SENATE COMMITTEE SUBSTITUTE

FOR

SENATE BILLS NOS. 63 & 111

AN ACT
To repeal section 195.015 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, section 195.050 as enacted by senate bill no. 491, ninety-seventh general assembly, second regular session, and section 195.050 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, 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. Section 195.015 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, section 195.050 as enacted by senate bill no. 491, ninety-seventh general assembly, second regular session, and section 195.050 as enacted by senate bills nos. 215 & 58, eighty-fifth general assembly, first regular session, RSMo, are repealed and twelve new sections enacted in lieu thereof, to be known as sections 195.015, 195.050, 195.050, 195.450, 195.453, 195.456, 195.458, 195.459, 195.462, 195.465, 195.466, and 195.468, to read as follows:

195.015. 1. The department of health and senior services shall administer sections 195.005 to [195.425] 195.468 and may add substances to the schedules after public notice and hearing. In making a determination regarding a substance, the department of health and senior services shall consider the following:

(1) The actual or relative potential for abuse;

(2) The scientific evidence of its pharmacological effect, if known;

(3) The state of current scientific knowledge regarding
the substance;

(4) The history and current pattern of abuse;

(5) The scope, duration, and significance of abuse;

(6) The risk to the public health;

(7) The potential of the substance to produce psychic or physiological dependence liability; and

(8) Whether the substance is an immediate precursor of a substance already controlled under sections 195.005 to 195.425.

2. After considering the factors enumerated in subsection 1 of this section the department of health and senior services shall make findings with respect thereto and issue a rule controlling the substance if it finds the substance has a potential for abuse.

3. If the department of health and senior services designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

4. If any substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice thereof is given to the department of health and senior services, the department of health and senior services shall similarly control the substance under sections 195.005 to 195.425 after the expiration of thirty days from publication in the federal register of a final order designating a substance as a controlled substance or rescheduling or deleting a substance, unless within that thirty-day period, the department of health and senior services objects to inclusion, rescheduling, or
deletion. In that case, the department of health and senior services shall publish the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the department of health and senior services shall publish its decision, which shall be final unless altered by statute. Upon publication of objection to inclusion, rescheduling or deletion under sections 195.005 to 195.425 by the department of health and senior services, control under sections 195.005 to 195.425 is stayed as to the substance in question until the department of health and senior services publishes its decision.

5. The department of health and senior services shall exclude any nonnarcotic substance from a schedule if such substance may, under the federal Food, Drug, and Cosmetic Act and the law of this state, be lawfully sold over the counter without a prescription.

6. The department of health and senior services shall prepare a list of all drugs falling within the purview of controlled substances. Upon preparation, a copy of the list shall be filed in the office of the secretary of state.

195.050. 1. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:

(1) To a manufacturer, wholesaler, or pharmacy;
(2) To a physician, dentist, podiatrist or veterinarian;
(3) To a person in charge of a hospital, but only for use in that hospital;
(4) To a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes.
2. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:

   (1) On a special written order accompanied by a certificate of exemption, as required by federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal or insular government, purchasing, receiving, possessing, or dispensing controlled substances by reason of his or her official duties;

   (2) To a master of a ship or person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft, when not in port; provided, such controlled substances shall be sold to the master of such ship or person in charge of such aircraft only in pursuance of a special order form approved by a commissioned medical officer or acting surgeon of the United States Public Health Service;

   (3) To a person in a foreign country if the provisions of federal laws are complied with.

3. An official written order for any controlled substance listed in Schedules I and II shall be signed in duplicate by the person giving the order or by his or her duly authorized agent. The original shall be presented to the person who sells or dispenses the controlled substance named therein. In event of the acceptance of such order by the person, each party to the transaction shall preserve his or her copy of such order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of this chapter or chapter 579. It shall be deemed a compliance with this subsection if the
parties to the transaction have complied with federal laws, respecting the requirements governing the use of order forms.

4. Possession of or control of controlled substances obtained as authorized by this section shall be lawful if in the regular course of business, occupation, profession, employment, or duty of the possessor.

5. A person in charge of a hospital or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled substances under the provisions of this section or otherwise, shall not administer, nor dispense, nor otherwise use such drugs, within this state, except within the scope of his or her employment or official duty, and then only for scientific or medicinal purposes and subject to the provisions of this chapter and chapter 579.

