SENATE SUBSTITUTE

FOR

HOUSE COMMITTEE SUBSTITUTE

FOR

HOUSE BILL NOS. 90 & 68

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:

- 1 Section A. Chapter 195, RSMo, is amended by adding thereto
- 2 seven new sections, to be known as sections 195.450, 195.453,
- 3 195.456, 195.459, 195.462, 195.465, and 195.468, to read as
- 4 follows:
- 5 195.450. 1. Sections 195.450 to 195.468 shall be known and
- 6 may be cited as the "Narcotics Control Act".
- 7 2. As used in sections 195.450 to 195.468, the following
- 8 terms shall mean:
- 9 (1) "Controlled substance", the same meaning given such
- 10 term in section 195.010;
- 11 (2) "Department", the department of health and senior
- 12 services;
- 13 (3) "Dispenser", a person who delivers a Schedule II, III,
- or IV controlled substance to a patient, but does not include:
- 15 (a) A hospital, as defined in section 197.020, that
- distributes such substances for the purpose of inpatient care or

1 dispenses prescriptions for controlled substances at the time of 2 discharge from such facility; 3 (b) A practitioner or other authorized person who 4 administers such a substance; or 5 (c) A wholesale distributor of a Schedule II, III, or IV 6 controlled substance; 7 (4) "Patient", a person who is the ultimate user of a drug 8 for whom a prescription is issued or for whom a drug is 9 dispensed, not including a hospice patient enrolled in a 10 Medicare-certified hospice program who has controlled substances dispensed to him or her by such hospice program; 11 12 (5) "Prescriber", a person who prescribes a Schedule II, 13 III, or IV controlled substance to a patient; (6) "Schedule II, III, or IV controlled substance", a 14 15 controlled substance that is listed in Schedule II, III, or IV of 16 the schedules provided under this chapter or the Controlled 17 Substances Act, 21 U.S.C. Section 812. 18 3. Notwithstanding any other law to the contrary, the 19 provisions of this section shall not apply to persons licensed 20 under chapter 340. 21 195.453. 1. The department shall establish and maintain a 22 program for the monitoring of prescribing and dispensing of all 23 Schedule II, III, and IV controlled substances by all 24 professionals licensed to prescribe or dispense such substances 25 in this state. The funding of the narcotics control program 26 shall be subject to appropriations. In addition to 27 appropriations from the general assembly, the department may

apply for available grants and shall be able to accept other

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1	gifts, grants, and donations to develop and maintain the program.
2	2. Each dispenser shall submit to the department by
3	electronic means information regarding each dispensation of a
4	drug included in subsection 1 of this section. The information
5	submitted for each dispensation shall include, but not be limited
6	<u>to:</u>
7	(1) The dispenser's Drug Enforcement Administration (DEA)
8	<pre>number;</pre>
9	(2) The date of the dispensation;
10	(3) The following, if there is a prescription:
11	(a) The prescription number or other unique identifier;
12	(b) Whether the prescription is new or a refill; and
13	(c) The prescriber's DEA or National Provider Identifier
14	(NPI) number;
15	(4) The National Drug Code (NDC) for the drug dispensed;
16	(5) The quantity and dosage of the drug dispensed;
17	(6) The patient's identification number including, but not
18	limited to, any one of the following:
19	(a) The patient's driver's license number;
20	(b) The patient's government-issued identification number;
21	<u>or</u>
22	(c) The patient's insurance cardholder identification
23	number; and
24	(7) The patient's name, address, and date of birth.
25	3. Each dispenser shall submit the information in
26	accordance with transmission standards established by the
27	American Society for Automation in Pharmacy or any successor
28	organization and shall report data within twenty-four hours of

1	dispensation.	Beginning	Januarv	1.	2019	, the	department	shall

- 2 begin phasing in a requirement that dispensers report data in
- 3 real time with all report data to be submitted in real time by
- 4 January 1, 2020.
- 5 4. (1) The department may issue a waiver to a dispenser
- 6 who is unable to submit dispensation information by electronic
- 7 means. Such waiver may permit the dispenser to submit
- 8 dispensation information by paper form or other means, provided
- 9 <u>all information required in subsection 2 of this section is</u>
- 10 submitted in such alternative format.
- 11 (2) The department may grant an extension to dispensers who
- are temporarily unable to electronically submit the dispensation
- information required in subsection 2 of this section in
- 14 <u>accordance with the time frame established in subsection 3 of</u>
- this section due to unforeseen circumstances. In cases in which
- 16 an extension is granted, dispensers shall be responsible for
- 17 reporting the required data in a subsequent submission.
- 18 5. A prescriber shall utilize the program prior to
- 19 prescribing any Schedule II, III, or IV controlled substance.
- 20 The provisions of this subsection shall not apply in the
- 21 following circumstances:
- 22 (1) During a medical emergency which, in the professional
- opinion of the prescriber, is likely to result in harm to the
- 24 patient;
- 25 (2) When it is not reasonably possible to utilize the
- 26 program due to circumstances beyond the control of the
- 27 prescriber;
- 28 (3) When the patient has a terminal illness, or resides in

