CALIFORNIA DEPARTMENT OF JUSTICE

NOTICE OF PROPOSED RULEMAKING ACTION

TITLE 11. LAW
DIVISION 1. ATTORNEY GENERAL

(Notice to be Published on October 4, 2019)

Notice is hereby given that the Department of Justice (Department) proposes to adopt sections 820 through 828 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), pursuant to the authority provided in Health and Safety Code (H&SC) section 11165, subdivision (c)(3).

PUBLIC HEARING

The Department will hold two public hearings to receive public comments on the proposed regulatory action, as follows:

Date:	November 21, 2019
Time:	9:00 a.m. – 12:00 p.m.
Location:	East End Complex Auditorium 1500 Capitol Avenue Sacramento, CA 95814

Date:	November 22, 2019
Time:	9:00 a.m. – 12:00 p.m.
Location:	Ronald Reagan State Building 300 South Spring Street Los Angeles, CA 90013

This hearing locations are wheelchair accessible. Parking will be available for a fee in a structure near the building.

At this hearing, any person may present oral or written comments regarding the proposed regulatory action. The Department requests, but does not require, that persons who make oral comments at the hearing also submit a written copy of their testimony.

WRITTEN COMMENT PERIOD

The public comment period for this regulatory action will begin on October 4, 2019. Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department. The written comment period closes at 5:00 p.m. on November 19, 2019. Only comments received by the Department by that time will be considered. Written comments shall be submitted to:

Ross Daley, Associate Governmental Program Analyst
Bureau of Criminal Identification and Investigative Services
California Justice Information Services Division
4949 Broadway
Sacramento, CA 95820
Email: CURESregulations@doj.ca.gov

Or

Haylee James, Staff Services Analyst
Bureau of Criminal Identification and Investigative Services
California Justice Information Services Division
4949 Broadway
Sacramento, CA 95820
Email: CURESregulations@doj.ca.gov

Please note that under the California Public Records Act (Gov. Code, § 6250 et seq.), 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

Subdivision (c)(3) of H&SC section 11165 authorizes the Department to adopt proposed regulations sections 820 to 828. The proposed regulatory action will implement, interpret, and make specific the provisions of H&SC sections 11030, 11150, 11153, 11153.5, 11165, 11165.1, 11165.3, 11165.4, 11165.6, and 11190; Business and Professions Code sections 208, 209, and 4170; Civil Code section 1798.24; Penal Code section 530.55; and Probate Code sections 4700 and 4701 as they relate to CURES.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Background:

CURES is a database of Schedule II, III and IV 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 (Chapter 738, Statutes of 1996). 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. In 2002, AB 2655 (Chapter 345, Statutes of 2002) extended the pilot and authorized licensed health care professionals to request CURES data for prescriptions dispensed to their patients.

In 2003, Senate Bill (SB) 151 (Chapter 406, Statutes of 2003) 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 (2003) 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 (Chapter 286, Statutes of 2006) added Schedule IV Controlled Substances.

In 2013, SB 809 (Chapter 400, Statutes of 2013) 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 (Chapter 708, Statutes of 2016) 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 (Chapter 607, Statutes of 2017) 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.

Current H&SC section 11165, subdivision (a), requires the 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. In accordance with H&SC section 11165, subdivision (a), CURES operates as a database of Controlled Substance prescriptions dispensed in California serving the public health, regulatory oversight agencies, and law enforcement. CURES is committed to the

reduction of prescription drug Abuse and Diversion without affecting legitimate medical practice or patient care.

The statute governing the operation of CURES provides the Department with discretion in regards to who may access information contained in the database. H&SC section 11165, subdivision (c)(2)(A), states that the Attorney General "shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES." Access to CURES is limited by the Department to licensed prescribers and licensed pharmacists for patients under their care, and Regulatory Agency employees and law enforcement officers or employees in their efforts to control the Diversion and Resultant Abuse of Controlled Substances. However, to date, the Department has not promulgated any formal regulations relating to CURES. Details as to who can access the system, and for what purposes, have not been substantially memorialized or put through a public rulemaking process. The details have been left instead to policies and procedures as permitted or required by statute.

Most recently, AB 1751 (Chapter 478, Statutes of 2018) 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 H&SC 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 have 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, as specified. 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 has drafted proposed Chapter 8.5 of the CCR, concerning CURES access and use. The Department is statutorily mandated to promulgate regulations for these purposes no later than July 1, 2020.