6. Every person registered to manufacture, distribute or dispense controlled substances under this chapter shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services. All registrants who dispense controlled substances shall maintain dispensing records and report the dispensing to the department's prescription drug monitoring program under sections 195.450 to 195.468 in conformance with the requirements in this chapter.

7. Manufacturers and wholesalers shall keep records of all narcotic and controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared,
and of all controlled substances received and disposed of by them, in accordance with this section.

8. Apothecaries shall keep records of all controlled substances received and disposed of by them, in accordance with the provisions of this section.

9. The form of records shall be prescribed by the department of health and senior services.

195.050. 1. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:

   (1) To a manufacturer, wholesaler, or pharmacy;
   (2) To a physician, dentist, podiatrist or veterinarian;
   (3) To a person in charge of a hospital, but only for use in that hospital;
   (4) To a person in charge of a laboratory, but only for use in that laboratory for scientific and medical purposes.

2. A duly registered manufacturer or wholesaler may sell controlled substances to any of the following persons:

   (1) On a special written order accompanied by a certificate of exemption, as required by federal laws, to a person in the employ of the United States government or of any state, territorial, district, county, municipal or insular government, purchasing, receiving, possessing, or dispensing controlled substances by reason of his official duties;

   (2) To a master of a ship or person in charge of any aircraft upon which no physician is regularly employed, for the actual medical needs of persons on board such ship or aircraft, when not in port; provided, such controlled substances shall be sold to the master of such ship or person in charge of such
aircraft only in pursuance of a special order form approved by a commissioned medical officer or acting surgeon of the United States Public Health Service;

(3) To a person in a foreign country if the provisions of federal laws are complied with.

3. An official written order for any controlled substance listed in Schedules I and II shall be signed in duplicate by the person giving the order or by his duly authorized agent. The original shall be presented to the person who sells or dispenses the controlled substance named therein. In event of the acceptance of such order by the person, each party to the transaction shall preserve his copy of such order for a period of two years in such a way as to be readily accessible for inspection by any public officer or employee engaged in the enforcement of sections 195.005 to 195.425. It shall be deemed a compliance with this subsection if the parties to the transaction have complied with federal laws, respecting the requirements governing the use of order forms.

4. Possession of or control of controlled substances obtained as authorized by this section shall be lawful if in the regular course of business, occupation, profession, employment, or duty of the possessor.

5. A person in charge of a hospital or of a laboratory, or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled substances under the provisions of this section or otherwise, shall not administer, nor dispense, nor otherwise use such drugs, within this state, except within the scope of his employment or
official duty, and then only for scientific or medicinal purposes and subject to the provisions of sections 195.005 to 195.425.

6. Every person registered to manufacture, distribute or dispense controlled substances under sections 195.005 to 195.425 shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the department of health and senior services.

All registrants who dispense controlled substances shall maintain dispensing records and report the dispensing to the department's prescription drug monitoring program under sections 195.450 to 195.468 in conformance with the requirements in this chapter.

7. Manufacturers and wholesalers shall keep records of all narcotic and controlled substances compounded, mixed, cultivated, grown, or by any other process produced or prepared, and of all controlled substances received and disposed of by them, in accordance with this section.

8. Apothecaries shall keep records of all controlled substances received and disposed of by them, in accordance with the provisions of this section.

9. The form of records shall be prescribed by the department of health and senior services.

195.450. 1. Sections 195.450 to 195.468 shall be known and may be cited as the "Prescription Drug Monitoring Program Act".

2. As used in sections 195.450 to 195.468, 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, 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;

(5) "Prescription drug monitoring program" or "PDMP", a program established by the department under sections 195.450 to 195.468, monitoring the dispensing of all Schedule II, III, or IV controlled substances;

(6) "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

Comment [B1]: This needs to be written in such a way that it ONLY applies to medications administered to inpatients, and NOT to apply to medications dispensed from outpatient pharmacies at the time of discharge. Discharge prescriptions can be for very large amounts of medication, and they need to be included.

Comment [B2]: This should only apply to patients in a residential hospice program where drugs are administered, not dispensed. Otherwise, there will be very large amounts of medication in people’s homes with no record of it having been dispensed. The hospices likely will object to the reporting requirement, but the amount of medication involved here will be substantial, and this constitutes a huge loophole.
provisions of sections 195.450 to 195.468 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 using an existing data aggregation platform through the state data center within the office of administration. The aggregated information from each dispenser data source shall remain segregated from any other data source and shall not be commingled with data from any other source. The information contained on the database shall not be entered onto any other database outside the control of the department. The information shall not be entered into the national prescription drug monitoring database. The funding of the prescription drug monitoring program shall be subject to appropriation. In addition to appropriations from the general assembly, the department may apply for available grants and shall be able to accept other gifts, grants, and donations to develop and maintain the program.

