FIRST REGULAR SESSION

HOUSE BILL NO. 333

94TH GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVES LIPKE (Sponsor) AND PAGE (Co-sponsor).

Read 1st time January 11, 2007 and copies ordered printed.

D. ADAM CRUMBLISS, Chief Clerk

0852L.02I

AN ACT

To amend chapter 195, RSMo, by adding thereto nine new sections relating to a controlled substances dispensation monitoring program, 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 nine new sections, to be

- 2 known as sections 195.450, 195.453, 195.456, 195.459, 195.462, 195.465, 195.468, 195.471,
- 3 and 195.474, to read as follows:
 - 195.450. 1. Sections 195.450 to 195.474 shall be known and may be cited as the
- 2 "Prescription Drug Monitoring Program Act".
 - 2. As used in sections 195.450 to 195.474, the following terms mean:
- 4 (1) "Controlled substance", the same meaning given such term in section 195.010;
 - (2) "Department", the department of health and senior services;
- 6 (3) "Dispenser", a person who delivers a schedule II, III, IV, or V controlled 7 substance to the ultimate user, but does not include:
- 8 (a) A hospital as defined in section 197.020, RSMo, that distributes such substances
- 9 for the purpose of inpatient hospital care or dispenses prescriptions for controlled 10 substances at the time of discharge from an inpatient stay at such facility;
- 11 (b) A practitioner or other authorized person who administers such a substance;
- 12 **or**

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13 (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.

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14 (4) "Patient", a person or animal who is the ultimate user of a drug for whom a 15 prescription is issued or for whom a drug is dispensed;

- 16 (5) "Schedule II, III, IV, or V controlled substance", a controlled substance that 17 is listed in schedules II, III, IV, or V of the schedules provided under this chapter or the 18 Federal Controlled Substances Act, 21 U.S.C. Section 812.
- 195.453. 1. Subject to appropriations, the department of health and senior services shall establish and maintain a program for the monitoring of prescribing and dispensing of all schedule II, III, IV, and V controlled substances, except schedule V controlled substance containing any detectable amount of pseudoephedrine, by all professionals licensed to prescribe or dispense such substances in this state. The department may apply for any available grants and accept any gifts, grants, or donations to assist in developing and maintaining 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 shall include, but not be limited to:
 - (1) The dispenser identification number;
- 12 **(2)** The date of the dispensation;
- 13 **(3) If there is a prescription:**

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- 14 (a) The prescription number;
- 15 **(b)** Whether the prescription is new or a refill;
- 16 (c) The prescriber identification number;
- 17 (d) The date the prescription is issued by the prescriber;
- 18 (e) The person who receives the prescription from the dispenser, if other than the patient;
 - (f) The source of payment for the prescription;
 - (4) The NDC code for the drug dispensed;
- 22 (5) The number of days' supply of the drug;
- 23 (6) The quantity dispensed;
- 24 (7) The patient identification number;
- 25 (8) The patient's name, address, and date of birth.
 - 3. Each dispenser shall submit the information in accordance with transmission methods and frequency established by the department; except that, each dispenser shall report at least every thirty days between the first and fifteenth of the month following the month of the dispensation.
- 4. The department may issue a waiver to a dispenser that is unable to submit dispensation information by electronic means. Such waiver may permit the dispenser to

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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.

- 195.456. 1. Dispensation information submitted to the department shall be confidential and not subject to public disclosure under chapter 610, RSMo, 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 personnel information collected, recorded, transmitted, and maintained is 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 dispensation information required for an investigation.
- 4. The department may provide data in the controlled substances dispensation monitoring 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 monitoring information in accordance with state law;
 - (3) The state board of pharmacy;
- (4) Any state board charged with regulating a professional that has the authority to prescribe or dispense controlled substances that requests data related to a specific professional under the authority of that board;
- (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 licit drugs based on a specific case and under a subpoena or court order;
- (6) The family support division within the department of social services regarding Medicaid program recipients;
 - (7) A judge or other judicial authority under a subpoena or court order; and
- (8) Personnel of the department of health and senior services for the administration and enforcement of sections 195.450 to 195.474.
- 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 or persons who received dispensations from dispensers.

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195.459. 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 prescription monitoring program. Any contractor shall comply with the provisions
4 regarding confidentiality of prescription information in section 195.456.

195.462. The department shall promulgate rules setting forth the procedures and methods of implementing sections 195.450 to 195.471. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, 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, RSMo, and, if applicable, section 536.028, RSMo. This section and chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, 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, 2007, shall be invalid and void.

- 195.465. 1. A dispenser who knowingly fails to submit dispensation monitoring information to the department as required in sections 195.450 to 195.474 or knowingly submits the incorrect dispensation information is guilty of a class A misdemeanor.
- 2. A person authorized to have dispensation monitoring information under sections 195.450 to 195.474 who knowingly discloses such information in violation of sections 195.450 to 195.474 or who uses such information in a manner and for a purpose in violation of sections 195.450 to 195.474 is guilty of a class A misdemeanor.
 - 195.468. 1. The department shall implement the following education courses:
- 2 (1) An orientation course during the implementation phase of the dispensation 3 monitoring program established in section 195.453;
 - (2) A course for persons who are authorized to access the dispensation monitoring information but who did not participate in the orientation course;
 - (3) A course for persons who are authorized to access the dispensation monitoring information but who have violated laws or breached occupational standards involving dispensing, prescribing, and use of substances monitored by the dispensation monitoring program established in section 195.453;

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- When appropriate, the department shall develop the content of the education courses described in subdivisions (1) to (3) of this subsection.
 - 2. The department shall, when appropriate:
- 14 (1) Work with associations for impaired professionals to ensure intervention, 15 treatment, and ongoing monitoring and followup; and

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16 (2) Encourage individual patients who are identified and who have become 17 addicted to substances monitored by the dispensation monitoring program established in 18 section 195.453 to receive addiction treatment.

195.471. The department of health and senior services shall develop and implement an electronic logbook to monitor the sale of schedule V controlled substances containing any detectable amount of pseudoephedrine. All pharmacists and registered pharmacy technicians shall submit their logbooks, as required under section 195.017, electronically in accordance with rules promulgated by the department.

195.474. Pursuant to section 23.253, RSMo, of the Missouri sunshine act:

- (1) The provisions of the new program authorized under sections 195.450 to 195.474 shall automatically sunset six years after the effective date of sections 195.450 to 195.474 unless reauthorized by an act of the general assembly; and
- (2) If such program is reauthorized, the program authorized under sections 195.450 to 195.474 shall automatically sunset six years after the effective date of the reauthorization of sections 195.450 to 195.474; and
- (3) Sections 195.450 to 195.474 shall terminate on September first of the calendar year immediately following the calendar year in which the program authorized under sections 195.450 to 195.474 is sunset.

Section B. Section A of this act shall become effective January 1, 2008.

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