SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair
2017 - 2018 Regular

Bill No:	AB 1751	**Hearing Date:**	June 26, 2018
Author:	Low		
Version:	January 3, 2018		
Urgency:	No	**Fiscal:**	Yes
Consultant:	SJ		

Subject: ***Controlled Substances: CURES Database***

HISTORY

Source: Author

Prior Legislation: AB 40 (Santiago), Ch. 607, Stats. 2017
SB 641 (Lara), was not heard in Assembly Public Safety 2017
SB 482 (Lara), Ch. 708. Stats. 2016
SB 360 (DeSaulnier), Ch.418, Stats. 2011
SB 151 (Burton), Ch. 406, Stats. 2003
AB 3042 (Takasugi), Ch.738, Stats. 1996

Support: America's Physician Groups; Biocom; California Association of Health Underwriters; California Chiropractic Association; California Dental Association; California District Attorneys Association; California Health + Advocates; California Life Sciences Association; California Medical Association; California Pharmacists Association; California Police Chiefs Association; California State Board of Pharmacy; California State Sheriffs' Association; Consumer Attorneys of California; County Behavioral Health Directors Association of California; County Health Executives Association of California; Kaiser Permanente; Medical Board of California; OCHIN; San Diego County District Attorney; Troy and Alana Pack Foundation

Opposition: ACLU of California (unless amended); California Academy of Family Physicians (unless amended); California Medical Association (unless amended); Electronic Frontier Foundation (unless amended)

Assembly Floor Vote: 75 - 0

PURPOSE

The purpose of this bill is to authorize the Department of Justice (DOJ) to enter into an agreement with an entity operating an interstate data share hub for the purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines.

Existing law classifies controlled substances into five schedules according to their danger and potential for abuse. (Health & Saf. Code, §§ 11054-11058.)

Existing law authorizes a physician and surgeon to prescribe for, or dispense or administer to, a person under his or her treatment for a medical condition dangerous drugs or prescription controlled substances for the treatment of pain or a condition causing pain, including, but not limited to, intractable pain. (Bus. & Prof. Code, § 2241.5.)

Existing law specifies which types of health care professionals may write or issue a prescription. (Health & Saf. Code, § 11150.)

Existing law specifies that a prescription for a controlled substance shall only be issued for a legitimate medical purpose and establishes responsibility for proper prescribing on the prescribing practitioner. A violation shall result in imprisonment for up to one year or a fine of up to $20,000, or both. (Health & Saf. Code, § 11153.)

Existing law establishes the Controlled Substances Utilization Review and Evaluation System (CURES), a prescription drug monitoring program (PDMP) maintained by the DOJ. States that the purpose of CURES is to assist law enforcement and regulatory agencies in controlling diversion and abuse of Schedule II, III and IV controlled substances and for statistical analysis, education and research. (Health & Saf. Code, § 11165, subd. (a).)

Existing law requires pharmacists and other dispensers to report information relating to prescriptions of Schedule II, III, and IV controlled substances to CURES as soon as reasonably possible but not more than seven days after the date a controlled substance is dispensed. (Health & Saf. Code, § 11165, subd. (d).)

Existing law requires health care practitioners in receipt of a Federal Drug Enforcement Administration (DEA) certificate providing authorization to prescribe controlled substances, as well as pharmacists, to register for access to the CURES database. (Health & Saf. Code, § 11165.1, subd. (a).)

Existing law requires certain health care practitioners to consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient, with certain exceptions. Provides that this requirement is not operative until six months after DOJ certifies that CURES is ready for statewide use. (Health & Saf. Code, § 11165.4.)

Existing law authorizes information technology systems that meet certain patient privacy and data security requirements to interoperate with the database, allowing prescribers and dispensers to make queries through their electronic health record applications. (Health & Saf. Code, § 11165.1.)

Existing law requires the CURES database to comply with all applicable federal and state privacy and security laws and regulations. Requires the DOJ to establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES. (Health & Saf. Code, § 11165, subd. (c).)

