FIRST REGULAR SESSION HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 1195

103RD GENERAL ASSEMBLY

2629H.03C JOSEPH ENGLER, Chief Clerk

AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof five new sections relating to access to medical products.

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

Section A. Section 338.010, RSMo, is repealed and five new sections enacted in lieu 2 thereof, to be known as sections 338.010, 338.740, 376.687, 376.689, and 1, to read as 3 follows:

338.010. 1. The "practice of pharmacy" includes:

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- (1) The interpretation, implementation, and evaluation of medical prescription orders, 2 including any legend drugs under 21 U.S.C. Section 353, and the receipt, transmission, or 4 handling of such orders or facilitating the dispensing of such orders;
- 5 The designing, initiating, implementing, and monitoring of a medication 6 therapeutic plan in accordance with the provisions of this section;
 - (3) The compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders;
- 9 (4) The ordering and administration of vaccines approved or authorized by the U.S.
- 10 Food and Drug Administration, excluding vaccines for cholera, monkeypox, Japanese encephalitis, typhoid, rabies, yellow fever, tick-borne encephalitis, anthrax, tuberculosis,
- dengue, Hib, polio, rotavirus, smallpox, and any vaccine approved after January 1, 2023, to
- persons at least seven years of age or the age recommended by the Centers for Disease
- 14 Control and Prevention, whichever is older, pursuant to joint promulgation of rules
- established by the board of pharmacy and the state board of registration for the healing arts 15
- 16 unless rules are established under a state of emergency as described in section 44.100;

EXPLANATION — Matter enclosed in bold-faced brackets [thus] in the above bill is not enacted and is intended to be omitted from the law. Matter in **bold-face** type in the above bill is proposed language.

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17 (5) The participation in drug selection according to state law and participation in drug utilization reviews;

- 19 (6) The proper and safe storage of drugs and devices and the maintenance of proper 20 records thereof;
- 21 (7) Consultation with patients and other health care practitioners, and veterinarians 22 and their clients about legend drugs, about the safe and effective use of drugs and devices;
- 23 (8) The prescribing and dispensing of any nicotine replacement therapy product under 24 section 338.665;
- 25 (9) The dispensing of HIV postexposure prophylaxis pursuant to section 338.730; 26 [and]
- 27 (10) The dispensing of an emergency supply of insulin under section 338.740; 28 and
 - (11) The offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy.
 - 2. No person shall engage in the practice of pharmacy unless he or she is licensed under the provisions of this chapter.
 - 3. 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.
 - 4. This chapter shall 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.
- 5. A pharmacist with a certificate of medication therapeutic plan authority may provide medication therapy services pursuant to a written protocol from a physician licensed under chapter 334 to patients who have established a physician-patient relationship, as described in subdivision (1) of subsection 1 of section 191.1146, with the protocol physician. The written protocol authorized by this section shall come only from the physician and shall not come from a nurse engaged in a collaborative practice arrangement under 334.104, or from a physician assistant engaged in a collaborative practice arrangement under section 334.735.
- 6. 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.

- 7. 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.
- 8. 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.
 - 9. This section shall not be construed to allow a pharmacist to diagnose or independently prescribe pharmaceuticals except to the extent described under section 338.740.
 - 10. 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 medication therapy services. Such rules shall require protocols to include provisions allowing for timely communication between the pharmacist and the protocol physician or similar body authorized by this section, 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 medication therapy services. 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.
 - 11. 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.
 - 12. 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 written protocol from a physician that may be specific to each patient for care by a pharmacist.
 - 13. 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.

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- 91 "Veterinarian", "doctor of veterinary medicine", "practitioner of veterinary 14. medicine", "DVM", "VMD", "BVSe", "BVMS", "BSe (Vet Science)", "VMB", "MRCVS", or 92 an equivalent title means a person who has received a doctor's degree in veterinary medicine 94 from an accredited school of veterinary medicine or holds an Educational Commission for 95 Foreign Veterinary Graduates (EDFVG) certificate issued by the American Veterinary 96 Medical Association (AVMA).
- 97 15. In addition to other requirements established by the joint promulgation of rules by 98 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.
 - 16. 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.
- 17. A pharmacist shall inform the patient that the administration of a vaccine will be entered into the ShowMeVax system, as administered by the department of health and senior 109 110 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 112 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 health care provider, if provided by the patient, containing:
- 115 (1) The identity of the patient;
- (2) The identity of the vaccine or vaccines administered; 116
- 117 (3) The route of administration;
- 118 (4) The anatomic site of the administration;
- 119 (5) The dose administered; and
- 120 (6) The date of administration.
- 121 18. A pharmacist licensed under this chapter may order and administer vaccines approved or authorized by the U.S. Food and Drug Administration to address a public health 122 123 need, as lawfully authorized by the state or federal government, or a department or agency 124 thereof, during a state or federally declared public health emergency.
 - 338.740. 1. Notwithstanding any other provision of law, a pharmacist may 2 dispense an emergency supply of insulin to a patient without a current, valid 3 prescription if:

