SENATE COMMITTEE ON PUBLIC SAFETY

Senator Nancy Skinner, Chair
2017 - 2018 Regular

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Author:	Lara		
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Urgency:	No	**Fiscal:**	Yes
Consultant:	SJ		

Subject: ***Controlled Substance Utilization Review and Evaluation System: privacy***

HISTORY

Source: California Medical Association

Prior Legislation: SB 482 (Lara) Ch. 708, Stats. 2016
SB 1258 (DeSaulnier) Held in Senate Appropriations (2014)
SB 809 (DeSaulnier) Ch. 400, Stats. 2013
SB 360 (DeSaulnier) Ch. 418, Stats. 2011
AB 2968 (Mullin) Ch. 286, Stats. 2006
SB 734 (Torlakson) Ch. 487, Stats. 2005
SB 151 (Burton) Ch. 406, Stats. 2004
AB 3042 (Takasugi) Ch. 738, Stats. 1996

Support: American College of Physicians- California Services Chapter

Opposition: California Narcotics Officers Association (unless amended); California Teamsters Public Affairs Council (unless amended); Consumer Attorneys of California (unless amended); Consumer Federation of California (unless amended); Consumer Watchdog (unless amended); Shatterproof (unless amended)

California Retailers Association (earlier); Center for Public Interest Law (earlier); National Association of Chain Drug Stores (earlier); The Troy and Alan Pack Foundation (earlier)

PURPOSE

The purpose of this bill is to prohibit the release of data obtained within the Controlled Substances Utilization Review and Evaluation System (CURES) to a law enforcement agency except pursuant to a valid court order or warrant based on probable cause and issued at the request of a law enforcement agency engaged in an open and active investigation.

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 provides that the Medical Board of California (MBC) may take any action against a physician and surgeon who violates laws related to inappropriate prescribing. Existing law further provides that a physician and surgeon shall exercise reasonable care in determining whether a particular patient or condition, or the complexity of a patient's treatment, including, but not limited to, a current or recent pattern of drug abuse, requires consultation with, or referral to, a more qualified specialist. (Bus. & Prof. Code § 2241.5.)

Existing law requires the Division of Medical Quality (DMQ) within MBC, to develop standards before June 1, 2002 to ensure competent review in cases concerning the management, including, but not limited to, the under-treatment, under-medication, and overmedication of a patient's pain. Authorizes DMQ to consult with entities such as the American Pain Society, the American Academy of Pain Medicine, the California Society of Anesthesiologists, the California Chapter of the American College of Emergency Physicians, and any other medical entity specializing in pain control therapies to develop the standards utilizing, to the extent they are applicable, current authoritative clinical practice guidelines. (Bus. & Prof. Code § 2241.6.)

Existing law defines "prescription" as an oral, written, or electronic transmission order that includes certain information. (Bus. and Prof. Code § 4040.)

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

Existing law defines "dispense" to deliver a controlled substance to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing, furnishing, packaging, labeling, or compounding necessary to prepare the substance for that delivery and "dispenser" as a practitioner who dispenses. (Health & Saf. Code §§ 11010 and 11011)

Existing law defines a drug as:

- A substance recognized as drugs in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them;

- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; and,

- A substances (other than food) intended to affect the structure or any function of the body of man or animals. (Health & Saf. Code § 11014.)

Existing law defines an opiate as a substance having an addiction-forming or addiction-sustaining effect similar to morphine, or that can be converted into a drug having addiction-forming or addiction-sustaining effects. (Health & Saf. Code § 11020.)

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

Existing law prohibits any person other than a physician, dentist, podiatrist, veterinarian, naturopathic doctor, pharmacist, certified nurse-midwife, nurse practitioner, a registered nurse or physician assistant acting within the scope of an experimental health workforce project

authorized by the Office of Statewide Health Planning and Development, an optometrist licensed under the Optometry Practice Act, or an out-of-state prescriber acting in an emergency situation from writing or issuing a prescription for a controlled substance. (Health & Saf. Code § 11150.)

