

FIRST REGULAR SESSION

HOUSE BILL NO. 1123

95TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE COOPER.

2072L.011

D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To amend chapter 195, RSMo, by adding thereto seven new sections relating to the monitoring of controlled substances, with penalty provisions and an effective date.

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 sections, to be known as sections 195.378, 195.381, 195.384, 195.387, 195.390, 195.393, and 195.396, to read as follows:

195.378. 1. Sections 195.378 to 195.396 shall be known and may be cited as the "Controlled Substances Monitoring Act".

2. Notwithstanding the provisions of section 195.010, as used in sections 195.378 to 195.396, the following terms mean:

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

(2) "Department", the department of health and senior services;

(3) "Dispenser", a person who delivers a schedule II, III, IV, or V controlled substance to the ultimate user, but does not include:

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

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

(c) A wholesale distributor of a schedule II, III, IV, or V controlled substance;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

15 (d) An ambulatory surgical center, as defined in section 197.200, RSMo, that
16 distributes such substances for the purpose of providing care in such center or dispenses
17 controlled substances at the time of discharge from such center;

18 (e) A veterinarian licensed under chapter 340, RSMo, who dispenses such
19 substances to animals from such veterinarian's own inventory;

20 (4) "Patient", a person or animal who is the ultimate user of a controlled substance
21 for whom a prescription is issued or for whom a controlled substance is dispensed;

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

195.381. 1. Subject to appropriations, the department of health and senior services
2 shall establish and maintain a program for the monitoring of prescribing and dispensing
3 of all schedule II, III, IV, or V controlled substances, except schedule V controlled
4 substances containing any detectable amount of pseudoephedrine that do not require a
5 prescription, by all professionals licensed to prescribe or dispense such substances in this
6 state.

7 2. Each dispenser shall submit to the department by electronic means information
8 regarding each dispensing of a controlled substance included in subsection 1 of this section.
9 The information required by the department to be submitted for each dispensing may
10 include, but shall not be limited to:

11 (1) The dispenser's United States Drug Enforcement Administration registration
12 number;

13 (2) The date the controlled substance is sold or the prescription is filled;

14 (3) The prescription number, if applicable;

15 (4) Whether the prescription is new or a refill;

16 (5) The NDC code for the controlled substance dispensed;

17 (6) The number of days' supply the controlled substance is dispensed;

18 (7) The quantity dispensed;

19 (8) Any identification issued by a state or federal government to the patient, or the
20 unique patient identifier assigned to the patient by the payor or pharmacy benefit
21 manager, or any other acceptable identification as defined by the department by rule;

22 (9) The patient's name, address, and date of birth, or if the patient is an animal, the
23 owner's name, address, and date of birth;

24 (10) The prescriber's United States Drug Enforcement Administration registration
25 number, if applicable;

26 (11) The date the prescription is issued by the prescriber, if applicable; and

27 (12) The source of payment for the controlled substance, as defined by rule of the
28 department.

29 3. Each dispenser shall submit the information in accordance with transmission
30 methods and frequency established by the department; except that, each dispenser shall
31 report at least every thirty days between the first and fifteenth of the month following the
32 month the drug was dispensed.

33 4. The department may issue a waiver to a dispenser who is unable to submit
34 dispensing information by electronic means. Such waiver may permit the dispenser to
35 submit dispensing information by paper form or other means, provided all information
36 required in subsection 2 of this section is submitted in such alternative format.

 195.384. 1. Controlled substance dispensing information submitted to the
2 department shall be confidential and not subject to public disclosure under chapter 610,
3 RSMo, except as provided in subsections 3 to 5 of this section.

4 2. The department shall maintain procedures to ensure that the privacy and
5 confidentiality of patients and patient information collected, recorded, transmitted, and
6 maintained is not disclosed to persons except as provided in subsections 3 to 5 of this
7 section.

8 3. The department shall review the dispensing information and if there is
9 reasonable cause to believe a violation of law or breach of professional standards may have
10 occurred, the department shall notify the appropriate law enforcement or professional
11 licensing, certification, or regulatory agency or entity, and provide dispensing information
12 required for an investigation.