Existing law prohibits any person from obtaining or attempting to obtain a prescription for controlled substances, by fraud, deceit, misrepresentation, subterfuge, or the concealment of a material fact. (Health & Saf. Code, § 11173.)

This bill authorizes DOJ to enter into an agreement with an entity operating an interstate data share hub for purposes of participating in interjurisdictional information sharing between prescription drug monitoring programs across state lines.

This bill requires any agreement entered into by DOJ for purposes of interstate data sharing complies with California law and meets the same patient privacy and data security standards employed and required for direct access of CURES.

COMMENTS

1. Need for This Bill

According to the author:

> Currently, the CURES prescription drug monitoring program database contains information related to Schedule II-IV prescriptions dispensed only within California. This means that when a health practitioner consults a patient's prescription history prior to writing a new prescription, information relating to prescriptions written in other states are not reflected in the activity report. For true "doctor shoppers," traveling across state lines to secure prescriptions of opioids is not uncommon. This is especially true in communities located near California's borders.
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> Forty-nine states including California and the District of Columbia currently have a PDMP. . . . Many of these states already participate in one of several interstate data share hubs that allow for the exchange of prescription information. For example, the National Association of Boards of Pharmacy administers PMP InterConnect, a technology solution developed in partnership with Appriss Health that currently connects 46 state PDMPs, including Nevada, Oregon, and Arizona. . . .
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> The CURES statute (HSC §§ 11165 et seq.) does not currently include interstate hub sharing among the expressly authorized uses of data within CURES. There is also no framework provided requiring the Department of Justice (DOJ) to insist on certain privacy and security minimums as part of any agreement it does choose to enter into. This bill would provide that framework and include those safeguards.

2. Prescription Drug Monitoring Programs

A PDMP is "an electronic database that tracks controlled substance prescriptions in a state. PDMPs can provide health authorities timely information about prescribing and patient behaviors." (https://www.cdc.gov/drugoverdose/pdmp/states.html.) With rising levels of abuse, law enforcement and regulatory bodies view PDMPs as a critical tool in assisting with their efforts to reduce drug diversion. Forty-nine states currently have monitoring programs.

California's PDMP is known as CURES. Data from CURES is managed by DOJ to assist state law enforcement and regulatory agencies in their efforts to reduce prescription drug diversion. CURES provides information that offers the ability to identify if a person is "doctor shopping," a

term used to describe a person who visits multiple doctors to obtain multiple prescriptions for drugs, or who uses multiple pharmacies to obtain prescription drugs. Information tracked in CURES contains the patient name, prescriber name, pharmacy name, drug name, amount and dosage, and is available to law enforcement agencies, regulatory bodies and qualified researchers. (https://oag.ca.gov/cures.) CURES can also report on the top drugs prescribed for a specific time period, drugs prescribed in a particular county, doctor prescribing data, pharmacy dispensing data, and is a critical tool for assessing whether multiple prescriptions for the same patient may exist.

There currently is momentum to share data across these programs from state to state. The National Boards of Pharmacy (NABP) currently operates a PDMP, InterConnect, that allows participating states to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide. Over 40 states are sharing data using InterConnect and several other are in the process of signing a Memorandum of Understanding to share data, or have expressed intent to do so. (https://nabp.pharmacy/initiatives/pmp-interconnect/.)

This bill would authorize the DOJ to enter into an agreement for interstate data sharing.

3. Privacy Implications of PDMPs

Data obtained from CURES can be provided to "appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes." (Health & Saf. Code, § 11165, subd. (c)(2)(A).) Data may be also provided to public or private entities, as approved by the DOJ, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. (*Ibid*.) Access to information in CURES depends on who is conducting the search as well as what information is sought.

A health care professional who prescribes or dispenses controlled substances checks CURES before prescribing or dispensing a controlled substance to a patient. In order to do so, the prescriber or dispenser will sign on to the database with a username and password and can query a patient's records based on last name, first name, and date of birth.

