MEMORANDUM

DATE July 10, 2013

TO Veterinary Medical Board

FROM Sue Geranen Executive Officer
DCA/Veterinary Medical Board

SUBJECT SB 809 - CURES

Background:
Senate Bill 809 would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

The bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient’s risk of abusing or diverting controlled substances and information relating to CURES.

The bill would require licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care, and, upon the happening of specified events, to be strongly encouraged to access and consult that information prior to prescribing or dispensing Schedule II, Schedule III, or Schedule IV controlled substances. The bill would make other related and conforming changes.

Staff is currently working with the Department on language and implementation issues within the Bill.

Action Requested:
Update report - no action requested.
SB-809 Controlled substances: reporting. (2013-2014)

AMENDED IN ASSEMBLY JUNE 26, 2013
AMENDED IN SENATE MAY 28, 2013
AMENDED IN SENATE MAY 24, 2013
AMENDED IN SENATE MAY 14, 2013
AMENDED IN SENATE MAY 01, 2013

CALIFORNIA LEGISLATURE—2013-2014 REGULAR SESSION

SENATE BILL No. 809

Introduced by Senator DeSaulnier, Steinberg
(Coauthor(s): Senator Hancock, Lieu, Pavley, Price)
(Coauthor(s): Assembly Member Blumenfield)

February 22, 2013

An act to add Sections 805.8 and 2196.8 to the Business and Professions Code, and to amend Sections 11164.1, 11165, and 11165.1 of, and to add Section 11165.4 to, the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

SB 809, as amended, DeSaulnier. Controlled substances: reporting.

(1) Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe or dispense these controlled substances.

Existing law requires dispensing pharmacies and clinics to report, on a weekly basis, specified information for each prescription of Schedule II, Schedule III, or Schedule IV controlled substances, to the department, as specified.

This bill would establish the CURES Fund within the State Treasury to receive funds to be allocated, upon appropriation by the Legislature, to the Department of Justice for the purposes of funding CURES, and would make related findings and declarations.

This bill would require the Medical Board of California, the Dental Board of California, the California State Board
of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine to charge practitioners under their supervision who are authorized to prescribe, order, administer, furnish, or dispense controlled substances a fee of up to 1.16% of the renewal fee that the licensee was subject to as of July 1, 2013, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. This bill would also require the California State Board of Pharmacy to charge wholesalers, nonresident wholesalers, and veterinary food-animal drug retailers under their supervision a fee of up to 1.16% of the renewal fee that the wholesaler, nonresident wholesaler, or veterinary food-animal drug retailer was subject to as of July 1, 2013, the proceeds of which would be deposited into the CURES Fund for support of CURES, as specified. The bill would require each of these fees to be due and payable at the time the license is renewed and require the fee to be submitted with the renewal fee. The bill would also permit specified insurers, health care service plans, and qualified manufacturers, to voluntarily contribute to the CURES Fund, as described.

(2) Existing law requires the Medical Board of California to periodically develop and disseminate information and educational materials regarding various subjects, including pain management techniques, to each licensed physician and surgeon and to each general acute care hospital in California. This bill would additionally require the board to periodically develop and disseminate to each licensed physician and surgeon and to each general acute care hospital in California information and educational materials relating to the assessment of a patient's risk of abusing or diverting controlled substances and information relating to CURES.

(3) Existing law permits a licensed health care practitioner, as specified, or a pharmacist to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care. Existing law also authorizes the Department of Justice to provide the history of controlled substances dispensed to an individual to licensed health care practitioners, pharmacists, or both, providing care or services to the individual. This bill would require licensed health care practitioners, as specified, and pharmacists to apply to the Department of Justice to obtain approval to access information stored on the Internet regarding the controlled substance history of a patient under his or her care, and, upon the happening of specified events, to be strongly encouraged to access and consult that information prior to prescribing or dispensing Schedule II, Schedule III, or Schedule IV controlled substances. The bill would make other related and conforming changes.

(4) This bill would declare that it is to take effect immediately as an urgency statute.

Vote: 2/3 Appropriation: no Fiscal Committee: yes Local Program: no

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. The Legislature finds and declares all of the following:

(a) The Controlled Substance Utilization Review and Evaluation System (CURES) is a valuable preventive, investigative, and educational tool for health care providers, regulatory boards, educational researchers, and law enforcement. Recent budget cuts to the Attorney General’s Division of Law Enforcement have resulted in insufficient funding to support the CURES Prescription Drug Monitoring Program (PDMP). The PDMP is necessary to ensure health care professionals have the necessary data to make informed treatment decisions and to allow law enforcement to investigate diversion of prescription drugs. Without a dedicated funding source, the CURES PDMP is not sustainable.

(b) Each year CURES responds to more than 800,000 requests from practitioners and pharmacists regarding all of the following:

(1) Helping identify and deter drug abuse and diversion of prescription drugs through accurate and rapid tracking of Schedule II, Schedule III, and Schedule IV controlled substances.

