OHIO LEGISLATIVE SERVICE COMMISSION

Final Analysis

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Sub. H.B. 505

131st General Assembly
(As Passed by the General Assembly)

Reps. Huffman and Pelanda, Becker, T. Johnson, Sprague, Ginter, Barnes, Brown, Butler, Schuring, Amstutz, Anielski, Antonio, Baker, Burkley, Dovilla, Gonzales, Green, Grossman, McClain, S. O'Brien, Rogers, Sears, R. Smith, Sweeney

Sens. Gardner, Jones, Cafaro, Brown, Beagle, Tavares, Coley, Hackett, Hite, Hughes, Lehner, Patton, Peterson, Schiavoni, Seitz, Thomas, Uecker, Yuko

Effective date: Emergency: Most provisions of the act (Sections 1 and 2) effective March 20, 2017; Section 3, pertaining to delaying the expiration of physician assistant supervision agreements, effective December 19, 2016

ACT SUMMARY

Biological products and drug substitution by pharmacists

- Authorizes a pharmacist to substitute an interchangeable biological product for a prescribed biological product under circumstances and conditions similar to those governing generic drug substitution.

- Requires a pharmacist who dispenses a drug for which an interchangeable biological product is available to inform the prescriber of the product that was dispensed.

- Modifies provisions regarding how a prescriber may prohibit a pharmacist from substituting a generic drug and applies those provisions to the substitution of biological products.

Health insurer prior authorization and regulation

- Changes the start date for the period within which a health plan issuer must complete a prior authorization review, from the date the issuer receives all information needed to process the review to the date the issuer receives the request for prior authorization.

- Exempts from specified application review under the Health Insuring Corporation Law health insuring corporations solely covering individuals in the Federal Employees Health Benefits Program.

Physician assistant supervision agreements

- Delays the expiration date of a physician assistant supervision agreement by one year if the agreement would otherwise expire on January 31, 2017.

CONTENT AND OPERATION

BIOLOGICAL PRODUCTS AND PHARMACIST DRUG SUBSTITUTION

Substitution of biological products

The act authorizes a pharmacist to substitute an interchangeable biological product for a prescribed biological product when filling a prescription. This authority applies in circumstances and is subject to conditions that are similar to a pharmacist's authority to make generic drug substitutions.

Generally, biological products are medical products made from natural human, animal, or microorganism sources. Because they are made from living organisms, interchangeable biological products have allowable differences from their counterparts, unlike generic drugs, which must have active ingredients that are identical to their counterparts. The U.S. Food and Drug Administration (FDA) approves interchangeable biological products that meet standards of biosimilarity and are expected to produce the same clinical results as the products they are compared to.[1]

Biological product definitions

The act generally defines "biological product" as a drug that is a biological product under the federal Public Health Service Act[2] as of March 20, 2017.[3] (For a discussion of how the act addresses future changes to federal law, see "**Automatic changes to definitions**," below). Federal law defines "biological product" as any of the following that apply to the prevention, treatment, or cure of a disease or condition of human beings: a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood

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

[2] 42 United States Code (U.S.C.) 262.

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

component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound).[4]

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

(1) A biological product that, as of March 20, 2017, 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;[5]

(2) A biological product that, prior to March 20, 2017, was determined by the FDA to be therapeutically equivalent as set forth in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," which contains drugs approved under the federal Food, Drug, and Cosmetic Act.[6]

Automatic changes to definitions

The act 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 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;

(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.[7]

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[4] 42 U.S.C. 262(i).

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

[6] R.C. 3715.01(A)(21)(b); U.S. Food and Drug Administration, *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)*, www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm (last updated August 15, 2016).

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

The act authorizes the State Board of Pharmacy to adopt rules to exclude 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.).[8] This provision is modeled on the statutes that authorize automatic changes to Ohio's controlled substances schedules when changes occur in the federal schedules.[9]

Misbranding and labeling

Similar to the misbranding restrictions that apply when a pharmacist dispenses other drugs, the act specifies that a biological product is considered to be misbranded if the drug is neither the brand or biological product prescribed nor an interchangeable biological product.[10]

The act extends continuing law provisions governing drug labeling to biological products when dispensed by a pharmacist. If a drug is an interchangeable biological product and has no brand name, the act requires the label to 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.[11]

Drug substitution procedures

Under continuing law that is largely unchanged by the act, there are several conditions that must be met before a pharmacist filling a prescription for a drug prescribed by its brand name may substitute the drug with a generically equivalent drug. The act applies those conditions to the substitution of interchangeable biological products and makes other changes relative to generic drug substitution.

