

FIRST REGULAR SESSION

# SENATE BILL NO. 63

98TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SATER.

Pre-filed December 1, 2014, and ordered printed.

ADRIANE D. CROUSE, Secretary.

0607S.011

## AN ACT

To repeal section 195.015 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, section 195.050 as enacted by senate bill no. 491, ninety-seventh general assembly, second regular session, and section 195.050 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, 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 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, section 195.050 as enacted by senate bill no. 491, ninety-seventh general assembly, second regular session, and section 195.050 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, RSMo, are repealed and ten new sections enacted in lieu thereof, to be known as sections 195.015, 195.050, 195.050, 195.450, 195.453, 195.456, 195.459, 195.462, 195.465, and 195.468, to read as follows:

195.015. 1. The department of health and senior services shall administer sections 195.005 to [195.425] **195.468** 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;

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

- 10 (5) The scope, duration, and significance of abuse;
- 11 (6) The risk to the public health;
- 12 (7) The potential of the substance to produce psychic or physiological  
13 dependence liability; and
- 14 (8) Whether the substance is an immediate precursor of a substance  
15 already controlled under sections 195.005 to 195.425.
- 16 2. After considering the factors enumerated in subsection 1 of this section  
17 the department of health and senior services shall make findings with respect  
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.

195.050. 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 195.468 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.

195.050. 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 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 duly authorized agent. The original shall be presented to the person who  
26 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 copy of such order for a period of two years in such a way as to be  
29 readily accessible for inspection by any public officer or employee engaged in the  
30 enforcement of sections 195.005 to 195.425. It shall be deemed a compliance with  
31 this subsection if the parties to the transaction have complied with federal laws,  
32 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 employment or official duty, and then only for scientific or medicinal  
42 purposes and subject to the provisions of sections 195.005 to 195.425.

43 6. Every person registered to manufacture, distribute or dispense  
44 controlled substances under sections 195.005 to 195.425 shall keep records and  
45 inventories of all such drugs in conformance with the record keeping and  
46 inventory requirements of federal law, and in accordance with any additional  
47 regulations of the department of health and senior services. **All registrants**  
48 **who dispense controlled substances shall maintain dispensing records**

49 **and report the dispensing to the department's prescription drug**  
50 **monitoring program under sections 195.450 to 195.468 in conformance**  
51 **with the requirements 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 195.468 shall be known and may**  
**2 be cited as the "Prescription Drug Monitoring Program Act".**

**3 2. As used in sections 195.450 to 195.468, 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**  
**20 Medicare-certified hospice program who has controlled substances**  
**21 dispensed to 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 sections 195.450 to 195.468 shall not apply to persons licensed under  
28 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 funding of the prescription drug monitoring program shall  
6 be subject to appropriation. In addition to appropriations from the  
7 general assembly, the department may apply for available grants and  
8 shall be able to accept other gifts, grants, and donations to develop and  
9 maintain the program.

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

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

16 (2) The date of the dispensation;

17 (3) If there is a prescription:

18 (a) The prescription number;

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

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

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

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

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

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

26 (6) The quantity dispensed;

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

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

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

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

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

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

36 report data within every seven days.

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

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

49 5. The department shall reimburse each dispenser for the fees of  
50 transmitting the information required by this 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 personal 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  
16 prescription drug 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 195.468.**

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 195.468 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.**

48           **7. Beginning August 28, 2017, the department shall discard the**  
49 **data obtained from the prescription drug monitoring program under**  
50 **sections 195.450 to 195.468 every two years.**

**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 **195.468. 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, 2015, 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 195.468, shall be  
3 submitted to the department in compliance with subsection 6 of section  
4 195.050. Knowingly failing to submit a report as required under this  
5 section is a violation of this chapter and such person shall be guilty of  
6 class A misdemeanor under section 195.252.

7 2. A person authorized to have dispensation monitoring  
8 information under sections 195.450 to 195.468 who knowingly discloses  
9 such information in violation of sections 195.450 to 195.468 or who uses  
10 such information in a manner and for a purpose in violation of sections  
11 195.450 to 195.468 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 provisions 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 provisions established in section  
12 195.453.

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 drug monitoring**  
20 **program established under sections 195.450 to 195.468 to receive**  
21 **addiction treatment.**

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