13 4. The department may provide data in the controlled substances monitoring
14 program to the following persons:

15 (1) Persons authorized to prescribe or dispense controlled substances for the
16 purpose of providing medical or pharmaceutical care for their patients;

17 (2) An individual who requests his or her own controlled substance monitoring
18 information in accordance with state law;

19 (3) The state board of pharmacy;

20 (4) Any state board charged with regulating a professional who has the authority
21 to prescribe controlled substances that requests data related to a specific professional
22 under the authority of such board;

23 (5) Federal, state, and local law enforcement or prosecutorial officials engaged in
24 the administration, investigation, or enforcement of the laws governing licit drugs based
25 on a specific case or under court order;

26 (6) The department of social services regarding MO HealthNet participants;

- 27 (7) A judge or other judicial authority under a court order;
- 28 (8) Personnel of the department of health and senior services for the administration
29 and enforcement of sections 195.378 to 195.396; and
- 30 (9) The department of mental health regarding department program recipients
31 receiving medication or medication-related services.
- 32 5. The department may provide data to public or private entities for statistical,
33 research, or educational purposes after removing information that could be used to identify
34 individual patients or persons who received prescriptions from dispensers.
- 35 6. Nothing in sections 195.378 to 195.396 shall require or otherwise obligate a
36 dispenser or prescriber to access or check the information in the controlled substance
37 monitoring program prior to dispensing, prescribing, or administering medications or as
38 part of their professional practice. Dispensers and prescribers shall not be liable to any
39 person for any claim of damages as a result of accessing or failing to access the information
40 in the controlled substance monitoring program and no lawsuit shall be predicated
41 thereon.

 195.387. 1. The department is authorized to contract with any other agency of this
2 state or with a private vendor, as necessary, to ensure the effective operation of the
3 controlled substance monitoring program. Any contractor, person, or other entity with
4 access to controlled substance monitoring information shall comply with the provisions
5 regarding confidentiality of controlled substance information in section 195.384.

6 2. Any contractor, person, or other entity with access to controlled substance
7 monitoring information who knowingly discloses controlled substance monitoring
8 information other than as provided in sections 195.378 to 195.396 or who uses such
9 information in a manner and for a purpose in violation of sections 195.378 to 195.396:

10 (1) Is guilty of a class A misdemeanor for the first violation and a class D felony for
11 any subsequent violations; and

12 (2) Is liable to the state for civil monetary penalties of up to twenty-five thousand
13 dollars for each violation.

 195.390. The department shall promulgate rules setting forth the procedures and
2 methods of implementing sections 195.378 to 195.396, which shall be consistent with
3 applicable federal regulations. Any rule or portion of a rule, as that term is defined in
4 section 536.010, RSMo, that is created under the authority delegated in this section shall
5 become effective only if it complies with and is subject to all of the provisions of chapter
6 536, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536,
7 RSMo, are nonseverable and if any of the powers vested with the general assembly
8 pursuant to chapter 536, RSMo, to review, to delay the effective date, or to disapprove and

9 annul a rule are subsequently held unconstitutional, then the grant of rulemaking
10 authority and any rule proposed or adopted after August 28, 2009, shall be invalid and
11 void.

195.393. A dispenser who knowingly fails to submit controlled substance
2 monitoring information to the department as required in sections 195.378 to 195.396 or
3 knowingly submits incorrect prescription information is guilty of a class A misdemeanor.

195.396. 1. The department shall implement the following education courses:

2 (1) An orientation course during the implementation phase of the controlled
3 substance monitoring program established in section 195.381;

4 (2) A course for persons who are authorized to access the controlled substance
5 monitoring information but who did not participate in the orientation course in subdivision
6 (1) of this subsection; and

7 (3) A course for persons who are authorized to access the controlled substance
8 monitoring information but who have violated laws or breached occupational standards
9 involving dispensing, prescribing, and use of substances monitored by the controlled
10 substance monitoring program established in section 195.381.

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12 As appropriate, the department shall develop the content of the education courses
13 described in this subsection.

14 2. The department shall, when appropriate, work with associations for impaired
15 professionals to ensure intervention, treatment, and ongoing monitoring and follow-up.

Section B. Section A of this act shall become effective January 1, 2010.

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