2. 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 for hardware or software. Any contractor shall comply with the provisions regarding confidentiality of prescription information under section 195.456.

3. Each dispenser at the time of filling a prescription controlled substance 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, but
       not limited to, 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. 4. Each dispenser shall submit the
       information in
       accordance with transmission standards established by the
American Society for Automation in Pharmacy, or any successor
organization.
5. (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 unforeseen circumstances. In cases where an extension is granted, dispensers shall be responsible for reporting the required data in a subsequent file.

6. The department shall reimburse each dispenser for the fees 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 personal 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 agency.
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 prescription drug monitoring program to the following persons:

(1) An individual patient or bureau of narcotics and dangerous drugs registrant who requests his or her own dispensation monitoring information in accordance with state law;

(2) The state board of pharmacy;

(3) 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;

(4) 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;

(5) The family support division within the department of social services regarding Medicaid program recipients;

(6) A judge or other judicial authority under a subpoena or court order;

(7) Personnel of the department of health and senior services for the administration and enforcement of sections 195.450 to 195.468; and

(8) Prescribers, pursuant to the provisions of section 195.459.

Comment [B5]: The question, then, would be if “doctor shopping” constitutes “reasonable cause to believe a violation of law” has occurred. If so, then this would result in notification of law enforcement each time this is detected. We need a clear standard for this provision, so as to prevent false positives to the greatest extent possible. Additionally, each time this notification happens, the law enforcement agency would be provided with the patient’s PDMP record.

Comment [B6]: It’s not clear to me why the state board of pharmacy should have unfettered access when the other licensing boards only have limited access. In my opinion, the board of pharmacy should be incorporated into paragraph 3. Further, paragraph 3 should specify that the “specific professional” must already be the subject of an open investigation, so as to prevent fishing expeditions.

Comment [B7]: There needs to be a limitation here, specifying that the only data provided will be those for the specific person who is the subject of the investigation. Otherwise, this could be construed to allow a massive data release, if the specific case involves, for instance, the dispensing of hydrocodone in St. Louis County.
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, dispensers, or persons who received dispensations from dispensers.

6. Beginning August 28, 2017, the department shall discard the data obtained from the prescription drug monitoring program under sections 195.450 to 195.468 every two years.

195.458. 1. No dispenser shall have access to the information contained in the PDMP database established under sections 195.450 to 195.468, but shall only transmit information to be included into it. All dispensers shall have a prominently posted sign in bold letters stating "ALL CONTROLLED SUBSTANCE PRESCRIPTIONS SHALL BE REPORTED TO THE BUREAU OF NARCOTICS AND DANGEROUS DRUGS AND SCREENED FOR VIOLATIONS".

2. After transmitting information to the PDMP database, a dispenser shall expect to receive a response from the department. If the department responds that no concern is detected, the dispenser may dispense the medications according to his or her professional judgment. If the department responds that a concern is detected, the dispenser shall dispense or not dispense the medication according to his or her professional judgment appropriate to the concern communicated by the department. If the department does not respond due to a technical or other problem, the dispenser shall dispense or not dispense the medication according to his or her professional judgment.

Comment [B8]: This needs to say that data more than 24 months old will be purged. As written, it suggests that all data in the program will be purged every two years, and the data collection will then start from scratch.

Comment [B9]: Note that this is one positive—it’s a real-time reporting scheme.

Comment [B10]: The earlier version of SB 111 had a 5-minute time limit, which seems to have been removed here. How long will the pharmacy now be expected to wait?

Comment [B11]: Really? What pharmacist will dispense a prescription if the state’s computer tells him/her that there is a concern about that prescription? That doesn’t even consider the fact that a computer algorithm to identify "concerns" does not currently exist, and would need to be developed, costing a lot of money and delaying implementation significantly.
3. No licensed dispenser following the provisions of sections 195.450 to 195.468, shall be subject to discipline by the Missouri board of pharmacy or by any other state agency for acting in good faith to fill a prescription for a controlled substance, nor for acting outside of these rules in an emergency.

