House _____ **Amendment NO.**____

Offered By

_____ _____

AMEND House Committee Substitute for Senate Bill No. 514, Page 1, Section A, Line 3, by inserting after all of said section and line the following:

"21.790. 1. There is hereby established the "Task Force on Substance Abuse Prevention and Treatment". The task force shall be composed of six members from the house of representatives, six members from the senate, and four members appointed by the governor. The senate members of the task force shall be appointed by the president pro tempore of the senate and the house members by the speaker of the house of representatives. There shall be at least two members from the minority party of the senate and at least two members from the minority party of the house of representatives. The members appointed by the governor shall include one member from the health care industry, one member who is a first responder or law enforcement officer, one member who is a member of the judiciary or a prosecuting attorney, and one member representing a substance abuse prevention advocacy group.

2. The task force shall select a chairperson and a vice-chairperson, one of whom shall be a member of the senate and one a member of the house of representatives. A majority of the members shall constitute a quorum. The task force shall meet at least once during each legislative session and at all other times as the chairperson may designate.

3. The task force shall:

(1) Conduct hearings on current and estimated future drug and substance use and abuse within the state;

(2) Explore solutions to substance abuse issues; and

(3) Draft or modify legislation as necessary to effectuate the goals of finding and funding education and treatment solutions to curb drug and substance use and abuse.

4. The task force may make reasonable requests for staff assistance from the research and appropriations staffs of the senate and house of representatives and the joint committee on legislative research. In the performance of its duties, the task force may request assistance or information from all branches of government and state departments, agencies, boards, commissions, and offices.

5. The task force shall report annually to the general assembly and the governor. The report shall include recommendations for legislation pertaining to substance abuse prevention and treatment.

191.1164. 1. Sections 191.1164 to 191.1168 shall be known and may be cited as the "Ensuring Access to High Quality Care for the Treatment of Substance Use Disorders Act".

2. As used in sections 191.1164 to 191.1168, the following terms shall mean:

(1) "Behavioral therapy", an individual, family, or group therapy designed to help patients engage in the treatment process, modify their attitudes and behaviors related to substance use, and increase healthy life skills;

(2) "Department of insurance", the department that has jurisdiction regulating health insurers;

(3) "Financial requirements", deductibles, co-payments, coinsurance, or out-of-pocket maximums;

(4) "Health care professional", a physician or other health care practitioner licensed, accredited, or certified by the state of Missouri to perform specified health services;

(5) "Health insurance plan", an individual or group plan that provides, or pays the cost of, health care items or services;

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(6) "Health insurer", any person or entity that issues, offers, delivers, or administers a health insurance plan;

(7) "Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA)", the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 found at 42 U.S.C. 300gg-26 and its implementing and related regulations found at 45 CFR 146.136, 45 CFR 147.160, and 45 CFR 156.115;

(8) "Nonquantitative treatment limitation" or "NQTL", any limitation on the scope or duration of treatment that is not expressed numerically;

(9) "Pharmacologic therapy", a prescribed course of treatment that may include methadone, buprenorphine, naltrexone, or other FDA-approved or evidence-based medications for the treatment of substance use disorder;

(10) "Pharmacy benefits manager", an entity that contracts with pharmacies on behalf of health carriers or any health plan sponsored by the state or a political subdivision of the state;

(11) "Prior authorization", the process by which the health insurer or the pharmacy benefits manager determines the medical necessity of otherwise covered health care services prior to the rendering of such health care services. "Prior authorization" also includes any health insurer's or utilization review entity's requirement that a subscriber or health care provider notify the health insurer or utilization review entity prior to receiving or providing a health care service;

(12) "Quantitative treatment limitation" or "QTL", numerical limits on the scope or duration of treatment, which include annual, episode, and lifetime day and visit limits;

(13) "Step therapy", a protocol or program that establishes the specific sequence in which prescription drugs for a medical condition that are medically appropriate for a particular patient are authorized by a health insurer or prescription drug management company;

(14) "Urgent health care service", a health care service with respect to which the application of the time period for making a non-expedited prior authorization, in the opinion of a physician with knowledge of the enrollee's medical condition:

(a) Could seriously jeopardize the life or health of the subscriber or the ability of the enrollee to regain maximum function; or

(b) Could subject the enrollee to severe pain that cannot be adequately managed without the care or treatment that is the subject of the utilization review.

3. For the purpose of this section, "urgent health care service" shall include services provided for the treatment of substance use disorders.

