SECOND REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 1679

98TH GENERAL ASSEMBLY

4359H.02P D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal section 338.010, RSMo, and to enact in lieu thereof three new sections relating to contraceptives.

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

Section A. Section 338.010, RSMo, is repealed and three new sections enacted in lieu thereof, to be known as sections 338.010, 338.660, and 376.1240, to read as follows:

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 twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, hepatitis A, hepatitis B, diphtheria, tetanus, pertussis, and meningitis 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 self-administered oral hormonal contraceptives under section 338.660;** and the offering or performing of those acts, services,

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.

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 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 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 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 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.

338.660. 1. For purposes of this chapter, "self-administered oral hormonal contraceptive" shall mean a drug composed of a combination of hormones that is approved by the Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

2. A pharmacist may prescribe and dispense self-administered oral hormonal contraceptives to a person who is:

(1) Eighteen years of age or older, regardless of whether the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a self-administered oral hormonal contraceptive; or

(2) Under eighteen years of age, if the person has evidence of a previous prescription from a primary care practitioner or women's health care practitioner for a self-administered oral hormonal contraceptive.

3. The board of pharmacy shall adopt rules, in consultation with the board of registration for the healing arts, board of nursing, and department of health and senior services, and in consideration of guidelines established by the American Congress of Obstetricians and Gynecologists, to establish standard procedures for the prescribing of self-administered oral hormonal contraceptives by pharmacists. The board of pharmacy shall adopt rules and regulations to implement the provisions of this section. 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, 2016, shall be invalid and void.

4. The rules adopted under this section shall require a pharmacist to:

(1) Complete a training program approved by the board of pharmacy that is related to prescribing self-administered oral hormonal contraceptives;

(2) Provide a self-screening risk assessment tool that the patient shall use prior to the pharmacist's prescribing the self-administered oral hormonal contraceptive;

(3) Refer the patient to the patient's primary care practitioner or women's health care practitioner upon prescribing and dispensing the self-administered oral hormonal contraceptive;

(4) Provide the patient with a written record of the self-administered oral hormonal contraceptive prescribed and dispensed and advise the patient to consult with a primary care practitioner or women's health care practitioner; and

(5) Dispense the self-administered oral hormonal contraceptive to the patient as soon as practicable after the pharmacist issues the prescription.

5. The rules adopted under this section shall prohibit a pharmacist from:

(1) Requiring a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a self-administered oral hormonal contraceptive; and

(2) Prescribing and dispensing a self-administered oral hormonal contraceptive to a patient who does not have evidence of a clinical visit for women's health within the three years immediately following the initial prescription and dispensation of a self-administered oral hormonal contraceptive by a pharmacist to the patient.

6. All state and federal laws governing insurance coverage of contraceptive drugs, devices, products, and services shall apply to self-administered oral hormonal contraceptives prescribed by a pharmacist under this section.

376.1240. 1. For purposes of this section, the terms "health carrier" and "health benefit plan" shall have the same meaning as defined in section 376.1350. The term "prescription contraceptive" shall mean a drug or device that requires a prescription and is approved by the Food and Drug Administration to prevent pregnancy.

2. Each health carrier or health benefit plan that offers or issues health benefit plans which are delivered, issued for delivery, continued, or renewed in this state on or after January 1, 2017, and that provides coverage for prescription contraceptives shall provide coverage to reimburse a health care provider or dispensing entity for a dispensing of prescription contraceptives intended to last for a:

(1) Three-month period for the first dispensing of the prescription contraceptive to an insured; and

(2) Twelve-month period for subsequent dispensations of the same contraceptive to the insured regardless of whether the insured was enrolled in the health benefit plan or policy at the time of the first dispensing.

3. The coverage required by this section shall not be subject to any greater deductible or co-payment than other similar health care services provided by the health benefit plan.

4. The provisions of this section shall not apply to a supplemental insurance policy including a life care contract, accident-only policy, specified disease policy, hospital policy providing a fixed daily benefit only, Medicare supplement policy, long-term care policy, short-term major medical policies of six months' or less duration, or any other supplemental policy as determined by the director of the department of insurance, financial institutions and professional registration.

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