Existing law specifies that a prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice and establishes responsibility for proper prescribing of controlled substances upon 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 requires special prescription forms for controlled substances to be obtained from security printers approved by the Department of Justice (DOJ), establishes certain criteria for features on the forms and requires controlled substance prescriptions to be made on the specified form. (Health & Saf. Code §§ 11161.5, 11162.1, 11164.)

Existing law establishes the Controlled Substances Utilization Review and Evaluation System (CURES) for electronic monitoring of Schedule II, III and IV controlled substance prescriptions.

- CURES provides for electronic transmission of Schedule II, III and IV controlled substance prescription information to the Department of Justice (DOJ) at the time prescriptions are dispensed. (Health & Saf. Code § 11165.)
- CURES is intended 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 that the operation of CURES comply with all applicable federal and state privacy and security laws and regulations. (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 public agencies or authorized for disciplinary, civil or criminal actions. 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. Non-identifying CURES data can 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 data disclosed to any individual or agency as described above shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. (Health & Saf. Code § 11165, subd. (c).)

Existing law requires 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 a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances from being provided data obtained from CURES. (Health & Saf. Code § 11165, subd. (c).)

Existing law authorizes a health care practitioner, in accordance with federal and state privacy laws and regulations, to provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided. Existing law further authorizes a health care practitioner to keep a copy of the report in the patient's medical record. (Health & Saf. Code § 11165, subd. (c).)

Existing law requires a pharmacy or clinic, in filling a controlled substance prescription, to provide weekly information to DOJ including:

- The patient's name, address, gender, and date of birth.
- The prescriber's category of license, license number, and other specified information.
- The pharmacy name, pharmacy number, and other specified information.
- The National Drug Code number of the drug, quantity of the drug, number of refills ordered, and whether the drug was dispensed a s refill or first-time request.
- Date of origin of the prescription and date of dispensing of the prescription. (Health & Saf. Code § 11165, subd. (d).)

Existing law provides that DOJ may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser invitees be licensed by a board or committee, as specified, in active practice in California, and a regular user of CURES. (Health & Saf. Code § 11165, subd. (e).)

Existing law requires that prior to upgrading CURES, DOJ consult with prescribers licensed by one of the boards or committees, as specified, one or more of the boards or committees, as specified, and any other stakeholder identified by DOJ. (Health & Saf. Code § 11165, subd. (f).)

Existing law authorizes DOJ to a process to educate authorized subscribers on how to access and use CURES. (Health & Saf. Code § 11165, subd. (g).)

Existing law requires a licensed health care practitioner eligible to prescribe Schedule II, III or IV controlled substances, or a pharmacist, to submit an application to obtain approval to access CURES Prescription Drug Monitoring Program (PDMP) information online by July 1, 2016. DOJ may deny an application or suspend a subscriber for certain violations and falsifying information. An authorized subscriber is required notify DOJ within 30 days of any changes to the subscriber account. (Health & Saf. Code § 11165.1 (a).)

Existing law requires that any request for, or release of, a controlled substance history pursuant to this section be made in accordance with guidelines developed by DOJ. (Health & Saf. Code § 11165.1 (b).)

Existing law provides that DOJ may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual in order to prevent the inappropriate, improper, or illegal use of controlled substances. (Health & Saf. Code § 11165.1 (c).)

Existing law provides that the history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from DOJ pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act. (Health & Saf. Code § 11165.1, subd. (d).)

Existing law provides that a health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information. (Health & Saf. Code § 11165.1, subd. (f).)

Existing law provides that DOJ may conduct audits of the CURES Prescription Drug Monitoring Program system and its users. (Health & Saf. Code § 11165.2, subd. (a).)

Existing law requires 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 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 specified exemptions. (Health & Saf. Code § 11165.4.)

Existing law authorizes DOJ to seek private, voluntary funds from insurers, health care service plans, qualified manufacturers, and other donors to support CURES. DOJ is required to make all sources and amounts of such contributions available to the public. (Health & Saf. Code § 11165.5.)