- (1) The pharmacist makes every reasonable attempt but is unable to obtain authorization to refill the prescription from the prescribing health care provider or another health care provider responsible for the patient's care;
 - (2) Either:
- 8 (a) The pharmacist has a record of a prescription at the pharmacy or has been 9 presented proof of a recent prescription for the insulin in the name of the patient who is 0 requesting the emergency supply; or
 - (b) In the pharmacist's professional judgment, the refusal to dispense an emergency supply of the insulin will endanger the patient's health or disrupt essential drug therapy for a chronic condition of the patient;
 - (3) The amount of insulin dispensed does not exceed the amount of the most recent prescription or the standard quantity or unit-of-use package of the drug; and
 - (4) The prescriber of the drug has not indicated that no emergency refills are authorized.
 - 2. A pharmacist, the pharmacist's employer, and the original prescriber of the drug are not civilly liable for an act or omission in connection with the dispensing of insulin under this section unless the act or omission constitutes negligence, recklessness, or willful or wanton misconduct.
 - 3. The board of pharmacy shall adopt rules, in consultation with the state board of registration for the healing arts and the state board of nursing, to establish standard procedures for pharmacists to follow in dispensing insulin under this section. The rules adopted shall include documentation requirements for a pharmacist to complete when dispensing insulin without a current prescription. 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, 2025, shall be invalid and void.

376.687. 1. As used in this section, the following terms mean:

- (1) "Diabetes device", a prescribed device used to cure, diagnose, mitigate, prevent, or treat diabetes or low blood sugar. The term "diabetes device" includes, but is not limited to, a blood glucose monitor, continuous glucose monitor, or insulin pump;
- (2) "Epinephrine delivery device", a single-use device used for the delivery of a premeasured dose of epinephrine into the human body;

- (3) "Prescription insulin drug", a prescription drug that contains insulin and is used to control blood glucose levels to treat diabetes but does not include an insulin drug that is administered to a patient intravenously.
- 2. This section applies to any group or individual policy of accident and health insurance amended, delivered, issued, or renewed on or after August 28, 2025.
- 3. (1) An insurer that provides coverage for prescription insulin drugs under the terms of a health coverage plan the insurer offers shall limit the total amount that an insured is required to pay for a thirty-day supply of covered prescription insulin drugs at an amount not to exceed thirty-five dollars, regardless of the quantity or type of covered prescription insulin drug used to fill the insured's prescription.
- (2) An insurer that provides coverage for diabetes devices under the terms of a health coverage plan the insurer offers shall limit the total amount that an insured is required to pay for one diabetes device at an amount not to exceed one hundred dollars, regardless of the type of diabetes device used to fill the insured's prescription.
- (3) An insurer that provides coverage for epinephrine delivery devices under the terms of a health coverage plan the insurer offers shall limit the total amount that an insured is required to pay for one covered epinephrine delivery device at an amount not to exceed one hundred dollars, regardless of the type of covered epinephrine delivery device used to fill the insured's prescription.
- 4. On January first of each year, the limit on the amount that an insured is required to pay for one diabetes device or epinephrine delivery device or for a thirty-day supply of a covered prescription insulin drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the Consumer Price Index of the Bureau of Labor Statistics of the United States Department of Labor.
- 5. If, under federal law, application of any requirement under this section would result in health savings account ineligibility under Section 223 of the Internal Revenue Code of 1986, as amended, the requirements of this section shall apply to health savings account-qualified high deductible health plans with respect to any cost-sharing of such a plan after the enrollee has satisfied the minimum deductible under Section 223, except with respect to items or services that are preventive care under Section 223(c)(2)(C) of the Internal Revenue Code of 1986, as amended, in which case the requirements of this section shall apply regardless of whether the minimum deductible under Section 223 has been satisfied.
- 6. The director of the department of commerce and insurance may promulgate all necessary rules and regulations for the administration of this section. Any rule or portion of a rule, as that term is defined in section 536.010, that is created under the

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authority delegated in this section shall become effective only if it complies with and is 45 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 47 48 disapprove and annul a rule are subsequently held unconstitutional, then the grant of 49 rulemaking authority and any rule proposed or adopted after August 28, 2025, shall be 50 invalid and void.

- 376.689. 1. Before November 1, 2025, the department of commerce and insurance, in conjunction with the department of health and senior services and the department of social services, shall make available to the public a report that details each department's findings for the following:
- (1) A summary of pricing practices for insulin, diabetes devices, and epinephrine delivery devices and variables that contribute to the pricing of health coverage plans;
- Public policy recommendations to control and prevent overpricing of prescription insulin drugs, diabetes devices, and epinephrine delivery devices made available to Missouri consumers; and
- 10 (3) Any other information that the department of commerce and insurance finds 11 necessary.
- 12 2. The provisions of this section terminate on January 1, 2026.
 - Section 1. 1. As used in this section, the terms "pharmacy" and "pharmacy benefits manager" shall have the same meanings given to the terms in section 376.388.
- 2. A pharmacy benefits manager shall not reimburse a pharmacy for each dispensed drug in an amount less than the actual acquisition cost of the drug. In addition to the reimbursement amount for the drug, the pharmacy benefits manager 5 shall pay the pharmacy a dispensing fee of at least fifteen dollars for each prescription drug dispensed to fairly compensate for professional services, operational costs, and patient counseling.

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