The process for law enforcement differs slightly and depends on whether law enforcement is seeking data on a patient or prescriber or dispenser. When law enforcement is seeking patient data, they must enter a patient's last name, first name, and date of birth. This committee has been informed that DOJ's policy requires law enforcement to additionally upload a case number, criminal code, and search warrant into CURES when accessing patient data. In contrast, to access prescriber or dispenser data in CURES, DOJ does not require a search warrant. Again, the search warrant practice is not codified in state law—it is part of current DOJ policy which is subject to change. SB 641 (Lara), a bill introduced during the 2017-2018 Legislative Session, sought to codify a warrant requirement.

The CURES statute generally mandates that the database comply with all applicable federal and state privacy and security laws and regulations. (Health & Saf. Code, § 11165, subd. (c)(2)(A).) However, whether a disclosure of CURES information violates a patient's right to privacy either under state or federal law has been the subject of litigation.

a) California Privacy Law

The California Constitution expressly provides for the right of privacy among the inalienable rights it guarantees the citizens of the State. (Cal. Const. art. I, § 1.)

Additionally, prescription information, *when in a person's medical record*, has the protections of the Confidential Medical Information Act (CMIA). The CMIAprovides that a health care provider is prohibited from disclosing a patient's medical information without his or her authorization except in specified circumstances. One such exception exists where a search warrant has been lawfully issued to a governmental law enforcement agency. (Cal. Civ. Code, § 56.10, subd. (b)(6).)

In *Lewis v. Superior Court*, the California Supreme Court addressed the constitutional right to privacy in the context of CURES. (*Lewis v. Superior Court* (2017) 3 Cal.5th 561.) The question before the court was whether the Medical Board of California violated the privacy rights of patients under the state constitution when it obtained data from CURES without a warrant or subpoena when it investigated the patients' physician. (*Id*. at 565.) The board, which investigates physicians based on complaints or on its own initiative, is charged with the duty to protect the public against incompetent, impaired or negligent physicians. (*Id*. at p. 567.) The board's investigators are peace officers. (*Ibid*.)

In deciding the case, the court balanced the patients' right to privacy in their controlled substance prescription records against the state's interest in protecting public from unlawful use and diversion of dangerous prescription drugs and protecting the public form negligent or incompetent physicians. (*Lewis, supra,* 3 Cal.5th at pp. 572-574.) The court found that while patients retain a reasonable expectation of privacy in their prescription records, it is not as high as the privacy interest associated with medical records. (*Id*. at p. 575.) The court noted that there are safeguards in statute to limit the degree to which a patient's privacy is invaded when the board examines prescription records. (*Id*. at p. 577.) Accordingly, the court concluded that the board did not violate the patients' constitutional right to privacy by examining the patient prescription records in CURES. (*Ibid*.)

b) Fourth Amendment Protections

In *Lewis, supra*, 3 Cal.5th 561, the Supreme Court declined to consider the petitioner's claim that the Medical Board's access CURES records violated the Fourth Amendment of the United States Constitution because that claim was not raised in the administrative proceedings. (*Id*. at p. 578.)

The Fourth Amendment guarantees "[t]he right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures." Application of the Fourth Amendment depends on whether the person invoking its protection can claim a justifiable, a reasonable, or a legitimate expectation of privacy that has been invaded by government action. Whether the Fourth Amendment protections apply to CURES and other PDMPs is an open question.

