SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair
2017 - 2018 Regular

Bill No:	AB 1752	**Hearing Date:**	June 26, 2018
Author:	Low		
Version:	June 20, 2018		
Urgency:	No	**Fiscal:**	Yes
Consultant:	SJ		

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

HISTORY

Source: California State Board of Pharmacy

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 1258 (DeSaulnier), held in Senate Appropriations 2014
AB 2986 (Mullin), Ch. 286, Stats. 2006
SB 151 (Burton), Ch. 406, Stats. 2003
AB 3042 (Takasugi), Ch.738, Stats. 1996

Support: California Association of Health Underwriters; California Chiropractic Association; California District Attorneys Association; California Medical Association; California Police Chiefs Association; California State Sheriffs' Association; Consumer Attorneys of California; County Behavioral Health Directors Association; Medical Board of California; Troy and Alana Pack Foundation; California Society of Anesthesiologists (support unless amended)

Opposition: ACLU of California; Electronic Frontier Foundation

Assembly Floor Vote: 76 - 0

PURPOSE

The purpose of this bill is to add Schedule V drugs to the Controlled Substance Utilization Review and Evaluation System (CURES) database and to shorten the length of time a dispenser has to report specified information related to the dispensing of controlled substances to CURES.

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

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 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 to CURES within seven days relating to prescriptions of Schedule II, III, and IV controlled substances. (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, pending certification of readiness by the DOJ, 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. (Health & Saf. Code, § 11165.4.)

Existing law authorizes health 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 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 requires all Schedule V controlled substances to be monitored in CURES.

This bill requires dispensers to report prescription information within one working day, instead of seven days, after the date a controlled substance is dispensed.

This bill requires that reports to CURES include the date of sale of the prescription.

COMMENTS

1. Need for This Bill

According to the author:

> …Because prescriptions for Schedule V drugs have been deemed by the DEA to represent those regulated by the Controlled Substances Act with the lowest potential for abuse, an argument has been made that the state's PDMP has no need to track them. However, assertions that Schedule V drugs like cough syrup with codeine are not susceptible to abuse or diversion were ultimately proven to be drastically misguided. Abuse of prescription-strength cough syrup containing codeine exploded as recreational use of the drug became popularized by hip-hop culture. Referred to through common slang terms like "purple drank," "sizzurp," "lean," and "dirty sprite," it has been widely reported that the theft of cough syrup containing codeine is one of the most prevalent causes for pharmacy break-ins. Consistently requiring dispensers to report all Schedule V drugs is the most straightforwardly implementable way of expanding existing reporting requirements for pharmacies. AB 1752 does not add Schedule V drugs to other mandates under California law relating to Schedule II-IV drugs; it does not, for example, add a requirement that health practitioners consult CURES prior to writing prescriptions for these substances. Tracking the drugs in the database will significantly assist health professionals, regulators, and law enforcement in investigating cases of theft and abuse among these controlled substances.
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> Currently, statute requires dispensers to report new prescriptions to CURES "as soon as reasonably possible, but not more than seven days." This means while data in the CURES 2.0 system is "real-time" in that reported prescriptions immediately appear in the database, for up to one week a dispensed prescription may not be appear in users' queries. Meanwhile, "doctor shoppers" are able to visit multiple prescribers to obtain prescriptions.
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> …
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> Reducing the amount of time provided to dispensers to report prescriptions to CURES from up to 7 days down to within the next business day will significantly improve the database's reliability for practitioners seeking to identify multi-prescriber seeking behavior among their patients. The change would not substantially change current practice for the vast majority of pharmacies. It will, however, ensure that doctor shoppers are not able to take advantage of a time delay when seeking to obtain multiple prescriptions.

2. Controlled Substances and CURES

Through the Controlled Substances Act of 1970, the federal government regulates the manufacture, distribution and dispensing of controlled substances. The act ranks into five schedules those drugs known to have potential for physical or psychological harm, based on three considerations: (a) their potential for abuse; (b) their accepted medical use; and, (c) their accepted safety under medical supervision.

Schedule I controlled substances have a high potential for abuse and no generally accepted medical use such as heroin, ecstasy, and LSD.

Schedule II controlled substances have a currently accepted medical use in treatment, or a currently accepted medical use with severe restrictions, and have a high potential for abuse and psychological or physical dependence. Schedule II drugs can be narcotics or non-narcotic. Examples of Schedule II controlled substances include combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), morphine, methadone, Ritalin, Demerol, Percocet, Percodan, fentanyl and Oxycontin.

Schedule III and IV controlled substances have a currently accepted medical use in treatment, less potential for abuse but are known to be mixed in specific ways to achieve a narcotic-like end product. Examples include Tylenol with codeine, testosterone, Xanax, Ambien and other anti-anxiety drugs.

Schedule V drugs have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.

With rising levels of prescription drug abuse, prescription drug monitoring programs (PDMPs) assist law enforcement and regulatory bodies with their efforts to reduce drug abuse and diversion. In California, CURES is an electronic tracking program that reports all pharmacy (and specified types of prescriber) dispensing of certain schedules of controlled drugs by drug name, quantity, prescriber, patient, and pharmacy. Data from CURES is managed by DOJ. 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, prescribers, dispensers, and qualified researchers. CURES provides information 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. The system 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.

