

FIRST REGULAR SESSION
SENATE COMMITTEE SUBSTITUTE FOR
SENATE BILL NO. 74
99TH GENERAL ASSEMBLY

Reported from the Committee on Health and Pensions, January 26, 2017, with recommendation that the Senate Committee Substitute do pass.

0207S.02C

ADRIANE D. CROUSE, Secretary.

AN ACT

To repeal section 195.050, RSMo, and to enact in lieu thereof twelve 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Section A. Section 195.050, RSMo, is repealed and twelve new sections
2 enacted in lieu thereof, to be known as sections 195.050, 195.450, 195.453,
3 195.456, 195.458, 195.459, 195.460, 195.462, 195.465, 195.466, 195.468, and
4 195.471, to read as follows:

195.050. 1. A duly registered manufacturer or wholesaler may sell
2 controlled substances to any of the following persons:

- 3 (1) To a manufacturer, wholesaler, or pharmacy;
- 4 (2) To a physician, dentist, podiatrist or veterinarian;
- 5 (3) To a person in charge of a hospital, but only for use in that hospital;
- 6 (4) To a person in charge of a laboratory, but only for use in that
7 laboratory for scientific and medical purposes.

8 2. A duly registered manufacturer or wholesaler may sell controlled
9 substances to any of the following persons:

10 (1) On a special written order accompanied by a certificate of exemption,
11 as required by federal laws, to a person in the employ of the United States
12 government or of any state, territorial, district, county, municipal or insular
13 government, purchasing, receiving, possessing, or dispensing controlled
14 substances by reason of his or her official duties;

15 (2) To a master of a ship or person in charge of any aircraft upon which
16 no physician is regularly employed, for the actual medical needs of persons on
17 board such ship or aircraft, when not in port; provided, such controlled substances
18 shall be sold to the master of such ship or person in charge of such aircraft only

19 in pursuance of a special order form approved by a commissioned medical officer
20 or acting surgeon of the United States Public Health Service;

21 (3) To a person in a foreign country if the provisions of federal laws are
22 complied with.

23 3. An official written order for any controlled substance listed in
24 Schedules I and II shall be signed in duplicate by the person giving the order or
25 by his or her duly authorized agent. The original shall be presented to the person
26 who sells or dispenses the controlled substance named therein. In event of the
27 acceptance of such order by the person, each party to the transaction shall
28 preserve his or her copy of such order for a period of two years in such a way as
29 to be readily accessible for inspection by any public officer or employee engaged
30 in the enforcement of this chapter or chapter 579. It shall be deemed a
31 compliance with this subsection if the parties to the transaction have complied
32 with federal laws, respecting the requirements governing the use of order forms.

33 4. Possession of or control of controlled substances obtained as authorized
34 by this section shall be lawful if in the regular course of business, occupation,
35 profession, employment, or duty of the possessor.

36 5. A person in charge of a hospital or of a laboratory, or in the employ of
37 this state or of any other state, or of any political subdivision thereof, and a
38 master or other proper officer of a ship or aircraft, who obtains controlled
39 substances under the provisions of this section or otherwise, shall not administer,
40 nor dispense, nor otherwise use such drugs, within this state, except within the
41 scope of his or her employment or official duty, and then only for scientific or
42 medicinal purposes and subject to the provisions of this chapter and chapter 579.

43 6. Every person registered to manufacture, distribute or dispense
44 controlled substances under this chapter shall keep records and inventories of all
45 such drugs in conformance with the record keeping and inventory requirements
46 of federal law, and in accordance with any additional regulations of the
47 department of health and senior services. **All registrants who dispense
48 controlled substances shall maintain dispensing records and report the
49 dispensing to the department's prescription drug monitoring program
50 under sections 195.450 to 195.471 in conformance with the requirements
51 in this chapter.**

52 7. Manufacturers and wholesalers shall keep records of all narcotic and
53 controlled substances compounded, mixed, cultivated, grown, or by any other
54 process produced or prepared, and of all controlled substances received and

55 disposed of by them, in accordance with this section.

