

FIRST REGULAR SESSION

SENATE BILL NO. 233

97TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Read 1st time January 29, 2013, and ordered printed.

TERRY L. SPIELER, Secretary.

0532S.011

AN ACT

To repeal section 195.015, RSMo, and to enact in lieu thereof ten new sections relating to a prescription drug monitoring program, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Section 195.015, RSMo, are repealed and ten new sections enacted in lieu thereof, to be known as sections 195.015, 195.450, 195.453, 195.456, 195.459, 195.462, 195.465, 195.468, 195.474, and 195.477, to read as follows:

195.015. 1. The department of health and senior services shall administer sections 195.005 to [195.425] **195.477** and may add substances to the schedules after public notice and hearing. In making a determination regarding a substance, the department of health and senior services shall consider the following:

- (1) The actual or relative potential for abuse;
- (2) The scientific evidence of its pharmacological effect, if known;
- (3) The state of current scientific knowledge regarding the substance;
- (4) The history and current pattern of abuse;
- (5) The scope, duration, and significance of abuse;
- (6) The risk to the public health;
- (7) The potential of the substance to produce psychic or physiological dependence liability; and
- (8) Whether the substance is an immediate precursor of a substance already controlled under sections 195.005 to 195.425.

2. After considering the factors enumerated in subsection 1 of this section the department of health and senior services shall make findings with respect

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

18 thereto and issue a rule controlling the substance if it finds the substance has a
19 potential for abuse.

20 3. If the department of health and senior services designates a substance
21 as an immediate precursor, substances which are precursors of the controlled
22 precursor shall not be subject to control solely because they are precursors of the
23 controlled precursor.

24 4. If any substance is designated, rescheduled, or deleted as a controlled
25 substance under federal law and notice thereof is given to the department of
26 health and senior services, the department of health and senior services shall
27 similarly control the substance under sections 195.005 to 195.425 after the
28 expiration of thirty days from publication in the federal register of a final order
29 designating a substance as a controlled substance or rescheduling or deleting a
30 substance, unless within that thirty-day period, the department of health and
31 senior services objects to inclusion, rescheduling, or deletion. In that case, the
32 department of health and senior services shall publish the reasons for objection
33 and afford all interested parties an opportunity to be heard. At the conclusion
34 of the hearing, the department of health and senior services shall publish its
35 decision, which shall be final unless altered by statute. Upon publication of
36 objection to inclusion, rescheduling or deletion under sections 195.005 to 195.425
37 by the department of health and senior services, control under sections 195.005
38 to 195.425 is stayed as to the substance in question until the department of
39 health and senior services publishes its decision.

40 5. The department of health and senior services shall exclude any
41 nonnarcotic substance from a schedule if such substance may, under the federal
42 Food, Drug, and Cosmetic Act and the law of this state, be lawfully sold over the
43 counter without a prescription.

44 6. The department of health and senior services shall prepare a list of all
45 drugs falling within the purview of controlled substances. Upon preparation, a
46 copy of the list shall be filed in the office of the secretary of state.

**195.450. 1. Sections 195.450 to 195.477 shall be known and may
2 be cited as the "Prescription Drug Monitoring Program Act".**

3 **2. As used in sections 195.450 to 195.477, the following terms**
4 **mean:**

5 **(1) "Controlled substance", the same meaning given such term in**
6 **section 195.010;**

7 **(2) "Department", the department of health and senior services;**

8 **(3) "Dispenser", a person who delivers a schedule II, III, or IV**

9 controlled substance to the ultimate user, but does not include:

10 (a) A hospital, as defined in section 197.020, that distributes such
11 substances for the purpose of inpatient care or dispenses prescriptions
12 for controlled substances at the time of discharge at such facility;

13 (b) A practitioner or other authorized person who administers
14 such a substance; or

15 (c) A wholesale distributor of a schedule II, III, or IV controlled
16 substance;

17 (4) "Patient", a person who is the ultimate user of a drug for
18 whom a prescription is issued or for whom a drug is dispensed, except
19 that patient shall not include a hospice patient enrolled in a Medicare-
20 certified hospice program who has controlled substances dispensed to
21 him or her by such hospice program;

22 (5) "Schedule II, III, or IV controlled substance", a controlled
23 substance that is listed in schedules II, III, or IV of the schedules
24 provided under this chapter or the Federal Controlled Substances Act,
25 21 U.S.C. Section 812.

