SENATE BILL 393

J5 5lr2195
CF 5lr3212

By: **Senator Lam**
Introduced and read first time: January 17, 2025
Assigned to: Finance

A BILL ENTITLED

AN ACT concerning

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

FOR the purpose of requiring certain carriers to post certain prescription drug formularies and changes to the formularies in a certain manner on a carrier's website; requiring certain insurers, nonprofit health service plans, and health maintenance organizations to make certain generic drugs and biosimilars available on a formulary with certain cost sharing; and generally relating to prescription drug formularies, generic drugs, and biosimilars.

BY adding to
Article – Insurance
Section 15–147 and 15–861
Annotated Code of Maryland
(2017 Replacement Volume and 2024 Supplement)

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Article – Insurance

15–147.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "CARRIER" MEANS:

(I) AN INSURER;

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

(II) A NONPROFIT HEALTH SERVICE PLAN;

(III) A HEALTH MAINTENANCE ORGANIZATION;

(IV) A DENTAL PLAN ORGANIZATION; OR

(V) ANY OTHER PERSON THAT PROVIDES HEALTH BENEFIT PLANS SUBJECT TO REGULATION BY THE STATE.

(3) "ENROLLEE" MEANS A PERSON ENTITLED TO HEALTH CARE BENEFITS FROM A CARRIER.

(4) "FORMULARY" MEANS A LIST OF PRESCRIPTION DRUGS THAT IS DEVELOPED BY A CARRIER'S PHARMACY AND THERAPEUTICS COMMITTEE OR OTHER CLINICAL AND PHARMACY EXPERTS AND REPRESENTS THE PRESCRIPTION DRUGS APPROVED FOR COVERAGE UNDER A HEALTH BENEFIT PLAN.

(B) EACH CARRIER SHALL POST ON ITS WEBSITE AN UPDATED, ACCURATE, AND COMPLETE FORMULARY THAT IS EASILY ACCESSIBLE TO AN ENROLLEE, A PROSPECTIVE ENROLLEE, THE STATE, AND THE PUBLIC.

(C) (1) A FORMULARY POSTED UNDER SUBSECTION (B) OF THIS SECTION SHALL:

(I) BE CLEARLY IDENTIFIED BY A LINK OR TAB ON THE CARRIER'S WEBSITE;

(II) INCLUDE ANY TIERING STRUCTURE; AND

(III) INDICATE ANY RESTRICTIONS ON THE MANNER IN WHICH A DRUG MAY BE OBTAINED.

(2) A CARRIER MAY NOT REQUIRE AN INDIVIDUAL TO CREATE OR ACCESS AN ACCOUNT OR ENTER A POLICY NUMBER ON THE CARRIER'S WEBSITE TO VIEW A FORMULARY POSTED UNDER SUBSECTION (B) OF THIS SECTION.

(D) IF A CARRIER OFFERS MORE THAN ONE PRESCRIPTION DRUG BENEFIT PLAN, THE CARRIER'S WEBSITE SHALL CLEARLY INDICATE WHICH FORMULARY APPLIES TO WHICH PLAN.

(E) IF A CARRIER MAKES A CHANGE TO A FORMULARY DURING A PLAN YEAR, WITHIN 30 DAYS AFTER THE DATE THE CHANGE WAS MADE, THE CARRIER SHALL:

(1) UPDATE THE FORMULARY POSTED ON THE CARRIER'S WEBSITE UNDER SUBSECTION (B) OF THIS SECTION; AND

(2) CLEARLY AND IN BOLD TYPE INDICATE THE DATE THE CHANGE WAS MADE AND A DESCRIPTION OF THE CHANGE ON THE CARRIER'S WEBSITE.

15–861.

(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.

(2) "BIOSIMILAR" MEANS A BIOLOGICAL PRODUCT THAT IS LICENSED UNDER 42 U.S.C. § 262(K) AND HAS BEEN LISTED IN THE FDA'S DATABASE OF LICENSED BIOLOGICAL PRODUCTS AS BIOSIMILAR TO OR INTERCHANGEABLE WITH A REFERENCE PRODUCT.

