

# **CURES 2.0 AND BEYOND: ADVANCING TECHNOLOGY TO COMBAT THE OPIOID CRISIS**

**Informational Hearing  
Assembly Committee on Business and Professions  
Tuesday, February 6, 2018 | 9:00 AM – 11:30 AM  
State Capitol Room 4202**

## **BACKGROUND PAPER**

### **Overview**

CURES, or the Controlled Substance Utilization Review and Evaluation System, is California’s prescription drug monitoring program (PDMP). It is a database managed by the California Department of Justice (DOJ) that contains records of prescriptions for Schedule II, III, and IV<sup>1</sup> controlled substances that have been dispensed within the state. Last year, approximately 50 million prescription records were uploaded into the system by dispensing pharmacists.<sup>2</sup>

The purpose and function of CURES has evolved over the years, with a revamped “CURES 2.0” launching in 2016. CURES currently serves several user populations: Physicians and other prescribers can look up a patient in the database before prescribing a new controlled substance. Pharmacists can also query a patient before dispensing a drug to them. Regulatory investigators like the Medical Board use the system to identify instances of overprescribing or other offenses within their licensing population. Finally, state and federal law enforcement utilize the system as part of their investigations into possible criminal conduct, such as illegal drug diversion.

PDMPs like CURES are widely believed to be among the most effective tools to combat the opioid crisis. Many victims of the crisis first become addicted to opioids through legitimate pain management, initially receiving too many pills or failing to withdraw from drug dependence following treatment. For years, health professionals have decried so-called “doctor shoppers” – addicts or drug diverters who “scam” prescribers into giving them more opioids. Consulting CURES before writing a new prescription helps address both these causes of the crisis.

Since its inception, the Legislature has regularly engaged in active oversight of CURES, as budget deficiencies and disparate policy perspectives result in discussions of how to best empower the use of prescription data. Interest at the State Capitol has only grown as the opioid crisis has worsened. The Assembly Business and Professions Committee’s informational hearing is intended to feature an overview of the opioid crisis and the role CURES plays in combating it; a dialogue about what policies should be in place to protect patient privacy; and a discussion of what future enhancements can be made to this critical technology.

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<sup>1</sup> See Appendix A for an explanation of each drug schedule.

<sup>2</sup> See Appendix B for CURES usage statistics.

## History of Prescription Drug Monitoring Legislation in California

California's scheme for tracking drug prescriptions dates back to the early twentieth century. Senate Bill 367 (Lukens) in 1905 first established the licensing and regulation of pharmacists in California, creating the California State Board of Pharmacy (BOP) and prohibiting any person to "manufacture, compound, sell, or dispense any drug" without a license.<sup>3</sup> In 1929, Senate Bill 182 (Young) outlawed the dispensing of certain drugs<sup>4</sup> without 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."<sup>5</sup> This requirement was later expanded to include all prescription drugs.<sup>6</sup>

The California Triplicate Prescription Program (TPP) became the nation's first comprehensive prescription tracking system when it launched in 1939 under Attorney General Earl Warren.<sup>7</sup> Under the TPP, physicians and other prescribing health professionals were required to use serialized triplicate prescription forms when prescribing a Schedule II<sup>8</sup> controlled substance. One copy was provided to the patient; another was retained for the prescriber's records. The third copy of each triplicated prescription was sent to the Bureau of Narcotics Enforcement within DOJ, which used the records to investigate potential fraud or criminal diversion of controlled substances.<sup>9</sup>

CURES was first established by Assembly Bill 3042 (Takasugi) in 1996, a bill sponsored by Attorney General Dan Lungren. AB 3042 effectuated a Controlled Substances Prescription Advisory Council recommendation that DOJ develop a "technologically sophisticated data monitoring system to collect as much data as is needed and provide easy access to the data collected for educational, law enforcement, regulatory, and research purposes."<sup>10</sup> CURES was initially a provisional pilot project operating concurrently with the TPP; both programs collected Schedule II prescription data for law enforcement to identify cases of diversion. Assembly Bill 2655 (Matthews) extended the pilot and authorized licensed health professionals to request CURES data for prescriptions dispensed to their patients.<sup>11</sup>

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<sup>3</sup> Stats. 1905, ch. 406

<sup>4</sup> "[C]ocaine, opium, morphine, codeine, heroin, alpha eucaine, flowering tops and leaves of hemp or loco weed (cannabis sativa) or Indian hemp, or chloralhydrate ... or their salts, derivatives or compounds."