The Department is committed to continuously working to improve the effectiveness of CURES. Even after these regulations are adopted, the Department will continue conducting research and stakeholder outreach to evaluate the future need for further regulations. The Department will engage in a separate rulemaking process upon the conclusion of the research and outreach to implement interstate data sharing, in order to further bolster efforts to control the Diversion and Resultant Abuse of Schedule II, Schedule III, and Schedule IV Controlled Substances.

Effect of the Proposed Rulemaking:

The proposed regulations codify and update existing policies and procedures governing CURES and provide necessary guidance on the process for approving individuals or entities seeking access to information in CURES and the purposes for which a prescriber, pharmacist, Interstate Prescriber or Pharmacist, Regulatory Agency, Law Enforcement Official, Research Requestor, and individual requestor may access and use CURES data. In addition, the regulations implement the procedures and security and privacy requirements necessary to facilitate interoperability between HIT Systems and CURES.

Proposed CCR, Title 11, Division 1, Chapter 8.5 interprets and details the specifics of these laws as follows:

Article 1 defines the terms used throughout the new chapter.

Article 2 specifies who may have access to CURES, the process and requirements for gaining access, and how and for what purposes CURES and the information contained therein may be used. Each section within Article 2 outlines the requirements for a specific type of user, i.e., prescriber, pharmacist, Interstate prescriber or Interstate Pharmacist, as defined, Regulatory Agency, Law Enforcement Agency, Research Requestor, and individual requestor.

Each section specifies who within each User type is eligible for access to CURES. For each respective Applicant Type, the sections specify the process for requesting and gaining access and the associated information that must be provided to the Department. They also specify the types of information that approved Users within each Applicant Type are able to access through CURES. They outline restrictions placed on each Applicant Type for accessing, using, and disclosing patient information. Lastly, they specify the procedures for accessing the reports available to each Applicant Type.

In addition to the information described above, some sections detail further requirements specific to the User type in question.

Sections 821 and 822 further delineate similar requirements and procedures for individuals to whom prescribers and pharmacists have delegated authority to order reports from CURES.

Section 823 further specifies the circumstances under which an Interstate Prescriber or Interstate Pharmacist, as defined, may access CURES.

Section 824 further specifies that a Regulatory Agency may obtain data from CURES for as long as the data is retained in CURES, and narrows the scope of Regulatory Agency access to CURES to delineated purposes that assist a Regulatory Agency's efforts to control the Diversion and Resultant Abuse of Controlled Substances.

Section 825 further specifies circumstances under which a Law Enforcement Official is required to provide a search warrant or a court order, unless otherwise specified, to obtain a Patient Activity Report, and specifies that a Law Enforcement Official may also obtain data from CURES for as long as the data is retained in CURES.

Section 826 further specifies requirements that a Research Requestor must meet once they have concluded a research project or report, including submission of a signed and dated certificate of data destruction confirming delineated actions.

Section 827 further specifies the requirements for use of the CURES-101 Information Practices Act Individual Request Form and the CURES-201 Information Practices Act Representative Request Form, as well as instructions for how to use those forms to retrieve audit history information.

Section 828 further specifies eligibility criteria and procedures for access specific to integration with the Information Exchange Web Service.

Comparable Federal Regulations:

H&SC section 11165, subdivision (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.

Anticipated Benefits of the Proposed Regulations:

The purpose of CURES is to reduce prescription drug abuse and diversion without affecting legitimate medical practice or patient care. The objective of the proposed rulemaking action is to clarify the requirements of H&SC section 11165 regarding the access and use of the information within CURES. These regulations are meant to ensure that all Users are aware of their roles and responsibilities when accessing CURES data and that the information contained in CURES is safeguarded.

The Department anticipates that these regulations will benefit the health, welfare, and safety of California residents because they 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, and to protect the security of the patient information contained within CURES. By clearly detailing the requirements for access and use for each Applicant Type, these regulations will provide transparency, empower prescribers and pharmacists to confidently utilize the system as a tool to facilitate care, and ensure that the information contained in CURES is used only for statutorily authorized purposes.

Evaluation of Inconsistency/Incompatibility with Existing State Regulations:

Pursuant to Government Code (GC) section 11346.5, subdivision (a)(3)(D), the Department shall evaluate whether the proposed regulations are inconsistent or incompatible with existing state regulations. Pursuant to this evaluation, the Department has reviewed existing regulations

in the CCR and has determined that no other regulations address CURES. Hence, these proposed regulations are not inconsistent or incompatible with existing state regulations.

