

AMENDED IN ASSEMBLY AUGUST 19, 2016

AMENDED IN ASSEMBLY AUGUST 1, 2016

AMENDED IN ASSEMBLY JUNE 21, 2016

AMENDED IN ASSEMBLY JUNE 6, 2016

AMENDED IN ASSEMBLY APRIL 7, 2016

AMENDED IN SENATE APRIL 30, 2015

AMENDED IN SENATE APRIL 16, 2015

## **SENATE BILL**

**No. 482**

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**Introduced by Senator Lara**

February 26, 2015

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An act to amend Sections 11165 and 11165.1 of, and to add Section 11165.4 to, the Health and Safety Code, relating to controlled substances.

### LEGISLATIVE COUNSEL'S DIGEST

SB 482, as amended, Lara. Controlled substances: CURES database.

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, administer, furnish, or dispense these controlled substances. Existing law requires dispensing pharmacies and clinics to report specified information for each prescription of a Schedule II, Schedule III, or Schedule IV controlled substance to the department.

This bill would require a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance to consult the CURES database to review a patient's controlled substance history no earlier than 24 hours, or the previous business day, before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every 4 months thereafter if the substance remains part of the treatment of the patient. The bill would exempt a veterinarian *and a pharmacist* from this requirement. The bill would also exempt a health care practitioner from this requirement under specified circumstances, including, among others, if prescribing, ordering, administering, or furnishing a controlled substance to a patient receiving hospice care, to a patient admitted to a specified facility for use while on facility premises, or to a patient as part of a treatment for a surgical procedure in a specified facility if the quantity of the controlled substance does not exceed a nonrefillable 5-day supply of the controlled substance that is to be used in accordance with the directions for use. The bill would require, if a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient pursuant to one of those exemptions, the health care practitioner to consult the CURES database before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every 4 months thereafter if the substance remains part of the treatment of the patient.

This bill would provide that a health care practitioner who ~~knowingly~~ fails to consult the CURES database is required to be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board. The bill would make the above-mentioned provisions operative 6 months after the Department of Justice certifies that the CURES database is ready for statewide ~~use~~. *use and that the department had adequate staff, user support, and education, as specified.*

This bill would also exempt 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, from civil or administrative liability arising from any false, incomplete, ~~or inaccurate~~ *inaccurate, or misattributed* information ~~submitted, to or reported by, 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.

*Existing law requires the operation of the CURES database to comply with all applicable federal and state privacy and security laws and regulations. Existing law authorizes the disclosure of data obtained from the CURES database to agencies and entities only for specified purposes and requires the Department of Justice to establish policies, procedures, and regulations regarding the use, access, disclosure, and security of the information within the CURES database.*

*This bill would authorize a health care practitioner to provide a patient with a copy of the patient's CURES patient activity report if no additional CURES data is provided. The bill would also prohibit a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances from obtaining data from the CURES database.*

Vote: majority. Appropriation: no. Fiscal committee: yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

- 1 SECTION 1. Section 11165 of the Health and Safety Code is
- 2 amended to read:
- 3 11165. (a) To assist health care practitioners in their efforts
- 4 to ensure appropriate prescribing, ordering, administering,
- 5 furnishing, and dispensing of controlled substances, law
- 6 enforcement and regulatory agencies in their efforts to control the
- 7 diversion and resultant abuse of Schedule II, Schedule III, and
- 8 Schedule IV controlled substances, and for statistical analysis,
- 9 education, and research, the Department of Justice shall, contingent
- 10 upon the availability of adequate funds in the CURES Fund,
- 11 maintain the Controlled Substance Utilization Review and
- 12 Evaluation System (CURES) for the electronic monitoring of, and
- 13 Internet access to information regarding, the prescribing and
- 14 dispensing of Schedule II, Schedule III, and Schedule IV controlled
- 15 substances by all practitioners authorized to prescribe, order,
- 16 administer, furnish, or dispense these controlled substances.
- 17 (b) The Department of Justice may seek and use grant funds to
- 18 pay the costs incurred by the operation and maintenance of
- 19 CURES. The department shall annually report to the Legislature

1 and make available to the public the amount and source of funds  
2 it receives for support of CURES.

