Ohio Revised Code

Section 4729.38 Selecting generically equivalent drugs or interchangeable biological products.

Effective: April 6, 2017
Legislation: House Bill 505, Senate Bill 319 - 131st General Assembly

(A) As used in this section, "biological product," "finished dosage form," "generically equivalent drug," and "interchangeable biological product" have the same meanings as in section 3715.01 of the Revised Code.

(B) Unless instructed otherwise by the person receiving the drug pursuant to the prescription, a pharmacist filling a prescription for a drug prescribed by its brand name may, subject to the following conditions, select a generically equivalent drug, or, in the case of a drug that is a biological product, select an interchangeable biological product:

(1) The pharmacist shall not select a generically equivalent drug or interchangeable biological product if either of the following applies:

(a) In the case of a written or electronic prescription, including a computer-generated prescription, the prescriber handwrites or actively causes to display on the prescription "dispense as written," "D.A.W.," "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. Such a designation shall not be preprinted or stamped on the prescription, but a reminder to the prescriber of the designation procedure may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.

(b) In the case of an oral prescription, the prescriber specifies that the drug as prescribed is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.

(2) The pharmacist shall not select a generically equivalent drug or interchangeable biological product unless its price to the patient is less than or equal to the price of the drug as prescribed.

(3) The pharmacist or the pharmacist's agent, assistant, or employee shall inform the patient or the

patient's agent if a generically equivalent drug or interchangeable biological product is available at a lower or equal cost and of the person's right to refuse the drug selected. Division (B)(3) of this section does not apply to any:

(a) Prescription that is billed to any agency, division, or department of this state which will reimburse the pharmacy;

(b) Prescriptions for patients of a hospital, nursing home, or similar patient care facility.

(C)(1) Unless the prescriber instructs otherwise, the label for every drug dispensed shall include information that meets the following requirements, using abbreviations as necessary:

(a) Except as provided in divisions (C)(1)(b) and (c) of this section, the label shall include the dispensed drug's brand name.

(b) If the drug dispensed has no brand name and is a generically equivalent drug, the label shall include the generic name of the drug and the distributor of the finished dosage form.

(c) If the drug dispensed has no brand name and is an interchangeable biological product, the label shall include the name of the interchangeable biological product, the manufacturer, and if the distributor is not the same as the manufacturer, the distributor of the finished dosage form.

(2) When dispensing at retail a drug that is a generically equivalent drug or interchangeable biological product for a drug prescribed by its brand name, the pharmacist shall indicate on the drug's label or container that a substitution was made.

(3) The labeling requirements established by divisions (C)(1) and (2) of this section are in addition to all other labeling requirements of Chapter 3715. of the Revised Code.

(D) A pharmacist who selects a drug that is a generically equivalent drug or interchangeable biological product pursuant to this section assumes no greater liability for selecting the dispensed drug than would be incurred in filling a prescription for a drug prescribed by its brand name.

(E) The failure of a prescriber to restrict a prescription by indicating an intent to prevent substitution pursuant to division (B)(1) of this section shall not constitute evidence of the prescriber's negligence unless the prescriber had reasonable cause to believe that the health condition of the patient for whom the drug was intended warranted the prescription of a specific brand name drug and no other. No prescriber shall be liable for civil damages or in any criminal prosecution arising from the substitution of a generically equivalent drug or interchangeable biological product for a prescribed brand name drug by a pharmacist, unless the prescribed brand name drug would have reasonably caused the same loss, damage, injury, or death.

(F)(1)(a) Except as provided in division (F)(1)(b) of this section, not later than five business days after a pharmacist dispenses a drug for which an interchangeable biological product is available, regardless of whether a substitution is made, the pharmacist or an individual designated by the pharmacist shall communicate to the prescriber information identifying the specific biological product that was dispensed, including the name of the biological product and its manufacturer.

(b) Communication of the information is not required when a biological product is dispensed by refilling a prescription and the product that is dispensed is the same product that was dispensed when the same prescription was last filled or refilled.

(2) When possible, communication of the information shall be conveyed by entering the information into a recordkeeping system that can reasonably be presumed to be electronically accessible to the prescriber. Such a system may include any of the following:

(a) An interoperable electronic medical records system;

(b) An electronic prescribing system;

(c) An electronic pharmacy benefit management system;

(d) An electronic pharmacy record system.

(3) Entering the complete information into one of the recordkeeping systems listed in division (F)(2) of this section is presumed to provide notice to the prescriber.

(4) When it is not possible to communicate the information by using one of the recordkeeping systems listed in division (F)(2) of this section, communication of the information shall be conveyed by telephone, facsimile, another form of electronic communication, or any other prevailing means of communication.

(G) No pharmacist shall knowingly engage in conduct that is prohibited by division (A), (B), or (C) of this section.

The Legislative Service Commission presents the text of this section as a composite of the section as amended by multiple acts of the General Assembly. This presentation recognizes the principle stated in R.C. 1.52(B) that amendments are to be harmonized if reasonably capable of simultaneous operation.