191.1165. 1. Medication-assisted treatment (MAT) shall include pharmacologic therapies. A formulary used by a health insurer or managed by a pharmacy benefits manager, or medical benefit coverage in the case of medications dispensed through an opioid treatment program, shall include:

(1) Buprenorphine tablets;

(2) Methadone;

(3) Naloxone;

(4) Extended-release injectable naltrexone; and

(5) Buprenorphine/naloxone combination.

2. All MAT medications required for compliance in this section shall be placed on the lowest cost-sharing tier of the formulary managed by the health insurer or the pharmacy benefits manager.

3. MAT medications provided for in this section shall not be subject to any of the following:

(1) Any annual or lifetime dollar limitations;

(2) Financial requirements and quantitative treatment limitations that do not comply with the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), specifically 45 CFR 146.136(c)(3);

(3) Step therapy or other similar drug utilization strategy or policy when it conflicts or interferes with a prescribed or recommended course of treatment from a licensed health care professional; and

(4) Prior authorization for MAT medications as specified in this section.

4. MAT medications outlined in this section shall apply to all health insurance plans delivered in the state of Missouri.

5. Any entity that holds itself out as a treatment program or that applies for licensure by the state to provide clinical treatment services for substance use disorders shall be required to disclose the MAT services it provides, as well as which of its levels of care have been certified by an independent, national, or other

organization that has competencies in the use of the applicable placement guidelines and level of care standards.

6. The MO HealthNet program shall cover the MAT medications and services provided for in this section and include those MAT medications in its preferred drug lists for the treatment of substance use disorders and prevention of overdose and death. The preferred drug list shall include all current and new formulations and medications that are approved by the U.S. Food and Drug Administration for the treatment of substance use disorders.

7. Drug courts or other diversion programs that provide for alternatives to jail or prison for persons with a substance use disorder shall be required to ensure all persons under their care are assessed for substance use disorders using standard diagnostic criteria by a licensed physician who actively treats patients with substance use disorders. The court or other diversion program shall make available the MAT services covered under this section, consistent with a treatment plan developed by the physician, and shall not impose any limitations on the type of medication or other treatment prescribed or the dose or duration of MAT recommended by the physician.

8. Requirements under this section shall not be subject to a covered person's prior success or failure of the services provided.

191.1167. Any contract provision, written policy, or written procedure in violation of sections 191.1164 to 191.1168 shall be deemed to be unenforceable and shall be null and void.

191.1168. If any provision of sections 191.1164 to 191.1168 or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of sections 191.1164 to 191.1168 which may be given effect without the invalid provision or application, and to that end the provisions of sections 191.1164 to 191.1168 are severable.

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. The 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.

195.080. 1. Except as otherwise provided in this chapter and chapter 579, this chapter and chapter 579 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 this chapter and chapter 579 shall apply to all liniments, ointments, and other preparations that contain coca leaves in any quantity or combination.

2. Unless otherwise provided in sections 334.037, 334.104, and 334.747, a practitioner, other than a veterinarian, shall not issue an initial prescription for more than a seven-day supply of any opioid controlled substance upon the initial consultation and treatment of a patient for acute pain. Upon any subsequent consultation for the same pain, the practitioner may issue any appropriate renewal, refill, or new prescription in compliance with the general provisions of this chapter and chapter 579. Prior to issuing an initial prescription for an opioid controlled substance, a practitioner shall consult with the patient regarding the quantity of the opioid and the patient's option to fill the prescription in a lesser quantity and shall inform the patient of the risks associated with the opioid prescribed. If, in the professional medical judgment of the practitioner, more than a seven-day supply is required to treat the patient's acute pain, the practitioner may issue a prescription for the quantity needed to treat the patient; provided, that the practitioner shall document in the patient's medical record the condition triggering the necessity for more than a seven-day supply and that a nonopioid alternative was not appropriate to address the patient's condition. The provisions of this subsection shall not apply to prescriptions for opioid controlled substances for a patient who is currently undergoing treatment for cancer <u>or sickle cell disease</u>, is receiving hospice care from a hospice certified under chapter 197 or palliative care, is a resident of a long-term care facility licensed under chapter 198, or is receiving treatment for substance abuse or opioid dependence.

3. A pharmacist or pharmacy shall not be subject to disciplinary action or other civil or criminal liability for dispensing or refusing to dispense medication in good faith pursuant to an otherwise valid prescription that exceeds the prescribing limits established by subsection 2 of this section.

4. Unless otherwise provided in this section, 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 this chapter and chapter 579. 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.

5. 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.

195.100. 1. It shall be unlawful to distribute any controlled substance in a commercial container unless such container bears a label containing an identifying symbol for such substance in accordance with federal laws.