(3) "BRAND DRUG" MEANS A DRUG FOR WHICH AN APPLICATION HAS BEEN APPROVED UNDER 21 U.S.C. § 355(C) OR A BIOLOGICAL PRODUCT OTHER THAN A BIOSIMILAR THAT IS LICENSED UNDER 42 U.S.C. § 262(A).

(4) "FDA" MEANS THE FEDERAL FOOD AND DRUG ADMINISTRATION.

(5) "FORMULARY" MEANS A LIST OF PRESCRIPTION DRUGS THAT IS DEVELOPED BY A CARRIER'S PHARMACY AND THERAPEUTICS COMMITTEE OR OTHER CLINICAL AND PHARMACY EXPERTS AND REPRESENTS THE PRESCRIPTION DRUGS APPROVED FOR COVERAGE UNDER A HEALTH BENEFIT PLAN.

(6) "GENERIC DRUG" MEANS A DRUG FOR WHICH AN APPLICATION HAS BEEN APPROVED UNDER 21 U.S.C. § 355(J) AND THAT HAS BEEN LISTED IN THE FDA'S APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS AS THERAPEUTICALLY EQUIVALENT TO A REFERENCE LISTED DRUG, INCLUDING A DRUG TO WHICH THE MANUFACTURER OF THE DRUG APPLIES A TRADE NAME.

(7) "REFERENCE LISTED DRUG" MEANS A PREVIOUSLY APPROVED DRUG IDENTIFIED BY THE FDA AS THE DRUG PRODUCT TO WHICH A PROPOSED GENERIC DRUG MUST BE COMPARED ON AN APPLICATION SUBMITTED FOR APPROVAL UNDER 21 U.S.C. § 355(J).

(8) "REFERENCE PRODUCT" MEANS A SINGLE BIOLOGICAL PRODUCT THAT IS LICENSED BY THE FDA UNDER 42 U.S.C. § 262(A) AGAINST WHICH A PROPOSED BIOSIMILAR OR INTERCHANGEABLE PRODUCT IS COMPARED AND THAT

IS LISTED AS A REFERENCE PRODUCT IN THE FDA'S DATABASE OF LICENSED BIOLOGICAL PRODUCTS.

(9) "WHOLESALE ACQUISITION COST" MEANS, WITH RESPECT TO A DRUG OR BIOLOGICAL PRODUCT, THE MANUFACTURER'S LIST PRICE FOR THE DRUG OR THE 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.

(B) (1) THIS SECTION APPLIES TO:

(I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS AND DEVICES TO INDIVIDUALS OR GROUPS UNDER HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE DELIVERED IN THE STATE;

(II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS AND DEVICES TO INDIVIDUALS OR GROUPS UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

(III) INSURERS, NONPROFIT HEALTH SERVICE PLANS, OR HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS AND DEVICES THROUGH A PHARMACY BENEFITS MANAGER.

(2) THIS SECTION DOES NOT APPLY TO A MANAGED CARE ORGANIZATION AS DEFINED IN § 15–101 OF THE HEALTH – GENERAL ARTICLE.

(C) (1) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION, AN ENTITY SUBJECT TO THIS SECTION THAT PROVIDES COVERAGE FOR THE REFERENCE LISTED DRUG FOR A GENERIC DRUG SHALL IMMEDIATELY MAKE THE GENERIC DRUG AVAILABLE ON A FORMULARY WITH MORE FAVORABLE COST SHARING THAN THE REFERENCE LISTED DRUG IF THE GENERIC DRUG:

(I) IS APPROVED BY THE FDA;

(II) IS MARKETED AS A GENERIC DRUG APPROVED BY THE FDA; AND

(III) HAS A WHOLESALE ACQUISITION COST THAT IS LESS THAN THE WHOLESALE ACQUISITION COST OF THE REFERENCE LISTED DRUG ON THE INITIAL DATE OF MARKETING FOR THE GENERIC DRUG.

(2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE:

(I) A PRIOR AUTHORIZATION OR STEP THERAPY REQUIREMENT OR OTHER LIMITATION ON THE COVERAGE FOR A GENERIC DRUG ADDED TO A FORMULARY UNDER PARAGRAPH (1) OF THIS SUBSECTION; OR

(II) 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 UNDER PARAGRAPH (1) OF THIS SUBSECTION THAN IT IS FOR THE ENROLLEE TO OBTAIN COVERAGE FOR OR ACCESS TO THE REFERENCE LISTED DRUG.