Documents Incorporated by Reference:

Documents will be incorporated in the regulation by reference as specified by the following sections:

1. National Institute of Standards and Technology (NIST) Special Publication 800-88, Revision 1, Guidelines for Media Sanitization, December 2014, (see subdivision (f)(7)(D) 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, September 2019, (see subdivision (b)(4) of section 828).
5. CURES Information Exchange Web Service Onboarding Questionnaire, September 2019, (see subdivision (b)(3) of section 828).

Mandated by Federal Law or Regulations:

The proposed regulations are not mandated by federal law or regulations.

Other Statutory Requirements:

H&SC section 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 worked with Health Care Practitioners, pharmacists, advocates, law enforcement, researchers, public health officials, and Regulatory Agency and government actors in drafting these regulations. In 2019, the Department held five public meetings throughout the state to receive, consider, and discuss stakeholder input on the regulations.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Mandate on Local Agencies and School Districts: None.

Cost or Savings to Any State Agency: Where relevant and appropriate, the Department analyzed instances of prior engagement and recent historical data and trends to determine projected fiscal effects on state government that state agencies or actors may incur to comply with this regulation for the current year and two subsequent fiscal years. For example, the Department conducted outreach with State Law Enforcement Agencies to determine the estimated fiscal effects on state government, in the form of time and resources, which a State Law Enforcement Official may incur to comply with this regulation. Marginal impacts were determined to public research organizations that are similar to the impacts discussed for public health offices. Additionally,

similar preparation and submission costs were found for state law enforcement officials, but to a considerably reduced extent. Using the information gathered from affected parties, the estimated fiscal effect of this regulation for the current year and two subsequent fiscal years to state government is $6,738 - $19,578.

Cost to Any Local Agency or School District Which Must Be Reimbursed in Accordance with Government Code Sections 17500 through 17630: None.

Other Nondiscretionary Cost or Savings Imposed on Local Agencies:

The estimated fiscal impact on local government was calculated by conducting outreach with affected local agencies or actors to determine the scale of projected effects. Where relevant and appropriate, the Department analyzed instances of prior engagement and recent historical data and trends to determine projected fiscal effects on local government that local agencies or actors may incur to comply with this regulation for the current year and two subsequent fiscal years. For example, the Department conducted outreach with local law enforcement to determine the estimated fiscal effects on local government, in the form of time and resources, which a law enforcement official may incur to comply with this regulation.

More specifically, the costs to local Law Enforcement Agencies related to search warrants, court orders, and prosecution subpoenas were factored into the total fiscal impact on local government. Additionally, the impact to local governmental research organizations was considered. Because the individuals who would perform duties related to research functions vary broadly, the Department used a Public Health Officer classification as the basis for estimating the low fiscal impact of the regulation on the local governmental research community and an Epidemiologist classification as the basis for estimating the high fiscal impact of the regulation on the local governmental research community. Using the information gathered from affected parties, the estimated fiscal effect of this regulation for the current year and two subsequent fiscal years to local government is $102,477 - $463,275.

Cost or Savings in Federal Funding to the State: None.

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, or on representative private persons. This is because the isolated economic impacts to businesses that are attributable to this regulation, rather than the underlying statutes, are nominal, if existent.

This regulation would set a Connectivity Fee for a HIT System. A HIT System is an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decision-making, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system. The mandatory, one-time Connectivity

Fee paid by an entity operating a HIT System, which covers the cost of connecting that HIT System to the Information Exchange Web Service and is set in the amount of $1,500, is authorized by H&SC section 11165.1, subdivision (a)(1)(H). Hospitals and health care networks would be the entities operating a HIT System. This Connectivity Fee would not result in an adverse economic impact because the cost is nominal in proportion to the scale of businesses engaging with this regulation.

Results of the Economic Impact Analysis/Assessment Prepared Pursuant to Government Code Section 11346.3, Subdivision (b):

Effect on Jobs/Businesses:

The Department has determined that the proposed regulatory action would not affect the creation or elimination of jobs or businesses within the State of California or the expansion of businesses currently doing business within the State of California. This determination is based on the fact that this proposed action only codifies requirements pertaining to existing licensed Health Care Practitioners and pharmacists. Furthermore, this proposed action would have no impact on any other businesses or jobs. 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 Health Care Practitioners or pharmacists would choose to do so or the extent of the modifications required.

