SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair
2017 - 2018 Regular

Bill No:	AB 1753	**Hearing Date:**	June 26, 2018
Author:	Low		
Version:	April 18, 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 809 (De Saulnier), Ch. 400, Stats. 2013
SB 360 (De Saulnier), Ch.418, Stats. 2011
SB 151 (Burton), Ch. 406, Stats. 2003
AB 3042 (Takasugi), Ch.738, Stats. 1996

Support: America's Physicians Group; California Association of Health Underwriters; California Chiropractic Association; California District Attorneys Association; California Life Sciences Association; California Police Chiefs Association; Consumer Attorneys of California; County Behavioral Health Directors Association of California; San Diego County District Attorney; Troy and Alana Pack Foundation

Opposition: None known

Assembly Floor Vote: 76 - 0

PURPOSE

The purpose of this bill is to authorize the Department of Justice (DOJ) to reduce or limit the number of approved controlled substance prescription security printers, as specified, and to require prescription forms for controlled substance prescriptions to have a uniquely serialized number, as specified.

Existing law establishes the Uniform Controlled Substances Act which regulates controlled substances. (Health & Saf. Code, § 11000 et seq.)

Existing law categorizes controlled substances into five schedules based on their danger and potential for abuse. (Health & Saf. Code, §§ 11007; 11054-11058.)

Existing law defines "prescription" as "an oral order or electronic transmission prescription for a controlled substance given individually for the person(s) for whom prescribed, directly from the

prescriber to the furnisher or indirectly by means of a written order of the prescriber." (Health & Saf. Code, §11027, subd. (a).)

Existing law specifies which health care professionals may write or issues 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. States that 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 requires that prescription forms for controlled substance prescriptions be obtained from security printers approved by the DOJ. (Health & Saf. Code, § 11161.5, subd. (a).)

Existing law requires controlled substance prescriptions to be made on the specified prescription form. (Health & Saf. Code, § 11164.)

Existing law requires that the prescription forms for controlled substances include certain features. (Health & Saf. Code, § 11162.1.)

Existing law establishes the Controlled Substance Utilization Review and Evaluation System (CURES) for electronic monitoring of Schedule II, III and IV controlled substance prescriptions. CURES provides for the electronic transmission of Schedule II, III and IV controlled substance prescription information to the DOJ at the time prescriptions are dispensed. (Health & Saf. Code, § 11165.)

Existing law provides 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 establishes privacy protections for patient data and specifies that CURES data can only be accessed by appropriate state, local and federal persons or public agencies for disciplinary, civil or criminal actions. Specifies that CURES data shall also only be provided, as determined by DOJ, to other agencies or entities for educating practitioners and others, in lieu of disciplinary, civil or criminal actions. Authorizes non-identifying CURES data to be provided to public and private entities for education, research, peer review and statistical analysis. (Health & Saf. Code, § 11165, subd. (c).)

Existing law provides that pharmacies or clinics, in filling a prescription for a federally Scheduled II, III or IV drug, shall provide weekly information to DOJ including the patient's name, date of birth, the name, form, strength and quantity of the drug, and the pharmacy name, pharmacy number and the prescribing physician information. (Health & Saf. Code, § 11165, subd. (d).)

Existing law provides that a licensed health care practitioner eligible to prescribe Schedule II, III or IV controlled substances, or a pharmacist, shall apply to participate in the CURES PDMP by January 1, 2016. Authorizes DOJ to deny an application or suspend a subscriber for certain violations and falsifying information. Provides that the history of controlled substances dispensed to a patient based on CURES data that is received by a practitioner or pharmacist shall

be considered medical information, subject to provisions of the Confidentiality of Medical Information Act. (Health & Saf. Code, § 11165.1.)

Existing law authorizes the DOJ to conduct audits of the CURES PDMP system and its users and create a system for issuing citations for violations. (Health & Saf. Code, 11165.2, subd. (a) & (b).)

Existing law requires a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance to consult the CURES database to review a patient's controlled substance history, as specified. (Health & Saf. Code, § 11165.4.)

Existing law requires health practitioners who prescribe or administer a controlled substance classified in Schedule II to make a record containing the name and address of the patient, date, and the character, name, strength, and quantity of the controlled substance prescribed, as well as the pathology and purpose for which the controlled substance was administered or prescribed. (Health & Saf. Code, § 11190, subd. (a) and (b).)

Existing law requires prescribers who are authorized to dispense Schedule II, III or IV controlled substance in their office or place of practice to record and maintain information for three years for each such prescription that includes the patient's name, address, gender, and date of birth, prescriber's license and license number, federal controlled substance registration number, state medical license number, National Drug Code number of the controlled substance dispensed, quantity dispensed, diagnosis code, if available, and original date of dispensing. Requires that this information be provided to DOJ on a monthly basis. (Health & Saf. Code, § 11190, subd. (c).)

This bill makes the following legislative declarations and findings:

1) The prevailing use of paper prescription pads to prescribe controlled substances leads to significant instances of theft and fraud each year, contributing to the prescription drug abuse crisis and fueling criminal enterprises engaged in drug diversion.
2) Prescribing controlled substances by means of electronic transmission prescription, or e-prescribing, has long been considered the most effective way to combat prescription pad theft and fraud.
3) Many states have begun to require that all controlled substances must be prescribed electronically as a means of addressing the public health and public safety crises associated with prescription drug abuse and diversion.
4) Until mandatory e-prescribing is established in California, it is critical that tighter restrictions be placed on the manufacturing and tracking of prescription pads used within the state.

This bill authorizes DOJ, in order to facilitate the standardization of all prescription forms and the serialization of prescription forms with unique identifiers, to cease issuing new approvals of security printers to the extent necessary to achieve these purposes.

