FIRST REGULAR SESSION

SENATE BILL NO. 314

99TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHATZ.

Read 1st time January 18, 2017, and ordered printed.

ADRIANE D. CROUSE, Secretary.

AN ACT

To amend chapter 195, RSMo, by adding thereto seven new sections relating to a program for the monitoring of certain prescribed controlled substances, with penalty provisions.

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

Section A. Chapter 195, RSMo, is amended by adding thereto seven new

- 2 sections, to be known as sections 195.450, 195.453, 195.456, 195.459, 195.462,
- 3 195.465, and 195.468, to read as follows:

195.450. 1. Sections 195.450 to 195.468 shall be known and may

- 2 be cited as the "Narcotics Control Act".
- 2. As used in sections 195.450 to 195.468, the following terms shall
- 4 mean:

 $1441 \mathrm{S.}01 \mathrm{I}$

- 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 a patient, 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 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, not
- 19 including a hospice patient enrolled in a Medicare-certified hospice

20 program who has controlled substances dispensed to him or her by 21 such hospice program;

- 22 (5) "Schedule II, III, or IV controlled substance", a controlled 23 substance that is listed in Schedule II, III, or IV of the schedules 24 provided under this chapter or the Controlled Substances Act, 21 U.S.C.
- 25 Section 812.
- 3. Notwithstanding any other law to the contrary, the provisions of this section shall not apply to persons licensed under chapter 340.
- 195.453. 1. The department shall establish and maintain a program for the monitoring of prescribing and dispensing of all Schedule II, III, and IV controlled substances by all professionals licensed to prescribe or dispense such substances in this state. The funding of the narcotics control program shall be subject to appropriations. In addition to appropriations from the general assembly, the department may apply for available grants and shall be able to accept other gifts, grants, and donations to develop and maintain the program.
- 2. Each dispenser shall submit to the department by electronic means information regarding each dispensation of a drug included in subsection 1 of this section. The information submitted for each dispensation shall include, but not be limited to:
- 14 (1) The pharmacy's Drug Enforcement Administration (DEA)
 15 number;
- 16 (2) The date of the dispensation;
- 17 (3) The following, if there is a prescription:
- 18 (a) The prescription number or other unique identifier;
- 19 **(b)** Whether the prescription is new or a refill; and
- 20 (c) The prescriber's DEA or National Provider Identifier (NPI)
- 21 number;

22

- (4) The National Drug Code (NDC) for the drug dispensed;
- 23 (5) The quantity and dosage of the drug dispensed;
- 24 (6) The patient's identification number including, but not limited 25 to, any one of the following:
- 26 (a) The patient's driver's license number;
- 27 (b) The patient's government-issued identification number; or
- 28 (c) The patient's insurance cardholder identification number;
- 29 and

30

35

36

3738

39

5

8

17

18

1920

- (7) The patient's name, address, and date of birth.
- 3. Each dispenser shall submit the information in accordance 32 with transmission standards established by the American Society for 33 Automation in Pharmacy or any successor organization and shall report 34 data within twenty-four hours of dispensation.
 - 4. (1) The department may issue a waiver to a dispenser who is unable to submit dispensation information by electronic means. Such waiver may permit the dispenser to submit dispensation information by paper form or other means, provided all information required in subsection 2 of this section is submitted in such alternative format.
- 40 (2) The department may grant an extension to dispensers who 41 are temporarily unable to electronically submit the dispensation 42 information required in subsection 2 of this section in accordance with 43 the time frame established in subsection 3 of this section due to 44 unforeseen circumstances. In cases in which an extension is granted, 45 dispensers shall be responsible for reporting the required data in a 46 subsequent submission.
 - 195.456. 1. Dispensation information submitted to the department shall be confidential and not subject to public disclosure under chapter 610 except as provided in subsections 3 to 5 of this section.
 - 2. The department shall maintain procedures to ensure that the privacy and confidentiality of patients and personal information collected, recorded, transmitted, and maintained are not disclosed to persons except as provided in subsections 3 to 5 of this section.
- 3. The department shall review the dispensation information and, if there is reasonable cause to believe a violation of law or breach of professional standards may have occurred, the department shall notify the appropriate law enforcement or professional licensing, certification, or regulatory agency or entity, and provide any dispensation information required for an investigation.
- 4. The department may provide data in the narcotics control program to the following persons:
 - (1) Persons both in-state and out-of-state authorized to prescribe or dispense controlled substances for the purpose of providing medical or pharmaceutical care for their patients;
 - (2) An individual who requests his or her own dispensation

42

43

44

- 21 information in accordance with state law;
- 22 (3) The state board of pharmacy;
- 23 (4) Any state board charged with regulating a professional who 24 has the authority to prescribe or dispense controlled substances that 25 requests data related to a specific professional under the authority of 26 such board if such board has a current and open investigation into such 27 professional and the data provided is limited to such professional;
- 28 (5) Local, state, and federal law enforcement or prosecutorial 29 officials, both in-state and out-of-state, engaged in the administration, 30 investigation, or enforcement of the laws governing prescription drugs 31 based on a specific case and under a subpoena issued by a court of 32 competent jurisdiction or court order;
- 33 (6) The MO HealthNet division within the department of social services regarding MO HealthNet program recipients; and
- 35 (7) A judge or other judicial authority under a subpoena issued 36 by a court of competent jurisdiction or court order.
- 5. The department may provide data to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual patients, prescribers, dispensers, or persons who received dispensations from dispensers.
 - 6. Nothing in sections 195.450 to 195.468 shall be construed to require a pharmacist or prescriber to obtain information about a patient from the database.
- 7. No dispensation information submitted to the department shall be used by any local, state, or federal authority to prevent an individual from owning or obtaining a firearm.

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

195.462. The department shall promulgate rules setting forth the procedures and methods of implementing sections 195.450 to 195.468. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the authority delegated in this section shall become effective only if it complies with and is subject to all of

the provisions of chapter 536 and, if applicable, section 536.028. This section and chapter 536 are nonseverable, and if any of the powers vested with the general assembly pursuant to chapter 536 to review, to delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2017, shall be invalid and void.

195.465. 1. A dispenser who knowingly fails to submit dispensation information to the department as required in sections 195.450 to 195.468 or knowingly submits the incorrect dispensation information shall be subject to an administrative penalty in the amount of one thousand dollars for each violation. The penalty shall be assessed through an order issued by the director of the department. Any person subject to an administrative penalty may appeal to the administrative hearing commission under the provisions of chapter 621.

2. Any person who unlawfully and knowingly accesses or discloses, or any person authorized to have prescription or dispensation information under sections 195.450 to 195.468 who knowingly discloses, such information in violation of sections 195.450 to 195.468, or knowingly uses such information in a manner and for a purpose in violation of sections 195.450 to 195.468 is guilty of a class E felony.

195.468. Under section 23.253 of the Missouri sunset act:

- 2 (1) The provisions of the new program authorized under sections 3 195.450 to 195.468 shall automatically sunset six years after the 4 effective date of sections 195.450 to 195.468 unless reauthorized by an 5 act of the general assembly;
- 6 (2) If such program is reauthorized, the program authorized 7 under sections 195.450 to 195.468 shall automatically sunset twelve 8 years after the effective date of the reauthorization of sections 195.450 9 to 195.468; and
- 10 (3) Sections 195.450 to 195.468 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 195.468 is sunset.