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, subds. (a) and (b).)

Existing law requires authorized prescribers who 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 and original date of dispensing. This information shall be provided to DOJ on a monthly basis. (Health & Saf. Code §§ 11190, subd. (c) and 11191.)

This bill requires that the Department of Justice only provide CURES data to a federal, state, or local law enforcement agency pursuant to a valid court order or warrant based on probable cause and issued at the request of a federal, state, or local law enforcement agency engaged in an open and active investigation regarding prescription drug abuse or diversion of prescription controlled substances involving the person to whom the requested information pertains.

This bill makes other non-substantive changes.

COMMENTS

1. Need for This Bill

According to the author:

> Every time a prescription for a Schedule II through IV controlled substance is filled, the prescription information is entered into the CURES database. Controlled substances, such as Morphine and Xanax, are prescribed for a wide range of serious medical conditions, including seizure disorders, chronic pain, narcolepsy, obesity, weight loss and nausea associated with AIDS and chemotherapy, testosterone deficiency, attention deficit hyperactivity disorder, and heroin addiction treatment. DOJ has reported that CURES typically receives about one million prescription reports per week.
>
> CURES is intended to assist health care practitioners when working with controlled substances, to assist law enforcement and regulatory agencies in their efforts to control diversion and abuse of controlled substances, and for statistical analysis, education, and research. While the statutory authority established for health care providers' access is clear, the authority granting government entities access to the data and under what circumstances is unclear. Health and Safety Code Section 11165 says that data from CURES "shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes."
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> SB 482 (Lara, 2016) required prescribers to check CURES prior to prescribing Schedule II through IV controlled substances, except in certain circumstances. SB 482 also established a small exclusion to government access for those licensing boards that do not license health care providers who work with controlled substances. However, the overarching statutory construct for privacy within the database is unclear and leaves patients' information vulnerable to inappropriate disclosure. The law gives DOJ the sole discretion to determine which government entities receive information from CURES and provides wide latitude for DOJ to change the criteria for access without the public's knowledge. The parameters of who can access Californians' prescription information and to whom the government can disclose such records – which can reveal information about an individual that is highly personal, sensitive, and private – should be established in statute and not left to agency discretion.
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> SB 641 seeks to establish a structure for disclosure of information in the CURES database to law enforcement. This prescription information, when in a person's medical record, has the protections of the Confidential Medical Information Act. In most instances, law enforcement access to it requires a warrant. This bill seeks to more closely align the requirements for law enforcement access to the medical information that is housed in CURES with the disclosure requirements for medical information in medical records. Without this protection, DOJ can change the standard without a public process. The sensitivity of this information warrants clear guidelines for access. Patients believe that their medical information has certain protections; they should know what the parameters for law enforcement access to their information in the database are.

2. Background on Controlled Substances and Prescription Drug Abuse

a. Controlled Substances

Through the Controlled Substances Act of 1970, the federal government regulates the manufacture, distribution and dispensing of controlled substances. The Act groups drugs into five schedules with decreasing 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. Federal law includes relatively detailed explanations of the factors and standards for placement of drugs in the various schedules. California law does not explain how the schedules are organized.

- Schedule I controlled substances, such as heroin, ecstasy, and LSD, have a high potential for abuse and no generally accepted medical use.
- 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 morphine, methadone, Ritalin, Demerol, Dilaudid, Percocet, Percodan, 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 effect. Examples include drugs include Vicodin, 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.