This bill authorizes DOJ, pursuant to regulation, to reduce the number of currently approved security printers to no fewer than three vendors.

This bill requires DOJ to ensure that any reduction or limitation of approved security printers does not impact the ability of vendors to meet demand for prescription forms.

This bill requires prescription forms for controlled substances to include a uniquely serialized number in a manner prescribed by the DOJ.

COMMENTS

1. Need for This Bill

According to the author:

> Under the DOJ's Security Prescription Printers Program, all paper prescriptions of any Schedule II through V controlled substance must use special tamper-resistant forms obtained from manufacturers approved by the DOJ. Vendors wishing to operate as approved security printers submit an application to the DOJ and are initially required to provide an applicant's name, address, and telephone number along with a description of the applicant's intended policies and procedures for ensuring that prescription pads are delivered only to valid prescribers. The DOJ then generally screens the applicant and any other individuals affiliated with the applicant's business for any disqualifying criminal history records. Once approved, printers are required to retain records for inspection by the DOJ and may have be fined or have their approval revoked for misconduct.
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> Th[e] list of requirements [for prescription pads] does not include a uniquely serialized number, and delivery information reported by security printers to the DOJ does not include information specifically identifying prescription pads through a serial number. This means that when prescription pads are lost or stolen, there is no way for the DOJ or law enforcement to effectively identify the circulation of prescriptions written on those pads. There is also no realistic method of linking a particular pad to dispensed prescriptions, even though the state tracks all Schedule II-IV drug prescriptions dispensed in California through CURES.
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> One of the stated challenges to requiring standardized serialization of prescription pads is that the number of approved security printers that are each individually manufacturing pads throughout the state without significant restriction or coordination. Approximately 43 security printers are currently approved by the DOJ and operating throughout the state. The DOJ has stated that it believes this to be too many printers to substantially standardize the production of forms in a way that would allow for unique identifiers to be consistently applied in a way that can be tracked through CURES or any other system.
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> Allowing the DOJ to limit the number of approved security printers to no fewer than three will provide for a more manageable amount of coordination between manufacturers. This will allow for prescription pads to be tracked by law enforcement when lost or stolen, and for serialized pads to be linked to CURES. The tighter regulation could also arguably make it easier for law enforcement to identify counterfeit or fraudulent prescription pads sold on the street.

2. Prescriptions

Written prescriptions have been regulated in the State of California since 1929, when a statute was first enacted to require that certain drugs be dispensed only with a written prescription from a licensed physician, dentist, or veterinarian. These prescriptions were required to include the name and address of the individual receiving the drug, and for three years all prescription records were required to remain "open to inspection by the prescriber and properly authorized officers of the law, including all inspectors of the division of narcotic enforcement and of the state board of pharmacy." This requirement was later expanded to include all prescription drugs.

Under the DOJ's Triplicate Prescription Program (TPP), first launched in 1939 under Attorney General Earl Warren, health practitioners were required to use serialized triplicate prescription forms when prescribing a Schedule II controlled substance. One copy was provided to the patient, and another was retained for the prescriber's records. The third copy of each triplicated prescription was sent to the Bureau of Narcotics Enforcement within the DOJ's Division of Law Enforcement, which used the records to investigate potential fraud or criminal diversion of controlled substances. When the TPP was replaced by the CURES database in 2005, the triplicate prescription form requirement for Schedule II drugs was replaced with a new requirement that these prescriptions be issued on a special form obtained from an approved printer.

Under the DOJ's Security Prescription Printers Program, all paper prescriptions of any Schedule II through V controlled substance must use special tamper-resistant forms obtained from manufacturers approved by the DOJ. Vendors wishing to operate as approved security printers submit an application to the DOJ and are initially required to provide an applicant's name, address, and telephone number along with a description of the applicant's intended policies and procedures for ensuring that prescription pads are delivered only to valid prescribers. The DOJ then generally screens the applicant and any other individuals affiliated with the applicant's business for any disqualifying criminal history records. Once approved, printers are required to retain records for inspection by the DOJ and may be fined or have their approval revoked for misconduct.

3. 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" (when a patient, often a prescription-drug addict, visits multiple doctors to obtain multiple prescriptions for drugs, or 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 percent) 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 (DOJ certified the system for statewide use on March 31, 2017; consultation requirements for prescribers outlined in SB 482 [Lara, Chapter 708, Statutes of 2016] take effect six months after DOJ certifies the system). Other recently enacted statutes require 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.

4. Argument in Support

The California Police Chiefs Association writes in support of AB 1751. According to Cal Chiefs, the bill would "empower the role of the Department of Justice in regulating private vendors entrusted with manufacturing prescription pads by adding new controls, limiting the number of approved printers, and linking unique serial numbers to CURES." Cal Chiefs describes the bill as part of a larger effort to "fight back against the alarming opioid crisis affecting our state and nation."

The District Attorney of San Diego County, Summer Stephan, supports the bill.
DA Stephan states that the bill "helps to further the administration of justice and promote safety in our community." The California District Attorneys Association echoes this sentiment on behalf of all 58 county district attorneys. CDAA writes that the bill "would help reduce prescription form forgery and fraud, which will help prevent prescription drug abuse."

The California Life Sciences Association supports AB 1753, representing the state's biotechnology, pharmaceutical, medical device and diagnostics companies, venture capital firms, research universities, and nearly 30,000 employees in the industry. CLSA cites specific examples of criminal cases where the legislation would have aided law enforcement investigations: "For instance, in Modesto, a single four-person prescription fraud ring put over 50,000 prescription opioids on the street within a year, using stolen prescription pads and forged prescriptions." CLSA writes that AB 1753 would be a "positive step towards eliminating illicit sources of prescription opioids."

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