However, several federal courts have held that the federal DEA need not secure a warrant to access data in a PDMP. Recently, in *Oregon Prescription Drug Monitoring Program v. United States DEA* (9th Cir. 2017) 800 F.3d 1228, the Ninth Circuit Court of Appeals ruled that the federal Drug Enforcement Agency does not need a court order to subpoena

Oregon's PDMP. Oregon's statute requires a court order in order for a federal, state, or local law enforcement agency engaged in a drug-related investigation to obtain prescription monitoring information. (*Id*. at p. 1232, citing Or. Rev. Stat. § 431A.865(2)(a)(F).) The DEA sought the PDMP records of a patient and of two doctors. Oregon argued that, under state law, it could not be compelled to produce the records without a federal court order. The American Civil Liberties Union (ACLU) sought to intervene in the case on behalf of four patients and a physician and argued that the use of investigative subpoenas violated the Fourth Amendment. (*Ibid*.) The court held that Oregon's statutory requirement for a court order in all cases conflicted with, and was preempted by the federal Controlled Substances Act, which authorizes the Attorney General to issue administrative subpoenas to investigate drug crimes. (*Id*. at pp. 1236-1237.) This authority has been delegated to the DEA. (*Id*. at pp. 1231.)

The court's ruling left open the question of whether administrative subpoenas by the DEA of the information in the PDMP would violate Fourth Amendment protections against unreasonable searches and seizures. That claim was not addressed because the court determined that the individuals represented by the ACLU did not have standing to seek relief that was different from the State of Oregon. (*Oregon Prescription Drug Monitoring Program, supra*, 800 F.3d at pp. 1231, & 1234-1235.)

To address privacy implications, this bill would require that any agreement entered into by DOJ for purposes of interstate data sharing to ensure complies with California law and meets the same patient privacy and data security standards used and required for direct access of CURES.

The ACLU, Electronic Frontier Foundation, California Medical Association, and the California Academy of Family Physicians have each opposed this bill based on privacy concerns. Opponents argue that given the lack of privacy protections currently in place for CURES records, it would be imprudent to allow other states' PDMPs to access CURES data. The author and committee may wish to consider if providing additional privacy protections would improve the bill.

4. Argument in Support

The California State Board of Pharmacy supports this bill, writing:

> This bill would enable California's prescription drug monitoring program (CURES) to share data with prescription drug monitoring programs in other states. The result will be more complete information for California's health care providers when prescribing or dispensing controlled substances.
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> Currently 45 states either share, or are in the process of setting up arrangements to share, dispensing information on controlled substances provided to patients in other states. California is not part of this system. Assembly Bill 1751 would correct this situation when the other states' systems meet the same patient privacy and security standards as CURES.

5. Argument in Opposition

According to the California Medical Association:

> While CMA believes participation in an interstate system will help in identifying opioid-abusing patients shopping for medications across state lines, we have serious concerns with the lack of adequate privacy protections for the confidential patient information contained in CURES when accessed from within California. As such, we strongly oppose efforts to grant access to this data across state lines without first establishing sufficient patient protections.
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> …California's CURES database has some qualities that put it outside standard practice. First, according to the National Alliance for Model State Drug laws (NAMSDL), California is one of three states which house its PDMP in a law enforcement entity. The majority are housed in a health department or Board of Pharmacy. Additionally, California is one of the few states that does not specify in statute the authorized recipients of information from [CURES].
>
> The sensitive and confidential nature of the information in the database requires a thoughtful sharing approach that balances California's longstanding policy of protecting patient privacy while also weighing the needs of the many different types of entities who may use CURES data, including for public health and safety purposes. The explicit delineation of privacy and access to information is a best practice that California has yet to implement and until implemented, the patient records contained in CURES should be vigorously protected, not opened for sharing through databases across the country.

The Electronic Frontier Foundation writes:

> [AB 1751] is unclear on whether out-of-state recipients must comply with California privacy and security standards with respect to access to the CURES database and the protection of Californians' personal information once accessed, and how Californians can hold out-of-state actors accountable for violating their privacy as a result of data sharing under AB 1751.
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> EFF has had grave concerns about the inadequacy of privacy protections for the sensitive patient information contained in CURES when accessed from within California. We strongly oppose efforts to grant access to this data throughout the United States unless the bill is amended to protect patients' personal information from unnecessary or wrongful disclosure and from access by federal, state, and local agencies without a warrant based on probable cause.

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