## SENATE COMMITTEE SUBSTITUTE

FOR

## SENATE BILL NO. 262

## AN ACT

To repeal sections 195.060, 196.100, 221.111, 338.015, 338.055, and 338.056, RSMo, and to enact in lieu thereof seven new sections relating to electronic prescriptions, with a penalty provision.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF MISSOURI, AS FOLLOWS:

Section A. Sections 195.060, 196.100, 221.111, 338.015, 338.055, and 338.056, RSMo, are repealed and seven new sections enacted in lieu thereof, to be known as sections 195.060, 195.550, 196.100, 221.111, 338.015, 338.055, and 338.056 to read as follows:

195.060. 1. Except as provided in subsection 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, except for electronic prescriptions. 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 or she 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. person filling the prescription shall either write the date of filling and his or her own signature on the prescription or retain the date of filling and the identity of the dispenser as electronic prescription information. The 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 4 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.

- 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.
- 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.
- 195.550. 1. Notwithstanding any other provision of this section or any other law to the contrary, beginning January 1, 2021, no person shall issue any prescription in this state for any Schedule II, III, or IV controlled substance unless the prescription is made by electronic prescription from the person issuing the prescription to a pharmacy, except for prescriptions:
  - (1) Issued by veterinarians;
- (2) Issued in circumstances where electronic prescribing is not available due to temporary technological or electrical failure;
- (3) Issued by a practitioner to be dispensed by a pharmacy located outside the state;
- (4) Issued when the prescriber and dispenser are the same entity;
- (5) Issued that include elements that are not supported by the most recently implemented version of the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard;

- (6) Issued by a practitioner for a drug that the federal Food and Drug Administration requires the prescription to contain certain elements that are not able to be accomplished with electronic processing;
- (7) Issued by a practitioner allowing for the dispensing of a nonpatient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a nonpatient specific prescription;
- (8) Issued by a practitioner prescribing a drug under a research protocol;
- (9) Issued by practitioners who have received an annual waiver, or a renewal thereof, from the requirement to use electronic prescribing, pursuant to a process established in regulation by the department of health and senior services, due to economic hardship, technological limitations, or other exceptional circumstances demonstrated by the practitioner;
- (10) Issued by a practitioner under circumstances where, notwithstanding the practitioner's present ability to make an electronic prescription as required by this subsection, such practitioner reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition; or
- (11) Issued where the patient specifically requests a written prescription.
  - 2. A pharmacist who receives a written, oral, or faxed

prescription is not required to verify that the prescription

properly falls under one of the exceptions from the requirement

to electronically prescribe. Pharmacists may continue to

dispense medications from otherwise valid written, oral, or fax

prescriptions that are consistent with state and federal laws and regulations.

- 3. An individual who violates this section commits a civil violation for which a fine of two hundred and fifty dollars per violation, not to exceed five thousand dollars per calendar year, may be assessed. The department of health and senior services shall be responsible for the enforcement of this section.
- 196.100. 1. Any manufacturer, packer, distributor or seller of drugs or devices in this state shall comply with the current federal labeling requirements contained in the Federal Food, Drug and Cosmetic Act, as amended, and any federal regulations promulgated thereunder. Any drug or device which contains labeling that is not in compliance with the provisions of this section shall be deemed misbranded.
- 2. A drug dispensed on an electronic prescription or a written prescription signed by a licensed physician, dentist, or veterinarian, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to a diagnosis by mail, shall be exempt from the requirements of this section if such physician, dentist, or veterinarian is licensed by law to administer such drug, and such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian.

- 3. The department is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of sections 196.010 to 196.120, drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of said sections upon removal from such processing, labeling, or repacking establishment.
- 221.111. 1. A person commits the offense of possession of unlawful items in a prison or jail if such person knowingly delivers, attempts to deliver, possesses, deposits, or conceals in or about the premises of any correctional center as the term "correctional center" is defined under section 217.010, or any city, county, or private jail:
- (1) Any controlled substance as that term is defined by law, except upon the written <u>or electronic</u> prescription of a licensed physician, dentist, or veterinarian;
- (2) Any other alkaloid of any kind or any intoxicating liquor as the term intoxicating liquor is defined in section 311.020;
- (3) Any article or item of personal property which a prisoner is prohibited by law, by rule made pursuant to section 221.060, or by regulation of the department of corrections from receiving or possessing, except as herein provided;
- (4) Any gun, knife, weapon, or other article or item of personal property that may be used in such manner as to endanger the safety or security of the institution or as to endanger the

life or limb of any prisoner or employee thereof.