The three classes of prescription drugs that are most commonly abused are: opioids, which are most often prescribed to treat pain; central nervous system (CNS) depressants, which are used to treat anxiety and sleep disorders; and stimulants, which are often prescribed to treat the sleep disorder narcolepsy and attention-deficit hyperactivity disorder (ADHD). Most of the drugs in each class of drugs can induce euphoria or intoxication. When administered by routes other than recommended, such as snorting or dissolving into a liquid to drink or inject, the effect of the drug is typically intensified. Synthetic opioids act on the same receptors as heroin and morphine and therefore can be highly addictive. Common opioids are: hydrocodone (Vicodin), oxycodone (OxyContin), propoxyphene (Darvon), hydromorphone (Dilaudid), meperidine (Demerol), and diphenoxylate (Lomotil).

b. Prescription Drug Abuse

For the past several years, abuse of prescription drugs (taking a prescription medication prescribed to someone else, or taking it for reasons or in dosages other than as prescribed) to get high has become increasingly prevalent. According to the 2008 National Survey on Drug Use and Health (NSDUH), approximately 52 million Americans aged 12 or older reported non-medical use of any psychotherapeutic at some point in their lifetimes, representing 20.8% of the population aged 12 or older. The National Institute on Drug Abuse's (NIDA) research report Prescription Drugs: Abuse and Addiction states that the elderly are among those most vulnerable to prescription drug abuse or misuse because they are prescribed more medications than their younger counterparts. Persons 65 years of age and above comprise only 13 percent of the population, yet account for approximately one-third of all medications prescribed in the United

States. Older patients are more likely to be prescribed long-term and multiple prescriptions, which could lead to unintentional misuse. The report also notes that studies suggest that women are more likely (in some cases, 55 percent more likely) than men to be prescribed a drug which can be abused, particularly narcotics and antianxiety drugs. A 2010 report, Monitoring the Future Study, showed that as many as 4 percent of high school students and 3 percent of young adults say they have used OxyContin in the past year.

Abuse can stem from the fact that prescription drugs are legal and potentially more easily accessible, as they can be found at home in a medicine cabinet. Data shows that individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a health care professional and thus are safe to take under any circumstances. NIDA data states that in actuality, prescription drugs act directly or indirectly on the same brain systems affected by illicit drugs, thus, their abuse carries substantial addiction liability and can lead to a variety of other adverse health effects.

c. Prescription Drug Deaths

A 2013 CDC analysis found that drug overdose deaths increased for the eleventh consecutive year in 2010 and prescription drugs, particularly opioid analgesics, are the top drugs leading the list of those responsible for fatalities. According to CDC, 38,329 people died from a drug overdose in 2010, up from 37,004 deaths in 2009, and 16,849 deaths in 1999. CDC found that nearly 60 percent of the overdose deaths in 2010, involved pharmaceutical drugs, with opioids associated with approximately 75 percent of these deaths. Nearly three out of four prescription drug overdoses are caused by opioid pain relievers. CDC recommends the use of prescription drug monitoring programs (PDMPs) with a focus on both patients at highest risk in terms of prescription painkiller dosage, numbers of prescriptions and numbers of prescribers, as well as prescribers who deviate from accepted medical practice and those with a high proportion of doctor shoppers among their patients. CDC also recommends that PDMPs link to electronic health records systems so that the information is better integrated into health care providers' day-to-day practices. CDC believes that state benefits programs like Medicaid and workers' compensation should consider monitoring prescription claims information and PDMP data for signs and inappropriate use of controlled substances. The organization also acknowledges the value of PDMPs in taking regulatory action against health care providers who do operate outside the limits of appropriate medical practice when it comes to prescription drug prescribing.

A *Los Angeles Times* series, "*Dying For Relief*," highlighted the role of prescription drugs in overdose deaths as determined through the examination of coroners' reports. Reporters conducted an analysis of coroners' reports for over 3000 deaths occurring in four counties (Los Angeles, Orange, Ventura and San Diego) where toxicology tests found a prescription drug in the deceased's system, usually a painkiller, anti-anxiety drug or other narcotic; coroners' investigators reported finding a container of the same medication bearing the doctor's name, or records of a prescription; the coroner determined that the drug caused or contributed to the death. The analysis found that in nearly half of the cases where prescription drug toxicity was listed as the cause of death, there was a direct connection to a prescribing physician. The *Times* created a database linking overdose deaths to the doctors who prescribed drugs, and found that more than 80 of the doctors whose names were listed on prescription bottles found at the home of or on the body of a decedent had been the prescribing physician for 3 or more dead patients. Their analysis found that one doctor was linked to as many as 16 dead patients.

