Ohio Legislative Service Commission

Bill Analysis

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Sub. H.B. 505

131st General Assembly
(As Reported by H. Health & Aging)

Reps. Huffman and Pelanda, Becker, T. Johnson, Sprague, Ginter, Barnes, Brown, Butler, Schuring

BILL SUMMARY

- Authorizes substitution of an interchangeable biological product for a prescribed biological product under circumstances and conditions similar to those of current law governing substitution of a generically equivalent drug for a prescribed drug.
- Defines "biological product" and "interchangeable biological product" by reference to federal law and provides that the definitions automatically include certain changes to the federal law, subject to rulemaking by the State Board of Pharmacy.
- Specifies information a pharmacist who dispenses a drug for which an interchangeable biological product is available must communicate to the prescriber.
- Modifies existing law with regard to how a prescriber may prohibit a pharmacist from substituting a generic drug for a drug prescribed by its brand name and applies this law to the substitution of biological products.

CONTENT AND OPERATION

Substitution of interchangeable biological products by pharmacists

The bill amends Ohio's Pure Food and Drug Law and its Pharmacy Law to authorize a pharmacist to substitute an interchangeable biological product for a prescribed biological product under similar circumstances and subject to similar conditions as substitution of a generic drug for a prescribed drug under current law. Generally, biological products are medical products made from natural human, animal, or microorganism sources. According to the United States Food and Drug

Administration (FDA), biological products are among the medications used to treat rheumatoid arthritis, anemia, psoriasis, and various forms of cancer.[1]

Whereas a generic drug is a copy of a brand-name drug that has the same active ingredient, an interchangeable biological product has allowable differences because it is made from living organisms. The FDA approves interchangeable biological products that meet standards of biosimilarity and are expected to produce the same clinical results as the reference products they are compared to.[2]

Biological product definition

Because Ohio law defines "drug" broadly, including articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals and articles, other than food, intended to affect the structure or any function of the body of humans or other animals,[3] a biological product is a drug under Ohio law. The bill generally defines a "biological product" as a drug that is a biological product under the federal Public Health Service Act[4] as of the bill's effective date.[5] (This reflects a holding of the Ohio Supreme Court that references in the Revised Code to federal law incorporate the federal law as it existed on the date the state law was enacted and do not incorporate amendments to federal law adopted after the state law's effective date.[6] For a discussion of how the bill addresses future changes to federal law, see "**Automatic changes to biological product definitions**," below).

Federal law defines "biological product" as any of the following applicable to the prevention, treatment, or cure of a disease or condition of human beings: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or

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[1] U.S. Food and Drug Administration, *Information for Consumers (Biosimilars)*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm241718.htm (last updated August 27, 2015).

[2] *Information for Consumers (Biosimilars)*.

[3] R.C. 3715.01(A)(3) and 4729.01(E).

[4] 42 U.S.C. 262.

[5] R.C. 3715.01(A)(20).

[6] *State v. Gill*, 63 Ohio St.3d 53, 55 (1992).

analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound).[7]

The bill generally defines "interchangeable biological product" as both of the following:

(1) A biological product that, as of the bill's effective date, has been determined by the FDA to meet federal interchangeability standards and has been licensed by the FDA under the federal Public Health Service Act;[8]

(2) A biological product that, prior to the bill's effective date, was determined by the FDA to be therapeutically equivalent as set forth in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations."[9] That publication, commonly referred to as the "Orange Book," contains drug products approved by the FDA under the federal Food, Drug, and Cosmetic Act[10] and may contain interchangeable biological products approved before the FDA began listing them in the current publication, which is commonly known as the "Purple Book."[11]

Automatic changes to biological product definitions

The bill provides that when one of the following changes occurs under federal law with respect to a biological product or interchangeable biological product, the change is automatically effected under Ohio's Pure Food and Drug Law and the Pharmacy Law, subject to rulemaking by the State Board of Pharmacy:

(1) An article is added to or removed from the definition of "biological product" under the federal Public Health Service Act;

(2) The FDA determines that a biological product meets standards for interchangeability under the federal Public Health Service Act and is licensed under that law;

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[7] 42 U.S.C. 262(i).