26 3. Notwithstanding any other law to the contrary, the provisions
27 of this section shall not apply to persons licensed under chapter 340.

195.453. 1. The department of health and senior services shall
2 establish and maintain a program for the monitoring of prescribing and
3 dispensing of all schedule II, III, and IV controlled substances by all
4 professionals licensed to prescribe or dispense such substances in this
5 state. The department may apply for any available grants and shall
6 accept any gifts, grants, or donations to develop and maintain the
7 program. All funding for prescription drug monitoring program shall
8 be provided exclusively by gifts, grants, and donations.

9 2. Each dispenser shall submit to the department by electronic
10 means information regarding each dispensation of a drug included in
11 subsection 1 of this section. The information submitted for each shall
12 include, but not be limited to:

13 (1) The pharmacy federal Drug Enforcement Administration
14 ("DEA") number;

15 (2) The date of the dispensation;

16 (3) If there is a prescription:

17 (a) The prescription number;

18 (b) Whether the prescription is new or a refill;

19 (c) The prescriber DEA or National Provider Identifier ("NPI")
20 number;

21 (d) The date the prescription is issued by the prescriber;

22 (e) The source of payment for the prescription;

23 (4) The National Drug Code ("NDC") for the drug dispensed;

24 (5) The number of days' supply of the drug;

25 (6) The quantity dispensed;

26 (7) The patient identification number, including, but not limited
27 to, any one of the following:

28 (a) The patient's driver's license number;

29 (b) The patient's government-issued identification number; or

30 (c) The patient's insurance cardholder identification number;

31 (8) The patient's name, address, and date of birth.

32 3. Each dispenser shall submit the information in accordance
33 with transmission standards established by the American Society for
34 Automation in Pharmacy, or any successor organization, and shall
35 report data within every seven days.

36 4. (1) The department may issue a waiver to a dispenser that is
37 unable to submit dispensation information by electronic means. Such
38 waiver may permit the dispenser to submit dispensation information
39 by paper form or other means, provided all information required in
40 subsection 2 of this section is submitted in such alternative format;

41 (2) The department may grant an extension to dispensers who
42 are temporarily unable to electronically submit the dispensation
43 information required in subsection 2 of this section in accordance with
44 the time frame established in subsection 3 of this section due to
45 unforeseen circumstances. In cases where an extension is granted,
46 dispensers shall be responsible for reporting the required data in a
47 subsequent file.

48 5. The department shall reimburse each dispenser for the fees
49 and other direct costs of transmitting the information required by this
50 section.

195.456. 1. Dispensation information submitted to the
2 department shall be confidential and not subject to public disclosure
3 under chapter 610 except as provided in subsections 3 to 5 of this
4 section.

5 2. The department shall maintain procedures to ensure that the

6 privacy and confidentiality of patients and personnel information
7 collected, recorded, transmitted, and maintained is not disclosed to
8 persons except as provided in subsections 3 to 5 of this section.

9 3. The department shall review the dispensation information
10 and, if there is reasonable cause to believe a violation of law or breach
11 of professional standards may have occurred, the department shall
12 notify the appropriate law enforcement or professional licensing,
13 certification, or regulatory agency or entity, and provide dispensation
14 information required for an investigation.

15 4. The department may provide data in the controlled substances
16 dispensation monitoring program to the following persons:

17 (1) Persons, both in-state and out-of-state, authorized to
18 prescribe or dispense controlled substances for the purpose of
19 providing medical or pharmaceutical care for their patients;

20 (2) An individual who requests his or her own dispensation
21 monitoring information in accordance with state law;

22 (3) The state board of pharmacy;

23 (4) Any state board charged with regulating a professional that
24 has the authority to prescribe or dispense controlled substances that
25 requests data related to a specific professional under the authority of
26 that board;

27 (5) Local, state, and federal law enforcement or prosecutorial
28 officials, both in-state and out-of-state engaged in the administration,
29 investigation, or enforcement of the laws governing licit drugs based
30 on a specific case and under a subpoena or court order;

31 (6) The family support division within the department of social
32 services regarding Medicaid program recipients;

33 (7) A judge or other judicial authority under a subpoena or court
34 order; and

35 (8) Personnel of the department of health and senior services for
36 the administration and enforcement of sections 195.450 to 195.477.

