

Chapter 615

(Senate Bill 931)

AN ACT concerning

**Maryland Medical Assistance Program and Health Insurance – Specialty Drugs
– Definition**

FOR the purpose of prohibiting the Secretary of Health from considering certain drugs to be specialty drugs for the purpose of providing services under the Maryland Medical Assistance Program; altering the definition of “specialty drug” for the purpose of excluding prescription drugs prescribed to treat certain medical conditions from the definition of “specialty drug” for the purposes of certain provisions of law limiting the authority of certain insurers, nonprofit health service plans, and health maintenance organizations to impose copayment and coinsurance requirements require a covered specialty drug to be obtained through a certain pharmacy or other sources and to provide coverage for specialty drugs through a managed care system; making conforming changes; providing for the application of this Act; making this Act an emergency measure; and generally relating to specialty drugs.

BY repealing and reenacting, without amendments,

Article – Health – General
Section 15–101(a) and (h)
Annotated Code of Maryland
(2019 Replacement Volume)

BY adding to

Article – Health – General
Section 15–118.1
Annotated Code of Maryland
(2019 Replacement Volume)

BY repealing and reenacting, with amendments,

Article – Insurance
Section 15–847
Annotated Code of Maryland
(2017 Replacement Volume and 2019 Supplement)

BY adding to

Article – Insurance
Section 15–847.1
Annotated Code of Maryland
(2017 Replacement Volume and 2019 Supplement)

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

Article – Health – General

15–101.

- (a) In this title the following words have the meanings indicated.
- (h) “Program” means the Maryland Medical Assistance Program.

15–118.1.

THE SECRETARY MAY NOT CONSIDER DRUGS PRESCRIBED TO TREAT DIABETES, HIV, OR AIDS TO BE SPECIALTY DRUGS FOR THE PURPOSE OF PROVIDING SERVICES UNDER THE PROGRAM.

Article – Insurance

15–847.

- (a) (1) In this section the following words have the meanings indicated.
 - (2) (i) “Complex or chronic medical condition” means a physical, behavioral, or developmental condition that:
 - 1. may have no known cure;
 - 2. is progressive; or
 - 3. can be debilitating or fatal if left untreated or undertreated.
 - (ii) “Complex or chronic medical condition” includes:
 - 1. multiple sclerosis;
 - 2. hepatitis C; and
 - 3. rheumatoid arthritis.
 - (3) “Managed care system” means a system of cost containment methods that an insurer, a nonprofit health service plan, or a health maintenance organization uses to review and preauthorize drugs prescribed by a health care provider for a covered individual to control utilization, quality, and claims.
 - (4) (i) “Rare medical condition” means a disease or condition that affects fewer than:

1. 200,000 individuals in the United States; or
2. approximately 1 in 1,500 individuals worldwide.

(ii) “Rare medical condition” includes:

1. cystic fibrosis;
2. hemophilia; and
3. multiple myeloma.

(5) (I) “Specialty drug” means a prescription drug that:

[(i)] 1. is prescribed for an individual with a complex or chronic medical condition or a rare medical condition;

[(ii)] 2. costs \$600 or more for up to a 30-day supply;

[(iii)] 3. is not typically stocked at retail pharmacies; and

[(iv)] 1.] 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

[2.] 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.

(b) This section applies to:

(1) 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

(2) health maintenance organizations that provide coverage for prescription drugs under individual or group contracts that are issued or delivered in the State.

(c) (1) Subject to paragraph (2) of this subsection, an entity subject to this section may not impose a copayment or coinsurance requirement on a covered specialty drug that exceeds \$150 for up to a 30-day supply of the specialty drug.

(2) On July 1 of each year, the limit on the copayment or coinsurance requirement on a covered specialty drug shall increase by a percentage equal to the percentage change from the preceding year in the medical care component of the March Consumer Price Index for All Urban Consumers, Washington Metropolitan Area, from the U.S. Department of Labor, Bureau of Labor Statistics.

(d) Subject to § 15–805 of this subtitle and notwithstanding § 15–806 of this subtitle, nothing in this article or regulations adopted under this article precludes 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.

(e) (1) A pharmacy registered under § 340B of the federal Public Health Services Act may apply to an entity subject to this section to be a designated pharmacy under subsection (d)(1) of this section for the purpose of enabling the pharmacy’s patients with [HIV, AIDS, or] hepatitis C to receive the copayment or coinsurance maximum provided for in subsection (c) of this section if:

(i) the pharmacy is owned by a federally qualified health center, as defined in 42 U.S.C. § 254B;

(ii) the federally qualified health center provides integrated and coordinated medical and pharmaceutical services to [HIV positive, AIDS, and] hepatitis C patients; and

(iii) the prescription drugs are covered specialty drugs for the treatment of [HIV, AIDS, or] hepatitis C.

(2) An entity subject to this section may not unreasonably withhold approval of a pharmacy’s application under paragraph (1) of this subsection.

(f) An entity subject to this section may provide coverage for specialty drugs through a managed care system.

(g) (1) A determination by an entity subject to this section that a prescription drug is not a specialty drug is considered a coverage decision under § 15–10D–01 of this title.

(2) For complaints filed with the Commissioner under this subsection, if the entity made its determination that a prescription drug is not a specialty drug on the basis that the prescription drug did not meet the criteria listed in subsection (a)(5)(i) of this section:

(i) the Commissioner may seek advice from an independent review organization or medical expert on the list compiled under § 15–10A–05(b) of this title; and

(ii) the expenses for any advice provided by an independent review organization or medical expert shall be paid for as provided under § 15–10A–05(h) of this title.

15–847.1.

(A) THIS SECTION APPLIES TO:

(1) 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

(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL GROUP CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

(B) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, AN ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A COPAYMENT OR COINSURANCE REQUIREMENT ON A PRESCRIPTION DRUG PRESCRIBED TO TREAT DIABETES, HIV, OR AIDS THAT EXCEEDS \$150 FOR UP TO A 30–DAY SUPPLY OF THE DRUG.

(2) ON JULY 1 EACH YEAR, THE LIMIT ON THE COPAYMENT OR COINSURANCE REQUIREMENT ON A PRESCRIPTION DRUG PRESCRIBED TO TREAT DIABETES, HIV, OR AIDS SHALL INCREASE BY A PERCENTAGE EQUAL TO THE PERCENTAGE CHANGE FROM THE PRECEDING YEAR IN THE MEDICAL CARE COMPONENT OF THE MARCH CONSUMER PRICE INDEX FOR ALL URBAN CONSUMERS, WASHINGTON METROPOLITAN AREA, FROM THE U.S. DEPARTMENT OF LABOR, BUREAU OF LABOR STATISTICS.

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

SECTION 3. AND BE IT FURTHER ENACTED, That this Act is an emergency measure, is necessary for the immediate preservation of the public health or safety, has

been passed by a ye and nay vote supported by three-fifths of all the members elected to each of the two Houses of the General Assembly, and shall take effect from the date it is enacted.

Enacted under Article II, § 17(c) of the Maryland Constitution, May 8, 2020.