- 2. The violation of subdivision (1) of subsection 1 of this section shall be a class D felony; the violation of subdivision (2) of this section shall be a class E felony; the violation of subdivision (3) of this section shall be a class A misdemeanor; and the violation of subdivision (4) of this section shall be a class B felony.
- 3. The chief operating officer of a county or city jail or other correctional facility or the administrator of a private jail may deny visitation privileges to or refer to the county prosecuting attorney for prosecution any person who knowingly delivers, attempts to deliver, possesses, deposits, or conceals in or about the premises of such jail or facility any personal item which is prohibited by rule or regulation of such jail or facility. Such rules or regulations, including a list of personal items allowed in the jail or facility, shall be prominently posted for viewing both inside and outside such jail or facility in an area accessible to any visitor, and shall be made available to any person requesting such rule or regulation. Violation of this subsection shall be an infraction if not covered by other statutes.
- 4. Any person who has been found guilty of a violation of subdivision (2) of subsection 1 of this section involving any alkaloid shall be entitled to expungement of the record of the violation. The procedure to expunge the record shall be pursuant to section 610.123. The record of any person shall not be expunged if such person has been found guilty of knowingly delivering, attempting to deliver, possessing, depositing, or

concealing any alkaloid of any controlled substance in or about the premises of any correctional center, or city or county jail, or private prison or jail.

- 338.015. 1. The provisions of sections 338.010 to 338.015 shall not be construed to inhibit the patient's freedom of choice to obtain prescription services from any licensed pharmacist. However, nothing in sections 338.010 to 338.315 abrogates the patient's ability to waive freedom of choice under any contract with regard to payment or coverage of prescription expense.
- 2. All pharmacists may provide pharmaceutical consultation and advice to persons concerning the safe and therapeutic use of their prescription drugs.
- 3. All patients shall have the right to receive a written prescription from their prescriber to take to the facility of their choice or to have an electronic prescription transmitted to the facility of their choice.
- 338.055. 1. The board may refuse to issue any certificate of registration or authority, permit or license required pursuant to this chapter for one or any combination of causes stated in subsection 2 of this section or if the designated pharmacist-in-charge, manager-in-charge, or any officer, owner, manager, or controlling shareholder of the applicant has committed any act or practice in subsection 2 of this section. The board shall notify the applicant in writing of the reasons for the refusal and shall advise the applicant of his or her right to file a complaint with the administrative hearing commission as provided by chapter 621.
  - 2. The board may cause a complaint to be filed with the

administrative hearing commission as provided by chapter 621 against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:

- (1) Use of any controlled substance, as defined in chapter 195, or alcoholic beverage to an extent that such use impairs a person's ability to perform the work of any profession licensed or regulated by this chapter;
- (2) The person has been finally adjudicated and found guilty, or entered a plea of guilty or nolo contendere, in a criminal prosecution under the laws of any state or of the United States, for any offense reasonably related to the qualifications, functions or duties of any profession licensed or regulated under this chapter, for any offense an essential element of which is fraud, dishonesty or an act of violence, or for any offense involving moral turpitude, whether or not sentence is imposed;
- (3) Use of fraud, deception, misrepresentation or bribery in securing any certificate of registration or authority, permit or license issued pursuant to this chapter or in obtaining permission to take any examination given or required pursuant to this chapter;
- (4) Obtaining or attempting to obtain any fee, charge, tuition or other compensation by fraud, deception or misrepresentation;
- (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the

functions or duties of any profession licensed or regulated by this chapter;

- (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
- (7) Impersonation of any person holding a certificate of registration or authority, permit or license or allowing any person to use his or her certificate of registration or authority, permit, license, or diploma from any school;
- (8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, including, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;
- (9) A person is finally adjudged incapacitated by a court of competent jurisdiction;
- (10) Assisting or enabling any person to practice or offer to practice any profession licensed or regulated by this chapter who is not registered and currently eligible to practice under this chapter;
- (11) Issuance of a certificate of registration or authority, permit or license based upon a material mistake of fact;
- (12) Failure to display a valid certificate or license if so required by this chapter or any rule promulgated hereunder;

