclusivity compacts, added peer-to-peer communication, and significantly improved user profile management.

In 2016, SB 482 (Statutes of 2016, Chapter 708) enacted the state’s first mandated use of CURES for prescribers. SB 482 required Health Care Practitioners to consult a patient’s history in CURES prior to prescribing them a Schedule II, Schedule III, or Schedule IV Controlled Substance for the first time, and then at least once every four months as long as the prescription continued to be renewed. The bill delayed implementation until six months following a certification by the Department that 1) CURES was ready for statewide use and 2) the program had adequate staff. On April 2, 2018, the Department certified that CURES was ready for statewide use and that there was adequate staffing, User support, and education. Mandatory CURES consultation became effective on October 2, 2018.

AB 40 (Statutes of 2017, Chapter 607) was chaptered in 2017, requiring the Department to facilitate interoperability between Health Information Technology (HIT) Systems and CURES, subject to a memorandum of understanding setting minimum security and privacy requirements. The bill intended to help seamlessly integrate the use of CURES into a busy practice setting by allowing for queries to be made within a Health Care Practitioner’s native electronic health record system.

AB 1751 (Statutes of 2018, Chapter 478) required the Department, no later than July 1, 2020, to adopt regulations regarding the access and use of the information within CURES by consulting with stakeholders, and addressing certain processes, purposes, and conditions in the regulations. Specifically, AB 1751 implemented the Health and Safety Code (HSC) section 11165, subdivision (c)(3) requirement that the Department regulations address, at minimum, the following:

- The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES;

- The purposes for which a Health Care Practitioner may access information in CURES;
- The conditions under which a warrant, subpoena, or court order is required for a Law Enforcement Agency to obtain information from CURES as part of a criminal investigation; and
- The process by which information in CURES may be provided for educational, Peer Review, statistical, or Research Purposes.

AB 1751 also authorized the Department, once final regulations had been issued, to enter into an agreement with any entity operating an interstate data-sharing hub, or any agency operating a prescription drug-monitoring program (PDMP) in another state, for purposes of interstate data sharing of PDMP information. The bill requires any agreement entered into by the Department for those purposes to ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

In response to AB 1751, the Department adopted Chapter 8.5 of the CCR, concerning CURES access and use. These regulations became effective on July 1, 2020.

More recently, 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 Drug Enforcement Agency (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. Additionally, AB 528 authorizes expanded access to delegates. 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. They also offer additional clarity to existing requirements.

Specifically, these proposed regulations clarify policies, procedures, requirements, and limitations for individuals who are statutorily required or permitted to consult CURES in the course of patient care, who utilize the system in efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, Schedule IV, and Schedule V Controlled Substances, and who wish to obtain access to CURES data for Research Purposes or to review their own CURES data.

Effect of the Proposed Rulemaking:

The proposed regulations update the requirements and procedures for approving individuals or entities seeking access to CURES information, and the purposes for which a Prescriber, Non-DEA Practitioner, Pharmacist, Delegate, Interstate Prescriber, Interstate Pharmacist, Interstate Non-DEA Practitioner, Regulatory Agency Official, Law Enforcement Official, Bona Fide Researcher, and individual requestor may access and use CURES data. In addition, the regulations include the procedures and security and privacy requirements necessary to facilitate interoperability between HIT Systems and CURES.

Anticipated Benefits of the Proposed Regulations:

The Department anticipates that these regulations would 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 patient information contained within CURES. By clearly detailing the requirements for access and use for each User type, including Delegates and Non-DEA Practitioners, these regulations would provide increased 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 the information contained in CURES is used only for statutorily-authorized purposes. Furthermore, these regulations would improve researcher access to CURES data to promote informed public policy while maintaining security of the data.

