

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

Introduced by Senator Lara

February 26, 2015

An act to amend ~~Section~~ *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~~ *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, ~~furnish, or dispense~~ *or furnish* a controlled substance to consult the CURES database to review a patient's controlled substance history no earlier than ~~24 hours~~ *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 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, ~~furnishing, or dispensing~~ *or furnishing* a controlled substance to a patient receiving hospice care, to a patient admitted to a specified ~~facility~~, *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 exempt a health care practitioner from this requirement if it is not reasonably possible for him or her to access the information in the CURES database in a timely manner, another health care practitioner or designee authorized to access the CURES database is not reasonably available, and the quantity of controlled substance prescribed, ordered, administered, furnished, or dispensed does not exceed a nonrefillable 5-day supply of the controlled substance that is to be used in accordance with the directions for use and no refill of the controlled substance is allowed.~~ *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.*

~~The~~

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.

~~The~~

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 information submitted, to or reported by, the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

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

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

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

19 (3) *In accordance with federal and state privacy laws and*
20 *regulations, a health care practitioner may provide a patient with*
21 *a copy of the patient's CURES patient activity report and keep a*
22 *copy of the report in the patient's medical record if reasonable*
23 *care has been taken to ensure that the report is provided or kept*
24 *in compliance with subdivision (d) of Section 11165.1.*

25 (d) For each prescription for a Schedule II, Schedule III, or
26 Schedule IV controlled substance, as defined in the controlled
27 substances schedules in federal law and regulations, specifically
28 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21
29 of the Code of Federal Regulations, the dispensing pharmacy,
30 clinic, or other dispenser shall report the following information to
31 the Department of Justice as soon as reasonably possible, but not
32 more than seven days after the date a controlled substance is
33 dispensed, in a format specified by the Department of Justice:

34 (1) Full name, address, and, if available, telephone number of
35 the ultimate user or research subject, or contact information as
36 determined by the Secretary of the United States Department of
37 Health and Human Services, and the gender, and date of birth of
38 the ultimate user.

39 (2) The prescriber's category of licensure, license number,
40 national provider identifier (NPI) number, if applicable, the federal

1 controlled substance registration number, and the state medical
2 license number of any prescriber using the federal controlled
3 substance registration number of a government-exempt facility.

4 (3) Pharmacy prescription number, license number, NPI number,
5 and federal controlled substance registration number.

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

8 (5) Quantity of the controlled substance dispensed.

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

11 (7) Number of refills ordered.

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

14 (9) Date of origin of the prescription.

15 (10) Date of dispensing of the prescription.

16 (e) The Department of Justice may invite stakeholders to assist,
17 advise, and make recommendations on the establishment of rules
18 and regulations necessary to ensure the proper administration and
19 enforcement of the CURES database. All prescriber and dispenser
20 invitees shall be licensed by one of the boards or committees
21 identified in subdivision (d) of Section 208 of the Business and
22 Professions Code, in active practice in California, and a regular
23 user of CURES.

24 (f) The Department of Justice shall, prior to upgrading CURES,
25 consult with prescribers licensed by one of the boards or
26 committees identified in subdivision (d) of Section 208 of the
27 Business and Professions Code, one or more of the boards or
28 committees identified in subdivision (d) of Section 208 of the
29 Business and Professions Code, and any other stakeholder
30 identified by the department, for the purpose of identifying
31 desirable capabilities and upgrades to the CURES Prescription
32 Drug Monitoring Program (PDMP).

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

36 **SECTION 1.**

37 *SEC. 2.* Section 11165.1 of the Health and Safety Code is
38 amended to read:

39 11165.1. (a) (1) (A) (i) A health care practitioner authorized
40 to prescribe, order, administer, furnish, or dispense Schedule II,

1 Schedule III, or Schedule IV controlled substances pursuant to
2 Section 11150 shall, before July 1, 2016, or upon receipt of a
3 federal Drug Enforcement Administration (DEA) registration,
4 whichever occurs later, submit an application developed by the
5 Department of Justice to obtain approval to access information
6 online regarding the controlled substance history of a patient that
7 is stored on the Internet and maintained within the Department of
8 Justice, and, upon approval, the department shall release to that
9 practitioner the electronic history of controlled substances
10 dispensed to an individual under his or her care based on data
11 contained in the CURES Prescription Drug Monitoring Program
12 (PDMP).

13 (ii) A pharmacist shall, before July 1, 2016, or upon licensure,
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 pharmacist the electronic history of controlled substances dispensed
20 to an individual under his or her care based on data contained in
21 the CURES PDMP.

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

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

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

28 (iii) Suspended or revoked federal DEA registration.

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

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

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

37 (2) A health care practitioner authorized to prescribe, order,
38 administer, furnish, or dispense Schedule II, Schedule III, or
39 Schedule IV controlled substances pursuant to Section 11150 or
40 a pharmacist shall be deemed to have complied with paragraph

1 (1) if the licensed health care practitioner or pharmacist has been
2 approved to access the CURES database through the process
3 developed pursuant to subdivision (a) of Section 209 of the
4 Business and Professions Code.

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

8 (c) In order to prevent the inappropriate, improper, or illegal
9 use of Schedule II, Schedule III, or Schedule IV controlled
10 substances, the Department of Justice may initiate the referral of
11 the history of controlled substances dispensed to an individual
12 based on data contained in CURES to licensed health care
13 practitioners, pharmacists, or both, providing care or services to
14 the individual.