- (13) Violation of any professional trust or confidence;
- (14) Use of any advertisement or solicitation which is false, misleading or deceptive to the general public or persons to whom the advertisement or solicitation is primarily directed;
- (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government;
- changing the content, formula or brand of any drug prescribed by written, electronic, or oral prescription without prior written or oral approval from the prescriber for the respective change in each prescription; provided, however, that nothing contained herein shall prohibit a pharmacist from substituting or changing the brand of any drug as provided under section 338.056, and any such substituting or changing of the brand of any drug as provided for in section 338.056 shall not be deemed unprofessional or dishonorable conduct unless a violation of section 338.056 occurs;
- (17) Personal use or consumption of any controlled substance unless it is prescribed, dispensed, or administered by a health care provider who is authorized by law to do so.
- 3. After the filing of such complaint, the proceedings shall be conducted in accordance with the provisions of chapter 621. Upon a finding by the administrative hearing commission that the grounds, provided in subsection 2 of this section, for disciplinary action are met, the board may, singly or in combination, censure or place the person named in the complaint on probation on such terms and conditions as the board deems appropriate for a period not to exceed five years, or may

suspend, for a period not to exceed three years, or revoke the license, certificate, or permit. The board may impose additional discipline on a licensee, registrant, or permittee found to have violated any disciplinary terms previously imposed under this section or by agreement. The additional discipline may include, singly or in combination, censure, placing the licensee, registrant, or permittee named in the complaint on additional probation on such terms and conditions as the board deems appropriate, which additional probation shall not exceed five years, or suspension for a period not to exceed three years, or revocation of the license, certificate, or permit.

4. If the board concludes that a licensee or registrant has committed an act or is engaging in a course of conduct which would be grounds for disciplinary action which constitutes a clear and present danger to the public health and safety, the board may file a complaint before the administrative hearing commission requesting an expedited hearing and specifying the activities which give rise to the danger and the nature of the proposed restriction or suspension of the licensee's or registrant's license. Within fifteen days after service of the complaint on the licensee or registrant, the administrative hearing commission shall conduct a preliminary hearing to determine whether the alleged activities of the licensee or registrant appear to constitute a clear and present danger to the public health and safety which justify that the licensee's or registrant's license or registration be immediately restricted or suspended. The burden of proving that the actions of a licensee or registrant constitute a clear and present danger to the public health and safety shall be upon the state board of pharmacy. The administrative hearing commission shall issue its decision immediately after the hearing and shall either grant to the board the authority to suspend or restrict the license or dismiss the action.

- 5. If the administrative hearing commission grants temporary authority to the board to restrict or suspend the licensee's or registrant's license, such temporary authority of the board shall become final authority if there is no request by the licensee or registrant for a full hearing within thirty days of the preliminary hearing. The administrative hearing commission shall, if requested by the licensee or registrant named in the complaint, set a date to hold a full hearing under the provisions of chapter 621 regarding the activities alleged in the initial complaint filed by the board.
- 6. If the administrative hearing commission dismisses the action filed by the board pursuant to subsection 4 of this section, such dismissal shall not bar the board from initiating a subsequent action on the same grounds.

338.056. 1. Except as provided in subsection 2 of this section, the pharmacist filling prescription orders for drug products prescribed by trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity and dosage form, and of the same generic drug or interchangeable biological product type, as determined by the United States Adopted Names and accepted by the Federal Food and Drug Administration. Selection pursuant to this section is within the discretion of the pharmacist, except as provided in

subsection 2 of this section. The pharmacist who selects the drug or interchangeable biological product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug or biological product as would be incurred in filling a prescription for a drug or interchangeable biological product prescribed by generic or interchangeable biologic name. The pharmacist shall not select a drug or interchangeable biological product pursuant to this section unless the product selected costs the patient less than the prescribed product.

- 2. A pharmacist who receives a prescription for a brand name drug or biological product may select a less expensive generically equivalent or interchangeable biological product unless:
- (1) The patient requests a brand name drug or biological product; or
- (2) The prescribing practitioner indicates that substitution is prohibited or displays "brand medically necessary", "dispense as written", "do not substitute", "DAW", or words of similar import on the prescription.
- 3. No prescription shall be valid without the signature of the prescriber, except an electronic prescription.
- 4. If an oral prescription is involved, the practitioner or the practitioner's agent, communicating the instructions to the pharmacist, shall instruct the pharmacist as to whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted. The pharmacist shall note the instructions on the file copy of the prescription.

- 5. Notwithstanding the provisions of subsection 2 of this section to the contrary, a pharmacist may fill a prescription for a brand name drug by substituting a generically equivalent drug or interchangeable biological product when substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.
  - 6. Violations of this section are infractions.