<sup>5</sup> Stats. 1929, ch. 216

<sup>6</sup> Stats. 1945, ch. 1193

<sup>7</sup> Castaneda, Christopher J. *Keeping the Promise: A History of the California Department of Justice*. 2006.

<sup>8</sup> Prescription drugs with a high risk of addiction and abuse. Current examples include opioids like fentanyl, morphine, oxycodone (OxyContin), meperidine (Demerol), and hydrocodone (Vicodin, Norco, Lorcet); also includes psychotropic drugs like methamphetamine, amphetamine (Adderall), and methylphenidate (Ritalin).

<sup>9</sup> Stats. 1939, ch. 60

<sup>10</sup> Stats. 1996, ch. 738

<sup>11</sup> Stats. 2002, ch. 345

In 2003, Senate Bill 151 (Burton) made CURES a permanent program and eliminated the TPP. This bill enacted a number of other significant reforms to state laws governing the prescribing of controlled substances, intending to “increase patient access to appropriate pain medication and prevent the diversion of controlled substances for illicit use.” SB 151 replaced the triplicate prescription form requirement for Schedule II drugs with a new requirement that these prescriptions be issued on a special form obtained from an approved security printer. This bill also added Schedule III drug data to CURES, contingent upon available funding from DOJ.<sup>12</sup> Schedule IV drugs were added by Assembly Bill 2986 (Mullin) in 2006.<sup>13</sup>

During this period of time, CURES was primarily used for investigatory searches of prescription records to identify potential fraud or diversion of controlled substances. However, after a series of high-profile prescription drug deaths, a growing national movement called for states to empower safer prescribing practices through web-based solutions to what became identified as a public health crisis. While CURES allowed prescribers to request patient activity reports through mail or fax, other states began to launch searchable “prescription drug monitoring program” databases (PDMPs) to enable health professionals to more easily access their patients’ prescription histories. In 2004, Kentucky became the first state to implement a PDMP with the release of its eKASPER program, and 23 other states soon followed suit.<sup>14</sup>

California’s efforts to upgrade CURES into a searchable, client-facing PDMP were initially inhibited by budget challenges. The database’s funding structure at the time made much of the system’s operation contingent on the availability of funding from the limited special funds for the state’s healing arts boards, with additional money provided by DOJ through its General Fund allocation and federal grant dollars. Implementing a new online database would require additional resources. In 2005, Attorney General Bill Lockyer sponsored Senate Bill 734 (Torlakson) to evaluate what would be necessary to create a real-time PDMP, contingent upon the acquisition of private outside funding.<sup>15</sup> Kaiser Permanente contributed to the funding of this feasibility study.

In 2008, Attorney General Jerry Brown announced that the new PDMP upgrades to CURES would be made possible through \$3.5 million in private funding secured through a partnership with the Troy and Alana Pack Foundation. This patient safety foundation was founded by activist Robert Pack in honor of his 7- and 10-year-old children, who were killed in a car accident caused by prescription drug abuse. DOJ launched the reinvented CURES PDMP in 2009, and its release was celebrated as a step forward both for combating prescription drug abuse from a public health perspective and for preventing criminal drug diversion through law enforcement investigations.

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<sup>12</sup> Stats. 2003, ch. 406

<sup>13</sup> Stats. 2006, ch. 286

<sup>14</sup> 49 states currently have a PDMP; Missouri began creating a PDMP pursuant to executive order in July 2017.

