FIRST REGULAR SESSION

[PERFECTED**]**

SENATE SUBSTITUTE FOR

SENATE BILL NO. 63

101ST GENERAL ASSEMBLY

INTRODUCED BY SENATOR REHDER.

0510S.02P ADRIANE D. CROUSE, Secretary

AN ACT

To repeal section 338.710, RSMo, and to enact in lieu thereof two new sections relating to 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Section A. Section 338.710, RSMo, is repealed and two new sections enacted in lieu thereof, to be known as sections 195.450 and 338.710, to read as follows:

195.450. 1. As used in this section, the following terms shall mean:

(1) "Controlled substance", as such term is defined in section 195.010;

(2) "Dispenser", a person who delivers a Schedule II, III, or IV controlled substance to a patient, but does not include:

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

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

(c) A wholesale distributor of a controlled substance;

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

(3) "Health care provider", as such term is defined in section 376.1350;

(4) "Patient", a person who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed, not including a hospice patient enrolled in a Medicare-certified hospice program who has controlled substances dispensed to him or her by such hospice program;

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

2. (1) There is hereby established within the office of administration the "Joint Oversight Task Force for Prescription Drug Monitoring", which shall be authorized to supervise the collection and use of patient dispensation information for prescribed Schedule II, III, or IV controlled substances as submitted by dispensers in this state under this section. The joint oversight task force shall consist of the following members:

(a) Two members of the state board of registration for the healing arts who are licensed physicians or surgeons;

(b) Two members of the state board of pharmacy who are licensed pharmacists;

(c) One member of the state board of nursing who is an advanced practice registered nurse; and

(d) One member of the Missouri dental board who is a licensed dentist.

(2) The task force members shall be appointed by their respective state regulatory boards and shall serve a term not to exceed their term on such regulatory board, but in no case shall any term on the joint oversight task force exceed four years. Any member shall serve on the joint oversight

task force until his or her successor is appointed. Any vacancy on the joint oversight task force shall be filled in the same manner as the original appointment. A chair of the joint oversight task force shall be selected by the members of the joint oversight task force.

(3) Members shall serve on the joint oversight task force without compensation, but may be reimbursed for their actual and necessary expenses from moneys appropriated to the office of administration. The office of administration shall provide technical, legal, and administrative support services as required by the joint oversight task force; provided, that the office of administration shall not have access to dispensation information or any other individually identifiable patient information submitted and retained under this section. The joint oversight task force shall be authorized to hire such staff as is necessary, subject to appropriations, to administer the provisions of this section.

(4) The joint oversight task force shall be considered a public body and shall be subject to the provisions of chapter 610.

3. (1) The joint oversight task force shall enter into a contract with a vendor, through a competitive bid process under chapter 34, for the operation of a program to monitor the dispensation of prescribed Schedule II, III, and IV controlled substances. The vendor shall be responsible for the collection and maintenance of patient dispensation information submitted to the vendor by dispensers in this state and shall comply with the provisions of this section and the rules and regulations promulgated by the joint oversight task force.

(2) In addition to appropriations from the general assembly, the joint oversight task force may apply for

available grants and shall be able to accept other gifts, grants, and donations to develop and maintain the program.

(3) The joint oversight task force shall be authorized to cooperate with the MO HealthNet division within the department of social services for the purposes of applying for and accepting any available federal moneys or other grants to develop and maintain the program; provided, that the joint oversight task force shall retain all authority over the program granted to it under this section and the MO HealthNet division shall not have access to the program or the information submitted to the program beyond such access as is granted to the division under this section.

4. Dispensation information submitted to the vendor under this section shall be as follows for each dispensation of a Schedule II, III, or IV controlled substance in this state:

(1) The pharmacy's Drug Enforcement Administration (DEA) number;

(2) The date of the dispensation;

(3) The following, if there is a prescription:

(a) The prescription number or other unique identifier;

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

(c) The prescriber's DEA or National Provider Identifier (NPI) number;

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

(5) The quantity and dosage of the drug dispensed;

(6) The patient's identification number including, but not limited to, any one of the following:

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

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

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

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

The addition of any further information to the list of dispensation information required to be submitted in this subsection shall be the sole purview of the general assembly.

5. Each dispenser shall submit the information to the vendor electronically within twenty-four hours of dispensation. Beginning January 1, 2023, the vendor shall begin phasing in a requirement that dispensers report patient dispensation information in real time, with all dispensation information to be submitted in real time by January 1, 2024. The joint oversight task force may promulgate rules regarding alternative forms of transmission or waivers of the time frame established under this subsection due to unforeseen circumstances.

6. Beginning August 28, 2023, the vendor shall maintain an individual's dispensation information obtained under this section for a maximum of three years from the date of dispensation, after which such information shall be deleted from the program.