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

6 (2) (A) CURES shall operate under existing provisions of law  
7 to safeguard the privacy and confidentiality of patients. Data  
8 obtained from CURES shall only be provided to appropriate state,  
9 local, and federal public agencies for disciplinary, civil, or criminal  
10 purposes and to other agencies or entities, as determined by the  
11 Department of Justice, for the purpose of educating practitioners  
12 and others in lieu of disciplinary, civil, or criminal actions. Data  
13 may be provided to public or private entities, as approved by the  
14 Department of Justice, for educational, peer review, statistical, or  
15 research purposes, provided that patient information, including  
16 any information that may identify the patient, is not compromised.  
17 Further, data disclosed to any individual or agency as described  
18 in this subdivision shall not be disclosed, sold, or transferred to  
19 any third-party, *unless authorized by, or pursuant to, state*  
20 *and federal privacy and security laws and regulations.* The  
21 Department of Justice shall establish policies, procedures, and  
22 regulations regarding the use, access, evaluation, management,  
23 implementation, operation, storage, disclosure, and security of the  
24 information within CURES, consistent with this subdivision.

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

29 (3) In accordance with federal and state privacy laws and  
30 regulations, a health care practitioner may provide a patient with  
31 a copy of the patient's CURES patient activity report *as long as*  
32 *no additional CURES data is provided* and keep a copy of the  
33 report in the patient's medical record ~~if reasonable care has been~~  
34 ~~taken to ensure that the report is provided or kept in compliance~~  
35 with subdivision (d) of Section 11165.1.

36 (d) For each prescription for a Schedule II, Schedule III, or  
37 Schedule IV controlled substance, as defined in the controlled  
38 substances schedules in federal law and regulations, specifically  
39 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21  
40 of the Code of Federal Regulations, the dispensing pharmacy,

1 clinic, or other dispenser shall report the following information to  
2 the Department of Justice as soon as reasonably possible, but not  
3 more than seven days after the date a controlled substance is  
4 dispensed, in a format specified by the Department of Justice:

5 (1) Full name, address, and, if available, telephone number of  
6 the ultimate user or research subject, or contact information as  
7 determined by the Secretary of the United States Department of  
8 Health and Human Services, and the gender, and date of birth of  
9 the ultimate user.

10 (2) The prescriber's category of licensure, license number,  
11 national provider identifier (NPI) number, if applicable, the federal  
12 controlled substance registration number, and the state medical  
13 license number of any prescriber using the federal controlled  
14 substance registration number of a government-exempt facility.

15 (3) Pharmacy prescription number, license number, NPI number,  
16 and federal controlled substance registration number.

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

19 (5) Quantity of the controlled substance dispensed.

20 (6) International Statistical Classification of Diseases, 9th  
21 revision (ICD-9) or 10th revision (ICD-10) Code, if available.

22 (7) Number of refills ordered.

23 (8) Whether the drug was dispensed as a refill of a prescription  
24 or as a first-time request.

25 (9) Date of origin of the prescription.

26 (10) Date of dispensing of the prescription.

27 (e) The Department of Justice may invite stakeholders to assist,  
28 advise, and make recommendations on the establishment of rules  
29 and regulations necessary to ensure the proper administration and  
30 enforcement of the CURES database. All prescriber and dispenser  
31 invitees shall be licensed by one of the boards or committees  
32 identified in subdivision (d) of Section 208 of the Business and  
33 Professions Code, in active practice in California, and a regular  
34 user of CURES.

35 (f) The Department of Justice shall, prior to upgrading CURES,  
36 consult with prescribers licensed by one of the boards or  
37 committees identified in subdivision (d) of Section 208 of the  
38 Business and Professions Code, one or more of the boards or  
39 committees identified in subdivision (d) of Section 208 of the  
40 Business and Professions Code, and any other stakeholder

1 identified by the department, for the purpose of identifying  
2 desirable capabilities and upgrades to the CURES Prescription  
3 Drug Monitoring Program (PDMP).

4 (g) The Department of Justice may establish a process to educate  
5 authorized subscribers of the CURES PDMP on how to access and  
6 use the CURES PDMP.

7 SEC. 2. Section 11165.1 of the Health and Safety Code is  
8 amended to read:

9 11165.1. (a) (1) (A) (i) A health care practitioner authorized  
10 to prescribe, order, administer, furnish, or dispense Schedule II,  
11 Schedule III, or Schedule IV controlled substances pursuant to  
12 Section 11150 shall, before July 1, 2016, or upon receipt of a  
13 federal Drug Enforcement Administration (DEA) registration,  
14 whichever occurs later, submit an application developed by the  
15 Department of Justice to obtain approval to access information  
16 online regarding the controlled substance history of a patient that  
17 is stored on the Internet and maintained within the Department of  
18 Justice, and, upon approval, the department shall release to that  
19 practitioner the electronic history of controlled substances  
20 dispensed to an individual under his or her care based on data  
21 contained in the CURES Prescription Drug Monitoring Program  
22 (PDMP).

23 (ii) A pharmacist shall, before July 1, 2016, or upon licensure,  
24 whichever occurs later, submit an application developed by the  
25 Department of Justice to obtain approval to access information  
26 online regarding the controlled substance history of a patient that  
27 is stored on the Internet and maintained within the Department of  
28 Justice, and, upon approval, the department shall release to that  
29 pharmacist the electronic history of controlled substances dispensed  
30 to an individual under his or her care based on data contained in  
31 the CURES PDMP.