<sup>15</sup> Stats. 2005, ch. 487

However, as California's economy fell into recession, the state's budget crisis imperiled continued operation of the database. In 2010, Senator Mark DeSaulnier introduced Senate Bill 1071 to provide permanent funding for CURES through a fee or tax on prescription drug manufacturers and importers, but the bill failed passage in committee. The next year, Senate Bill 360 by Senator DeSaulnier was signed into law, which codified the new CURES PDMP and established a CURES Program Special Fund where administrative fines imposed by DOJ for system misuse could be deposited.<sup>16</sup> The system still lacked a dedicated funding source.

Sustainable funding for CURES was effectively eliminated when the 2011-12 Budget Act cut DOJ's General Fund allocation by \$71 million, defunding the entire Bureau of Narcotics Enforcement along with its support for CURES. DOJ attempted to preserve the program within existing resources, utilizing unpaid interns and temporarily redirecting staff. Without stable funding, however, the program struggled with technical challenges and gained a reputation in the health professional community for being difficult to use and offering poor user support.

In 2012, Senator DeSaulnier authored Senate Bill 616 to support the CURES budget through healing arts board licensing fee increases that could be triggered in the event that DOJ could not find sufficient funding to cover the costs of operating CURES. This bill failed passage in committee. Much of the opposition to the bill came from members of the health professional community, who resisted the proposal that the system's users should fund its operation through increased licensing fees without receiving the benefit of a demonstrably better resulting database.

Attorney General Kamala Harris sponsored Senate Bill 809 in 2013, again authored by Senator DeSaulnier, to ultimately resolve the CURES funding crisis. The bill assessed a new \$6 annual fee on healing arts board licenses, generating reliable revenue for the CURES Fund. In exchange, the bill codified a number of improvements to the system that would be implemented by DOJ through an approximately \$3 million budget allocation that was included in the 2013-14 Budget Act. New features included the ability for licensees to delegate their authority to initiate a CURES query to an assistant and a new "streamlined application and approval process" to replace the previous paper-based registration process. The bill also required all licensees with controlled substances prescribing rights to register for the system by January 1, 2016.<sup>17</sup>

The new funding arrangement required DOJ to partner with the Department of Consumer Affairs (DCA), which administered the CURES Fund, in its development of the upgraded system. The improved database, which would come to be called "CURES 2.0," was built through a pair of vendor contracts, redesigning a new user interface and developing a series of algorithms to automatically alert prescribers of patterns indicative of at-risk patient behavior. The new 2.0 system also allowed prescribers to flag exclusivity compacts, added peer-to-peer communication, and significantly improved user profile management.

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<sup>16</sup> Stats. 2011, ch. 418

<sup>17</sup> Stats. 2013, ch. 400

The rollout of CURES 2.0 is generally considered to have been successful, with a soft launch of the newly redesigned database beginning in July of 2015. The full rollout of the system was delayed until January 1, 2016 when it was discovered that many health professionals were utilizing outdated internet browser technology that did not meet CURES 2.0's enhanced security requirements.<sup>18</sup> In addition, technical issues delayed the release of the new web-based registration system, resulting in urgency legislation to push back the deadline for prescribers to register with CURES to July 1, 2016.<sup>19</sup>

With a consistently funded and thoroughly modernized CURES database in place, advocates resumed calling for use of the system to become a requirement for practitioners who prescribe new controlled substances. A requirement that health professionals consult CURES before writing a new prescription for controlled substances was originally included in SB 809 but was subsequently amended out. Proposition 46, referred to as the Troy and Alana Pack Patient Safety Act of 2014, included provisions that would have required prescribers to check CURES before prescribing a Schedule II or III drug for the first time; this initiative failed in part due to opposition arguments against mandating CURES use before the system upgrades were complete. After the proposition was defeated, supporters remained committed to pursuing legislation.

Senate Bill 482 (Lara), introduced in 2015 and subsequently signed into law in 2016, represented a significant achievement for the patient safety advocacy community when it enacted the state's first mandated use of the CURES database for prescribers. Absent certain exceptions, SB 482 required health practitioners to consult a patient's history in CURES prior to prescribing them a Schedule II, III, or IV controlled substance for the first time, and then at least once every four months as long as the prescription continued to be renewed.<sup>20</sup> However, this law is not currently in effect because the bill delayed implementation until 6 months following a certification by DOJ that the database is ready for statewide use and that the program has adequate staff. At this time,<sup>21</sup> DOJ has not yet issued this certification.

