Department of Legislative Services

Maryland General Assembly
2025 Session

FISCAL AND POLICY NOTE
First Reader

Senate Bill 393 (Senator Lam)
Finance

Health Insurance - Prescription Drug Formularies and Coverage for Generic Drugs and Biosimilars

This bill requires each "carrier" to post their prescription drug formularies and any changes to the formularies on the carrier's website, as specified. An insurer, nonprofit health service plan, and health maintenance organization (HMO) that provides coverage for prescription drugs and devices (including through a pharmacy benefits manager (PBM)) must make specific generic drugs and biosimilars available on a prescription drug formulary (1) with more favorable cost sharing than the reference listed drug or reference product and (2) without prior authorization, step therapy, or other limitations on coverage. The bill prohibits restrictions on pharmacies that make it more difficult for an enrollee to obtain coverage for or access to a generic drug or biosimilar added to a prescription drug formulary as required under the bill. **The bill takes effect January 1, 2026, and applies to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after that date.**

Fiscal Summary

State Effect: Any fiscal or operational impacts on the Maryland Insurance Administration are assumed to be minimal and absorbable within existing budgeted resources. Indeterminate but significant net expenditure increase for the State Employee and Retiree Health and Welfare Benefits Program beginning in FY 2026, as discussed below.

Local Effect: To the extent the bill increases costs for carriers, insurers, nonprofit health service plans, and HMOs, health insurance expenditures likely increase for local governments that buy fully insured plans. Revenues are not affected.

Small Business Effect: Minimal.

Analysis

Bill Summary: "Carrier" means an insurer, a nonprofit health service plan, an HMO, a dental plan organization, and any other person that provides health benefit plans subject to regulation by the State.

"Reference listed drug" means a previously approved drug identified by the U.S. Food and Drug Administration (FDA) as the drug product to which a proposed generic drug must be compared on an application submitted for approval under specified federal law.

"Wholesale acquisition cost" (WAC) means, with respect to a drug or biological product, the manufacturer's list price for the drug or biological product to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates, or reductions in price, for the most recent month for which the information is available as reported in wholesale price guides or other publications of drug or biological product pricing data.

Prescription Drug Formularies

Each carrier must post on its website an updated, accurate, and complete formulary that is easily accessible to an enrollee, prospective enrollee, the State, and the public. A posted formulary must be clearly identified by a link or tab on the carrier's website, include any tiering structure, and indicate any restrictions on the manner in which a drug may be obtained. A carrier may not require an individual to create or access an account or enter a policy number to view the formulary. If a carrier offers more than one prescription drug benefit plan, the website must clearly indicate which formulary applies to which plan. If a carrier makes a change to the formulary during a plan year, within 30 days after the change, the carrier must update the posted formulary and clearly indicate in bold type the change and a description of the change on the carrier's website.

Generic Drugs

An insurer, nonprofit health service plan, and HMO subject to the bill that provides coverage for the reference listed drug for a generic drug must immediately make the generic drug available on a formulary with more favorable cost sharing than the reference listed drug if the generic drug is FDA-approved, is marketed as an FDA-approved generic drug, and has a WAC that is less than the WAC of the reference listed drug on the initial date of marketing for the generic drug. If a generic drug is added to a formulary, an entity must inform enrollees of the change in formulary, as specified.

An insurer, nonprofit health service plan, or HMO may not impose (1) a prior authorization, step therapy, or other limitation on the coverage for a generic drug added to a formulary in

this manner or (2) a restriction on a pharmacy that makes it more difficult for an enrollee to obtain coverage for, or access to, a generic drug added to a formulary in this manner than it is for the enrollee to obtain coverage for the reference listed drug.

These requirements do not apply if the WAC of the generic drug becomes greater than the WAC of the reference listed drug.