Benefits of the Proposed Regulation:

The purpose of CURES is to reduce prescription drug abuse and diversion without affecting legitimate medical practice or patient care. The regulations proposed in this rulemaking action would standardize the procedures and processes for obtaining access to CURES and the information therein. The regulations would eliminate confusion surrounding access, uses, and purposes thereof for CURES, as well as create as much transparency as possible into its workings.

In addition, the proposed regulatory action will positively impact the privacy of California residents by establishing policies and responsibilities for those who access and use CURES data. This will enable the Department to ensure that all users are adhering to policies and procedures necessary to protect the information contained in CURES.

Cost Impacts on Representative Private Persons or Business:

The Department has determined that a representative private person or business would necessarily incur a cost of $11.00 - $20.00 per person in reasonable compliance with the proposed action. This cost is a result of the requirement that an individual seeking his or her own personal CURES data submit notarized documents, as specified.

This regulation would set a Connectivity Fee for a HIT System, as discussed above. The mandatory, one-time Connectivity Fee is set in the amount of $1,500. Hospitals and health care networks would be the entities operating a HIT System. This connectivity fee would not result in

a significant cost impact on representative private business because the impact is nominal to the scale of businesses engaging with this regulation. Private persons would not be impacted here.

Business Report:

These regulations do not require a report that applies to businesses.

Small Business Determination:

The Department has determined that 47.3% of the HIT Systems and research organizations impacted by these regulations would qualify as small businesses. In order to comply with this regulation over its lifetime, the total cost for these HIT Systems was determined to be in the range of $17,311 - $34,621, and the total cost for these research organizations was determined to be in the range of $636 - $3,812.

CONSIDERATION OF ALTERNATIVES

Before taking final action on the amendments, the Department must determine that no reasonable alternative it considered, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, or would be as effective and less burdensome to affected private persons than the 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 invites interested persons to present statements or arguments, with respect to alternatives, to the proposed regulations during the 45-day written comment period.

CONTACT PERSONS

Inquiries concerning the proposed regulatory action may be directed to:

Ross Daley, Associate Governmental Program Analyst
Bureau of Criminal Identification and Investigative Services
California Justice Information Services Division
4949 Broadway
Sacramento, CA 95820
(916) 210-3007

The backup contact person for these inquiries is:

Haylee James, Staff Services Analyst
Bureau of Criminal Identification and Investigative Services
California Justice Information Services Division
4949 Broadway
Sacramento, CA 95820
(916) 210-3180

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. The text of the proposed regulation (the "express terms"), the Initial Statement of Reasons, and the information upon which the proposed rulemaking is based are available at the Department's website at https://oag.ca.gov/bciis/regs. Copies may also be obtained by contacting:

Ross Daley, Associate Governmental Program Analyst
Bureau of Criminal Identification and Investigative Services
California Justice Information Services Division
4949 Broadway
Sacramento, CA 95820
(916) 210-3007

AVAILABILITY OF CHANGED OR MODIFIED TEXT

This regulatory proceeding will be conducted in accordance with the California Administrative Procedure Act, Government Code, Title 2, Division 3, Part 1, Chapter 3.5 (commencing with section 11340).

After the Department analyzes all timely and relevant comments received during the 45-day public comment period, the Department will either adopt the regulations as described in this notice, or make modifications based on the comments. If the Department makes modifications which are sufficiently related to the original text of the proposed regulations, the amended text, with the changes clearly indicated, will be made available for an additional 15-day public comment period, before the Department adopts the regulations. The Department will accept written comments on the modifications to the regulations during the 15-day public comment period.

AVAILABILITY OF FINAL STATEMENT OF REASONS

Upon completion, the Final Statement of Reasons will be available on the Department's website at https://oag.ca.gov/bciis/regs. You may also obtain a written copy of the Final Statement of Reasons by contacting:

Ross Daley, Associate Governmental Program Analyst
Bureau of Criminal Identification and Investigative Services
California Justice Information Services Division
4949 Broadway
Sacramento, CA 95820
(916) 210-3007

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the

regulations in underline and strikeout format, as well as the Final Statement of Reasons once completed, are available on the Department's website at https://oag.ca.gov/bciis/regs.