3. Prescription Drug Monitoring Programs (PDMPs) and CURES

With rising levels of prescription drug abuse, PDMPs assist law enforcement and regulatory bodies with their efforts to reduce drug abuse and diversion. Forty-nine states currently have monitoring programs. California has the oldest prescription drug monitoring program in the nation. Of these 50 programs throughout the nation, seven are or will be housed at the state's Department of Justice, 18 are or will be housed at a state Department of Health or substance abuse agency and 25 are or will be housed at a state Board of Pharmacy or state professional licensing agency. There is widespread interest in sharing data from these programs from state to state. The National Boards of Pharmacy (NABP) currently operates a PDMP, InterConnect, that facilitates the transfer of PDMP data across state lines, providing a more effective means of combating drug diversion and drug abuse nationwide. As of April 2017, forty-one states were participating in InterConnect to exchange prescription data, with several additional states intending to or in the process of signing a memorandum of understanding to share data using InterConnect.

In California, CURES is an electronic tracking program that reports all pharmacy (and specified types of prescriber) dispensing of controlled drugs by drug name, quantity, prescriber, patient, and pharmacy. AB 3042 (Takasugi, Chapter 738, Statutes of 1996) established a three-year pilot program, beginning in July 1997, for the electronic monitoring of prescribing and dispensing of Schedule II controlled substances. Subsequent legislation extended the sunset date on the CURES program until it was made permanent in 2003. In 2009, the online CURES system was launched by DOJ. Subsequent legislation established a funding mechanism to update and maintain CURES, required all prescribing health care practitioners to apply to access CURES information, and established processes and procedures for regulating prescribing licensees through CURES and securing private information. Most recently, SB 482 (Lara, Chapter 708, Statutes of 2016) required health care practitioner to consult the CURES database prior to prescribing a controlled substance to the patient for the first time, with specified exemptions.

Data from CURES is managed by DOJ to assist state law enforcement and regulatory agencies in their efforts to reduce prescription drug diversion. DOJ hires a private contractor to actually manage the information in CURES. CURES provides information that offers the ability to identify if a person is "doctor shopping" (when a prescription-drug addict visits multiple doctors to obtain multiple prescriptions for drugs, or uses multiple pharmacies to obtain prescription drugs). Information tracked in the system 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. 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. In addition to the Board, CURES data can be obtained by the MBC, Dental Board of California, Board of Registered Nursing, Osteopathic Medical Board of California and Veterinary Medical Board.

Since 2009, more than 8,000 doctors and pharmacists have signed up to use CURES, which has more than 100 million prescriptions. The system also has been accessed more than 1 million times for patient activity reports and has been key in investigations of doctor shoppers and nefarious physicians. According to the AG's office, CURES assisted in targeting the top 50 doctor shoppers in the state, who averaged more than 100 doctor and pharmacy visits to collect massive quantities of addictive drugs and the crackdown led to the arrest of dozens of suspects.

CURES also provided information on the prescribing history of a Southern California physician accused of writing hundreds of fraudulent prescriptions to feed his patients' drug addictions, seven of whom died from prescription-drug overdoses. The system has also alerted law enforcement and licensed medical professionals to signs of illegal drug diversions, including a criminal ring that stole the identities of eight doctors, illegally wrote prescriptions, stole the identities of dozens of innocent citizens who they designated as patients in order to fill the fraudulent prescriptions, resulting in the group obtaining more than 11,000 pills of highly addictive drugs like OxyContin and Vicodin. DOJ continues to modernize CURES to more efficiently serve prescribers, pharmacists and entities that may utilize the data. The new CURES 2.0 has been operational since 2016.