Other legislative measures have been introduced to take advantage of CURES 2.0's new scalable architecture, which allows for additional upgrades to be more easily made to the database. Assembly Bill 40 (Santiago) was chaptered in 2017, requiring 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. Sponsored by the California Chapter of the American College of Emergency Physicians, the bill intended to help seamlessly integrate the use of CURES into a busy practice setting by allowing for queries to be made within a practitioner's native electronic health record system.<sup>22</sup>

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<sup>18</sup> CURES 2.0 users must use Internet Explorer version 11.0 or higher, Mozilla Firefox, Google Chrome, or Safari. Attorney General Harris sent a letter to prescribers in December 2015, urging them to upgrade unsecure browsers.

<sup>19</sup> Stats. 2015, ch. 778

<sup>20</sup> Stats. 2016, ch. 708

<sup>21</sup> Last updated January 31, 2018.

<sup>22</sup> Stats. 2017, ch. 607

As the attention of lawmakers remains focused on the prescription drug abuse crisis, it is likely that additional legislation impacting the CURES program will be introduced in the coming years.

### **Privacy Implications of Prescription Drug Monitoring Programs**

The value of prescription drug databases as a tool for curbing abuse and diversion of controlled substances has long been evangelized by advocates engaged in combating the opioid crisis. However, there continue to be unsettled discussions regarding how privacy expectations are impacted by programs like CURES and what policies should be enacted to protect them. These debates tend to recur during each legislation session when new policies to advance the monitoring of prescription drugs are proposed.

Statute governing the operation of CURES provides DOJ with significant discretion with regards to who may access information contained in the database. The law states that the Attorney General “shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES.”<sup>23</sup> To date, DOJ has not promulgated any formal regulations relating to the present day CURES program. Details as to who can access the system and for what purpose have not been substantially memorialized or put through a public rulemaking process, left instead to informal policies and procedures as permitted by statute.

The CURES statute broadly requires the system to “operate under existing provisions of law to safeguard the privacy and confidentiality of patients.”<sup>24</sup> A number of state laws dictating broader privacy rights may apply to CURES. California is one of the few states to guarantee citizens a right to privacy in its constitution.<sup>25</sup> The Information Practices Act, which governs how state agencies must generally handle personal information, applies generally to CURES.<sup>26</sup> The California Medical Information Act, which limits the disclosure of medical information by health entities, is also widely believed to apply to the disclosure of data in CURES.<sup>27</sup> State medical information laws regarding patient access to health records also give individuals a right to receive copies of information about them contained in CURES.<sup>28</sup>

In terms of federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) is frequently purported to apply to the database, though it is unclear under what circumstances it dictates how CURES data is shared and used. It is largely accepted that once prescription information has become part of a patient’s medical file, it must be treated according to HIPAA within the practice setting. SB 482 clarified that pursuant to HIPAA provisions, physicians and other prescribers must provide a copy of that record to the patient upon request.

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<sup>23</sup> Cal. Health & Saf. Code § 11165; see Appendix D for full text.

<sup>24</sup> *Id.*

<sup>25</sup> Cal. Const., art. I, § 1

<sup>26</sup> Cal. Civ. Code § 1798 et seq.

<sup>27</sup> Cal. Civ. Code § 56 et seq.

<sup>28</sup> Cal. Health & Saf. Code § 123100 et seq.

Whether the Fourth Amendment of the U.S. Constitution’s protections against “unreasonable searches and seizures”<sup>29</sup> apply to CURES is an actively debated question. Since California’s history of tracking controlled substances traces back to programs that are firmly rooted in a law enforcement context, the ability to search prescription records as part of a criminal investigation has been a consistent feature of CURES 2.0 and its predecessors. The Bureau of Narcotics Enforcement, a branch of DOJ’s law enforcement division, maintained the TPP and subsequently the early iterations of CURES for the principal benefit of its local law enforcement counterparts, who frequently received records without securing a warrant or court order. This practice was not substantially changed when the launch of the state’s PDMP first transformed CURES into a public health tool used by licensed healing arts practitioners.

