FIRST REGULAR SESSION

SENATE BILL NO. 146

97TH GENERAL ASSEMBLY

INTRODUCED BY SENATOR SCHAAF.

Read 1st time January 16, 2013, and ordered printed.

TERRY L. SPIELER, Secretary.

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AN ACT

To amend chapter 195, RSMo, by adding thereto nine new sections relating to a prescription drug monitoring program, with penalty provisions and a referendum clause.

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 known as sections 195.450, 195.453, 195.456, 195.459, 195.462, 195.465, 195.468, 195.474, and 195.477, to read as follows:

195.450. 1. Sections 195.450 to 195.477 shall be known and may be cited as the "Prescription Drug Monitoring Program Act".

2. As used in sections 195.450 to 195.477, the following terms mean:

(1) "Cash transactions", a payment to a dispenser by a patient by means other than through a third party payer which conducts business for the purpose of making payment for health care services delivered to a patient, including but not limited to a health carrier defined under section 376.1350 and self-insured entities;

(2) "Controlled substance", the same meaning given such term in section 195.010;

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

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

(a) A hospital, as 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 at such facility;

(b) A practitioner or other authorized person who administers

such a substance; or

(c) A wholesale distributor of a schedule II controlled substance or a schedule III controlled substance containing dihydrocodone;

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

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

3. Notwithstanding any other law to the contrary, the provisions of sections 195.450 to 195.477 shall not apply to persons licensed under chapter 340.

195.453. 1. The department of health and senior services shall establish and maintain a program for the monitoring of prescribing and dispensing of all schedule II controlled substances and all schedule III controlled substances containing dihydrocodone by all professionals licensed to prescribe or dispense such substances in this state and where such substances are purchased by a cash transaction. The department may apply for any available grants and shall accept any gifts, grants, or donations to develop and maintain the program. All funding for the prescription drug monitoring program shall be provided exclusively by gifts, grants, and donations.

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 pharmacy federal Drug Enforcement Administration "DEA" number;

(2) The date of the dispensation;

(3) If there is a prescription:

(a) The prescription number;

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

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

(d) The date the prescription is issued by the prescriber;

(e) The source of payment for the prescription;

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

(5) The number of days' supply of the drug;

(6) The quantity dispensed;

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

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

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

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

3. Each dispenser shall submit the information in accordance with transmission standards established by the American Society for Automation in Pharmacy, or any successor organization, and shall report data within every seven days except that such information under this subsection shall be transmitted immediately once the department has provided for the information to be transmitted in real-time. Such real-time transmission shall occur by August 28, 2016, or sooner if such technology becomes available.

4. (1) 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 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.

(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 accordance with the time frame established in subsection 3 of this section due to unforseen circumstances. In cases where an extension is granted, dispensers shall be responsible for reporting the required data in a subsequent file.

5. The department shall reimburse each dispenser for the fees and other direct costs of transmitting the information required by this section.

195.456. 1. Dispensation information submitted to the department shall be confidential and not subject to public disclosure

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under chapter 610 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 prescription drug 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 195.477.

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,

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prescribers, dispensers, or persons who received dispensations from dispensers.

6. A pharmacist or prescriber shall not be held liable for damages to any person in any civil action for injury, death, or loss to person or property on the basis that the pharmacist or prescriber did or did not seek or obtain information from the database.

7. The department shall not retain the data obtained from the prescription drug monitoring program under sections 195.450 to 195.477 for more than ninety days after the prescription was written or was filled by the patient, whichever is sooner.

195.459. The department is authorized to contract with any other agency of this state or any other state with a private vendor, or any state government that currently runs a prescription monitoring program. Any contractor shall comply with the provisions 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 195.474. 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 the effective date of this act 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 195.477, or knowingly submits the 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 director of the department. Any person subject to an administrative penalty may appeal to the administrative hearing commission under the provisions of chapter 621.

2. A person authorized to have dispensation monitoring

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information under sections 195.450 to 195.477 who knowingly discloses such information in violation of sections 195.450 to 195.477 or who uses such information in a manner and for a purpose in violation of sections 195.450 to 195.477 is guilty of a class A misdemeanor.

3. Neither the sovereign nor the official immunity doctrines shall apply to a person or a department authorized to have private prescription-related medical information under sections 195.450 to 195.477 in instances when such information is disclosed. If the department is responsible in whole or in part for private prescription-related medical information being negligently disclosed, then the person whose information was disclosed shall have a cause of action to recover liquidated damages in the amount of twenty-five thousand dollars in addition to compensatory economic and non-economic damages, attorney fees, and court costs. If it is determined by a court of competent jurisdiction that such disclosure was done intentionally and maliciously, then the person shall be entitled to punitive damages in addition to the damages above. None of the foregoing damages shall be paid out from the state legal expense fund but shall be paid out of the appropriations to the department for its operations.