4. What This Bill Does

This bill requires that a valid court order or warrant based on probable cause be obtained by a federal, state, or local law enforcement agency in order for DOJ to provide CURES data to the law enforcement agency. This bill also requires that the law enforcement agency seeking the court order or warrant in order to access CURES data be engaged in an open and active investigation regarding prescription drug abuse or diversion of prescription controlled substances. The investigation must involve the person to whom the requested information pertains.

5. Fourth Amendment Issues

a. Challenges to Law Enforcement Access to Prescription Drug Records

Historically, it has largely been assumed that allowing law enforcement agencies access to controlled substance prescription information or data does not violate the Fourth Amendment prohibition on unreasonable searches and seizures. There have been recent challenges to law enforcement agencies' accessing of prescription records and data. In *Oregon Prescription Drug Monitoring Program v. United States DEA* (2014) 988 F. Supp. 2d 957, the State of Oregon challenged a DEA claim that the agency could obtain Oregon prescription records with a non-judicial administrative subpoena, not a warrant. Although the Oregon prescription drug monitoring statute includes a requirement that law enforcement agencies obtain a warrant to access information in the database for an investigation, the DEA claimed that a federal law allowed it to access the state's database using only an administrative subpoena. The court ruled that patients have a reasonable expectation of privacy in their drug prescription records, and that law enforcement must obtain a warrant in order to search such information.[1]

Other federal courts have reached the opposite conclusion regarding whether the Fourth Amendment requires a law enforcement agency to obtain a warrant prior to obtaining confidential pharmacy or prescription records. The district court in Colorado found that DEA subpoenas of pharmacists' records met Fourth Amendment requirements and were per se reasonable because they were authorized, properly served, and contained an adequate description of information relevant to the investigations. (*U.S. Department of Justice v. Colorado Board of Pharmacy* (2010) U.S. Dist. LEXIS 92778 at *10). A district court in Texas extended the rationale of *Colorado Board of Pharmacy* to physicians and their patients in finding that the

[1] This case is currently pending appeal in the U.S. Court of Appeals for the Ninth Circuit.

DEA's subpoenas of physician records satisfied Fourth Amendment requirements, in part because physicians and patients have a reduced expectation of privacy in medical records regarding controlled substances given the pervasive regulation of the pharmaceutical industry. (*U.S. v. Zandeh* (2014) U.S. Dist. LEXIS 181500 at *25).

b. Privacy Concerns

The California Constitution expressly provides for the right of privacy. (Cal. Const. art. I, § 1.). Information contained within CURES is subject to the Confidentiality of Medical Information Act. (Cal. Civ. Code §§ 56 to 56.7.) The Act provides 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(b)(6).)

The issue of whether a physician's patients have a protected privacy interest in the controlled substance prescription data contained within CURES when the patient's physician is being investigated by the CMB is currently being litigated. The Second District Court of Appeal held that in balancing the patient's right to privacy in their controlled substance prescription records against the state's interest in protecting public health by regulating controlled substance and protecting the public form negligent or incompetent physicians, CURES does not present an impermissible invasion of a patient's state constitutional right to privacy because sufficient safeguards exist to prevent unwarranted public disclosure and unauthorized access to CURES data. (*Lewis v. Superior Court* (2014) 226 Cal.App.4th 933.). Oral argument in *Lewis v. Superior Court*[2] is scheduled to be heard before the California Supreme Court on May 3, 2017.

6. Requirement to Obtain a Valid Court Order or Warrant

Given that this bill addresses the release of CURES data to law enforcement agencies during the course of an open and active investigation, the members of the committee may wish to consider if these agencies should be required to obtain a warrant rather than the proposed requirement that the law enforcement agency obtain a warrant *or* a court order. A valid court order that is not a warrant may be appropriate in the context of an investigation involving agencies other than law enforcement agencies. However, this bill only pertains to the release of CURES data to law enforcement agencies.

7. Proposed Amendment

The author intends to add the word "criminal" in front of "investigation" on page 4 line 1.