While CURES 2.0 was under development, Attorney General Harris convened an internal working group to determine how respect for patient privacy should be incorporated into the system’s registration and access policies. The result was a new requirement that law enforcement users of the database must provide a copy of a search warrant along with their request for data in CURES when the query is part of a criminal investigation into a patient. Investigations into prescribers continued to be unencumbered by this new policy, requiring only a case number and crime code. The determination was that while a patient should reasonably expect that simply receiving medication should not result in warrantless searches, this is distinct from cases where a health professional is suspected of engaging in unlawful prescribing practices. The new warrant policies have not been codified or proposed as formal regulations.

The process by which law enforcement may register with CURES has also not been memorialized. Peace officers and investigators applying for access to the system are approved primarily on an ad hoc basis; instead of going through the web-based registration process, law enforcement applicants contact DOJ directly to request user credentials. DOJ staff then require proof of law enforcement agency employment (e.g., badge number) and certification by a supervisor that their investigative work extends to the kind of criminal activity that would be evidenced through prescription records. DOJ then applies a general “need to know” standard when determining whether to grant access.

Law enforcement use of CURES is a relatively small percentage of total activity on the database. There are fewer than 1,500 registered law enforcement users of the system compared with over 150,000 prescriber and dispenser users. Law enforcement also represents a small share of data queries; activity reports generated for criminal investigations typically number in the hundreds each month out of a million or more total searches. Nevertheless, privacy advocates argue that any warrantless search of the database constitutes a potential violation of rights constitutionally guaranteed to patients.

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<sup>29</sup> U.S. Const. amend. IV.

The American Civil Liberties Union (ACLU) has spoken out nationally in support of applying a full constitutional right to privacy standard to all law enforcement uses of PDMPs, arguing that prescription data is “sensitive information that law enforcement should need a warrant to get its hands on.” The ACLU points out that an individual’s prescription history can reveal intimate personal details, such as transgender transition, mental illness, or HIV/AIDS. In Oregon, the ACLU won a ruling that held that patients have a Fourth Amendment right to privacy in their prescription histories; however, the Ninth Circuit reversed the decision on the basis that the ACLU lacked sufficient standing to bring the case.<sup>30</sup> Since then, there has been no precedential case law speaking to the constitutionality of warrantless searches of PDMPs by law enforcement.

The question of whether a warrant should be required for searches of CURES has also extended into investigations by regulatory boards for purposes of disciplinary actions against licensees. This practice has existed since the early iterations of the database, though SB 482 expressly limited DCA investigator searches to regulatory boards whose licensees prescribe, order, administer, furnish, or dispense controlled substances. Each month, DCA investigators run hundreds of activity reports – still a very small relative portion of overall user activity – to determine whether prescribers and other licensees are misusing their professional privileges. Regulatory user activity is virtually unfettered and does not always result in the same type of auditable logging that other users incur when searching the system.

In 2008, the Medical Board of California (MBC) began an investigation into Dr. Alwin Carl Lewis, a licensed physician who recommended a controversial diet in which patients were encouraged to eat two meals consisting of only five bites of food each day. As part of this inquiry, MBC investigators ran a search for Dr. Lewis in CURES to determine if he had misused his prescribing privileges in addition to offering questionable nutritional advice. The search resulted in the board filing additional charges for overprescribing. Dr. Lewis immediately sought to have the overprescribing charges dismissed on the basis that because the allegations against him relating to his diet recommendations were irrelevant to his drug prescribing history, the MBC did not have good cause to conduct the CURES search without a warrant.