Biosimilar Products

An insurer, nonprofit health service plan, or HMO that provides coverage for a reference product for a biosimilar must immediately make at least one biosimilar for the reference product available on their formulary with more favorable cost sharing than the reference product if the biosimilar is licensed by FDA, is marketed as a biosimilar licensed by FDA, and has a WAC that is less than the WAC of the reference product on the initial date of marketing for the biosimilar. If a biosimilar is added to a formulary, an entity must inform enrollees of the change in formulary, as specified.

An insurer, nonprofit health service plan, or HMO may not impose (1) a prior authorization, step therapy, or other limitation on the coverage for a biosimilar added to a formulary in this manner or (2) a restriction on a pharmacy that makes it more difficult for an enrollee to obtain coverage for or access to a biosimilar added to a formulary in this manner than it is for the enrollee to obtain coverage for the reference product.

These requirements do not apply if the WAC of the biosimilar becomes greater than the WAC of the reference product. If a biosimilar is added to a formulary, an entity must inform enrollees of the change in formulary, as specified.

Additional Provisions

The bill does not require coverage for (1) a brand drug after a generic drug is FDA-approved or a biosimilar is licensed by FDA and marketed or (2) a brand drug, generic drug, or biosimilar if the pharmacy and therapeutics committee or other clinical and pharmacy experts that determine the entity's formulary determine that the brand name drug, generic drug, or biosimilar is no longer medically appropriate or cost-effective.

The bill may not be construed to interfere with a pharmacist complying with the Maryland Pharmacy Act. The Insurance Commissioner may adopt regulations to implement the bill.

Current Law: Under Maryland law, there are more than 50 mandated health insurance benefits that certain carriers must provide to their enrollees, including several regarding prescription drugs. For example, an insurer, nonprofit health service plan, and HMO that provides prescription drug coverage (including through a PBM) and limits coverage of

prescription drugs or devices to those in a formulary must implement a procedure by which a member may receive a drug or device that is not on, or has been removed from, the formulary or continue the same cost-sharing requirements if the prescription drug or device has been moved to a higher deductible, copayment, or coinsurance tier. If a drug is removed from a formulary, the insurer, nonprofit health services plan, or HMO must provide the member and the member's health care provider with (1) notice of the change at least 30 days before the change is implemented and (2) the process for requesting an exemption.

The federal Patient Protection and Affordable Care Act requires nongrandfathered health plans to cover 10 essential health benefits (EHBs), which include prescription drugs. Under § 31-116 of the Insurance Article, EHBs must be included in the State benchmark plan and, notwithstanding any other benefits mandated by State law, must be the benefits required in (1) all individual health benefit plans and health benefit plans offered to small employers (except for grandfathered health plans) offered outside the Maryland Health Benefit Exchange (MHBE) and (2) all qualified health plans offered in MHBE.

A pharmacist may substitute a generically equivalent drug or device product or an interchangeable biological product, of the same dosage form and strength, for any brand name drug or device product prescribed if (1) the prescriber does not state expressly that the prescription is to be dispensed only as directed; (2) the substitution is recognized in FDA's current list of approved drug or device products with therapeutic equivalence evaluation or is an interchangeable biological product for the brand name drug; and (3) the consumer is charged less for the substituted drug or device or interchangeable biological product than the price of the brand name drug or device.

State Expenditures: The Department of Budget and Management (DBM) advises that the State Employee and Retiree Health and Welfare Benefits Program currently utilizes a "lowest net cost" strategy formula with its PBM, MedImpact. While a biosimilar drug may have a lower ingredient cost than its reference product, the reference product cost, together with rebates, results in the lowest net cost to the plan. DBM notes that placing generic drugs and biosimilars on a drug formulary with more favorable cost sharing puts drug rebates for the program at risk, which in turn has a *significant* fiscal impact on net program expenditures (all funds).

Additional Information

Recent Prior Introductions: Similar legislation has not been introduced within in the last three years.

Designated Cross File: HB 529 (Delegate Taveras, *et al.*) - Health and Government Operations.

Information Source(s): Department of Budget and Management; Maryland Department of Health; Maryland Insurance Administration; Department of Legislative Services

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