

Controlled Substance Utilization Review and Evaluation System (CURES) Regulations

BACKGROUND

The California Department of Justice (Department) maintains the Controlled Substance Utilization Review and Evaluation System (CURES). This database contains Schedule II, III, and IV controlled substance prescription history information for controlled substances dispensed in California. CURES has several purposes, set forth in Section 11165(a) of the Health and Safety Code:

- To assist healthcare practitioners in 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, III, and IV controlled substances; and
- For statistical analysis, education, and research.

Pursuant to AB 1751 of 2019, the California Department of Justice is required to adopt regulations by July 1, 2020, regarding access to CURES and the use of CURES information. After consulting with stakeholders, the Department released proposed regulations on October 4, 2019. The Department received comments from the public on the proposed regulations, including at two public hearings in November 2019. The Department then released revisions on January 16, 2020, and sought additional comments. Information and updates on the CURES rulemaking process is available on the Department's website at <https://oag.ca.gov/jdis/regs#cures>.

OVERVIEW OF THE PROPOSED REGULATIONS

The proposed CURES regulations concern who may access CURES, the purposes for healthcare practitioners to access CURES data, the means and requirements for law enforcement access, and the use of CURES data for education or research.

Prescribers

- Licensed health care practitioners authorized to prescribe controlled substances, such as doctors, dentists, and veterinarians, who practice in California and are registered with the U.S. Drug Enforcement Administration (DEA), must register for CURES access. Prescribers located outside of California may also register.
- Prescribers may view a list of patients and patient activity reports.
- Prescribers may view information in CURES for the purposes of (1) treating patients under their care and (2) consulting CURES before prescribing a Schedule II, III or IV controlled substance for the first time and at least once every four months during the course of a treatment with a controlled substance.

Pharmacists

- Pharmacists with California licenses must register for access to CURES. Pharmacists licensed and practicing in other states may also register.

- Pharmacists may view patient activity reports. Pharmacists who have a DEA number associated with their CURES account may also view a list of patients to whom they have prescribed controlled substances, as reported to CURES.
- Pharmacists may view information in CURES for the purposes of treating patients under their care and for obtaining a list of patients for whom they are listed as the prescribing pharmacist.

Regulators

- Regulatory Agency Officials at the California Department of Consumer Affairs and the boards and committees (such as the Medical Board of California or the State Board of Pharmacy) are eligible for access to CURES.
- Regulatory Agency Officials may access patient activity reports, prescriber history reports, and pharmacy history reports.
- Regulatory Agency Officials may access CURES data only to investigate or discipline prescribers or pharmacists for the purpose of controlling the diversion and resultant abuse of controlled substances.
- Regulatory officials who are investigating criminal offenses must follow the procedures that apply to Law Enforcement Officials.

Law Enforcement

- Law Enforcement officials are eligible for access to CURES.
- Law Enforcement Officials may access patient activity reports, prescriber history reports, and pharmacy history reports.
- Law Enforcement Officials may access CURES information only in connection with an investigation or prosecution related to controlled substances.
 - To access prescriber or pharmacy history reports, a Law Enforcement Official must provide (1) a case number and (2) a violation or crime code.
 - Law Enforcement Officials acting in the capacity of a coroner or medical examiner, or directly assisting an individual acting in the capacity of a coroner or medical examiner, are prohibited from obtaining prescriber or pharmacy history reports.
 - To access patient activity reports, a Law Enforcement Official must provide (1) a case number, (2) a violation or crime code, and (3) a search warrant or court order.
 - Law Enforcement Officials acting in the capacity of a coroner or medical examiner, or directly assisting an individual acting in the capacity of a coroner or medical examiner, are not required to provide a violation or crime code when the subject of the search is deceased.
 - In place of a search warrant or court order, a Law Enforcement Official may present (1) a federal grand jury subpoena, (2) a subpoena from a federal, state, or local prosecutor, which requests a defendant's records be delivered directly to the court where the defendant is being tried, (3) an administrative subpoena under the Controlled Substances Act, (4) a federal civil subpoena, (5) documentation that the individual was a Medi-Cal beneficiary or applicant and that the investigation concerns Medi-Cal fraud, or (6) a copy of an individual's death certificate or a memorandum

produced on Law Enforcement Agency's official letterhead that meets specified requirements.

Research

- Researchers and research entities may request data from CURES for purposes of education, peer review, statistics, or research.
- Verified researchers may access aggregated data, de-identified individual data, and identified individual data. Non-verified researchers may obtain only aggregated data.
 - To obtain individual data, verified researchers must submit an application to CURES that (1) explains the project, the data requested, and the intended use of the data; (2) includes a copy of approval by an institutional review board; and (3) describes the security measures the researchers will take to protect the data.
 - If verified researchers wish to obtain identified individual data, they must provide written voluntary consent of the individuals whose data they are requesting.
 - Upon completion of a project, researchers must destroy all copies of individual data.
- The Department's Research Center must approve any reports or other publications based on data that may identify an individual before the results can be disseminated, unless the individual consents in writing.
- Researchers must avoid disclosing CURES data if there is a reasonable possibility that an identifiable person can be linked to the information. Researchers must aggregate individual data before publishing to avoid the risk of identifying individuals

Individuals

- Individuals are eligible to receive their own prescription history that is stored in CURES.
- Authorized representatives of deceased individuals, parents or guardians of minors, guardians of individuals placed under conservatorship, and health care agents for incapacitated individuals may also request CURES data on behalf of an individual.

Data Disclosure

- CURES data may be disclosed only for the purpose for which the data was requested and in compliance with all federal and state privacy and confidentiality laws.