SECOND REGULAR SESSION

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NOS. 1366 & 1878

98TH GENERAL ASSEMBLY

4897H.02C D. ADAM CRUMBLISS, Chief Clerk

AN ACT

To repeal sections 338.056, 338.059, and 338.100, RSMo, and to enact in lieu thereof four new sections relating to interchangeable biological products.

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

Section A. Sections 338.056, 338.059, and 338.100, RSMo, are repealed and four new sections enacted in lieu thereof, to be known as sections 338.056, 338.059, 338.085, and 338.100, to read as follows:

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, unless requested otherwise by the purchaser, select a less expensive generically equivalent **or interchangeable biological** product under the following circumstances:

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.

(1) If a written prescription is involved, the prescription form used shall have two signature lines at opposite ends at the bottom of the form. Under the line at the right side shall be clearly printed the words: "Dispense as Written". Under the line at the left side shall be clearly printed the words "Substitution Permitted". The prescriber shall communicate the instructions to the pharmacist by signing the appropriate line. No prescription shall be valid without the signature of the prescriber on one of these lines;

(2) 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.

3. All prescriptions written in the state of Missouri by practitioners authorized to write prescriptions shall be on forms which comply with subsection 2 hereof.

4. 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 **[**generic**]** substitution is allowed in accordance with the laws of the state where the prescribing practitioner is located.

5. Violations of this section are infractions.

338.059. 1. It shall be the duty of a licensed pharmacist or a physician to affix or have affixed by someone under the pharmacist's or physician's supervision a label to each and every container provided to a consumer in which is placed any prescription drug **or biological product** upon which is typed or written the following information:

(1) The date the prescription is filled;

(2) The sequential number or other unique identifier;

(3) The patient's name;

(4) The prescriber's directions for usage;

(5) The prescriber's name;

(6) The name and address of the pharmacy;

(7) The exact name and dosage of the drug dispensed;

(8) There may be one line under the information provided in subdivisions (1) to (7) of this subsection stating "Refill" with a blank line or squares following or the words "No Refill";

(9) When a generic **or interchangeable biological** substitution is dispensed, the name of the manufacturer or an abbreviation thereof shall appear on the label or in the pharmacist's records as required in section 338.100.

2. The label of any drug **or biological product** which is sold at wholesale in this state and which requires a prescription to be dispensed at retail shall contain the name of the manufacturer, expiration date, if applicable, batch or lot number and national drug code.

338.085. 1. As used in this chapter, the following terms shall mean:

(1) "Biological product", the same meaning as such term is defined under 42 U.S.C. Section 262;

(2) "Interchangeable biological product", a biological product that the Food and Drug Administration:

(a) Has licensed and determined meets the standards for interchangeability under 42 U.S.C. Section 262(k)(4); or

(b) Has determined is therapeutically equivalent as set forth in the latest edition of or supplement to the Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book).

2. A pharmacist may substitute an interchangeable biological product for a prescribed product only if all of the following conditions are met:

(1) The substituted product has been determined by the Food and Drug Administration to be an interchangeable biological product, as defined under subsection 1 of this section, with the prescribed biological product;

(2) The substitution occurs according to the provisions of section 338.056; and

(3) The pharmacy informs the patient of the substitution.

3. Within five business days following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall make an entry of the specific product provided to the patient including the name of the product and manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through:

(1) An interoperable electronic medical records system; or

(2) An electronic prescribing technology; or

(3) A pharmacy benefit management system; or

(4) A pharmacy record.

4. Entry into an electronic records system as described in this subsection is presumed to provide notice to the prescriber. Otherwise, if an entry cannot be made under the provisions of subsection 3 of this section, the pharmacist shall communicate the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required if:

(1) There is no Food and Drug Administration-approved interchangeable biological product for the product prescribed; or

(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

5. The pharmacist shall maintain records in a manner consistent with section 338.100.

6. The pharmacist shall label prescriptions in a manner consistent with section 338.059.

7. The board of pharmacy shall maintain a link on its website to the current list of all biological products determined by the Food and Drug Administration to be interchangeable with a specific biological product.

8. The board of pharmacy may promulgate rules for compliance with 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.

338.100. 1. Every permit holder of a licensed pharmacy shall cause to be kept in a uniform fashion consistent with this section a suitable book, file, or electronic record-keeping system in which shall be preserved, for a period of not less than five years, the original or order of each drug **or biological product** which has been compounded or dispensed at such pharmacy, according to and in compliance with standards provided by the board, and shall produce the same in court or before any grand jury whenever lawfully required. A licensed pharmacy may maintain its prescription file on readable microfilm for records maintained over three years. After September, 1999, a licensed pharmacy may preserve prescription files on microfilm or by electronic media storage for records maintained over three years. The pharmacist in charge shall be responsible for complying with the permit holder's record-keeping system in compliance with this section. Records maintained by a pharmacy that contain medical or drug information on patients or their care shall be considered as confidential and shall only be released according to standards provided by the board. Upon request, the pharmacist in charge of such pharmacy shall furnish to the prescriber, and may furnish to the person for whom such prescription was compounded or dispensed, a true and correct copy of the original prescription. The file of original prescriptions kept in any format in compliance with this section, and other confidential records, as defined by law, shall at all times be open for inspection by board of pharmacy representatives. Records maintained in an electronic record-keeping system shall contain all information otherwise required in a manual record-keeping system. Electronic records shall be readily retrievable. Pharmacies may electronically maintain the original prescription or

prescription order for each drug **or biological product** and may electronically annotate any change or alteration to a prescription record in the electronic record-keeping system as authorized by law; provided however, original written and faxed prescriptions shall be physically maintained on file at the pharmacy under state and federal controlled substance laws.

2. An institutional pharmacy located in a hospital shall be responsible for maintaining records of the transactions of the pharmacy as required by federal and state laws and as necessary to maintain adequate control and accountability of all drugs. This shall include a system of controls and records for the requisitioning and dispensing of pharmaceutical supplies where applicable to patients, nursing care units and to other departments or services of the institution. Inspection performed pursuant to this subsection shall be consistent with the provisions of section 197.100.

3. "Electronic record-keeping system", as used in this section, shall mean a system, including machines, methods of organization, and procedures, that provides input, storage, processing, communications, output, and control functions for digitized images of original prescriptions.

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