195.468. 1. The department shall create and implement the following education courses:

(1) An orientation course during the implementation phase of the provisions 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 provisions established in section 195.453.

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:

(1) Work with associations for impaired professionals to ensure intervention, treatment, and ongoing monitoring and followup; and

(2) Encourage individual patients who are identified and who

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have become addicted to substances monitored by the drug monitoring program under sections 195.450 to 195.477 to receive addiction treatment.

195.474. Under section 23.253 of the Missouri sunset 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.

195.477. 1. By no later than January 1, 2016, the bureau of narcotics and dangerous drugs within the department of health and senior services shall establish a two-year statewide pilot project for the reporting of fraudulently obtained prescription controlled substances. The pilot project shall include the following:

(1) Provide a toll-free number for reporting to the bureau by physicians, pharmacists, and other health care professionals with prescriptive authority who have reason to believe that a person is fraudulently attempting to obtain a prescription for a controlled substance or is attempting to obtain an excessive amount of a controlled substance by prescription;

(2) Establish a system within the bureau for receiving such reports under subdivision (1) of this subsection along with any evidence offered or submitted by the reporter which indicates the fraud; and

(3) Forward such reports, along with any evidence offered or submitted to the appropriate prosecuting attorney or the state attorney general for investigation and prosecution.

2. On or before February 1, 2015, and February 1, 2016, the bureau of narcotics and dangerous drugs shall submit a report to the general assembly detailing the following specifics regarding the pilot project:

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(1) The number of reports received under this section;

(2) The type of evidence offered or submitted indicating the fraud;

(3) The number of referrals to the attorney general and each local prosecuting attorney;

(4) The number of cases investigated and prosecuted as a result of such reporting, and the number of convictions or pleas resulting from such investigations and prosecutions. The attorney general and local prosecuting attorneys shall cooperate with the bureau in the submission and collection of the information necessary for inclusion in the report; and

(5) Any recommendations regarding continuance of and improvements in the pilot project.

Nothing in this section shall be construed as authorizing the inclusion or release of any identifying information of any reporter or person who is identified as a person who is attempting to fraudulently obtain prescription controlled substances.

3. Any person who in good faith reports to the bureau under this section shall be immune from any civil or criminal liability as the result of such good faith reporting.

4. The department of health and senior services may promulgate rules 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 the effective date of this act shall be invalid and void.

5. The department shall implement and provide all monitoring under the pilot project with existing department employees. Nothing in this section shall be construed as authorizing the hiring of additional employees to implement this pilot project and the department is required to implement this pilot project upon receipt of gifts, grants, and donations received for such purpose, without any

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additional state appropriations or department staff; except that, the department may enter into agreements with other state agencies or a private vendor, as necessary, to ensure the effective operations of the program if such agreements are funded solely from gifts, grants, and donations. Any agency or private vendor entering into an agreement with the department for the pilot project shall comply with the confidentiality provisions regarding the prescription information under section 195.456.

6. Under section 23.253 of the Missouri sunset act:

(1) The provisions of the new program authorized under this section shall automatically sunset three years after the effective date of this section unless reauthorized by an act of the general assembly; and

(2) If such program is reauthorized, the program authorized under this section shall automatically sunset twelve years after the effective date of the reauthorization of this section; and

(3) This section shall terminate on September first of the calendar year immediately following the calendar year in which the program authorized under this section is sunset.

Section B. This act is hereby submitted to the qualified voters of this state for approval or rejection at an election which is hereby ordered and which shall be held and conducted on Tuesday next following the first Monday in November, 2014, pursuant to the laws and constitutional provisions of this state for the submission of referendum measures by the general assembly, and this act shall become effective when approved by a majority of the votes cast thereon at such election and not otherwise.

Section C. Pursuant to chapter 116, RSMo, and other applicable constitutional provisions and laws of this state allowing the general assembly to adopt ballot language for the submission of this act to the voters of this state, the official ballot title of this act shall be as follows:

"Shall the Missouri Statutes be amended to create a database of the controlled substances dispensed to each person, searchable by name, drug, prescriber, and other elements, and accessible by all physicians and others as authorized, with the intent of preventing criminal doctor shopping?"

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