Patient instructions: As with generic drug substitution, the act does not permit a pharmacist to substitute an interchangeable biological product for a prescribed drug if instructed otherwise by the person receiving the drug.[12]

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

[9] See R.C. 3719.43 and 3719.44 (not in the act); *State v. Klinck*, 44 Ohio St.3d 108, 110 (1989); and Ohio Constitution, Art. II, Secs. 1 and 26.

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

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

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

Prescriber instructions: The act modifies the actions a prescriber must take to prevent drug substitution by including additional types of instructions that may be indicated by the prescriber and accounting for computer-generated prescriptions as a type of electronic prescription. For written prescriptions, a prescriber continues to be able to prevent substitution by handwriting "dispense as written" or "D.A.W.". The act also permits a prescriber to use these instructions on electronic prescriptions by actively causing them to be displayed. For both written and electronic prescriptions, the act permits a prescriber to handwrite or actively cause to be displayed any of the following: "do not substitute," "brand medically necessary," or any other statement or numerical code that indicates the prescriber's intent to prevent substitution. For oral prescriptions, the act continues to permit a prescriber to prevent substitution by specifying that the drug is medically necessary as prescribed, but it adds that the prescriber may otherwise indicate the prescriber's intent to prevent substitution.[13]

Price and right to refuse: The act extends two other conditions in continuing law regarding generic drugs to the substitution of interchangeable biological products: (1) that the price to the patient cannot be greater than that of the brand name and (2) that the patient must be informed of the right to refuse the drug selected.[14]

Labeling: In addition to the labeling requirements discussed above (see "**Misbranding and labeling**") the act 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.[15]

Liability: The act maintains and applies to the substitution of interchangeable biological products provisions that address pharmacist liability for substitution and prescriber liability for failing to restrict substitution.[16]

Communication with prescribers regarding biological products

When a pharmacist dispenses a drug for which an interchangeable biological product is available, the act requires the pharmacist or the pharmacist's designee to communicate to the prescriber information identifying the specific biological product that was dispensed, including the name of the biological product and its

[13] R.C. 4729.38(B)(1).

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

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

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

manufacturer.[17] This applies regardless of whether a substitution is made. The communication must be made within five business days.

When possible, the act requires the communication to be conveyed by entering the information into a recordkeeping system that is likely 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.[18]

The act provides that entering the complete information into one of the systems listed above is presumed to provide notice to the prescriber. When it is not possible to use one of those systems, the information must be communicated by telephone, facsimile, another form of electronic communication, or by any other prevailing means of communication.[19]

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.[20]

Prohibition

Under continuing law, it is a minor misdemeanor for a pharmacist to fail to comply with the law governing generic drug substitution. The act creates a specific prohibition to correspond with the penalty and adds a culpable mental state specification.[21] Under the act, a pharmacist is prohibited from *knowingly* failing to comply with the generic drug substitution laws, as well as the act's provisions on interchangeable biological product substitution.[22]

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

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

[19] R.C. 4729.38(F)(3) and (4).

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

[21] See S.B. 361 of the 130th General Assembly.

[22] R.C. 4729.38(G) and 4729.99(A).

Dangerous drug definition

The act adds to the definition of "dangerous drug" any drug that is a biological product. This makes biological products subject to the laws administered by the State Board of Pharmacy and other provisions of law governing dangerous drugs. "Dangerous drug" generally refers to drugs that are available only by prescription.[23]

HEALTH INSURANCE

Prior authorization – biological products

As part of authorizing substitution of interchangeable biological products, the act makes corresponding changes to provisions of law that govern health insurance and Medicaid prior authorization requirements addressing substitution of generic drugs. Under continuing law, prior authorization requirements are notification or approval requirements upon which coverage of a service, drug, or device is dependent.