1	а	facility	/ licensed	under	chapter	198	; or

- 2 (4) For the treatment of pain resulting from a surgical or
- 3 <u>invasive procedure in which the prescription does not exceed a</u>
- 4 five-day supply.
- 5 195.456. 1. Dispensation information submitted to the
- 6 department shall be confidential and not subject to public
- disclosure under chapter 610 except as provided in subsections 3
- 8 to 5 of this section.
- 9 2. The department shall maintain procedures to ensure that
- 10 the privacy and confidentiality of patients and personal
- information collected, recorded, transmitted, and maintained are
- 12 <u>not disclosed to persons except as provided in subsections 3 to 5</u>
- of this section.
- 14 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
- 18 professional licensing, certification, or regulatory agency or
- 19 entity, and provide any dispensation information required for an
- 20 investigation.
- 21 <u>4. The department may provide data in the narcotics control</u>
- 22 program to the following persons:
- 23 (1) Persons both in-state and out-of-state authorized to
- 24 prescribe or dispense controlled substances for the purpose of
- 25 providing medical or pharmaceutical care for their patients;
- 26 (2) An individual who requests his or her own dispensation
- 27 information <u>in accordance with state law;</u>
- 28 (3) The state board of pharmacy;

1	(4) Any state board charged with regulating a professional
2	who has the authority to prescribe or dispense controlled
3	substances that requests data related to a specific professional
4	under the authority of such board if such board has a current and
5	open investigation into such professional and the data provided
6	is limited to such professional;

- (5) Local, state, and federal law enforcement or prosecutorial officials, both in-state and out-of-state, engaged in the administration, investigation, or enforcement of the laws governing prescription drugs based on a specific case and under a subpoena issued by a court of competent jurisdiction or court order;
- (6) The MO HealthNet division within the department of social services regarding MO HealthNet program recipients; and
- (7) A judge or other judicial authority under a subpoena issued 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 dispenser or prescriber, except as otherwise provided in subsection 5 of section 195.453, 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.

- 1 8. No dispensation information submitted to the department 2 under sections 195.450 to 195.468 shall be the sole basis for 3 probable cause to obtain an arrest or search warrant as part of a 4 criminal investigation. 5 195.459. The department is authorized to contract with any 6 other agency of this state, any state government that currently 7 runs a narcotics control program, or any private vendor. Any 8 contractor shall comply with the provisions regarding 9 confidentiality of prescription and dispensation information in 10 section 195.456. 11 195.462. 1. The department shall promulgate rules setting forth the procedures and methods of implementing sections 195.450 12 13 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 14 15 delegated in this section shall become effective only if it 16 complies with and is subject to all of the provisions of chapter 17 536 and, if applicable, section 536.028. This section and 18 chapter 536 are nonseverable, and if any of the powers vested 19 with the general assembly pursuant to chapter 536 to review, to 20 delay the effective date, or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking 21 22 authority and any rule proposed or adopted after August 28, 2017, 23 shall be invalid and void. 2. The provisions of section 23.253 of the Missouri sunset act shall not apply to sections 195.450 to 195.468.
- 24 25
- 26 195.465. 1. A dispenser who knowingly fails to submit 27 dispensation information to the department as required in 28 sections 195.450 to 195.468 or knowingly submits the incorrect

- 1 dispensation information shall be subject to an administrative
- 2 penalty in the amount of one thousand dollars for each violation.
- 3 The penalty shall be assessed through an order issued by the
- 4 director of the department. Any person subject to an
- 5 administrative penalty may appeal to the administrative hearing
- 6 commission under the provisions of chapter 621.
- 7 2. Any person who unlawfully and knowingly accesses or
- 8 discloses, or any person authorized to have prescription or
- 9 dispensation information under sections 195.450 to 195.468 who
- 10 knowingly discloses such information in violation of sections
- 11 195.450 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
- 13 quilty of a class E felony.
- 3. A prescriber required to utilize the program under
- subsection 5 of section 195.453 who knowingly fails to comply
- 16 with the provisions of such subsection shall be subject to
- disciplinary action by the prescriber's respective professional
- 18 state regulatory board.
- 19 195.468. If a political subdivision of this state is
- 20 operating a program for the monitoring of the prescribing and
- 21 <u>dispensing of all Schedule II, III, and IV controlled substances</u>
- 22 by professionals licensed to prescribe or dispense such
- 23 substances in this state, the political subdivision shall
- 24 surrender and the state shall assume all obligations of the
- 25 political subdivision under any existing user or other agreement
- for such program, and be responsible for its continued
- functioning until such time as sections 195.450 to 195.468 and
- the rules promulgated under section 195.462 become effective. If

- 1 <u>an unforeseen issue arises that prevents the state from assuming</u>
- 2 the obligations of the political subdivision's program, this
- 3 <u>subsection shall be void and control of the political</u>
- 4 subdivision's program shall revert to the political subdivision
- 5 and not be prohibited.