56 8. Apothecaries shall keep records of all controlled substances received
57 and disposed of by them, in accordance with the provisions of this section.

58 9. The form of records shall be prescribed by the department of health and
59 senior services.

**195.450. 1. Sections 195.450 to 195.471 shall be known and may
2 be cited as the "Prescription Drug Monitoring Program Act".**

**3 2. As used in sections 195.450 to 195.471, 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 from inpatient care
13 at such facility;**

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

**16 (c) A wholesale distributor of a Schedule II, III, or IV controlled
17 substance;**

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

**23 (5) "Prescriber", a person who prescribes a Schedule II, III, or IV
24 controlled substance to a patient;**

**25 (6) "Prescription drug monitoring program" or "PDMP", a
26 program established by the department under sections 195.450 to
27 195.471 to monitor the prescription and dispensation of all Schedule II,
28 III, or IV controlled substances;**

**29 (7) "Schedule II, III, or IV controlled substance", a controlled
30 substance that is listed in Schedules II, III, or IV of the schedules
31 provided under this chapter or the federal Controlled Substances Act,
32 21 U.S.C. Section 812.**

33 **3. Notwithstanding any other law to the contrary, the provisions**
34 **of sections 195.450 to 195.471 shall not apply to persons licensed under**
35 **chapter 340.**

195.453. 1. The department, using an existing data aggregation
2 **platform through the state data center within the office of**
3 **administration, shall establish and maintain a program to monitor the**
4 **prescription and dispensation of all Schedule II, III, and IV controlled**
5 **substances by all professionals licensed to prescribe or dispense such**
6 **substances in this state. The aggregated information from each**
7 **prescriber and dispenser data source shall remain segregated from any**
8 **other data source and shall not be commingled with data from any**
9 **other source. The information contained on the database shall not be**
10 **entered into any other database outside the control of the**
11 **department. The information shall not be entered into any national**
12 **PDMP database.**

13 **2. The funding of the PDMP shall be subject to appropriation. In**
14 **addition to appropriations from the general assembly, the department**
15 **may apply for available grants and may accept other gifts, grants, and**
16 **donations necessary to develop and maintain the program.**

17 **3. The department is authorized to contract with any other**
18 **agency of this state or with any other state that currently runs, or**
19 **contracts with a private vendor to run, a PDMP for any necessary**
20 **hardware or software to establish and maintain the PDMP. Any**
21 **contractor shall comply with the provisions regarding confidentiality**
22 **of prescription and dispensation information under section 195.456.**

23 **4. At the time of filling a prescription for a drug included in**
24 **subsection 1 of this section, each dispenser shall electronically submit**
25 **to the department the following information, including but not limited**
26 **to:**

27 **(1) The pharmacy federal Drug Enforcement Administration**
28 **("DEA") number;**

29 **(2) The date of the dispensation;**

30 **(3) If there is a prescription:**

31 **(a) The prescription number;**

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

33 **(c) The prescriber DEA or National Provider Identifier ("NPI")**
34 **number;**

35 (d) The date the prescriber issued the prescription; and
36 (e) The source of payment for the prescription;
37 (4) The dispensed drug's National Drug Code ("NDC");
38 (5) The number of days' supply of the drug;
39 (6) The quantity dispensed;
40 (7) The patient identification number, including but not limited
41 to, any one of the following:

42 (a) The patient's driver's license number;
43 (b) The patient's government-issued identification number; or
44 (c) The patient's insurance cardholder identification number;
45 and
46 (8) The patient's name, address, and date of birth.

47 5. At the time of prescribing a drug included in subsection 1 of
48 this section, each prescriber may, and all prescribers who hold
49 themselves out to the public as a specialist in pain management and
50 who are prescribing a Schedule II controlled substance shall,
51 electronically submit to the department the following information,
52 including but not limited to:

53 (1) The prescriber's DEA or NPI number;
54 (2) The date of the prescription;
55 (3) The prescription number;
56 (4) The controlled substance being prescribed;
57 (5) Whether the prescription is new or a refill;
58 (6) The number of days' supply of the drug;
59 (7) The quantity to be dispensed; and
60 (8) The patient's name, address, and date of birth.

