SECOND REGULAR SESSION

SENATE COMMITTEE SUBSTITUTE FOR

SENATE BILL NO. 710

96TH GENERAL ASSEMBLY

Reported from the Committee on Financial and Governmental Organizations and Elections, February 23, 2012, with recommendation that the Senate Committee Substitute do pass.

TERRY L. SPIELER, Secretary.

4886S.05C

AN ACT

To repeal sections 195.060, 195.080, and 334.747, RSMo, and to enact in lieu thereof twelve new sections relating to a prescription drug monitoring program, with penalty provisions.

Be it enacted by the General Assembly of the State of Missouri, as follows:

Section A. Sections 195.060, 195.080, and 334.747, RSMo, is repealed and twelve new sections enacted in lieu thereof, to be known as sections 195.060, 195.080, 195.450, 195.453, 195.456, 195.459, 195.462, 195.465, 195.468, 195.474, 195.477, and 334.747, to read as follows:

195.060. 1. Except as provided in subsection **[**3**]** **4** of this section, a pharmacist, in good faith, may sell and dispense controlled substances to any person only upon a prescription of a practitioner as authorized by statute, provided that the controlled substances listed in Schedule V may be sold without prescription in accordance with regulations of the department of health and senior services. All written prescriptions shall be signed by the person prescribing the same. All prescriptions shall be dated on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is prescribed, and the full name, address, and the registry number under the federal controlled substances laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of the animal for which the drug is prescribed. The person filling the prescription shall either write the date of filling and his own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The

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

prescription or electronic prescription information shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of two years, so as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this law. No prescription for a drug in Schedule I or II shall be filled more than six months after the date prescribed; no prescription for a drug in schedule I or II shall be refilled; no prescription for a drug in Schedule III or IV shall be filled or refilled more than six months after the date of the original prescription or be refilled more than five times unless renewed by the practitioner.

2. **A pharmacist, in good faith, may sell and dispense controlled substances to any person upon a prescription of a practitioner located in another state, provided that the:**

(1) Prescription was issued according to and in compliance with the applicable laws of that state and the United States; and

(2) Quantity limitations in subsection 2 of section 195.080 apply to prescriptions dispensed to patients located in this state.

3. The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in such drugs, may sell the stock to a manufacturer, wholesaler, or pharmacist, but only on an official written order.

[3.**]** **4.** A pharmacist, in good faith, may sell and dispense any Schedule II drug or drugs to any person in emergency situations as defined by rule of the department of health and senior services upon an oral prescription by an authorized practitioner.

[4.**]** **5.** Except where a bona fide physician-patient-pharmacist relationship exists, prescriptions for narcotics or hallucinogenic drugs shall not be delivered to or for an ultimate user or agent by mail or other common carrier.

195.080. 1. Except as otherwise in sections 195.005 to 195.425 specifically provided, sections 195.005 to 195.425 shall not apply to the following cases: prescribing, administering, dispensing or selling at retail of liniments, ointments, and other preparations that are susceptible of external use only and that contain controlled substances in such combinations of drugs as to prevent the drugs from being readily extracted from such liniments, ointments, or preparations, except that sections 195.005 to 195.425 shall apply to all liniments, ointments, and other preparations that contain coca leaves in any quantity or combination.

2. The quantity of Schedule II controlled substances prescribed or dispensed at any one time shall be limited to a thirty-day supply. The quantity

of Schedule III, IV or V controlled substances prescribed or dispensed at any one time shall be limited to a ninety-day supply and shall be prescribed and dispensed in compliance with the general provisions of sections 195.005 to 195.425. The supply limitations provided in this subsection may be increased up to three months if the physician describes on the prescription form or indicates via telephone, fax, or electronic communication to the pharmacy to be entered on or attached to the prescription form the medical reason for requiring the larger supply. The supply limitations provided in this subsection shall not apply if**:**

(1) The prescription is issued by a practitioner located in another state according to and in compliance with the applicable laws of that state and the United States and dispensed to a patient located in another state; or

(2) The prescription is dispensed directly to a member of the United States armed forces serving outside the United States.

