

Chapter 422

(House Bill 761)

AN ACT concerning

Health Insurance – Specialty Drugs

FOR the purpose of prohibiting certain insurers, nonprofit health service plans, and health maintenance organizations from imposing a copayment or coinsurance requirement on a covered specialty drug that exceeds a certain dollar amount; providing for an annual increase to the copayment or coinsurance requirement limit; providing that, under certain circumstances, certain provisions of law or certain regulations do not preclude certain insurers, nonprofit health service plans, and health maintenance organizations from requiring a covered specialty drug to be obtained through a certain source or a pharmacy participating in the provider network of the insurer, nonprofit health service plan, or health maintenance organization under certain conditions; authorizing a pharmacy registered under a certain provision of federal law to apply to be a designated pharmacy for a certain purpose, under certain conditions; prohibiting an insurer, nonprofit health service plan, or health maintenance organization from unreasonably withholding certain approval; authorizing certain insurers, nonprofit health service plans, and health maintenance organizations to provide coverage for specialty drugs through a managed care system; providing that a certain determination is considered a coverage decision under certain provisions of law; authorizing the Maryland Insurance Commissioner to seek advice from certain persons relating to certain complaints filed with the Commissioner; requiring the expenses for the advice to be paid for as provided under certain provisions of law; defining certain terms; making the provisions of this Act applicable to health maintenance organizations; providing for the application of this Act; and generally relating to specialty drugs.

BY adding to

Article – Insurance

Section 15–847

Annotated Code of Maryland

(2011 Replacement Volume and 2013 Supplement)

BY adding to

Article – Health – General

Section 19–706(oooo)

Annotated Code of Maryland

(2009 Replacement Volume and 2013 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.

(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) "SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG THAT:

(I) IS PRESCRIBED FOR AN INDIVIDUAL WITH A COMPLEX OR CHRONIC MEDICAL CONDITION OR A RARE MEDICAL CONDITION;

(II) COSTS \$600 OR MORE FOR UP TO A 30-DAY SUPPLY;

(III) IS NOT TYPICALLY STOCKED AT RETAIL PHARMACIES;
AND

(IV) 1. REQUIRES A DIFFICULT OR UNUSUAL PROCESS OF DELIVERY TO THE PATIENT IN THE PREPARATION, HANDLING, STORAGE, INVENTORY, OR DISTRIBUTION OF THE DRUG; OR

2. REQUIRES ENHANCED PATIENT EDUCATION, MANAGEMENT, OR SUPPORT, BEYOND THOSE REQUIRED FOR TRADITIONAL DISPENSING, BEFORE OR AFTER ADMINISTRATION OF THE DRUG.

(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-BALTIMORE, 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.

~~(E)~~ (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.

Article - Health - General

19-706.

(OOOO) THE PROVISIONS OF § 15-847 OF THE INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

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, 2016.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2014.

Approved by the Governor, May 5, 2014.