37 5. The department may provide data to public or private entities
38 for statistical, research, or educational purposes after removing
39 information that could be used to identify individual patients,
40 prescribers, dispensers, or persons who received dispensations from
41 dispensers.

42 6. Nothing in sections 195.450 to 195.477 shall be construed to

43 require a pharmacist or prescriber to obtain information about a
44 patient from the database. A pharmacist or prescriber shall not be held
45 liable for damages to any person in any civil action for injury, death,
46 or loss to person or property on the basis that the pharmacist or
47 prescriber did or did not seek or obtain information from the database.

195.459. The department is authorized to contract with any other
2 agency of this state or any other state with a private vendor, or any
3 state government that currently runs a prescription monitoring
4 program. Any contractor shall comply with the provisions regarding
5 confidentiality of prescription information in section 195.456.

195.462. The department shall promulgate rules setting forth the
2 procedures and methods of implementing sections 195.450 to
3 195.474. Any rule or portion of a rule, as that term is defined in section
4 536.010, that is created under the authority delegated in this section
5 shall become effective only if it complies with and is subject to all of
6 the provisions of chapter 536 and, if applicable, section 536.028. This
7 section and chapter 536 are nonseverable and if any of the powers
8 vested with the general assembly pursuant to chapter 536 to review, to
9 delay the effective date, or to disapprove and annul a rule are
10 subsequently held unconstitutional, then the grant of rulemaking
11 authority and any rule proposed or adopted after August 28, 2013, shall
12 be invalid and void.

195.465. 1. A dispenser who knowingly fails to submit
2 dispensation monitoring information to the department as required in
3 sections 195.450 to 195.477 or knowingly submits the incorrect
4 dispensation information shall be subject to an administrative penalty
5 in the amount of one thousand dollars for each violation. The penalty
6 shall be assessed through an order issued by the director of the
7 department. Any person subject to an administrative penalty may
8 appeal to the administrative hearing commission under the provisions
9 of chapter 621.

2. A person authorized to have dispensation monitoring
11 information under sections 195.450 to 195.477 who knowingly discloses
12 such information in violation of sections 195.450 to 195.477 or who uses
13 such information in a manner and for a purpose in violation of sections
14 195.450 to 195.477 is guilty of a class A misdemeanor.

195.468. 1. The department shall create and implement the

2 following education courses:

3 (1) An orientation course during the implementation phase of the
4 dispensation monitoring program established in section 195.453;

5 (2) A course for persons who are authorized to access the
6 dispensation monitoring information but who did not participate in the
7 orientation course;

8 (3) A course for persons who are authorized to access the
9 dispensation monitoring information but who have violated laws or
10 breached occupational standards involving dispensing, prescribing, and
11 use of substances monitored by the dispensation monitoring program
12 established in section 195.453.

13 When appropriate, the department shall develop the content of the
14 education courses described in subdivisions (1) to (3) of this subsection.

15 2. The department shall, when appropriate:

16 (1) Work with associations for impaired professionals to ensure
17 intervention, treatment, and ongoing monitoring and followup; and

18 (2) Encourage individual patients who are identified and who
19 have become addicted to substances monitored by the dispensation
20 monitoring program established in section 195.453 to receive addiction
21 treatment.

195.474. Under section 23.253 of the Missouri sunset act:

2 (1) The provisions of the new program authorized under sections
3 195.450 to 195.474 shall automatically sunset six years after the
4 effective date of sections 195.450 to 195.474 unless reauthorized by an
5 act of the general assembly; and

6 (2) If such program is reauthorized, the program authorized
7 under sections 195.450 to 195.474 shall automatically sunset six years
8 after the effective date of the reauthorization of sections 195.450 to
9 195.474; and

10 (3) Sections 195.450 to 195.474 shall terminate on September first
11 of the calendar year immediately following the calendar year in which
12 the program authorized under sections 195.450 to 195.474 is sunset.

