

SECOND REGULAR SESSION
SENATE COMMITTEE SUBSTITUTE FOR
HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NOS. 1366 & 1878
98TH GENERAL ASSEMBLY

Reported from the Committee on Veterans' Affairs and Health, April 14, 2016, with recommendation that the Senate Committee Substitute do pass.

ADRIANE D. CROUSE, Secretary.

4897S.03C

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Section A. Sections 338.056, 338.059, and 338.100, RSMo, are repealed
2 and four new sections enacted in lieu thereof, to be known as sections 338.056,
3 338.059, 338.085, and 338.100, to read as follows:

338.056. 1. Except as provided in subsection 2 of this section, the
2 pharmacist filling prescription orders for drug products prescribed by trade or
3 brand name may select another drug product with the same active chemical
4 ingredients of the same strength, quantity and dosage form, and of the same
5 generic drug **or interchangeable biological product** type, as determined by
6 the United States Adopted Names and accepted by the Federal Food and Drug
7 Administration. Selection pursuant to this section is within the discretion of the
8 pharmacist, except as provided in subsection 2 of this section. The pharmacist
9 who selects the drug **or interchangeable biological** product to be dispensed
10 pursuant to this section shall assume the same responsibility for selecting the
11 dispensed drug **or biological** product as would be incurred in filling a
12 prescription for a drug **or interchangeable biological** product prescribed by
13 generic **or interchangeable biologic** name. The pharmacist shall not select
14 a drug **or interchangeable biological** product pursuant to this section unless
15 the product selected costs the patient less than the prescribed product.

16 2. A pharmacist who receives a prescription for a brand name drug **or**
17 **biological product** may, unless requested otherwise by the purchaser, select a

EXPLANATION—Matter enclosed in bold-faced brackets [thus] in this bill is not enacted and is intended to be omitted in the law.

18 less expensive generically equivalent **or interchangeable biological** product
19 under the following circumstances:

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

27 (2) If an oral prescription is involved, the practitioner or the practitioner's
28 agent, communicating the instructions to the pharmacist, shall instruct the
29 pharmacist as to whether or not a therapeutically equivalent generic drug **or**
30 **interchangeable biological product** may be substituted. The pharmacist
31 shall note the instructions on the file copy of the prescription.

32 3. All prescriptions written in the state of Missouri by practitioners
33 authorized to write prescriptions shall be on forms which comply with subsection
34 2 hereof.

35 4. Notwithstanding the provisions of subsection 2 of this section to the
36 contrary, a pharmacist may fill a prescription for a brand name drug by
37 substituting a generically equivalent drug **or interchangeable biological**
38 **product** when [generic] substitution is allowed in accordance with the laws of
39 the state where the prescribing practitioner is located.

40 5. Violations of this section are infractions.

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

- 6 (1) The date the prescription is filled;
- 7 (2) The sequential number or other unique identifier;
- 8 (3) The patient's name;
- 9 (4) The prescriber's directions for usage;
- 10 (5) The prescriber's name;
- 11 (6) The name and address of the pharmacy;
- 12 (7) The exact name and dosage of the drug dispensed;
- 13 (8) There may be one line under the information provided in subdivisions

14 (1) to (7) of this subsection stating "Refill" with a blank line or squares following
15 or the words "No Refill";

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

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

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

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

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

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

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

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

16 (1) The substituted product has been determined by the Food
17 and Drug Administration to be an interchangeable biological product
18 with the prescribed biological product;

19 (2) The substitution occurs according to the provisions of section
20 338.056; and

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

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

- 29 **(1) An interoperable electronic medical records system;**
30 **(2) An electronic prescribing technology;**
31 **(3) A pharmacy benefit management system; or**
32 **(4) A pharmacy record.**

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

- 40 **(1) There is no Food and Drug Administration approved**
41 **interchangeable biological product for the product prescribed; or**
42 **(2) A refill prescription is not changed from the product**
43 **dispensed on the prior filling of the prescription.**

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

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

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

52 **8. The board of pharmacy may promulgate rules for compliance**
53 **with the provisions of this section. Any rule or portion of a rule, as**
54 **that term is defined in section 536.010, that is created under the**
55 **authority delegated in this section shall become effective only if it**
56 **complies with and is subject to all of the provisions of chapter 536 and,**
57 **if applicable, section 536.028. This section and chapter 536 are**
58 **nonseverable, and if any of the powers vested with the general**
59 **assembly pursuant to chapter 536 to review, to delay the effective date,**
60 **or to disapprove and annul a rule are subsequently held**
61 **unconstitutional, then the grant of rulemaking authority and any rule**
62 **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
2 kept in a uniform fashion consistent with this section a suitable book, file, or
3 electronic record-keeping system in which shall be preserved, for a period of not

4 less than five years, the original or order of each drug **or biological product**
5 which has been compounded or dispensed at such pharmacy, according to and in
6 compliance with standards provided by the board, and shall produce the same in
7 court or before any grand jury whenever lawfully required. A licensed pharmacy
8 may maintain its prescription file on readable microfilm for records maintained
9 over three years. After September, 1999, a licensed pharmacy may preserve
10 prescription files on microfilm or by electronic media storage for records
11 maintained over three years. The pharmacist in charge shall be responsible for
12 complying with the permit holder's record-keeping system in compliance with this
13 section. Records maintained by a pharmacy that contain medical or drug
14 information on patients or their care shall be considered as confidential and shall
15 only be released according to standards provided by the board. Upon request, the
16 pharmacist in charge of such pharmacy shall furnish to the prescriber, and may
17 furnish to the person for whom such prescription was compounded or dispensed,
18 a true and correct copy of the original prescription. The file of original
19 prescriptions kept in any format in compliance with this section, and other
20 confidential records, as defined by law, shall at all times be open for inspection
21 by board of pharmacy representatives. Records maintained in an electronic
22 record-keeping system shall contain all information otherwise required in a
23 manual record-keeping system. Electronic records shall be readily
24 retrievable. Pharmacies may electronically maintain the original prescription or
25 prescription order for each drug **or biological product** and may electronically
26 annotate any change or alteration to a prescription record in the electronic
27 record-keeping system as authorized by law; provided however, original written
28 and faxed prescriptions shall be physically maintained on file at the pharmacy
29 under state and federal controlled substance laws.

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

38 3. "Electronic record-keeping system", as used in this section, shall mean
39 a system, including machines, methods of organization, and procedures, that

40 provides input, storage, processing, communications, output, and control functions
41 for digitized images of original prescriptions.

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