(2) Helping practitioners make better prescribing decisions.

(3) Helping reduce misuse, abuse, and trafficking of those drugs.
(c) Schedule II, Schedule III, and Schedule IV controlled substances have had deleterious effects on private and public interests, including the misuse, abuse, and trafficking in dangerous prescription medications resulting in injury and death. It is the intent of the Legislature to work with stakeholders to fully fund the operation of CURES which seeks to mitigate those deleterious effects and serve as a tool for ensuring safe patient care, and which has proven to be a cost-effective tool to help reduce the misuse, abuse, and trafficking of those drugs.

(d) The following goals are critical to increase the effectiveness and functionality of CURES:

1. Upgrading the PDMP so that it is capable of accepting real-time updates and is accessible in real-time, 24 hours a day, seven days a week.

2. Upgrading all prescription drug monitoring programs in California so that they are capable of operating in conjunction with all national prescription drug monitoring programs.

3. Providing subscribers to prescription drug monitoring programs access to information relating to controlled substances dispensed in California, including those dispensed through the federal United States Department of Veterans Affairs, the Indian Health Service, the Department of Defense, and any other entity with authority to dispense controlled substances in California.

4. Upgrading the PDMP so that it is capable of accepting electronic prescriptions, thereby enabling more reliable, complete, and timely prescription monitoring.

SEC. 2. Section 805.8 is added to the Business and Professions Code, to read:

805.8. (a) (1) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board of California, the State Board of Optometry, and the California Board of Podiatric Medicine shall charge each licensee authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances a fee of up to 1.16 percent of the renewal fee that the licensee was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the licensee renews his or her license and shall be submitted with the licensee’s renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating prescribers and dispensers of controlled substances licensed or certificated by these boards.

(2) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the California State Board of Pharmacy shall charge wholesalers and nonresident wholesalers of dangerous drugs, licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9, a fee of up to 1.16 percent of the renewal fee that the wholesaler or nonresident wholesaler was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the wholesaler or nonresident wholesaler renews its license and shall be submitted with the wholesaler’s or nonresident wholesaler’s renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating wholesalers and nonresident wholesalers of dangerous drugs licensed or certificated by that board.

(3) In addition to the fees charged for licensure, certification, and renewal, at the time those fees are charged, the California State Board of Pharmacy shall charge veterinary food-animal drug retailers, licensed pursuant to Article 15 (commencing with Section 4196) of Chapter 9, a fee of up to 1.16 percent of the renewal fee that the drug retailer was subject to as of July 1, 2013, to be assessed annually. This fee shall be due and payable at the time the drug retailer renews its license and shall be submitted with the drug retailer’s renewal fee. In no case shall this fee exceed the reasonable costs associated with operating and maintaining CURES for the purpose of regulating veterinary food-animal drug retailers licensed or certificated by that board.

(b) The funds collected pursuant to subdivision (a) shall be deposited in the CURES accounts, which are hereby created, within the Contingent Fund of the Medical Board of California, the State Dentistry Fund, the Pharmacy Board Contingent Fund, the Veterinary Medical Board Contingent Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor’s Fund, the Osteopathic Medical Board of California Contingent Fund, the Optometry Fund, and the Board of Podiatric Medicine Fund. Moneys in the CURES accounts of each of those funds shall, upon appropriation by the Legislature, be available to the Department of Justice solely for operating and
maintaining CURES for the purposes of regulating prescribers and dispensers of controlled substances. All moneys received by the Department of Justice pursuant to this section shall be deposited in the CURES Fund described in Section 11165 of the Health and Safety Code.

SEC. 3. Section 2196.8 is added to the Business and Professions Code, to read:

2196.8. The board shall periodically develop and disseminate information and educational material regarding assessing a patient’s risk of abusing or diverting controlled substances and information relating to the Controlled Substance Utilization Review and Evaluation System (CURES), described in Section 11165 of the Health and Safety Code, to each licensed physician and surgeon and to each general acute care hospital in this state. The board shall consult with the State Department of Health Care Services and the Department of Justice in developing the materials to be distributed pursuant to this section.

SEC. 4. Section 11164.1 of the Health and Safety Code is amended to read:

11164.1. (a) (1) Notwithstanding any other provision of law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II and Schedule III controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (e) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2005.

SEC. 5. Section 11165 of the Health and Safety Code is amended to read:

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 accounts within the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor’s Fund, the Osteopathic Medical Board of California Contingent Fund, the Veterinary Medical Board Contingent Fund, the Optometry Fund, the Board of Podiatric Medicine Fund, and 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 reporting of Schedule III and Schedule IV controlled substance prescriptions to CURES shall be contingent upon the availability of adequate funds for the Department of Justice for the purpose of funding CURES.