61 6. If a dispenser does not otherwise transmit the prescription of
62 a drug to a third party payor, then each dispenser shall submit the
63 information in accordance with transmission standards established by
64 the American Society for Automation in Pharmacy, or any successor
65 organization, and shall report data within every seven days.

66 7. (1) The department may issue a waiver to a dispenser that is
67 unable to submit dispensation information by electronic means. Such
68 waiver may permit the dispenser to submit dispensation information
69 by paper form or other means, provided all information required in
70 subsection 4 of this section is submitted in such alternative format.

71 (2) The department may grant an extension to dispensers who

72 are temporarily unable to electronically submit the dispensation
73 information required in subsection 4 of this section in accordance with
74 the time frame established in subsection 6 of this section due to
75 unforeseen circumstances. In cases where an extension is granted,
76 dispensers shall be responsible for reporting the required data in a
77 subsequent file.

78 8. The department shall reimburse each dispenser for the fees of
79 transmitting the information required by this section.

80 9. All communications and data transmitted under sections
81 195.450 to 195.471 shall be encrypted.

82 10. The provisions of sections 195.450 to 195.471 shall not apply
83 to Schedule II, III, or IV controlled substances prescribed or dispensed
84 where the ultimate user is an individual under eighteen years of age.

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

5 2. The department shall maintain procedures to ensure that the
6 privacy and confidentiality of patients and personal information
7 collected, recorded, transmitted, and maintained is not disclosed to
8 persons except as provided in subsections 3 and 4 of this section.

9 3. The department may only provide data in the PDMP to the
10 following persons under the following circumstances:

11 (1) An individual patient or bureau of narcotics and dangerous
12 drugs registrant who requests his or her own prescription and
13 dispensation monitoring information in accordance with state law;

14 (2) The state board of pharmacy, when used to further an
15 investigation based on a complaint filed under section 338.055;

16 (3) The state board of registration for healing arts, when used to
17 further an investigation based on a complaint filed under sections
18 334.100 or 334.741;

19 (4) The state board of nursing, when used to further an
20 investigation based on a complaint filed under section 335.066;

21 (5) Local, state, and federal law enforcement or prosecutorial
22 officials, both in-state and out-of-state, who are engaged in the
23 administration, investigation, or enforcement of the laws governing
24 licit drugs based on a specific case and under a court-issued subpoena

25 or court order;

26 (6) Medical examiners and coroners for the purpose of
27 investigating the cause of death of any person under the jurisdiction
28 of the medical examiner or coroner;

29 (7) The family support division within the department of social
30 services regarding MO HealthNet program recipients;

31 (8) A judge or other judicial authority under a subpoena or court
32 order;

33 (9) Personnel of the bureau of narcotics and dangerous drugs, or
34 its successor agency within the department, for the administration and
35 enforcement of sections 195.450 to 195.471; and

36 (10) Dispensers and prescribers, pursuant to the provisions of
37 sections 195.458 and 195.459.

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

43 5. Nothing in sections 195.450 to 195.471 shall be construed to
44 require a dispenser or prescriber to obtain information about a patient
45 from the PDMP. A dispenser or prescriber shall not be held liable for
46 damages to any person in any civil action for injury, death, or loss to
47 person or property on the basis that the dispenser or prescriber did or
48 did not seek or obtain information from the PDMP.

49 6. Beginning August 28, 2019, the department shall maintain an
50 individual's prescription and dispensation information obtained under
51 sections 195.450 to 195.471 for a maximum of one hundred eighty
52 days. Such prescription or dispensation information shall thereafter
53 be deleted from the PDMP after one hundred eighty days.