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

35 (i) Materially falsifying an application for a subscriber.

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

38 (iii) Suspended or revoked federal DEA registration.

39 (iv) Any subscriber who is arrested for a violation of law  
40 governing controlled substances or any other law for which the

1 possession or use of a controlled substance is an element of the  
2 crime.

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

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

7 (2) A health care practitioner authorized to prescribe, order,  
8 administer, furnish, or dispense Schedule II, Schedule III, or  
9 Schedule IV controlled substances pursuant to Section 11150 or  
10 a pharmacist shall be deemed to have complied with paragraph  
11 (1) if the licensed health care practitioner or pharmacist has been  
12 approved to access the CURES database through the process  
13 developed pursuant to subdivision (a) of Section 209 of the  
14 Business and Professions Code.

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

18 (c) In order to prevent the inappropriate, improper, or illegal  
19 use of Schedule II, Schedule III, or Schedule IV controlled  
20 substances, the Department of Justice may initiate the referral of  
21 the history of controlled substances dispensed to an individual  
22 based on data contained in CURES to licensed health care  
23 practitioners, pharmacists, or both, providing care or services to  
24 the individual.

25 (d) The history of controlled substances dispensed to an  
26 individual based on data contained in CURES that is received by  
27 a practitioner or pharmacist from the Department of Justice  
28 pursuant to this section is medical information subject to the  
29 provisions of the Confidentiality of Medical Information Act  
30 contained in Part 2.6 (commencing with Section 56) of Division  
31 1 of the Civil Code.

32 (e) Information concerning a patient's controlled substance  
33 history provided to a prescriber or pharmacist pursuant to this  
34 section shall include prescriptions for controlled substances listed  
35 in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code  
36 of Federal Regulations.

37 (f) A health care practitioner, pharmacist, and any person acting  
38 on behalf of a health care practitioner or pharmacist, when acting  
39 with reasonable care and in good faith, is not subject to civil or  
40 administrative liability arising from any false, incomplete, or

1 ~~inaccurate~~ *inaccurate, or misattributed* information submitted to,  
2 ~~or~~ reported by, *or relied upon in* the CURES database or for any  
3 resulting failure of the CURES database to accurately or timely  
4 report that information.

5 SEC. 3. Section 11165.4 is added to the Health and Safety  
6 Code, to read:

7 11165.4. (a) (1) (A) (i) A health care practitioner authorized  
8 to prescribe, order, administer, or furnish a controlled substance  
9 shall consult the CURES database to review a patient's controlled  
10 substance history before prescribing a Schedule II, Schedule III,  
11 or Schedule IV controlled substance to the patient for the first time  
12 and at least once every four months thereafter if the substance  
13 remains part of the treatment of the patient.

14 (ii) If a health care practitioner authorized to prescribe, order,  
15 administer, or furnish a controlled substance is not required,  
16 pursuant *to* an exemption described in subdivision (c), to consult  
17 the CURES database the first time he or she prescribes, orders,  
18 administers, or furnishes a controlled substance to a patient, he or  
19 she shall consult the CURES database to review the patient's  
20 controlled substance history before subsequently prescribing a  
21 Schedule II, Schedule III, or Schedule IV controlled substance to  
22 the patient and at least once every four months thereafter if the  
23 substance remains part of the treatment of the patient.

24 (B) For purposes of this paragraph, "first time" means the initial  
25 occurrence in which a health care practitioner, in his or her role  
26 as a health care practitioner, intends to prescribe, order, administer,  
27 or furnish a Schedule II, Schedule III, or Schedule IV controlled  
28 substance to a patient and has not previously prescribed a controlled  
29 substance to the patient.

30 (2) A health care practitioner shall obtain a patient's controlled  
31 substance history from the CURES database no earlier than 24  
32 hours, or the previous business day, before he or she prescribes,  
33 orders, administers, or furnishes a Schedule II, Schedule III, or  
34 Schedule IV controlled substance to the patient.

35 (b) The duty to consult the CURES database, as described in  
36 subdivision (a), does not apply to ~~veterinarians~~. *veterinarians or*  
37 *pharmacists*.

38 (c) The duty to consult the CURES database, as described in  
39 subdivision (a), does not apply to a health care practitioner in any  
40 of the following circumstances:



1 (1) If a health care practitioner prescribes, orders, or furnishes  
2 a controlled substance to be administered to a patient while the  
3 patient is admitted to any of the following facilities or during an  
4 emergency transfer between any of the following facilities for use  
5 while on facility premises:

6 (A) A licensed clinic, as described in Chapter 1 (commencing  
7 with Section 1200) of Division 2.