(c) 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. Grant funds shall not be appropriated from the Contingent Fund of the Medical Board of California, the Pharmacy Board Contingent Fund, the State Dentistry Fund, the Board of Registered Nursing Fund, the Naturopathic Doctor’s Fund, the Osteopathic Medical Board of California Contingent Fund, the Veterinary Medical Board Contingent Fund, the Optometry Fund, or the Board of Podiatric Medicine Fund, for the purpose of funding CURES.

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

(2) **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. The Department of Justice may establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, and security of the information within CURES, consistent with this subdivision.

(e) 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, unless monthly reporting is permitted pursuant to subdivision (f) of Section 11190, and in a format specified by the Department of Justice:

1. Full name, address, and 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 and license number, 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, and federal controlled substance registration number.

4. National Drug Code (NDC) number of the controlled substance dispensed.

5. Quantity of the controlled substance dispensed.


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.

(f) 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 invitees shall be licensed by one of the boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(g) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (a) of Section 805.8 of the Business and Professions Code, one or more of the regulatory boards or committees identified in subdivision (a) of Section 805.8 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.

(h) The Department of Justice may establish a process to educate authorized subscribers of CURES on how to access and use CURES.

(i) The CURES Fund is hereby established within the State Treasury. The CURES Fund shall consist of all funds made available to the Department of Justice for the purpose of funding CURES. Money in the CURES Fund shall, upon appropriation by the Legislature, be available for allocation to the Department of Justice for the purpose of funding CURES.
SEC. 6. Section 11165.1 of the Health and Safety Code is amended to read:

11165.1. (a) (1) A licensed health care practitioner eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances or a pharmacist shall submit an application developed by the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the Department of Justice, and, upon approval, the department shall release to that practitioner or pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(A) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal Drug Enforcement Administration (DEA) registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(B) Any authorized subscriber shall notify the Department of Justice within 30 days of any changes to the subscriber account.

(2) To allow sufficient time for licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and a pharmacist to apply and receive access to PDMP, a written request may be made, until July 1, 2012, and the Department of Justice may release to that practitioner or pharmacist the history of controlled substances dispensed to an individual under his or her care based on data contained in CURES.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the Department of Justice.

(c) (1) Until the Department of Justice has issued the notification described in paragraph (3), in order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the Department of Justice 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.

(2) Upon the Department of Justice issuing the notification described in paragraph (3), licensed health care practitioners eligible to prescribe Schedule II, Schedule III, or Schedule IV controlled substances and pharmacists shall be strongly encouraged to access and consult the electronic history of controlled substances dispensed to an individual under his or her care prior to prescribing or dispensing a Schedule II, Schedule III, or Schedule IV controlled substance.

(3) The Department of Justice shall notify licensed health care practitioners and pharmacists who have submitted the application required pursuant to subdivision (a) when the department determines that CURES is capable of accommodating all users, but not before June 1, 2015. The department shall provide a copy of the notification to the Secretary of State, the Secretary of the Senate, the Chief Clerk of the Assembly, and the Legislative Counsel, and shall post the notification on the department's Internet Web site.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the Department of Justice pursuant to this section shall be considered medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.
SEC. 7. Section 11165.4 is added to the Health and Safety Code, to read:

11165.4. (a) The Department of Justice may seek private funds from insurers, health care service plans, and qualified manufacturers for the purpose of supporting CURES. Insurers, health care service plans, and qualified manufacturers may contribute by submitting their payment to the Controller for deposit into the CURES Fund established pursuant to subdivision (e) of Section 11165. The department shall make information about the amount and the source of all private funds it receives for support of CURES available to the public. Contributions to the CURES Fund pursuant to this subdivision shall be nondeductible for state tax purposes.

(b) For purposes of this section, the following definitions apply:

(1) "Controlled substance" means a drug, substance, or immediate precursor listed in any schedule in Section 11055, 11056, or 11057 of the Health and Safety Code.

(2) "Health care service plan" means an entity licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(3) "Insurer" means an admitted insurer writing health insurance, as defined in Section 106 of the Insurance Code, and an admitted insurer writing workers’ compensation insurance, as defined in Section 109 of the Insurance Code.

(4) "Qualified manufacturer" means a manufacturer of a controlled substance, but does not mean a wholesaler or nonresident wholesaler of dangerous drugs, regulated pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2 of the Business and Professions Code, a veterinary food-animal drug retailer, regulated pursuant to Article 15 (commencing with Section 4196) of Chapter 9 of Division 2 of the Business and Professions Code, or an individual regulated by the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Committee of the Medical Board of California, the Osteopathic Medical Board of California, the State Board of Optometry, or the California Board of Podiatric Medicine.

SEC. 8. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to protect the public from the continuing threat of prescription drug abuse at the earliest possible time, it is necessary that this act take effect immediately.