195.459. When a dispenser electronically sends a prescription to be added to the PDMP database, the department shall electronically screen its PDMP database and the national prescription drug monitoring database to determine if the prescription may be properly dispensed and that a similar medication has not been dispensed within the allowable day's supply limits set by the department. If no concern is detected, the department shall electronically and automatically issue a communication to the dispenser that no concern was detected. If a concern is detected, the department shall electronically and automatically issue a communication to the dispenser that a concern is detected, and shall state the nature of the concern identified by the computer algorithm used by the department. The department shall, as time and staff permit and subject to appropriations, review the concerns generated. If after staff review, it appears that there is reasonable cause to believe that a person has obtained a prescription fraudulently from more than one prescriber, the department shall contact the prescribers and, as appropriate, inform them of the concern and the details about the patient receiving prescriptions from other prescribers, and request copies of medical records concerning the prescriptions of concern. The prescribers shall provide the records, if possible, by fax or electronically. If after

Comment [B12]: So, if the state’s computer tells you that there is a problem, and you go ahead and fill the prescription anyway, are you still “acting in good faith”?

Comment [B13]: 1) There is no “national PDMP database”, so how does its absence affect the enforceability of this provision, and by extension, the entire bill’s provisions? 2) If this means the PMPI, then how does that work? Do the authors expect PMPI to allow them to receive data, but not share it? I don’t see any authorization for the MO PDMP to share data with any outside program, and as noted above, there may be an outright prohibition against doing so. If they end up only being able to screen scripts from within Missouri, then they are not going to solve the problem with people hopping back and forth across state lines. In fact, they may give an “all clear” for a patient who is a prolific doctor shopper in another state if that is true.

Comment [B14]: Obviously, we’d need details as to how this would be determined. Could be a complicating factor.

Comment [B15]: What is the fiscal note on this provision?

Comment [B16]: Again, how is “reasonable cause” defined? If there is concern about prescribers and pharmacists seeing the records of their own patients, then how is it OK for someone employed by the state, who may or may not have ANY clinical medical experience, to be charged with reviewing patient records, making a judgment on what they see, and taking action?

Comment [B17]: And now, we compound this inappropriate violation of a patient’s privacy by REQUIRING that prescribers provide medical records to this same state agency, where they will again be reviewed by someone who may or may not even be a medical professional?

Comment [B18]: This is very likely impossible to do electronically, and extremely difficult to do by fax—especially if the record is very lengthy.
department review of the provided records, it is clear that a person has obtained prescriptions under false pretenses, the entire matter shall be referred to the appropriate law enforcement agency or local prosecuting attorney for action.

195.462. The department shall promulgate rules setting forth the procedures and methods of implementing sections 195.450 to 195.468. 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, 2015, shall be invalid and void.

195.465. 1. All dispensing information that is required to be reported to the department in sections 195.450 to 195.468, shall be submitted to the department in compliance with subsection 6 of section 195.050. Knowingly failing to submit a report as required under this section is a violation of this chapter and such person shall be guilty of a class A misdemeanor under section 195.252 and beginning on January 1, 2017, section 579.084.
2. Any person who unlawfully and knowingly accesses or discloses, or a person authorized to have dispensation monitoring information under sections 195.450 to 195.468 who knowingly discloses, such information in violation of sections 195.450 to 195.468 or who uses such information in a manner and for a purpose in violation of sections 195.450 to 195.468 is guilty of a class D felony until December 31, 2016, and a class E felony starting January 1, 2017.

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 195.468 in instances when such information is disclosed to an unauthorized party. If the department is responsible in whole or in part for private prescription-related medical information being negligently disclosed to an unauthorized party, 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.

195.466. The department shall annually provide to the general assembly a report as to the number of controlled
substances dispensed, broken down by drug, the number of incidents of fraudulent prescriptions identified and any other pertinent information requested by the general assembly.

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 have become addicted to substances monitored by the drug monitoring program established under sections 195.450 to 195.468 to receive addiction treatment.

Comment [B21]: To what end? Is this going to generate pressure to decrease the “number” of controlled substances dispensed, regardless of the consequences of doing so for people using them appropriately?

Comment [B22]: This entire section is largely moot if prescribers and dispensers are not authorized to access the data. I suppose the department would need to develop these educational programs for its employees, for law enforcement, and for state agencies that are allowed to access the data.

Comment [B23]: 1) Who is going to be making the diagnosis of an addiction here? 2) The may encourage them to receive addiction treatment, but they will be doing that at the same time that they are referring them to law enforcement. I don’t think that’s the best way to proceed.