15 (d) The history of controlled substances dispensed to an
16 individual based on data contained in CURES that is received by
17 a practitioner or pharmacist from the Department of Justice
18 pursuant to this section is medical information subject to the
19 provisions of the Confidentiality of Medical Information Act
20 contained in Part 2.6 (commencing with Section 56) of Division
21 1 of the Civil Code.

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

27 (f) A health care practitioner, pharmacist, and any person acting
28 on behalf of a health care practitioner or pharmacist, when acting
29 with reasonable care and in good faith, is not subject to civil or
30 administrative liability arising from any false, incomplete, or
31 inaccurate information submitted to, or reported by, the CURES
32 database or for any resulting failure of the CURES database to
33 accurately or timely report that information.

34 ~~SEC. 2.~~

35 *SEC. 3.* Section 11165.4 is added to the Health and Safety
36 Code, to read:

37 11165.4. (a) (1) (A) (i) A health care practitioner authorized
38 to prescribe, order, administer, ~~furnish, or dispense or furnish~~ a
39 controlled substance shall consult the CURES database to review
40 a patient's controlled substance history before prescribing a

1 Schedule II, Schedule III, or Schedule IV controlled substance to
2 the patient for the first time and at least once every four months
3 thereafter if the substance remains part of the treatment of the
4 patient.

5 *(ii) If a health care practitioner authorized to prescribe, order,*
6 *administer, or furnish a controlled substance is not required,*
7 *pursuant an exemption described in subdivision (c), to consult the*
8 *CURES database the first time he or she prescribes, orders,*
9 *administers, or furnishes a controlled substance to a patient, he*
10 *or she shall consult the CURES database to review the patient's*
11 *controlled substance history before subsequently prescribing a*
12 *Schedule II, Schedule III, or Schedule IV controlled substance to*
13 *the patient and at least once every four months thereafter if the*
14 *substance remains part of the treatment of the patient.*

15 (B) For purposes of this paragraph, “first time” means the initial
16 occurrence in which a health care practitioner, in his or her role
17 as a health care practitioner, intends to prescribe, order, administer,
18 ~~furnish, or dispense~~ *or furnish* a Schedule II, Schedule III, or
19 Schedule IV controlled substance to a patient and has not
20 previously prescribed a controlled substance to the patient.

21 (2) A health care practitioner shall obtain a patient's controlled
22 substance history from the CURES database no earlier than 24
23 ~~hours~~ *hours, or the previous business day*, before he or she
24 prescribes, orders, administers, ~~furnishes, or dispenses~~ *or furnishes*
25 a Schedule II, Schedule III, or Schedule IV controlled substance
26 to the patient.

27 (b) The duty to consult the CURES database, as described in
28 subdivision (a), does not apply to veterinarians.

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

32 (1) If a health care practitioner prescribes, orders, or furnishes
33 a controlled substance to be administered ~~or dispensed~~ to a patient
34 while the patient is admitted to any of the following facilities or
35 during an emergency transfer between any of the following
36 ~~facilities:~~ *facilities for use while on facility premises:*

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

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

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

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

5 (2) ~~When~~*If* a health care practitioner prescribes, orders,
6 administers, ~~furnishes, or dispenses~~ *or furnishes* a controlled
7 substance in the emergency department of a general acute care
8 hospital ~~if~~ *and* the quantity of the controlled substance does not
9 exceed a *nonrefillable* seven-day supply of the controlled substance
10 to be used in accordance with the directions for use.

11 (3) If a health care practitioner prescribes, orders, administers,
12 ~~furnishes, or dispenses~~ *or furnishes* a controlled substance to a
13 patient as part of the patient’s treatment for a surgical ~~procedure,~~
14 ~~if procedure~~ *and* the quantity of the controlled substance does not
15 exceed a nonrefillable five-day supply of the controlled substance
16 to be used in accordance with the directions for ~~use,~~ *use* in any of
17 the following facilities:

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

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

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

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

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

28 (4) If a health care practitioner prescribes, orders, administers,
29 ~~furnishes, or dispenses~~ *or furnishes* a controlled substance to a
30 patient currently receiving hospice care, as defined in Section
31 1339.40.

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

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

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

37 (iii) ~~The~~ The quantity of controlled substance prescribed, ordered,
38 administered, ~~furnished, or dispensed~~ *or furnished* does not exceed
39 a nonrefillable five-day supply of the controlled substance to be

1 used in accordance with the directions for use and no refill of the
2 controlled substance is allowed.

3 (B) A health care practitioner who does not consult the CURES
4 database under subparagraph (A) shall document the reason he or
5 she did not consult the database in the patient’s medical record.

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

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

15 (8) If the CURES database cannot be accessed because of
16 exceptional circumstances, as demonstrated by a health care
17 practitioner.

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

22 (2) This section does not create a private cause of action against
23 a health care practitioner. This section does not limit a health care
24 practitioner’s liability for the negligent failure to diagnose or treat
25 a patient.

26 (e) This section is not operative until six months after the
27 Department of Justice certifies that the CURES database is ready
28 for statewide use. The department shall notify the Secretary of
29 State and the office of the Legislative Counsel of the date of that
30 certification.

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

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

O