SECOND REGULAR SESSION

HOUSE BILL NO. 3008

103RD GENERAL ASSEMBLY

INTRODUCED BY REPRESENTATIVE COOK.

5158H.01I JOSEPH ENGLER, Chief Clerk

AN ACT

To repeal sections 338.010 and 338.055, RSMo, and to enact in lieu thereof two new sections relating to the practice of pharmacy.

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

Section A. Sections 338.010 and 338.055, RSMo, are repealed and two new sections enacted in lieu thereof, to be known as sections 338.010 and 338.055, to read as follows:

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

(1) The interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353, and the receipt, transmission, or handling of such orders or facilitating the dispensing of such orders;

(2) The designing, initiating, implementing, and monitoring of a medication 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;

(4) The ordering and administration of vaccines approved or authorized by the U.S. 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 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 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.

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

(6) The proper and safe storage of drugs and devices and the maintenance of proper records thereof;

(7) 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;

(8) The prescribing and dispensing of any nicotine replacement therapy product under section 338.665;

(9) **The prescribing of drugs and devices for any of the following conditions:**

(a) A condition that does not require a new diagnosis;

(b) A condition that is minor and generally self-limiting;

(c) A condition for which a test waived under the Clinical Laboratory Improvement Amendments of 1988 is used to guide diagnosis or clinical decision-making; or

(d) A condition that is an emergency for the patient in the professional judgment of the pharmacist;

(10) The dispensing of HIV postexposure prophylaxis pursuant to section 338.730; and

[~~(10)~~**] (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. **(1)** 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.

(2) To determine whether a specific act is within the scope of the practice of pharmacy in or into this state, or whether an act can be delegated to other individuals under the supervision of a licensee or registrant, the licensee or registrant shall independently determine whether the act is:

(a) Expressly prohibited by:

a. This chapter; or

b. Any applicable state or federal laws;

(b) Consistent with the education, training, and experience of the licensee or registrant; and

(c) Within the accepted standard of care that would be provided in a similar setting by a reasonable and prudent licensee or registrant with similar education, training, and experience.

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 section 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 **or devices for any purpose other than the purposes specifically described in this section**.

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.

14. "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).

15. 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.

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 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 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.

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 need, as lawfully authorized by the state or federal government, or a department or agency thereof, during a state or federally declared public health emergency.

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**; or**

(18) Any act or omission within the practice of pharmacy that fails to meet the standard of care provided by other qualified licensees or registrants in the same or similar setting.

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 **or registration**. 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 registration** 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 **or registration**, 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.

7. The board shall not deny, revoke, or suspend, or otherwise take any disciplinary action against, a certificate of registration or authority, permit, or license required by this chapter for any person due to the lawful dispensing, distributing, or selling of ivermectin tablets or hydroxychloroquine sulfate tablets for human use in accordance with prescriber directions. A pharmacist shall not contact the prescribing physician or the patient to dispute the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets for human use unless the physician or patient inquires of the pharmacist about the efficacy of ivermectin tablets or hydroxychloroquine sulfate tablets.

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