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OHIO LEGISLATIVE SERVICE COMMISSION

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Office

H.B. 291
135th General Assembly

Bill Analysis

Version: As Introduced

Primary Sponsors: Reps. Liston and Carruthers

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SUMMARY

- Prohibits health insurers from taking certain actions with respect to drugs during a health benefit plan year, including increasing cost-sharing, reducing coverage, and removing drugs from plan formularies.

DETAILED ANALYSIS

Health plan issuers and drug coverage

The bill prohibits a health plan issuer – during a health benefit plan year – from taking any of the following actions regarding a drug:

- Increasing a covered person’s cost-sharing burden for the drug;
- Limiting or reducing drug coverage, including subjecting the drug to prior authorization requirements;
- Moving the drug to a more restrictive tier of the plan’s drug formulary;
- Removing the drug from the formulary (see “**Removing drugs from formularies**” below).¹

Should a health plan issuer take such an action, it is an unfair and deceptive practice in the business of insurance, which may result in the Superintendent of Insurance imposing certain penalties on the health plan issuer.²

The bill also specifies that it does not prevent any of the following from occurring:

¹ R.C. 3902.63.

² R.C. 3902.63(D) and 3901.21, not in the bill. *See also* R.C. 3901.20 to 3901.25, not in the bill.

- A health plan issuer adding a drug to the plan's formulary;
- A health plan issuer removing a drug from its formulary if the drug's manufacturer no longer sells the drug in the United States;
- A health care provider prescribing another covered drug that the provider considers medically appropriate;
- A pharmacist substituting another epinephrine autoinjector for a prescribed autoinjector.

The bill also provides that in the case of a prescribed drug for which a generically equivalent drug or interchangeable biological product is available, it does not prevent any of the following from occurring:

- A pharmacist substituting a generic or biological product for the prescribed drug;
- A health plan issuer requiring the use of the generic or biological product;
- A covered person using the generic or biological product.³

Review of mandated benefits legislation

The bill specifies that its prohibitions are not subject to an existing law that could prevent the prohibitions from being applied until a review by the Superintendent of Insurance has been conducted with respect to mandated health benefits. Under current law, legislation mandating health benefits cannot be applied to any health benefits arrangement after the legislation is enacted unless the Superintendent holds a public hearing and determines that it can be applied fully and equally in all respects to (1) employee benefits plans that are subject to ERISA and (2) employee benefit plans established or modified by the state or its political subdivisions.⁴

Affected plans

The bill's requirements apply to health benefit plans delivered, issued for delivery, modified, or renewed on or after the bill's effective date.⁵

³ R.C. 3902.63(C).

⁴ R.C. 3902.50(E) and R.C. 3901.71, not in the bill, and 29 United States Code (U.S.C.) 1001 *et seq.*, not in the bill. ERISA is a comprehensive federal statute governing the administration of employee benefit plans. ERISA generally precludes state regulation of benefits offered by private employers that self-insure their benefit programs. Larger employers frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from a sickness and accident insurer or health insuring corporation.

⁵ R.C. 3902.63(B).

Removing drugs from formularies

While the bill generally prohibits a health plan issuer from removing a drug from its formulary, a drug may be removed under the bill when any of the following occur:

- The federal Food and Drug Administration (FDA) has issued a statement calling into the question the clinical safety of the drug;
- The drug's manufacturer has notified the FDA, as required by federal law, that its manufacture has been interrupted or permanently discontinued;
- The drug's manufacturer has removed the drug from sale in the United States.⁶

Definitions

"Generically equivalent drug" means a drug (1) that contains identical amounts of the identical active ingredients, but not necessarily containing the same inactive ingredients, (2) that meets the identical compendial or other applicable standards for specified qualities as the prescribed brand name drug, and (3) the manufacturer or distributor holds, if applicable, either an approved new drug application or an approved abbreviated new drug application unless other approval by law or from the FDA is required. A drug is not a generically equivalent drug if the FDA has listed it as having proven bioequivalence problems.

"Interchangeable biological product" means a biological product that has been determined by the FDA to meet the certain specified standards for interchangeability or a biological product that was determined by the FDA to be therapeutically equivalent.⁷

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or any trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.⁸

HISTORY

Action	Date
Introduced	10-03-23

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⁶ R.C. 3902.63(B)(3).

⁷ R.C. 3902.63(A) and R.C. 3715.01, not in the bill.

⁸ R.C. 3715.01 and 42 U.S.C. 262(i)(1), not in the bill.