Comparable Federal Regulations:

HSC 11165(c) requires that CURES operate in compliance with all applicable federal and state privacy and security laws and regulations. Applicable federal privacy and security regulations are as follows:

- Code of Federal Regulations, Title 45, Parts 160 and 164, governing the protection and confidentiality of individuals' medical records and protecting patients' privacy rights in their health information.

This regulation is consistent with those federal regulations.

Determination of Inconsistency/Incompatibility with Existing State Regulations:

The Department has determined that these proposed regulations are not inconsistent or incompatible with existing State regulations. After conducting a review for any regulations that would relate to or affect this area, the Department has concluded that these are the only regulations that concern CURES.

Documents Incorporated by Reference:

1. Department of Justice (DOJ) Consent for Use of Personal Information from CURES, CURES 0001, orig. 07/2021 (see subdivision (c)(11)(H) of section 828.6)
2. DOJ Research Center (DOJRC) Security Variance Form for Data Access Non-Compliance of Security Requirements, DOJRC 0001, orig. 07/2021 (see subdivision (d) of section 828.6)
3. DOJRC Researcher Confidentiality and Non-Disclosure (CND) Agreement, DOJRC 0003, orig. 07/2021 (see subdivision (d) of section 828.6)
4. DOJRC Researcher Data Access User Agreement, DOJRC 0002, orig. 07/2021 (see subdivision (d) of section 828.6)
5. DOJ CURES Information Exchange Web Service Onboarding Questionnaire, CURES 0002, rev. 07/2021 (see subdivision (c)(2) of section 830.2)
6. DOJ CURES Information Exchange Web Service Overview, rev. 07/2021 (see subdivision (d) of section 830.2)

7. Information Practices Act Individual Request Form, CURES 101, rev. 07/2021 (see subdivision (a) of section 829.2)
8. Information Practices Act Representative Request Form, CURES 201, rev. 07/2021 (see subdivision (b) of section 829.2)

Other Statutory Requirements:

HSC 11165 requires the Department to consult with all stakeholders identified by the Department during the rulemaking process when promulgating regulations governing CURES. (Health & Saf. Code, § 11165, subd. (c)(3).) The Department consulted with the Department of Consumer Affairs in drafting these regulations.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department's Initial Determinations:

Mandate on local agencies or school districts: None.

Cost or savings to any state agency: None.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code sections 17500 through 17630: None.

Other non-discretionary costs or savings imposed on local agencies: None.

Cost or savings in federal funding to the state: None.

Cost impacts on representative person or business: The Department has determined that while not all Prescribers will establish a Delegate, the average cost incurred for a Prescriber to establish a Delegate would range from \$36.87-\$73.74 per person in reasonable compliance with the proposed action. The Department has determined that while not all Pharmacists will establish a Delegate, the average cost incurred for a Pharmacist to establish a Delegate would range from \$31.71-\$63.42 per person in reasonable compliance with the proposed action. The average cost incurred for a Delegate would be \$10.09 per person in reasonable compliance with the proposed action. The Department estimates that as few as 55,107 and as many as 110,213 Prescribers and Non-DEA Practitioners would enter into Delegate Agreements, and as few as 11,711 and as many as 23,421 Pharmacists would enter into Delegate Agreements. For each Prescriber, Non-DEA Practitioner, and Pharmacist who enters into a Delegate Agreement, there would be a corresponding Delegate. If there are a total of 267,268 Users and as many as 133,634 Delegates, the total cost ranges from \$747,279-\$9,239,156. This cost is a result of the requirement that an Authorizing User and Delegate must enter into a Delegate Agreement prior to authorizing a Delegate to access CURES on behalf of that Authorizing User.

The Department has determined that the cost incurred by each HIT System business to make the changes necessary to comply with the proposed action would range from \$1,074-\$4,198.

Significant effect on housing costs: None.