2. It shall be unlawful for any manufacturer of any controlled substance to distribute such substance unless the labeling thereof conforms to the requirements of federal law and contains the identifying symbol required in subsection 1 of this section.

3. The label of a controlled substance in Schedule II, III or IV shall, when dispensed to or for a patient, contain a clear, concise warning that it is a criminal offense to transfer such narcotic or dangerous drug to any person other than the patient.

4. Whenever a manufacturer sells or dispenses a controlled substance and whenever a wholesaler sells or dispenses a controlled substance in a package prepared by him or her, the manufacturer or wholesaler

shall securely affix to each package in which that drug is contained a label showing in legible English the name and address of the vendor and the quantity, kind, and form of controlled substance contained therein. No person except a pharmacist for the purpose of filling a prescription under this chapter, shall alter, deface, or remove any label so affixed.

5. Whenever a pharmacist or practitioner sells or dispenses any controlled substance on a prescription issued by a physician, physician assistant, dentist, podiatrist, veterinarian, or advanced practice registered nurse, the pharmacist or practitioner shall affix to the container in which such drug is sold or dispensed a label showing his or her own name and address of the pharmacy or practitioner for whom he or she is lawfully acting; the name of the patient or, if the patient is an animal, the name of the owner of the animal and the species of the animal; the name of the physician, physician assistant, dentist, podiatrist, advanced practice registered nurse, or veterinarian by whom the prescription was written; the name of the collaborating physician if the prescription is written by an advanced practice registered nurse or **[**~~the supervising physician if the prescription is written by~~**]** a physician assistant, and such directions as may be stated on the prescription. No person shall alter, deface, or remove any label so affixed.

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 the provisions of this section may be subject to discipline by his or her professional licensing board.

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."; and

Further amend said bill, Page 7, Section 208.151, Line 228, by inserting after all of said section and line the following:

"208.790. 1. The applicant shall have or intend to have a fixed place of residence in Missouri, with the present intent of maintaining a permanent home in Missouri for the indefinite future. The burden of establishing proof of residence within this state is on the applicant. The requirement also applies to persons residing in long-term care facilities located in the state of Missouri.

2. The department shall promulgate rules outlining standards for documenting proof of residence in Missouri. Documents used to show proof of residence shall include the applicant's name and address in the state of Missouri.

3. Applicant household income limits for eligibility shall be subject to appropriations, but in no event shall applicants have household income that is greater than one hundred eighty-five percent of the federal poverty level for the applicable family size for the applicable year as converted to the MAGI equivalent net income standard. **[**~~The provisions of this subsection shall only apply to Medicaid dual eligible individuals.~~**]**

4. The department shall promulgate rules outlining standards for documenting proof of household income.

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 or electronic 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.

332.361. 1. For purposes of this section, the following terms shall mean:

(1) "Acute pain", shall have the same meaning as in section 195.010;

(2) "Long-acting or extended-release opioids", formulated in such a manner as to make the contained medicament available over an extended period of time following ingestion.

2. Any duly registered and currently licensed dentist in Missouri may write, and any pharmacist in Missouri who is currently licensed under the provisions of chapter 338 and any amendments thereto, may fill any prescription of a duly registered and currently licensed dentist in Missouri for any drug necessary or proper in the practice of dentistry, provided that no such prescription is in violation of either the Missouri or federal narcotic drug act.

[~~2.~~**]** 3. Any duly registered and currently licensed dentist in Missouri may possess, have under his control, prescribe, administer, dispense, or distribute a "controlled substance" as that term is defined in section 195.010 only to the extent that:

(1) The dentist possesses the requisite valid federal and state registration to distribute or dispense that class of controlled substance;

(2) The dentist prescribes, administers, dispenses, or distributes the controlled substance in the course of his professional practice of dentistry, and for no other reason;

(3) A bona fide dentist-patient relationship exists; and

(4) The dentist possesses, has under his control, prescribes, administers, dispenses, or distributes the controlled substance in accord with all pertinent requirements of the federal and Missouri narcotic drug and controlled substances acts, including the keeping of records and inventories when required therein.

4. Long-acting or extended-release opioids shall not be used for the treatment of acute pain. If in the professional judgement of the dentist, a long-acting or extended-release opioid is necessary to treat the patient, the dentist shall document and explain in the patient's dental record the reason for the necessity for the long-acting or extended-release opioid.