3. The partial filling of a prescription for a Schedule II substance is permissible as defined by regulation by the department of health and senior services.

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

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

(3) "Dispenser", a person who delivers a schedule II, III, or IV controlled substance 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, III, or IV controlled substance;

(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;

(5) "Schedule II, III, or IV controlled substance", a controlled

substance that is listed in schedules II, III, or IV 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 this section 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, III, and IV controlled substances by all professionals licensed to prescribe or dispense such substances in this state. 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 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;

(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 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;

(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 and shall report data every seven days.

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 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 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 195.477.

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, prescribers, or persons who received dispensations from dispensers.

6. Nothing in sections 195.450 to 195.477 shall be construed to require a pharmacist or prescriber to obtain information about a patient from the database. 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.

195.459. The department is authorized to contract with any other agency of this state or any other state with a private vendor, as necessary, to ensure the effective operation of the 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 August 28, 2012, 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 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.

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

(1) An orientation course during the implementation phase of the dispensation 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.

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 have become addicted to substances monitored by the dispensation monitoring program established in section 195.453 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, 2014, 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, 2014, and February 1, 2015, the bureau of narcotics and dangerous drugs shall submit a report to the general assembly detailing the following specifics regarding the pilot

project:

(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 August 28, 2012, 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 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.

334.747. 1. A physician assistant with a certificate of controlled substance prescriptive authority as provided in this section may prescribe any controlled substance listed in schedule III, IV, or V of section 195.017 when delegated the authority to prescribe controlled substances in a supervision agreement. Such authority shall be listed on the supervision verification form on file with the state board of healing arts. The supervising physician shall maintain the right to limit a specific scheduled drug or scheduled drug category that the physician assistant is permitted to prescribe. Any limitations shall be listed on the supervision form. Physician assistants shall not prescribe controlled substances for themselves or members of their families. Schedule III controlled substances shall be limited to a five-day supply without refill. Physician assistants who are authorized to prescribe controlled substances under this section shall register with the federal Drug Enforcement Administration and the state bureau of narcotics and dangerous drugs, and shall include **[**such**]** **the Drug Enforcement Administration** registration **[**numbers**]** **number** on prescriptions for controlled substances.

2. The supervising physician shall be responsible to determine and document the completion of at least one hundred twenty hours in a four-month period by the physician assistant during which the physician assistant shall practice with the supervising physician on-site prior to prescribing controlled substances when the supervising physician is not on-site. Such limitation shall not apply to physician assistants of population-based public health services as defined in 20 CSR 2150-5.100 as of April 30, 2009.

3. A physician assistant shall receive a certificate of controlled substance prescriptive authority from the board of healing arts upon verification of the completion of the following educational requirements:

(1) Successful completion of an advanced pharmacology course that includes clinical training in the prescription of drugs, medicines, and therapeutic devices. A course or courses with advanced pharmacological content in a physician assistant program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency shall satisfy such requirement;

(2) Completion of a minimum of three hundred clock hours of clinical training by the supervising physician in the prescription of drugs, medicines, and therapeutic devices;

(3) Completion of a minimum of one year of supervised clinical practice or supervised clinical rotations. One year of clinical rotations in a program accredited by the Accreditation Review Commission on Education for the Physician Assistant (ARC-PA) or its predecessor agency, which includes pharmacotherapeutics as a component of its clinical training, shall satisfy such requirement. Proof of such training shall serve to document experience in the prescribing of drugs, medicines, and therapeutic devices;

(4) A physician assistant previously licensed in a jurisdiction where physician assistants are authorized to prescribe controlled substances may obtain a state bureau of narcotics and dangerous drugs registration if a supervising physician can attest that the physician assistant has met the requirements of subdivisions (1) to (3) of this subsection and provides documentation of existing federal Drug Enforcement Agency registration.

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