Years of litigation resulted from this dispute. Dr. Lewis’s objections to the CURES search were rejected by an administrative law judge, the Los Angeles County Superior Court, and the Court of Appeal, respectively. Eventually, the case was granted review by the Supreme Court of California in *Lewis v. Superior Court*. The Court conducted a thorough analysis of the Legislature’s intent in creating CURES, the privacy rights implicated by searches of the system, and whether the MBC had violated any state or federal protections in its use of the database to investigate Dr. Lewis. Amicus briefs in support of Dr. Lewis’s privacy objections were submitted by the ACLU, the Electronic Frontier Foundation, the California Medical Association, the California Psychiatric Association, and the California Dental Association. The Center for Public Interest Law filed a brief in support of the Attorney General’s representation of the MBC.

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<sup>30</sup> *Or. Prescription Drug Monitoring Program v. United States DEA*, (9th Cir. 2017) 860 F.3d 1228.



In its opinion issued in July of 2017, the Court ruled in favor of the MBC. The Court found that patients did indeed have a privacy interest in their prescription records, and that the MBC's search encroached upon this interest. However, the Court held that "even assuming the Board's actions constituted a serious intrusion on a legally protected privacy interest, its review of these records was justified by the state's dual interest in protecting the public from the unlawful use and diversion of a particularly dangerous class of prescription drugs and protecting patients from negligent or incompetent physicians."<sup>31</sup>

The balancing test employed by the Court in *Lewis* reflects generally the priorities that must be weighed for any CURES policies invoking patient privacy rights. Whether these policies should take the form of legislated statute, formal regulation, or informal department practices remains an outstanding question. In any event, CURES's role as a tool for empowering safe prescribing must be weighed thoughtfully against expectations of patients that their prescription information is treated with sufficient sensitivity.

### **"... And Beyond": The Future of CURES**

Supporting and enhancing the CURES database as a solution to the opioid crisis is the subject of multiple legislative measures in the current 2017-18 session. Assemblymember Evan Low, Chair of the Assembly Business and Professions Committee, is authoring a package of three bills aimed at addressing the overprescribing, abuse, and diversion of controlled substances. Assembly Bill 1751 would create a framework for connecting CURES with other states' prescription drug databases. Assembly Bill 1752 would add Schedule V controlled substances to CURES and change the current reporting timeline from seven days to a next business day requirement. Assembly Bill 1753 would further regulate DOJ's Security Printers program in an effort to help law enforcement combat fraudulently obtained prescription pads.

As technology evolves, so might the features of the CURES program expand to include new and improved tools to combat prescription drug abuse and diversion. By improving the way health professionals, regulators, and law enforcement access and use prescription data, California can continue to lead as an innovator in safeguarding public health and safety. Any new functionality will need to be balanced with recognized patient privacy expectations to ensure that constitutional rights remain protected. Ultimately, sustained support for CURES and other data-driven programs arguably represents one of the most effective ways to comprehensively address the opioid crisis.

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<sup>31</sup> *Lewis v. Superior Court* (2017) 3 Cal.5th 561 [220 Cal.Rptr.3d 319, 397 P.3d 1011].

## APPENDIX A

### Federal Drug Enforcement Administration Drug Schedules

**Schedule I** drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.

Some examples of Schedule I drugs are: Heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), 3,4-methylenedioxymethamphetamine (ecstasy), methaqualone, and peyote.

**Schedule II** drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence. These drugs are also considered dangerous.

Some examples of Schedule II drugs are: Combination products with less than 15 milligrams of hydrocodone per dosage unit (Vicodin), cocaine, methamphetamine, methadone, hydromorphone (Dilaudid), meperidine (Demerol), oxycodone (OxyContin), fentanyl, Dexedrine, Adderall, and Ritalin.

**Schedule III** drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence. Schedule III drugs abuse potential is less than Schedule I and Schedule II drugs but more than Schedule IV.

Some examples of Schedule III drugs are: Products containing less than 90 milligrams of codeine per dosage unit (Tylenol with codeine), ketamine, anabolic steroids, testosterone.

**Schedule IV** drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.

Some examples of Schedule IV drugs are: Xanax, Soma, Darvon, Darvocet, Valium, Ativan, Talwin, Ambien, Tramadol.