8 (B) An outpatient setting, as described in Chapter 1.3  
9 (commencing with Section 1248) of Division 2.

10 (C) A health facility, as described in Chapter 2 (commencing  
11 with Section 1250) of Division 2.

12 (D) A county medical facility, as described in Chapter 2.5  
13 (commencing with Section 1440) of Division 2.

14 (2) If a health care practitioner prescribes, orders, administers,  
15 or furnishes a controlled substance in the emergency department  
16 of a general acute care hospital and the quantity of the controlled  
17 substance does not exceed a nonrefillable seven-day supply of the  
18 controlled substance to be used in accordance with the directions  
19 for use.

20 (3) If a health care practitioner prescribes, orders, administers,  
21 or furnishes a controlled substance to a patient as part of the  
22 patient's treatment for a surgical procedure and the quantity of the  
23 controlled substance does not exceed a nonrefillable five-day  
24 supply of the controlled substance to be used in accordance with  
25 the directions for use, in any of the following facilities:

26 (A) A licensed clinic, as described in Chapter 1 (commencing  
27 with Section 1200) of Division 2.

28 (B) An outpatient setting, as described in Chapter 1.3  
29 (commencing with Section 1248) of Division 2.

30 (C) A health facility, as described in Chapter 2 (commencing  
31 with Section 1250) of Division 2.

32 (D) A county medical facility, as described in Chapter 2.5  
33 (commencing with Section 1440) of Division 2.

34 (E) A place of practice, as defined in Section 1658 of the  
35 Business and Professions Code.

36 (4) If a health care practitioner prescribes, orders, administers,  
37 or furnishes a controlled substance to a patient currently receiving  
38 hospice care, as defined in Section 1339.40.

39 (5) (A) If all of the following circumstances are satisfied:

1 (i) It is not reasonably possible for a health care practitioner to  
2 access the information in the CURES database in a timely manner.

3 (ii) Another health care practitioner or designee authorized to  
4 access the CURES database is not reasonably available.

5 (iii) The quantity of controlled substance prescribed, ordered,  
6 administered, or furnished does not exceed a nonrefillable five-day  
7 supply of the controlled substance to be used in accordance with  
8 the directions for use and no refill of the controlled substance is  
9 allowed.

10 (B) A health care practitioner who does not consult the CURES  
11 database under subparagraph (A) shall document the reason he or  
12 she did not consult the database in the patient's medical record.

13 (6) If the CURES database is not operational, as determined by  
14 the department, or when it cannot be accessed by a health care  
15 practitioner because of a temporary technological or electrical  
16 failure. A health care practitioner shall, without undue delay, seek  
17 to correct any cause of the temporary technological or electrical  
18 failure that is reasonably within his or her control.

19 (7) If the CURES database cannot be accessed because of  
20 technological limitations that are not reasonably within the control  
21 of a health care practitioner.

22 ~~(8) If the CURES database cannot be accessed because of~~  
23 ~~exceptional circumstances, as demonstrated by a health care~~  
24 ~~practitioner.~~

25 *(8) If consultation of the CURES database would, as determined*  
26 *by the health care practitioner, result in a patient's inability to*  
27 *obtain a prescription in a timely manner and thereby adversely*  
28 *impact the patient's medical condition, provided that the quantity*  
29 *of the controlled substance does not exceed a nonrefillable five-day*  
30 *supply if the controlled substance were used in accordance with*  
31 *the directions for use.*

32 (d) (1) A health care practitioner who knowingly fails to consult  
33 the CURES database, as described in subdivision (a), shall be  
34 referred to the appropriate state professional licensing board solely  
35 for administrative sanctions, as deemed appropriate by that board.

36 (2) This section does not create a private cause of action against  
37 a health care practitioner. This section does not limit a health care  
38 practitioner's liability for the negligent failure to diagnose or treat  
39 a patient.

1 (e) This section is not operative until six months after the  
2 Department of Justice certifies that the CURES database is ready  
3 for statewide ~~use~~. *use and that the department has adequate staff,*  
4 *which, at a minimum, shall be consistent with the appropriation*  
5 *authorized in Schedule (6) of Item 0820-001-0001 of the Budget*  
6 *Act of 2016 (Chapter 23 of the Statutes of 2016), user support,*  
7 *and education.* The department shall notify the Secretary of State  
8 and the office of the Legislative Counsel of the date of that  
9 certification.

10 (f) All applicable state and federal privacy laws govern the  
11 duties required by this section.

12 (g) The provisions of this section are severable. If any provision  
13 of this section or its application is held invalid, that invalidity shall  
14 not affect other provisions or applications that can be given effect  
15 without the invalid provision or application.