195.458. 1. Notwithstanding the provisions of subsection 3 of
2 section 195.456, no dispenser shall have access to the information
3 contained in the PDMP established under sections 195.450 to 195.471,
4 but shall only transmit information to be included in the PDMP. All
5 dispensers shall have a prominently posted sign in bold letters stating
6 "ALL CONTROLLED SUBSTANCE PRESCRIPTIONS SHALL BE
7 REPORTED TO THE BUREAU OF NARCOTICS AND DANGEROUS
8 DRUGS AND SCREENED FOR VIOLATIONS".

9 2. After transmitting information to the PDMP, a dispenser shall
10 expect to receive a response from the department. If the department
11 responds that no concern is detected, the dispenser may dispense the
12 prescription according to his or her professional judgment. If the
13 department responds that a concern is detected, the dispenser shall
14 dispense or not dispense the prescription according to his or her
15 professional judgment, appropriate to the concern communicated by
16 the department. If the department does not respond due to a technical
17 or other problem, the dispenser shall dispense or not dispense the
18 prescription according to his or her professional judgment.

19 3. No licensed dispenser following the provisions of sections
20 195.450 to 195.471 shall be subject to discipline by the Missouri board
21 of pharmacy or by any other state agency for acting in good faith to fill
22 a prescription for a controlled substance, nor for acting outside of
23 these rules in an emergency.

195.459. 1. Notwithstanding the provisions of subsection 3 of
2 section 195.456, no prescriber shall have access to the information
3 contained in the PDMP established under sections 195.450 to 195.471,
4 but shall only transmit information to be included in the PDMP.

5 2. After transmitting information to the PDMP, a prescriber shall
6 expect to receive a response from the department. If the department
7 responds that no concern is detected, the prescriber may issue a
8 prescription according to his or her professional judgment. If the
9 department responds that a concern is detected, the prescriber shall
10 issue or not issue the prescription according to his or her professional
11 judgment, appropriate to the concern communicated by the
12 department. If the department does not respond due to a technical or
13 other problem, the prescriber shall issue or not issue the prescription
14 according to his or her professional judgment.

15 3. No licensed prescriber following the provisions of sections
16 195.450 to 195.471, shall be subject to discipline by the Missouri board
17 of healing arts or by any other state agency for acting in good faith to
18 prescribe a controlled substance, nor for acting outside of these rules
19 in an emergency.

195.460. 1. When a dispenser electronically sends the department
2 the information required under subsection 4 of section 195.453, the
3 department shall electronically screen its PDMP database and any

4 national PDMP database to determine if the prescription may be
5 properly dispensed and if a similar prescription has been dispensed
6 within the allowable day's supply limits set by the department. If no
7 concern is detected, the department shall electronically and
8 automatically issue a communication to the dispenser that no concern
9 was detected. If a concern is detected, the department shall
10 electronically and automatically issue a communication to the
11 dispenser that a concern is detected, and shall state the nature of the
12 concern identified by the computer algorithm used by the department.

13 2. When a prescriber electronically sends the department the
14 information required under subsection 5 of section 195.453, the
15 department shall electronically screen its PDMP database and any
16 national PDMP database to determine if the prescription may be
17 properly issued and if a similar prescription has been issued within the
18 allowable day's supply limits set by the department. If no concern is
19 detected, the department shall electronically and automatically issue
20 a communication to the prescriber that no concern was detected. If a
21 concern is detected, the department shall electronically and
22 automatically issue a communication to the prescriber that a concern
23 is detected, and shall state the nature of the concern identified by the
24 computer algorithm used by the department.

25 3. The department shall, as time and staff permit and subject to
26 appropriations, review the concerns generated under subsections 1 and
27 2 of this section. If, after staff review, there is reasonable cause to
28 believe that a person has obtained a prescription fraudulently from
29 more than one prescriber, the department shall contact the prescribers
30 and, as appropriate, inform them of the concern and the details about
31 the patient receiving prescriptions from other prescribers, and request
32 copies of the controlled substance records relating to the prescriptions
33 of concern. The prescribers shall provide the records, if possible, by
34 fax or electronically. If, after department review of the provided
35 records, it is clear that a person has obtained prescriptions under false
36 pretenses, the entire matter shall be referred to the appropriate law
37 enforcement agency or local prosecuting attorney for action.