**Schedule V** drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics. Schedule V drugs are generally used for antidiarrheal, antitussive, and analgesic purposes.

Some examples of Schedule V drugs are: Cough preparations with less than 200 milligrams of codeine or per 100 milliliters (Robitussin AC), Lomotil, Motofen, Lyrica, Parepectolin.

*Source: <https://www.dea.gov/druginfo/ds.shtml>*

## APPENDIX B

### 2017 CURES User Approvals

	Practitioner	Pharmacist	LEA	DCA Board	DOJ Users	Total
January	642	124	8	14	0	788
February	553	145	7	1	0	706
March	665	75	10	0	0	750
April	498	81	4	0	0	583
May	560	74	6	0	0	640
June	533	110	5	4	2	654
July	662	90	11	8	3	774
August	749	180	16	3	3	951
September	687	519	7	1	2	1,216
October	632	322	8	3	2	967
November	514	184	2	1	1	702
December	518	151	3	1	0	673
<b>TOTAL</b>	<b>7,213</b>	<b>2,055</b>	<b>87</b>	<b>36</b>	<b>13</b>	<b>9,404</b>

### Total CURES User Approvals by Year

	Practitioner	Pharmacist	LEA	DCA Board	DOJ Users	Total
2010	2,731	527	251	Unavailable	Unavailable	3,509
2011	2,405	368	127	Unavailable	Unavailable	2,900
2012	3,395	1,369	242	2	15	5,023
2013	4,027	3,507	197	3	6	7,740
2014	8,666	6,635	214	11	16	15,542
2015	17,637	10,412	203	13	56	28,321
2016	82,071	15,777	87	26	22	97,983
2017	7,213	2,055	87	36	13	9,404
<b>TOTAL</b>	<b>128,145</b>	<b>40,650</b>	<b>1,408</b>	<b>91</b>	<b>128</b>	<b>170,422</b>

### 2017 Prescription Records Uploaded

January	4,088,845	July	4,435,579
February	3,742,644	August	4,175,433
March	4,354,899	September	3,759,868
April	4,100,388	October	4,219,357
May	4,847,802	November	3,692,947
June	4,353,598	December	3,729,405
<b>TOTAL: 49,500,765</b>			

**2017 CURES Activity Reports Processed**

	<b>Practitioner</b>	<b>Pharmacist</b>	<b>LEA</b>	<b>DCA Board</b>	<b>DOJ Users</b>	<b>TOTAL</b>
<b>January</b>	376,911	567,361	153	1,544	220	946,189
<b>February</b>	354,635	537,496	174	1,201	180	894,309
<b>March</b>	413,648	622,014	191	892	229	1,036,641
<b>April</b>	309,810	468,568	99	302	47	778,826
<b>May</b>	347,604	500,856	144	361	108	849,073
<b>June</b>	329,881	471,694	205	280	92	802,152
<b>July</b>	299,832	442,259	119	382	74	742,666
<b>August</b>	349,191	468,457	503	158	29	818,338
<b>September</b>	315,210	425,149	106	349	122	740,936
<b>October</b>	349,017	453,729	119	535	321	803,721
<b>November</b>	339,098	453,150	158	321	57	792,784
<b>December</b>	322,555	458,988	137	348	188	782,216
<b>TOTAL</b>	4,106,789	5,870,344	2,108	6,673	1,667	<b>9,987,851</b>

**Total Activity Reports by Year**

<b>2010</b>	516,726	<b>2014</b>	3,553,551
<b>2011</b>	827,803	<b>2015</b>	6,174,394
<b>2012</b>	1,301,892	<b>2016</b>	9,591,970
<b>2013</b>	2,370,574	<b>2017</b>	9,987,851
<b>TOTAL: 34,324,761</b>			