(3) THIS SUBSECTION DOES NOT APPLY IF THE WHOLESALE ACQUISITION COST OF THE GENERIC DRUG BECOMES GREATER THAN THE WHOLESALE ACQUISITION COST OF THE REFERENCE LISTED DRUG.

(D) (1) EXCEPT AS PROVIDED IN PARAGRAPH (3) OF THIS SUBSECTION, AN ENTITY SUBJECT TO THIS SECTION THAT PROVIDES COVERAGE FOR A REFERENCE PRODUCT FOR A BIOSIMILAR SHALL IMMEDIATELY MAKE AT LEAST ONE BIOSIMILAR FOR THE REFERENCE PRODUCT AVAILABLE ON THE ENTITY'S FORMULARY WITH MORE FAVORABLE COST SHARING THAN THE REFERENCE PRODUCT IF THE BIOSIMILAR:

(I) IS LICENSED BY THE FDA;

(II) IS MARKETED AS A BIOSIMILAR LICENSED BY THE FDA; AND

(III) HAS A WHOLESALE ACQUISITION COST THAT IS LESS THAN THE WHOLESALE ACQUISITION COST OF THE REFERENCE PRODUCT ON THE INITIAL DATE OF MARKETING FOR THE BIOSIMILAR.

(2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE:

(I) A PRIOR AUTHORIZATION OR STEP THERAPY REQUIREMENT OR OTHER LIMITATION ON THE COVERAGE FOR A BIOSIMILAR ADDED TO A FORMULARY UNDER PARAGRAPH (1) OF THIS SUBSECTION; OR

(II) 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 UNDER PARAGRAPH (1) OF THIS SUBSECTION THAN IT IS FOR THE ENROLLEE TO OBTAIN COVERAGE FOR OR ACCESS TO THE REFERENCE PRODUCT.

(3) THIS SUBSECTION DOES NOT APPLY IF THE WHOLESALE ACQUISITION COST OF THE BIOSIMILAR BECOMES GREATER THAN THE WHOLESALE ACQUISITION COST OF THE REFERENCE PRODUCT.

(E) IF A GENERIC DRUG IS ADDED TO A FORMULARY UNDER SUBSECTION (C) OF THIS SECTION OR A BIOSIMILAR IS ADDED TO A FORMULARY UNDER SUBSECTION (D) OF THIS SECTION, AN ENTITY SUBJECT TO THIS SECTION SHALL INFORM ENROLLEES OF THE CHANGE IN FORMULARY IN ACCORDANCE WITH § 15–147 OF THIS TITLE.

(F) THIS SECTION DOES NOT REQUIRE AN ENTITY SUBJECT TO THIS SECTION TO PROVIDE COVERAGE FOR A BRAND DRUG AFTER A GENERIC DRUG IS APPROVED BY THE FDA OR A BIOSIMILAR IS LICENSED BY THE FDA AND MARKETED, AS APPLICABLE.

(G) THIS SECTION DOES NOT REQUIRE AN ENTITY SUBJECT TO THIS SECTION TO PROVIDE COVERAGE FOR A BRAND DRUG, GENERIC DRUG, OR BIOSIMILAR IF THE PHARMACY AND THERAPEUTICS COMMITTEE OR OTHER CLINICAL AND PHARMACY EXPERTS THAT DEVELOP THE ENTITY'S FORMULARY DETERMINE THAT THE BRAND DRUG, GENERIC DRUG, OR BIOSIMILAR IS NO LONGER MEDICALLY APPROPRIATE OR COST–EFFECTIVE.

(H) THIS SECTION MAY NOT BE CONSTRUED TO INTERFERE WITH A PHARMACIST COMPLYING WITH THE MARYLAND PHARMACY ACT.

(I) THE COMMISSIONER MAY ADOPT REGULATIONS TO CARRY OUT THIS SECTION.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or after January 1, 2026.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 2026.