5. Dentists shall avoid prescribing doses greater than fifty morphine milligram equivalent (MME) per day for treatment of acute pain. If in the professional judgement of the dentist, doses greater than fifty MME are necessary to treat the patient, the dentist shall document and explain in the patient's dental record the reason for the necessity for the dose greater than fifty MME. The relative potency of opioids is represented by a value assigned to individual opioids known as a morphine milligram equivalent (MME). The MME value represents how many milligrams of a particular opioid is equivalent to one milligram of morphine. The Missouri dental board shall maintain a MME conversion chart and instructions for calculating MME on its website to assist licensees with calculating MME."; and

Further amend said bill, Pages 7 to 10, Section 338.010, by removing all of said section from the bill and inserting in lieu thereof the following:

"338.010. 1. The "practice of pharmacy" means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis vaccines by written protocol authorized by a physician for persons at least seven years of age or the age recommended by the Centers for Disease Control and Prevention, whichever is higher, or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, meningitis, and viral influenza

vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; the prescribing and dispensing of any nicotine replacement therapy product under section 338.665; the dispensing of self-administered oral hormonal contraceptives under section 338.720; and the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he or she is licensed under the provisions of this chapter. This chapter shall not be construed to prohibit the use of auxiliary personnel under the direct supervision of a pharmacist from assisting the pharmacist in any of his or her duties. This assistance in no way is intended to relieve the pharmacist from his or her responsibilities for compliance with this chapter and he or she will be responsible for the actions of the auxiliary personnel acting in his or her assistance. This chapter shall also not be construed to prohibit or interfere with any legally registered practitioner of medicine, dentistry, or podiatry, or veterinary medicine only for use in animals, or the practice of optometry in accordance with and as provided in sections 195.070 and 336.220 in the compounding, administering, prescribing, or dispensing of his or her own prescriptions.

2. Any pharmacist who accepts a prescription order for a medication therapeutic plan shall have a written protocol from the physician who refers the patient for medication therapy services. The written protocol and the prescription order for a medication therapeutic plan shall come from the physician only, and shall not come from a nurse engaged in a collaborative practice arrangement under section 334.104, or from a physician assistant engaged in a **[**~~supervision agreement~~**]** collaborative practice arrangement under section 334.735.

3. Nothing in this section shall be construed as to prevent any person, firm or corporation from owning a pharmacy regulated by sections 338.210 to 338.315, provided that a licensed pharmacist is in charge of such pharmacy.

4. Nothing in this section shall be construed to apply to or interfere with the sale of nonprescription drugs and the ordinary household remedies and such drugs or medicines as are normally sold by those engaged in the sale of general merchandise.

5. No health carrier as defined in chapter 376 shall require any physician with which they contract to enter into a written protocol with a pharmacist for medication therapeutic services.

6. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals.

7. The state board of registration for the healing arts, under section 334.125, and the state board of pharmacy, under section 338.140, shall jointly promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the referring physician, and any other patient protection provisions deemed appropriate by both boards. In order to take effect, such rules shall be approved by a majority vote of a quorum of each board. Neither board shall separately promulgate rules regulating the use of protocols for prescription orders for medication therapy services and administration of viral influenza vaccines. 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, 2007, shall be invalid and void.

8. The state board of pharmacy may grant a certificate of medication therapeutic plan authority to a licensed pharmacist who submits proof of successful completion of a board-approved course of academic clinical study beyond a bachelor of science in pharmacy, including but not limited to clinical assessment skills, from a nationally accredited college or university, or a certification of equivalence issued by a nationally recognized professional organization and approved by the board of pharmacy.

9. Any pharmacist who has received a certificate of medication therapeutic plan authority may

engage in the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by a prescription order from a physician that is specific to each patient for care by a pharmacist.

10. Nothing in this section shall be construed to allow a pharmacist to make a therapeutic substitution of a pharmaceutical prescribed by a physician unless authorized by the written protocol or the physician's prescription order.

11. "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or an equivalent title means a person who has received a doctor's degree in veterinary medicine from an accredited school of veterinary medicine or holds an Educational Commission for Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary Medical Association (AVMA).

12. In addition to other requirements established by the joint promulgation of rules by the board of pharmacy and the state board of registration for the healing arts:

(1) A pharmacist shall administer vaccines by protocol in accordance with treatment guidelines established by the Centers for Disease Control and Prevention (CDC);

(2) A pharmacist who is administering a vaccine shall request a patient to remain in the pharmacy a safe amount of time after administering the vaccine to observe any adverse reactions. Such pharmacist shall have adopted emergency treatment protocols;

(3) In addition to other requirements by the board, a pharmacist shall receive additional training as required by the board and evidenced by receiving a certificate from the board upon completion, and shall display the certification in his or her pharmacy where vaccines are delivered.