Continuing law stipulates that prior authorization requirements do not prohibit the substitution of any drug that has received a 12-month prior approval when there is a release of an FDA-approved generic drug that is listed as therapeutically equivalent in the FDA's Orange Book publication.[24] The act adds that the prior authorization requirements do not prohibit substitution when there is a release of an interchangeable biological product. As a condition, however, for both generic drugs and interchangeable biological products, the act specifies that the substitution must be made in accordance with Ohio's requirements for drug substitution by pharmacists.

Prior authorization deadlines – health care generally

The act amends the deadlines imposed on health plan issuers related to the completion of a prior authorization review for a health care service, product, or drug. These prior authorization deadlines apply to health insuring corporations, sickness and accident insurers, multiple employer welfare arrangements, and the Department of Medicaid. Under continuing law, unchanged by the act, a health plan issuer has either 48 hours, for urgent services, or ten calendar days, for all other services, to complete a prior authorization review. Under former law, this period began upon receipt of all information needed to process the prior authorization review by the health plan issuer. Under the act, the period begins once a request for prior authorization is received by the health plan issuer. Additionally, the act removes a 72-hour deadline in which health

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

[24] R.C. 1751.72(B)(8), 3923.041(B)(8), and 5160.34(B)(8).

service providers had to provide additional information should the prior authorization request be incomplete.[25]

The act also makes other technical changes to prior authorization provisions.

Exemption from application review requirements

Overview

The act exempts from the application review requirements under the Health Insuring Corporation Law health insuring corporations that cover individuals in the Federal Employees Health Benefits (FEHB) Program.

Under continuing law, a health insuring corporation must obtain a certificate of authority from the Superintendent of Insurance to operate in Ohio. A health insuring corporation is a corporation that, under a contract, reimburses or arranges for health care services for enrollees through either an open network or closed network plan. (A common type of health insuring corporation is an HMO.)[26]

Generally, the Superintendent is required to review each application submitted by an individual or entity seeking certification as a health insuring corporation. The Superintendent must make findings as to whether the applicant has met certain criteria relating to its ability to provide adequate health care coverage to enrollees. Some of the criteria include whether the applicant has demonstrated the ability to ensure that:

(1) The covered health care services are provided to enrollees;

(2) Enrollees have access to qualified health care providers.[27]

Exemptions

Continuing Health Insuring Corporation Law exempts from the review requirements health insuring corporations that cover (1) solely Medicare beneficiaries, (2) solely Medicaid recipients, or (3) both.

The act adds to these exemptions health insuring corporations that cover solely federal employees and other eligible individuals under the FEHB Program.[28] The FEHB

[25] R.C. 1751.72, 3923.041, and 5160.34; R.C. 1739.05, not in the act.

[26] R.C. 1751.01(O) and 1751.02, not in the act.

[27] R.C. 1751.04(A).

[28] R.C. 1751.04(D).

Program provides health care coverage to federal employees, annuitants, and their families.[29] Therefore, under the act, the Superintendent is not required to review and make findings regarding an application if the applicant only provides health care coverage to federal employees, annuitants, and their families under the FEHB Program.

PHYSICIAN ASSISTANT SUPERVISION AGREEMENTS

Delayed expiration

Under continuing law, the supervision agreement that each physician assistant must enter into with a physician expires two years after becoming effective.[30] However, for supervision agreements scheduled to expire on January 31, 2017, the act delays the expiration by one year so that they are valid until February 1, 2018. The act permits those agreements to be renewed beginning August 1, 2017.[31]

HISTORY

ACTION	DATE
Introduced	04-04-16
Reported, H. Health & Aging	05-05-16
Passed House (96-0)	05-11-16
Reported, S. Health & Human Services	11-30-16
Passed Senate (32-0)	12-07-16
House concurred in Senate amendments (92-1)	12-08-16

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[29] U.S. Office of Personnel Management, *The Federal Employees Health Benefits (FEHB) Program*, https://www.opm.gov/healthcare-insurance/healthcare/ (accessed December 4, 2016).

[30] R.C. 4730.19, not in the act.

[31] Sections 3 and 5.