Source: California Department of Justice

## APPENDIX C

### CURES Section and Position Summary

Section	Title	Count	Status	Classification
<b>Managers</b>	DOJA II	1	Filled	Full-Time Permanent
	DOJA I Special Projects / Security Printer	1	Vacant	Full-Time Permanent
	SSM I, Help Desk	1	Filled	Full-Time Limited Term
<b>Help Desk</b>	AGPA	1	Filled	Full-Time Limited Term
	SSA	1	Filled	Full-Time Permanent
	CIS II	1	Filled	Full-Time Permanent
	CIS I	1	Vacant	Full-Time Permanent
	PT II	1	Filled	Full-Time Permanent
	PT II	1	Filled	Full-Time Permanent
	PT II	1	Filled	Full-Time Permanent
	RA (SSA)	1	Filled	Part-Time
	RA (SSA)	1	Filled	Part-Time
	RA (SSA)	1	Filled	Part-Time
	Student	1	Filled	Part-Time
	Student	1	Filled	Part-Time
	Youth Aid	1	Filled	Part-Time
<b>Special Projects</b>	AGPA	1	Filled	Full-Time Limited Term
	AGPA	1	Vacant	Full-Time Permanent
	SSA	1	Filled	Full-Time Limited Term
	SSA	1	Vacant	Full-Time Permanent
<b>Security Printer</b>	AGPA	1	Filled	Full-Time Permanent
	SSA	1	Filled	Full-Time Limited Term
<b>TOTAL COUNT</b>		22	18 Filled/ 4 Vacant	

### Help Desk Description of Duties

The Help Desk is responsible for researching, providing consultation, and writing Controlled Substance Utilization Review and Evaluation System (CURES) program policy responses. This group handles the more complex CURES policy, regulatory, and technical issues, and serves as subject matter experts on issues brought forth by medical and pharmacy stakeholders who regularly access and query the CURES 2.0 system. These individuals prepare training materials, including PowerPoint presentations, Webinars, and tutorial videos, to be used by prescribers and dispensers with authority to use CURES, as well as law enforcement. The Help Desk is largely responsible for identifying system issues, designing, testing, and implementing system changes that enhance the client's experience with CURES 2.0.

### **Special Projects Description of Duties**

The Special Projects Unit works with the California Justice Information Services (CJIS) Division Legislation and Regulation section performing legislative analysis related to all aspects of the CURES Program. The unit's members act as subject matter experts on the program's legal process, and they serve as liaisons to Department of Justice Deputy Attorneys General and agencies involved with CURES administrative/legal cases. They prepare subpoena responses and provide testimony in administrative hearings and/or court relative to CURES Program data inquiries. The Special Projects team serves as the subject matter experts on CURES application design changes. They provide training materials and tutorial videos for the CURES website as well as conduct outreach to law enforcement, healthcare providers, and regulatory board members on CURES 2.0 system query tools and data analysis.

### **Security Printer Description of Duties**

The California Security Printers Unit (SPU) is responsible for identifying legislative ambiguities, making recommendations to management regarding policy, and designing new regulations. The unit routinely provides guidance and consultation regarding Health & Safety Code sections 11162.1 and 11161.5 to law enforcement, approved printers, prospective printers, prescribers, and pharmacies, responds to inquiries regarding non-compliance, and investigates these regulatory non-compliance issues. Where regulatory non-compliance is noted, the unit is responsible for preparing corrective action plans and administrative discipline complaints. The unit reviews/approves security printer applications by verifying fingerprint results, policies, and procedures, and performing site inspections. They also perform audits; inspect facilities, records, and policies; and prepare reports for management. As subject matter experts, they travel and provide training to law enforcement agencies and approved security printers.

*Source: California Department of Justice*

## APPENDIX D

### Health and Safety Code § 11165

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and Internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, provided that patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision 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. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data is provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as

soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

- (1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.
  - (2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility.
  - (3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.
  - (4) National Drug Code (NDC) number of the controlled substance dispensed.
  - (5) Quantity of the controlled substance dispensed.
  - (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.
  - (7) Number of refills ordered.
  - (8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.
  - (9) Date of origin of the prescription.
  - (10) Date of dispensing of the prescription.
- (e) The Department of Justice 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 shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.
- (f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).
- (g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.



**FOR FURTHER INFORMATION:**

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