38 4. The bureau of narcotics and dangerous drugs, or its successor
39 agency within the department, shall do the following:

40 (1) Review the prescription and dispensation information; and

41 **(2) If there is reasonable cause to believe a violation of law or**
42 **breach of professional standards may have occurred, the bureau of**
43 **narcotics and dangerous drugs shall, subject to rules promulgated**
44 **under section 195.462, refer the matter to the appropriate law**
45 **enforcement or professional licensing, certification, or regulatory**
46 **agency or entity, and provide the prescription and dispensation**
47 **information required for an investigation.**

48 **5. Nothing in the PDMP database shall be the sole basis for**
49 **probable cause to obtain an arrest or search warrant as part of a**
50 **criminal investigation.**

195.462. The department shall promulgate rules setting forth the
2 **procedures and methods of implementing sections 195.450 to**
3 **195.471. 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, 2017, shall**
12 **be invalid and void.**

195.465. 1. All dispensing information that is required to be
2 **reported to the department in sections 195.450 to 195.471 shall be**
3 **submitted to the department in compliance with subsection 6 of section**
4 **195.050 and subsection 4 of section 195.453. All prescribing information**
5 **that is required to be reported to the department in sections 195.450 to**
6 **195.471 shall be submitted to the department in compliance with**
7 **subsection 5 of section 195.453. Knowingly failing to submit a report as**
8 **required under this section is a violation of this chapter and such**
9 **person shall be guilty of a class A misdemeanor under section 579.084.**

10 **2. Any person who unlawfully and knowingly accesses or**
11 **discloses, or a person authorized to have prescription or dispensation**
12 **monitoring information under sections 195.450 to 195.471 who**
13 **knowingly discloses, such information in violation of sections 195.450**
14 **to 195.471, or knowingly uses such information in a manner and for a**
15 **purpose in violation of sections 195.450 to 195.471 is guilty of a class E**

16 felony.

17 **3. Neither the sovereign nor the official immunity doctrine shall**
18 **apply to a person or a department authorized to have an individual's**
19 **prescription and dispensation information under sections 195.450 to**
20 **195.471 in instances when such information is disclosed to an**
21 **unauthorized party. If a person unlawfully and knowingly accesses or**
22 **discloses, or if a person authorized to have prescription or dispensation**
23 **information under sections 195.450 to 195.471 knowingly discloses such**
24 **information in violation of sections 195.450 to 195.471 or knowingly**
25 **uses such information in a manner and for a purpose in violation of**
26 **sections 195.450 to 195.471, the person whose information was disclosed**
27 **shall have a cause of action to recover liquidated damages in the**
28 **amount of twenty-five thousand dollars in addition to compensatory**
29 **economic and noneconomic damages, attorney fees, and court costs. If**
30 **it is determined by a court of competent jurisdiction that such**
31 **disclosure was done intentionally and maliciously, the person shall be**
32 **entitled to punitive damages in addition to any other damages.**

195.466. The department shall annually provide to the general
2 **assembly a report as to the number of controlled substances dispensed,**
3 **broken down by drug, the number of incidents of fraudulent**
4 **prescriptions identified and any other pertinent information requested**
5 **by the general assembly.**

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 **provisions established in sections 195.450 to 195.471;**

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

8 **(3) A course for persons who are authorized to access the**
9 **prescription or dispensation information but who have violated laws or**
10 **breached occupational standards involving dispensing, prescribing, or**
11 **using substances monitored by the provisions established in sections**
12 **195.450 to 195.471.**

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 PDMP to receive**
20 **addiction treatment.**

195.471. 1. Sections 195.450 to 195.471 shall preempt all
2 **ordinances, rules, and regulations of political subdivisions relating to**
3 **the monitoring of the prescription and dispensation of all schedule II,**
4 **III, and IV controlled substances.**

5 **2. Notwithstanding the provisions of section 23.253 of the**
6 **Missouri sunset act to the contrary, the provisions of sections 195.450**
7 **to 195.471 shall expire on August 28, 2023.**

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Bill

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