7. (1) The vendor shall treat patient dispensation information and any other individually identifiable patient information submitted under this section as protected health information under the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), P.L. 104-191, and the regulations promulgated thereunder. Such information shall only be accessed and utilized in accordance with the privacy and security provisions of HIPAA and the provisions of this section.

(2) Dispensation information and any other individually identifiable patient information submitted under this section shall be confidential and not subject to public disclosure under chapter 610.

8. (1) The patient dispensation information submitted under this section shall only be utilized for the provision of health care services to the patient. Prescribers, dispensers, and other health care providers shall be permitted to access a patient's dispensation information collected by the vendor in course of providing health care services to the patient. The vendor shall provide dispensation information to the individual patient, upon his or her request.

(2) The patient dispensation information submitted under this section shall be shared with any health information exchange operating in this state, upon the request of the health information exchange. Charges assessed to the health information exchange by the vendor shall not exceed the cost of the actual technology connection or recurring maintenance thereof. Any health information exchange receiving patient dispensation information under this subdivision shall comply with the provisions of subsection 7 of this section and such patient dispensation information shall only be utilized in accordance with the provisions of this section. For purposes of this subdivision, "health information exchange" means the electronic exchange of individually identifiable patient information among unaffiliated organizations according to nationally-recognized standards as administered by a health information organization, which shall not include an organized health care arrangement, as defined in 45 CFR 160.103, or a research institution that oversees and

governs the electronic exchange of individually identifiable information among unaffiliated organizations for research purposes only.

9. The dispensation information of MO HealthNet program recipients submitted under this section may be shared with the MO HealthNet division for purposes of providing the division and MO HealthNet providers patient dispensation history and facilitating MO HealthNet claims processing and information retrieval; provided, that no patient dispensation information submitted under this section shall be utilized for any purpose prohibited under this section.

10. The joint oversight task force may provide data to public and private entities for statistical, research, or educational purposes only after removing information that could be used to identify individual patients, prescribers, dispensers, or persons who received dispensations from dispensers.

11. No patient dispensation information shall be provided to local, state, or federal law enforcement or prosecutorial officials, both in-state and out-of-state, or any regulatory board, professional or otherwise, for any purposes other than those explicitly set forth in HIPAA and any regulations promulgated thereunder.

12. No dispensation information submitted under this section shall be used by any local, state, or federal authority to prevent an individual from owning or obtaining a firearm.

13. No dispensation information submitted under this section shall be the basis for probable cause to obtain an arrest or search warrant as part of a criminal investigation.

14. (1) A dispenser who knowingly fails to submit dispensation information to the vendor as required under this section, or who knowingly submits 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 joint oversight task force. 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 purposefully accesses or discloses, or any person authorized to have patient dispensation information under this section who purposefully discloses, such information in violation of this section or purposefully uses such information in a manner and for a purpose in violation of this section is guilty of a class E felony.

15. (1) The provisions of this section shall supercede any local laws, ordinances, orders, rules, or regulations enacted by a county, municipality, or other political subdivision of this state for the purpose of monitoring the prescription or dispensation of prescribed controlled substances within the state. Any such prescription drug monitoring program in operation prior to August 28, 2021, shall cease operation within this state when the vendor's program under this section is available for utilization by prescribers and dispensers throughout the state.

(2) The joint oversight task force may enter into an agreement, or authorize the vendor to enter into an agreement, with any prescription drug monitoring program operated by a county, municipality, or other political

subdivision of this state prior to August 28, 2021, to transfer patient dispensation information from the county, municipality, or other program to the vendor's program created under this section; provided, that such patient dispensation information shall be subject to the provisions of this section.

16. The provisions of this section shall not apply to persons licensed under chapter 340.

17. The joint oversight task force shall promulgate rules and regulations to implement the provisions of this section. 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, 2021, shall be invalid and void.

338.710. 1. There is hereby created in the Missouri board of pharmacy the "RX Cares for Missouri Program". The goal of the program shall be to promote medication safety and to prevent prescription drug abuse, misuse, and diversion in Missouri.

2. The board, in consultation with the department, shall be authorized to expend, allocate, or award funds appropriated to the board to private or public entities to develop or provide programs or education to promote medication safety or to suppress or prevent prescription

drug abuse, misuse, and diversion in the state of Missouri. In no case shall the authorization include, nor the funds be expended for, any state prescription drug monitoring program including, but not limited to, such as are defined in 38 CFR 1.515. Funds disbursed to a state agency under this section may enhance, but shall not supplant, funds otherwise appropriated to such state agency.

3. The board shall be the administrative agency responsible for implementing the program in consultation with the department. The board and the department may enter into interagency agreements between themselves to allow the department to assist in the management or operation of the program. The board may award funds directly to the department to implement, manage, develop, or provide programs or education pursuant to the program.

4. After a full year of program operation, the board shall prepare and submit an evaluation report to the governor and the general assembly describing the operation of the program and the funds allocated. Unless otherwise authorized by the general assembly, the program shall expire on August 28, **[**2019**]** **2026.**

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