Chapter 728

(Senate Bill 975)

AN ACT concerning

Health Insurance - Coverage for Specialty Drugs

FOR the purpose of prohibiting certain insurers, nonprofit health service plans, and health maintenance organizations from excluding coverage for certain specialty drugs that are administered or dispensed by a provider that meets certain criteria; requiring the reimbursement rate for certain specialty drugs to meet certain criteria; and generally relating to health insurance coverage for specialty drugs.

BY repealing and reenacting, without amendments,

Article – Insurance Section 15–847(a)(1) and (5) Annotated Code of Maryland (2017 Replacement Volume and 2024 Supplement)

BY repealing and reenacting, with amendments,

Article – Insurance Section 15–847(d), 15–1611.1, and 15–1612 Annotated Code of Maryland (2017 Replacement Volume and 2024 Supplement)

BY adding to Article – Insurance Section <u>15–847(h) and</u> 15–847.2 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 - 847.

(a) (1) In this section the following words have the meanings indicated.

(5) (i) "Specialty drug" means a prescription drug that:

1. is prescribed for an individual with a complex or chronic medical condition or a rare medical condition;

2. costs \$600 or more for up to a 30-day supply;

3. is not typically stocked at retail pharmacies; and

4. A. requires a difficult or unusual process of delivery to the patient in the preparation, handling, storage, inventory, or distribution of the drug; or

B. requires enhanced patient education, management, or support, beyond those required for traditional dispensing, before or after administration of the drug.

(ii) "Specialty drug" does not include a prescription drug prescribed to treat diabetes, HIV, or AIDS.

(d) Subject to <u>SUBSECTION (H) OF THIS SECTION AND</u> § 15–805 of this subtitle [and], notwithstanding § 15–806 of this subtitle, [nothing in] AND EXCEPT AS PROVIDED IN § 15–847.2 OF THIS SUBTITLE, this article or regulations adopted under this article [precludes] DO NOT PRECLUDE an entity subject to this section from requiring a covered specialty drug to be obtained through:

(1) a designated pharmacy or other source authorized under the Health Occupations Article to dispense or administer prescription drugs; or

(2) a pharmacy participating in the entity's provider network, if the entity determines that the pharmacy:

- (i) meets the entity's performance standards; and
- (ii) accepts the entity's network reimbursement rates.

(H) THIS SECTION MAY NOT BE CONSTRUED TO SUPERSEDE THE AUTHORITY OF THE HEALTH SERVICES COST REVIEW COMMISSION TO SET RATES FOR SPECIALTY DRUGS ADMINISTERED TO PATIENTS IN A SETTING REGULATED BY THE HEALTH SERVICES COST REVIEW COMMISSION.

15-847.2.

(A) IN THIS SECTION, "SPECIALTY DRUG" HAS THE MEANING STATED IN § 15–847 OF THIS SUBTITLE.

(B) (1) THIS SECTION APPLIES TO:

(I) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL, GROUP, OR BLANKET HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND (II) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL OR GROUP CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

(2) AN INSURER, A NONPROFIT HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT PROVIDES COVERAGE FOR PRESCRIPTION DRUGS THROUGH A PHARMACY BENEFITS MANAGER IS SUBJECT TO THE REQUIREMENTS OF THIS SECTION.

(C) AN ENTITY SUBJECT TO THIS SECTION MAY NOT EXCLUDE COVERAGE FOR A COVERED SPECIALTY DRUG ADMINISTERED OR DISPENSED BY A PROVIDER UNDER § 12–102 OF THE HEALTH OCCUPATIONS ARTICLE IF THE ENTITY DETERMINES THAT:

(1) THE PROVIDER THAT ADMINISTERS OR DISPENSES THE COVERED SPECIALTY DRUG:

(I) IS AN IN–NETWORK PROVIDER OF COVERED MEDICAL ONCOLOGY SERVICES; AND

(II) COMPLIES WITH STATE REGULATIONS FOR THE ADMINISTERING AND DISPENSING OF SPECIALTY DRUGS; AND

(2) THE COVERED SPECIALTY DRUG IS:

(I) INFUSED, AUTO–INJECTED, OR AN ORAL TARGETED IMMUNE MODULATOR; OR

(II) AN ORAL MEDICATION THAT:

1. REQUIRES COMPLEX DOSING BASED ON CLINICAL PRESENTATION; OR

2. IS USED CONCOMITANTLY WITH OTHER INFUSION OR RADIATION THERAPIES.

(D) (1) THE SUBJECT TO SUBSECTION (F) OF THIS SECTION, THE REIMBURSEMENT RATE FOR SPECIALTY DRUGS COVERED UNDER THIS SECTION SHALL BE:

(1) AGREED TO BY THE COVERED, IN–NETWORK PROVIDER AND THE ENTITY SUBJECT TO THIS SECTION; AND

(2) (II) BILLED AT A NONHOSPITAL LEVEL OF CARE OR PLACE OF SERVICE.

(2) UNLESS OTHERWISE AGREED TO BY THE COVERED, IN-NETWORK PROVIDER AND THE ENTITY SUBJECT TO THIS SECTION, THE REIMBURSEMENT RATE FOR SPECIALTY DRUGS COVERED UNDER THIS SECTION MAY NOT EXCEED THE RATE APPLICABLE TO A DESIGNATED SPECIALTY PHARMACY FOR DISPENSING THE COVERED SPECIALTY DRUGS.

(E) THIS SECTION DOES NOT PROHIBIT AN ENTITY SUBJECT TO THIS SECTION FROM REFUSING TO AUTHORIZE OR APPROVE OR FROM DENYING COVERAGE FOR A COVERED SPECIALTY DRUG ADMINISTERED OR DISPENSED BY A PROVIDER IF ADMINISTERING OR DISPENSING THE DRUG FAILS TO SATISFY MEDICAL NECESSITY CRITERIA.

(F) THIS SECTION MAY NOT BE CONSTRUED TO SUPERSEDE THE AUTHORITY OF THE HEALTH SERVICES COST REVIEW COMMISSION TO SET RATES FOR SPECIALTY DRUGS ADMINISTERED TO PATIENTS IN A SETTING REGULATED BY THE HEALTH SERVICES COST REVIEW COMMISSION.

15 - 1611.1.

(a) This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b) Except as provided in subsection (c) of this section, a pharmacy benefits manager may not require that a beneficiary use a specific pharmacy or entity to fill a prescription if:

(1) the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager has an ownership interest in the pharmacy or entity; or

(2) the pharmacy or entity has an ownership interest in the pharmacy benefits manager or a corporate affiliate of the pharmacy benefits manager.

(c) [A] EXCEPT AS PROVIDED IN § 15-847.2 OF THIS TITLE, A pharmacy benefits manager may require a beneficiary to use a specific pharmacy or entity for a specialty drug as defined in § 15-847 of this title.

15 - 1612.

(a) This section applies only to a pharmacy benefits manager that provides pharmacy benefits management services on behalf of a carrier.

(b) This section does not apply to reimbursement:

(1) EXCEPT AS PROVIDED IN § 15–847.2 OF THIS TITLE, for specialty drugs;

(2) for mail order drugs; or

(3) to a chain pharmacy with more than 15 stores or a pharmacist who is an employee of the chain pharmacy.

(c) A pharmacy benefits manager may not reimburse a pharmacy or pharmacist for a pharmaceutical product or pharmacist service in an amount less than the amount that the pharmacy benefits manager reimburses itself or an affiliate for providing the same product or service.

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.

Approved by the Governor, May 20, 2025.