13. A pharmacist shall inform the patient that the administration of the vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior services. The patient shall attest to the inclusion of such information in the system by signing a form provided by the pharmacist. If the patient indicates that he or she does not want such information entered into the ShowMeVax system, the pharmacist shall provide a written report within fourteen days of administration of a vaccine to the patient's primary health care provider, if provided by the patient, containing:

(1) The identity of the patient;

(2) The identity of the vaccine or vaccines administered;

(3) The route of administration;

(4) The anatomic site of the administration;

(5) The dose administered; and

(6) The date of administration.

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 <u>or to have an electronic prescription transmitted to the facility of their choice</u>.

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;

(16) The intentional act of substituting or otherwise 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<u>, except an electronic prescription</u>.

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.

338.140. 1. The board of pharmacy shall have a common seal, and shall have power to adopt such rules and bylaws not inconsistent with law as may be necessary for the regulation of its proceedings and for the discharge of the duties imposed pursuant to sections 338.010 to 338.198, and shall have power to employ an attorney to conduct prosecutions or to assist in the conduct of prosecutions pursuant to sections 338.010 to 338.198.

2. The board shall keep a record of its proceedings.

3. The board of pharmacy shall make annually to the governor and, upon written request, to persons licensed pursuant to the provisions of this chapter a written report of its proceedings.

4. The board of pharmacy shall appoint an advisory committee composed of six members, one of whom shall be a representative of pharmacy but who shall not be a member of the pharmacy board, three of whom shall be representatives of wholesale drug distributors as defined in section 338.330, one of whom shall be a representative of drug manufacturers, and one of whom shall be a licensed veterinarian recommended to the board of pharmacy by the board of veterinary medicine. The committee shall review and make recommendations to the board on the merit of all rules and regulations dealing with pharmacy distributors, wholesale drug distributors, drug manufacturers, and veterinary legend drugs which are proposed by the board.

5. A majority of the board shall constitute a quorum for the transaction of business.

6. Notwithstanding any other provisions of law to the contrary, the board may issue letters of reprimand, censure or warning to any holder of a license or registration required pursuant to this chapter for any violations that could result in disciplinary action as defined in section 338.055. Alternatively, at the discretion of the board, the board may enter into a voluntary compliance agreement with a licensee, permit holder, or registrant to ensure or promote compliance with this chapter and the rules of the board, in lieu of board discipline. The agreement shall be a public record. The time limitation identified in section 324.043 for commencing a disciplinary proceeding shall be tolled while an agreement authorized by this section is in effect.

338.143. 1. For purposes of this section, the following terms shall mean:

(1) "Remote medication dispensing", dispensing or assisting in the dispensing of medication outside of a licensed pharmacy;

(2) "Technology assisted verification", the verification of medication or prescription information using a combination of scanning technology and visual confirmation by a pharmacist.

2. The board of pharmacy may approve, modify, and establish requirements for pharmacy pilot or demonstration research projects related to technology assisted verification or remote medication dispensing that are designed to enhance patient care or safety, improve patient outcomes, or expand access to pharmacy services.

3. To be approved, pilot or research projects shall be within the scope of the practice of pharmacy as defined by chapter 338, be under the supervision of a Missouri licensed pharmacist, and comply with applicable compliance and reporting as established by the board by rule, including any staff training or education requirements. Board approval shall be limited to a period of up to eighteen months, provided the board grant an additional six month extension if deemed necessary or appropriate to gather or complete research data or if deemed in the best interests of the patient. The board may rescind approval of a pilot project at any time if deemed necessary or appropriate in the interest of patient safety.

4. The provisions of this subsection shall expire on August 28, 2023. The board shall provide a final report on approved projects and related data or findings to the general assembly on or before December 31, 2022. The name, location, approval dates, general description of and responsible pharmacist for an approved pilot or research project shall be deemed an open record.

338.665. 1. For the purposes of this chapter, "nicotine replacement therapy product" means any drug or product, regardless of whether it is available over-the-counter, that delivers small doses of nicotine to a person and that is approved by the federal Food and Drug Administration for the sole purpose of aiding in tobacco cessation or smoking cessation.

2. The board of pharmacy and the board of healing arts shall jointly promulgate rules governing a pharmacist's authority to prescribe and dispense nicotine replacement therapy products. Neither board shall separately promulgate rules governing a pharmacist's authority to prescribe and dispense nicotine replacement therapy products under this subsection.

3. Nothing in this section shall be construed to require third party payment for services described in this section.

4. 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, 2019, shall be invalid and void."; and

Further amend said bill by amending the title, enacting clause, and intersectional references accordingly.