8. Argument in Support

According to the California Medical Association, the sponsor of the bill:

> CURES began as a pilot project in 1996 when the DOJ sought to compare the efficiencies of an automated reporting system for Schedule II controlled substances versus Schedule II triplicate reporting. The bill, AB 3042 (Takasugi), established the

[2] http://appellatecases.courtinfo.ca.gov/search/case/dockets.cfm?dist=0&doc_id=2081730&doc_no=S219811

general framework for disclosure of information in the database to include "appropriate state, local, and federal persons or public agencies for disciplinary, civil, or criminal purposes." This framework has remained the same despite significant changes to the database over the years.

Though initially intended only to assist law enforcement and regulatory agencies and include only Schedule II, the system was eventually expanded to allow health care providers to access patient information to inform prescribing decisions, first via fax and then through an internet portal, and also expanded to cover Schedule III and IV substances. Health care practitioners who can prescribe, furnish, order, administer, and dispense controlled substances now pay for the system through licensing fees. Last year, SB 482 (Lara) established a duty to consult CURES requirement for prescribers, thus further transforming CURES into a clinical tool for health care providers.

Though each state's PDMP has its own unique statutory authority, California's CURES 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 houses 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 the statute the authorized recipients of information from the PDMP. The sensitive and confidential nature of the information in the database requires a thoughtful 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 the information is a best practice that California has yet to implement and which, given that a law enforcement entity oversees the database, increases the desirability of such clarity.

Model legislation…are crafted to include a specific articulation of entities to whom PDMP data may be provided. In its "Components of a Strong Prescription Monitoring Program," NAMSDL states that "direct access to the [PDMP] database should be limited to prescribers, dispensers, and their designees, and any other individual or official who may require direct access for the purpose of patient safety, such as a representative of a drug and alcohol addiction treatment program." The construct established in SB 641 aligns with that recommendation.

Under the Confidentiality of Medical Information Act, absent a warrant, law enforcement generally do not have the authority to access a patient's medical record without patient authorization. Thus the existing CURES statutory construct subjects, without the imprimatur of legislative authority, different privacy standards for medical records and the same information in the CURES database. SB 641 seeks to better align these standards for the CURES database, while recognizing the multiple intended functions of the database.

California has a longstanding history of protecting patient and consumer privacy. It should maintain that standard for the millions of patient records that are housed in the CURES database.

9. Argument in Opposition

According to the California Narcotics Officers Association, Consumer Attorneys of California, California Teamsters Public Affairs Council, Consumer Watchdog, and Shatterproof:

> While we understand requiring a warrant to examine a *patient's* activity report (patients have an expectation of privacy in their medical and prescribing information); we believe that requiring a warrant for *over prescribers* is a step too far. Doctors have no expectation of privacy in oversight of their professional activities. Nothing justifies this special protection. A warrant requirement on a doctor's prescribing history places an unnecessary hurdle on effective law enforcement investigations into over prescribing.
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> SB 641 would require a very specific warrant before law enforcement can access a doctor's prescribing information.
>
> As amended, SB 641 would severely limit law enforcement's access to CURES data by requiring the Department of Justice to only provide data obtained from CURES "to a federal, state, or local law enforcement agency pursuant to a valid court order or warrant based on probable cause and issued at the request of a federal, state, or local law enforcement agency engaged in an open and active investigation regarding prescription drug abuse or diversion of prescription of controlled substances involving the individual to whom the requested information pertains." (Section 11165 (c)(2)(B)). This is an incredibly narrow warrant requirement.
>
> The narrow warrant requirement would hamper law enforcement's ability to identify and stop criminal activities, such as pill mills run by doctors who sell prescriptions for cash. The activity we are talking about is criminal. SB 641 will harm both patients who obtain prescriptions from these doctors and the safety of our communities if physicians are allowed to continue selling drugs unchecked. Public safety officials are making great strides in the attempt to address the opioid overdose crisis in California, and restricting use of this key tool will set those efforts back. Regulatory boards will also lose an important source of information as they often find out about this kind of illegal activity only once law enforcement has taken action.
>
> We remain concerned that the bill would limit law enforcement from identifying and effectively stopping over prescribing doctors.

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