[8] R.C. 3715.01(A)(21)(a).

[9] R.C. 3715.01(A)(21)(b).

[10] U.S. Food and Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations*, http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm (last updated March 29, 2016).

[11] U.S. Food and Drug Administration, *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm (last updated April 5, 2016).

(3) The FDA determines that a biological product no longer meets the standards for interchangeability under the federal Public Health Service Act and the product's license is suspended or revoked.[12]

The bill authorizes the State Board of Pharmacy to adopt rules to exclude from the definitions discussed above a biological product or interchangeable biological product that would otherwise automatically be included due to a change in federal law. The Board's rules must establish criteria to be used in determining whether a product is to be excluded. All rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119.).[13]

This provision is modeled on Ohio's Controlled Substances Law, which provides for automatic updates of the controlled substance schedules to correspond to actions of the U.S. Attorney General, subject to rulemaking by the State Board of Pharmacy.[14] The Ohio Supreme Court has upheld this approach and found it not to violate Ohio's constitution, which generally prohibits delegation of legislative authority to other entities, including the federal government.[15]

Ohio Pure Food and Drug Law changes

Misbranding

Current law provides many circumstances under which a drug is considered misbranded, including when a drug that is sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist, is neither the brand or drug prescribed, or a generically equivalent drug. The bill adds that in the case of a drug that is a biological product, it is considered misbranding if the drug is neither the brand or biological product prescribed nor an interchangeable biological product.[16]

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[12] R.C. 3715.011(A).

[13] R.C. 3715.011(B).

[14] R.C. 3719.43 and 3719.44, not in the bill.

[15] *State v. Klinck*, 44 Ohio St.3d 108, 110 (1989); Ohio Const., Art. II, Secs. 1 and 26.

[16] R.C. 3715.64(A)(10)(d).

Labeling

Current law unchanged by the bill provides that drugs dispensed pursuant to a written, electronic, or oral prescription from a prescriber are exempted from certain misbranding requirements if the drug bears a label containing specified information.[17]

Current law also provides that, unless the prescription directions prohibit labeling, the label must include the brand name of the drug dispensed, or its generic name and distributor if it has no brand name. Instead, the bill provides that unless the prescriber instructs otherwise, the label for the dispensed drug must include the dispensed drug's brand name unless the dispensed drug has no brand name. In that case, if the drug is a generically equivalent drug, the label must include the generic name and the distributor of the finished dosage form; if the drug is an interchangeable biological product, the label must include the name of the product, the manufacturer, and if the distributor is not the same as the manufacturer, the distributor of the finished dosage form. Abbreviations may be used if necessary.[18]

Pharmacy Law changes

Selection of generically equivalent drugs and interchangeable biological products

Current law specifies several conditions that must be met before a pharmacist filling a prescription for a drug prescribed by its brand name may select a generically equivalent drug. The bill largely maintains the conditions and applies them to the selection of interchangeable biological products.

Under the bill, unless instructed otherwise by the person receiving the prescribed drug, a pharmacist filling a prescription for a drug by its brand name may select a generically equivalent drug, or in the case of a drug that is a biological product, select an interchangeable biological product, subject to several conditions.[19]

Both current law and the bill prohibit substitution if the prescriber takes action to prevent it. Under current law, substitution of generically equivalent drugs is prohibited if the prescriber handwrites "dispense as written" or "D.A.W." on written prescriptions or indicates a drug is medically necessary in the case of an electronic or oral prescription. The bill generally maintains this but provides that in the case of a written or electronic prescription, including a computer generated prescription, substitution of a generically equivalent drug or interchangeable biological product is prohibited if the

[17] R.C. 3715.64(B)(1).

[18] R.C. 3715.64(B)(2).

[19] R.C. 4729.38(B).