Every dispenser of controlled substances and every health practitioner authorized by the DEA to prescribe controlled substances is required to obtain a login for access to CURES. For each dispensed Schedule II, III, or IV drug, pharmacists and other dispensers are required to report basic information about the patient and their prescription within 7 days. This information is then made available to other system users in a variety of possible contexts. For example, physicians may query a patient's prescription history prior to writing a new prescription; pharmacists can check the system before agreeing to fill a prescription for a controlled substance; regulators may review a licensee's prescribing practices as part of a disciplinary investigation; and law enforcement can incorporate a search of the system into a potential criminal case of drug diversion.

Over 50 million prescription records have been uploaded into the system by dispensers since the beginning of the CURES program. As of January 1, 2018, 170,422 users had been approved for access to the system. Last year, close to 10 million activity reports had been processed by practitioners, pharmacists, law enforcement, and regulatory users. The vast majority of these searches (over 99%) were queries made by prescribers and dispensers seeking to review a

patient's prescription history as a component of exercising informed clinical judgment before providing access to opioids or other controlled substances.

Health practitioners will soon be required to consult the CURES database prior to writing a prescription for a Schedule II, III, or IV drug for the first time, and then at least once every four months as long as the prescription continues to be renewed. A recently enacted statute requires the DOJ to facilitate interoperability between health information technology systems and the CURES database, subject to a memorandum of understanding setting minimum security and privacy requirements.

As attention to the opioid crisis continues to grow, CURES and other PDMPs are regularly mentioned as powerful tools for curbing the abuse of prescription drugs.

3. CURES Reporting Timeline

Under current law, dispensers are required to report new prescriptions 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).) This means while data in the CURES 2.0 system is "real-time" in that reported prescriptions immediately appear in the database, for up to one week a dispensed prescription may not be appear in users' queries. Meanwhile, "doctor shoppers" are able to visit multiple prescribers to obtain prescriptions.

The majority of pharmacies in California do not report prescriptions directly into CURES. Atlantic Associates, a technology vendor, operates a Direct Dispense Application that facilitates reports between pharmacists and CURES. (https://www.oag.ca.gov/cures.) This application typically collects all Schedule II-IV prescriptions dispensed by the pharmacy each day and uploads them all into CURES overnight in a single batch process. The standard turnaround time for these uploads is within one day. While some pharmacies with smaller numbers of daily prescriptions manually upload files to CURES, this process is nearly universal for most prescriptions dispensed within the state.

The sponsor of this bill argues that reducing the amount of time provided to dispensers to report prescriptions to CURES from up to seven days down to within the next business day will significantly improve the database's reliability for practitioners seeking to identify multi-prescriber seeking behavior among their patients. The change would not substantially change current practice for the vast majority of pharmacies. It will, however, ensure that doctor shoppers are not able to take advantage of a time delay when seeking to obtain multiple prescriptions.

4. Date of Sale Requirement

Currently, reports to CURES are required by statute to include a date representing when the prescription was dispensed. However, this is often not a reliable date. "Dispensed" is traditionally intended to refer to when drug production occurs and the prescription is prepared by a pharmacy for a patient to pick up. When a day or more passes between the patient ordering their prescription and physically coming to retrieve it, the date reflected in the prescription's CURES report does not accurately reflect when the patient was in possession of the drug. When a patient fails to come retrieve their medicine or when the pharmacy declines to fill the prescription, the CURES report may not correctly represent the patient having the drug at all.

These issues are resolved through the addition of a "date of sale" reporting requirement as provided for in this bill.

5. Argument in Support

According to the County Behavioral Health Directors Association of California:

> Prescription drug monitoring programs like CURES are one of the most effective ways to combat the growing opioid abuse crisis. . . However, CURES currently only contains prescription information for Schedule II, III, and IV controlled substances. Schedule V substances are not reported to the database due to an outdated assumption that these drugs present a relatively low risk of abuse and diversion. Yet the recent rise in street use of cough syrups containing the opioid codeine has led to a spike in theft and abuse of Schedule V drugs.

6. Argument in Opposition

According to the Electronic Frontier Foundation:

> Ab 1752 would expand the tracking and monitoring of patient prescriptions done under CURES by adding all prescriptions for Schedule V drugs and any drug the State Board of Pharmacy deems poses a substantial risk of abuse or diversion. Yet the bill expressly adds Schedule V drugs, which are defined to include drugs that have a low potential for abuse relative to Schedule IV substances. . . .AB 1752 leaves open the possibility that any prescription drug could be tracked and monitored.
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> …AB 1752 undermines legal protections for patient privacy by expanding the list of prescription medications that would be tracked in CURES by the state Department of Justice. Because DOJ is not an entity covered by either the Confidentiality of Medical Information Act or the federal HIPAA, the privacy and security protections of those laws do not apply to it, and AB 1752 would essentially exempt more sensitive personal information—more prescription history—from these laws.

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