

SENATE SUBSTITUTE
FOR
SENATE BILL NO. 63
AN ACT

To amend chapter 195, RSMo, by adding thereto one new section 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. Chapter 195, RSMo, is amended by adding thereto
2 one new section, to be known as section 195.450, to read as
3 follows:

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

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

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

8 (a) A hospital, as such term is defined in section
9 197.020, that distributes such substances for the purpose of
10 inpatient care or dispenses prescriptions for controlled
11 substances at the time of discharge from such facility;

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

14 (c) A wholesale distributor of a controlled substance;

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

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

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

26 2. (1) There is hereby established within the office
27 of administration the "Joint Oversight Task Force for
28 Prescription Drug Monitoring", which shall be authorized to
29 supervise the collection and use of patient dispensation
30 information for prescribed Schedule II, III, or IV
31 controlled substances as submitted by dispensers in this
32 state under this section. The joint oversight task force
33 shall consist of the following members:

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

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

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

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

42 (2) The task force members shall be appointed by their
43 respective state regulatory boards and shall serve a term
44 not to exceed their term on such regulatory board, but in no
45 case shall any term on the joint oversight task force exceed
46 four years. Any member shall serve on the joint oversight
47 task force until his or her successor is appointed. Any
48 vacancy on the joint oversight task force shall be filled in
49 the same manner as the original appointment. A chair of the
50 joint oversight task force shall be selected by the members
51 of the joint oversight task force.

52 (3) Members shall serve on the joint oversight task
53 force without compensation, but may be reimbursed for their
54 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.

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.

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

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

94 (2) The date of the dispensation;

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

96 (a) The prescription number or other unique identifier;

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

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

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

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

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

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

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

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

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

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

114 5. Each dispenser shall submit the information to the
115 vendor electronically within twenty-four hours of
116 dispensation. Beginning January 1, 2023, the vendor shall
117 begin phasing in a requirement that dispensers report
118 patient dispensation information in real time, with all
119 dispensation information to be submitted in real time by
120 January 1, 2024. The joint oversight task force may

121 promulgate rules regarding alternative forms of transmission
122 or waivers of the time frame established under this
123 subsection due to unforeseen circumstances.

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

129 7. (1) The vendor shall treat patient dispensation
130 information and any other individually identifiable patient
131 information submitted under this section as protected health
132 information under the federal Health Insurance Portability
133 and Accountability Act of 1996 (HIPAA), P.L. 104-191, and
134 the regulations promulgated thereunder. Such information
135 shall only be accessed and utilized in accordance with the
136 privacy and security provisions of HIPAA and the provisions
137 of this section.

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

142 8. (1) The patient dispensation information submitted
143 under this section shall only be utilized for the provision
144 of health care services to the patient. Prescribers,
145 dispensers, and other health care providers shall be
146 permitted to access a patient's dispensation information
147 collected by the vendor in course of providing health care
148 services to the patient. The vendor shall provide
149 dispensation information to the individual patient, upon his
150 or her request.

151 (2) The patient dispensation information submitted
152 under this section shall be shared with any health
153 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,

186 dispensers, or persons who received dispensations from
187 dispensers.

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

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

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

201 14. (1) A dispenser who knowingly fails to submit
202 dispensation information to the vendor as required under
203 this section, or who knowingly submits incorrect
204 dispensation information, shall be subject to an
205 administrative penalty in the amount of one thousand dollars
206 for each violation. The penalty shall be assessed through
207 an order issued by the joint oversight task force. Any
208 person subject to an administrative penalty may appeal to
209 the administrative hearing commission under the provisions
210 of chapter 621.

211 (2) Any person who unlawfully and purposefully
212 accesses or discloses, or any person authorized to have
213 patient dispensation information under this section who
214 purposefully discloses, such information in violation of
215 this section or purposefully uses such information in a
216 manner and for a purpose in violation of this section is
217 guilty of a class E felony.

218 15. (1) The provisions of this section shall
219 supercede any local laws, ordinances, orders, rules, or
220 regulations enacted by a county, municipality, or other
221 political subdivision of this state for the purpose of
222 monitoring the prescription or dispensation of prescribed
223 controlled substances within the state. Any such
224 prescription drug monitoring program in operation prior to
225 August 28, 2021, shall cease operation within this state
226 when the vendor's program under this section is available
227 for utilization by prescribers and dispensers throughout the
228 state.

229 (2) The joint oversight task force may enter into an
230 agreement, or authorize the vendor to enter into an
231 agreement, with any prescription drug monitoring program
232 operated by a county, municipality, or other political
233 subdivision of this state prior to August 28, 2021, to
234 transfer patient dispensation information from the county,
235 municipality, or other program to the vendor's program
236 created under this section; provided, that such patient
237 dispensation information shall be subject to the provisions
238 of this section.

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

241 17. The joint oversight task force shall promulgate
242 rules and regulations to implement the provisions of this
243 section. Any rule or portion of a rule, as that term is
244 defined in section 536.010, that is created under the
245 authority delegated in this section shall become effective
246 only if it complies with and is subject to all of the
247 provisions of chapter 536 and, if applicable, section
248 536.028. This section and chapter 536 are nonseverable and
249 if any of the powers vested with the general assembly
250 pursuant to chapter 536 to review, to delay the effective

251 date, or to disapprove and annul a rule are subsequently
252 held unconstitutional, then the grant of rulemaking
253 authority and any rule proposed or adopted after August 28,
254 2021, shall be invalid and void.