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.[20] In the case of an oral prescription, the bill provides that substitution is prohibited if the prescriber specifies that the drug is medically necessary or otherwise indicates the prescriber's intent to prevent substitution.[21]

The bill maintains a provision of current law that prohibits "D.A.W." designations from being preprinted or stamped on prescriptions. However, the bill modifies a corresponding provision specifying that this prohibition does not preclude a reminder of the procedure to prevent generic substitution from being preprinted on prescriptions. Under the bill, in the case of either a written or electronic prescription, a reminder to the prescriber of the procedure for designating an intent to prevent substitution may be preprinted or displayed on the prescription form or electronic system the prescriber uses to issue the prescription.[22]

The bill maintains two other conditions of current law: (1) that the price to the patient must not be greater than that of the brand name and (2) that the patient must be informed of the right to refuse the drug selected. The bill makes those conditions applicable to the substitution of interchangeable biological products as well.[23]

Regarding labeling, the bill modifies existing law to account for the substitution of interchangeable biological products and also makes the labeling requirements the same as those of the Pure Food and Drug Law (see "**Labeling**," above).[24] The bill maintains a requirement that the pharmacist, when dispensing at retail a substituted drug for a drug prescribed by its brand name, indicate on the label that a substitution was made.[25]

The bill also maintains and applies to the substitution of interchangeable biological products existing provisions that address pharmacist liability for substitution and prescriber liability for failing to restrict substitution.[26]

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[20] R.C. 4729.38(B)(1)(a).

[21] R.C. 4729.38(B)(1)(b).

[22] R.C. 4729.38(B)(1)(a).

[23] R.C. 4729.38(B)(2) and (3).

[24] R.C. 4729.38(C)(1).

[25] R.C. 4729.38(C)(2).

[26] R.C. 4729.38(D) and (E).

Communication with interchangeable biological product substitution

The bill generally requires that not later than five business days after a pharmacist dispenses a drug for which an interchangeable biological product is available the pharmacist or someone designated by the pharmacist must communicate to the prescriber information identifying the specific biological product that was dispensed, including the name of the biological product and its manufacturer.[27] This applies regardless of whether a substitution is made.

When possible, the bill requires the communication to be conveyed by entering the information into a recordkeeping system that can reasonably be presumed to be electronically accessible to the prescriber, including any of the following:

(1) An interoperable electronic medical records system;

(2) An electronic records prescribing system;

(3) An electronic pharmacy benefit management system;

(4) An electronic pharmacy record system.[28]

The bill provides that entering the complete information into one of the systems listed above is presumed to provide notice to the prescriber.[29] When it is not possible to communicate the information by using one of the systems listed above, communication of the information must be by telephone, facsimile, another form of electronic communication, or by any other prevailing means of communication.[30]

The communication discussed above 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 prescription was last filled or refilled.[31]

Prohibition

Under current law, it is a minor misdemeanor for a pharmacist to fail to comply with the law governing generic drug substitution. The bill adds a provision specifically prohibiting a pharmacist from knowingly engaging in the conduct prohibited by the

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[27] R.C. 4729.38(F)(1)(a).

[28] R.C. 4729.38(F)(2).

[29] R.C. 4729.38(F)(3).

[30] R.C. 4729.38(F)(4).

[31] R.C. 4729.38(F)(1)(b).

bill's provisions specifying (1) conditions that must be met for substitution to be authorized and (2) labeling requirements.[32] As under current law, violation of those provisions is a minor misdemeanor.[33]

Definition changes

The bill adds to the current definition of "dangerous drug" any drug that is a biological product, as defined in the bill. This makes all biological products subject to all provisions of the Pharmacy Law applicable to other dangerous drugs. "Dangerous drug" generally refers to prescription drugs.[34]

HISTORY

ACTION	DATE
Introduced	04-04-16
Reported, H. Health & Aging	05-05-16

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[32] R.C. 4729.38(G).

[33] R.C. 4729.99(A).

[34] R.C. 4729.01(F)(4).