195.477. 1. By no later than January 1, 2015, the bureau of
2 narcotics and dangerous drugs within the department of health and
3 senior services shall establish a two-year statewide pilot project for the
4 reporting of fraudulently obtained prescription controlled
5 substances. The pilot project shall include the following:

6 (1) Provide a toll-free number for reporting to the bureau by
7 physicians, pharmacists, and other health care professionals with
8 prescriptive authority who have reason to believe that a person is
9 fraudulently attempting to obtain a prescription for a controlled
10 substance or is attempting to obtain an excessive amount of a
11 controlled substance by prescription;

12 (2) Establish a system within the bureau for receiving such
13 reports under subdivision (1) of this subsection along with any
14 evidence offered or submitted by the reporter which indicates the
15 fraud; and

16 (3) Forward such reports, along with any evidence offered or
17 submitted to the appropriate prosecuting attorney or the state attorney
18 general for investigation and prosecution.

19 2. On or before February 1, 2015, and February 1, 2016, the
20 bureau of narcotics and dangerous drugs shall submit a report to the
21 general assembly detailing the following specifics regarding the pilot
22 project:

23 (1) The number of reports received under this section;

24 (2) The type of evidence offered or submitted indicating the
25 fraud;

26 (3) The number of referrals to the attorney general and each
27 local prosecuting attorney;

28 (4) The number of cases investigated and prosecuted as a result
29 of such reporting, and the number of convictions or pleas resulting
30 from such investigations and prosecutions. The attorney general and
31 local prosecuting attorneys shall cooperate with the bureau in the
32 submission and collection of the information necessary for inclusion in
33 the report; and

34 (5) Any recommendations regarding continuance of and
35 improvements in the pilot project.

36 Nothing in this section shall be construed as authorizing the inclusion
37 or release of any identifying information of any reporter or person who
38 is identified as a person who is attempting to fraudulently obtain
39 prescription controlled substances.

40 3. Any person who in good faith reports to the bureau under this
41 section shall be immune from any civil or criminal liability as the
42 result of such good faith reporting.

43 4. The department of health and senior services may promulgate
44 rules to implement the provisions of this section. Any rule or portion
45 of a rule, as that term is defined in section 536.010, that is created
46 under the authority delegated in this section shall become effective
47 only if it complies with and is subject to all of the provisions of chapter
48 536 and, if applicable, section 536.028. This section and chapter 536 are
49 nonseverable and if any of the powers vested with the general assembly
50 pursuant to chapter 536 to review, to delay the effective date, or to
51 disapprove and annul a rule are subsequently held unconstitutional,
52 then the grant of rulemaking authority and any rule proposed or
53 adopted after August 28, 2013, shall be invalid and void.

54 5. The department shall implement and provide all monitoring
55 under the pilot project with existing department employees. Nothing
56 in this section shall be construed as authorizing the hiring of
57 additional employees to implement this pilot project and the
58 department is required to implement this pilot project upon receipt of
59 gifts, grants, and donations received for such purpose, without any
60 additional state appropriations or department staff; except that, the
61 department may enter into agreements with other state agencies or a
62 private vendor, as necessary, to ensure the effective operations of the
63 program if such agreements are funded solely from gifts, grants, and
64 donations. Any agency or private vendor entering into an agreement
65 with the department for the pilot project shall comply with the
66 confidentiality provisions regarding the prescription information under
67 section 195.456.

68 6. Under section 23.253 of the Missouri sunset act:

69 (1) The provisions of the new program authorized under this
70 section shall automatically sunset three years after the effective date
71 of this section unless reauthorized by an act of the general assembly;
72 and

73 (2) If such program is reauthorized, the program authorized
74 under this section shall automatically sunset twelve years after the
75 effective date of the reauthorization of this section; and

76 (3) This section shall terminate on September first of the
77 calendar year immediately following the calendar year in which the
78 program authorized under this section is sunset.