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

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 Departments' revised technology requirements. The Department determined that 47.3 percent of HIT Systems impacts would be to small businesses. In order to calculate the low range of costs that could be incurred by small business HIT Systems as a result of the regulation, the Department used the low range estimate (\$54,500) to determine the total cost to HIT Systems, multiplied that total by 47.3 percent, then divided that total by the estimated number of small businesses (24 Hit Systems ((47.3 percent)) of the 50 HIT Systems). The same formula was applied to the high range of small business HIT Systems and both the low and high range of costs for typical business HIT Systems. Costs for a small business HIT System are estimated to be \$1,074–\$1,105.

Results of the Economic Impact Assessment (EIA):

The Department concludes that it is (1) unlikely that the proposal would create or eliminate jobs within the state, (2) unlikely that the proposal would create new businesses or eliminate existing businesses within the state, (3) unlikely that the proposal would result in the expansion of businesses currently doing business within the state.

Benefits of the proposed action: The Department anticipates that these regulations would 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 patient information contained within CURES. By clearly detailing the requirements for access and use for each User, these regulations would provide transparency; empower Prescribers, Non-DEA Practitioners, Pharmacists, Delegates, Regulatory Agency Officials, and Law Enforcement Officials to confidently utilize the system as a tool to facilitate care or control the Diversion and Resultant Abuse of Controlled Substances; and ensure the information contained in CURES is used only for statutorily-authorized purposes. Furthermore, these regulations would improve researcher access to CURES data to promote informed public policy while maintaining security of the data.

Business report requirement: None.

Small business determination: The Department has determined that this proposed action affects small businesses.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Department must determine that no reasonable alternative considered by the Department or that has been brought to the attention of the Department would be more effective in carrying out the purpose for which this action is proposed or would be as effective and less burdensome to affected private persons than

this proposed action or would be more cost-effective to affected persons and equally effective in implementing the statutory policy or other provision of law.

The Department has determined that these proposed regulations are the most effective way to ensure the safe prescribing and dispensing of Controlled Substances and protect the security of the patient information contained within CURES.

CONTACT PERSONS

Inquiries concerning this proposed administrative action may be directed to:

California Department of Justice
Justice Data and Investigative Services Bureau
Attn: Haylee James
P.O. Box 160447
Sacramento, CA 95816-0608
(916) 210-3180
CURESregulations@doj.ca.gov

Questions regarding procedure, comments, or the substance of this proposed action should be addressed to the above contact person. In the event the contact person is unavailable, inquiries regarding this proposed action may be directed to the following backup contact person:

California Department of Justice
Justice Data and Investigative Services Bureau
Attn: Amber Davidson
P.O. Box 160447
Sacramento, CA 95816-0608
(916) 210-2486
CURESregulations@doj.ca.gov

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the above address. As of the date this Notice of Proposed Rulemaking (Notice) is published in the Notice Register, the rulemaking file consists of this Notice, the Text of Proposed Regulations (the “express terms” of the regulations), the Initial Statement of Reasons, and any information upon which the proposed rulemaking is based. The text of this Notice, the express terms, the Initial Statement of Reasons, and any information upon which the proposed rulemaking is based are available at the Department’s website at <https://oag.ca.gov/jdis/reggs>. Please refer to the contact information listed above to obtain copies of these documents.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After the Department analyzes all timely and relevant comments received during the 45-day public comment period, the Department will either adopt these regulations substantially as described in this Notice or make modifications based on the comments. If the Department makes modifications which are sufficiently related to the originally-proposed text, it will make the modified text (with the changes clearly indicated, available to the public for at least 15 days before the Department adopts the regulations as revised. Please send requests for copies of any modified regulations to the attention of the name and address indicated above. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, a copy of the Final Statement of Reasons will be available on the Department's website at <https://oag.ca.gov/jdis/regs>. Please refer to the contact information listed above to obtain a written copy of the Final Statement of Reasons.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of this Notice, the express terms, the Initial Statement of Reasons, and any information upon which the proposed rulemaking is based are available on the Department's website at <https://oag.ca.gov/jdis/regs>.