

HOUSE BILL 761

C3

(4lr1315)

ENROLLED BILL

— Health and Government Operations/Finance —

Introduced by ~~Delegate Hammen~~ Delegates Hammen, Holmes, Bromwell, Costa, Cullison, Donoghue, Elliott, Hubbard, Kach, A. Kelly, Kipke, Krebs, McDonough, Morhaim, Murphy, Nathan-Pulliam, Oaks, Pena-Melnyk, Pendergrass, Ready, Reznik, and V. Turner

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this _____ day of _____ at _____ o'clock, _____ M.

Speaker.

CHAPTER _____

1 AN ACT concerning

2 **Health Insurance – Specialty Drugs**

3 FOR the purpose of prohibiting certain insurers, nonprofit health service plans, and
4 health maintenance organizations from imposing a copayment or coinsurance
5 requirement on a covered specialty drug that exceeds a certain dollar amount;
6 providing for an annual increase to the copayment or coinsurance requirement
7 limit; providing that, under certain circumstances, certain provisions of law or
8 certain regulations do not preclude certain insurers, nonprofit health service
9 plans, and health maintenance organizations from requiring a covered specialty
10 drug to be obtained through a certain source or a pharmacy participating in the
11 provider network of the insurer, nonprofit health service plan, or health
12 maintenance organization under certain conditions; authorizing a pharmacy

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.

Italics indicate opposite chamber/conference committee amendments.



1 registered under a certain provision of federal law to apply to be a designated
 2 pharmacy for a certain purpose, under certain conditions; prohibiting an
 3 insurer, nonprofit health service plan, or health maintenance organization from
 4 unreasonably withholding certain approval; authorizing certain insurers,
 5 nonprofit health service plans, and health maintenance organizations to provide
 6 coverage for specialty drugs through a managed care system; providing that a
 7 certain determination is considered a coverage decision under certain provisions
 8 of law; authorizing the Maryland Insurance Commissioner to seek advice from
 9 certain persons relating to certain complaints filed with the Commissioner;
 10 requiring the expenses for the advice to be paid for as provided under certain
 11 provisions of law; defining certain terms; making the provisions of this Act
 12 applicable to health maintenance organizations; providing for the application of
 13 this Act; and generally relating to specialty drugs.

14 BY adding to
 15 Article – Insurance
 16 Section 15–847
 17 Annotated Code of Maryland
 18 (2011 Replacement Volume and 2013 Supplement)

19 BY adding to
 20 Article – Health – General
 21 Section 19–706(oooo)
 22 Annotated Code of Maryland
 23 (2009 Replacement Volume and 2013 Supplement)

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

26 **Article – Insurance**

27 **15–847.**

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

30 **(2) (I) “COMPLEX OR CHRONIC MEDICAL CONDITION” MEANS**
 31 **A PHYSICAL, BEHAVIORAL, OR DEVELOPMENTAL CONDITION THAT:**

32 **1. MAY HAVE NO KNOWN CURE;**

33 **2. IS PROGRESSIVE; OR**

34 **3. CAN BE DEBILITATING OR FATAL IF LEFT**
 35 **UNTREATED OR UNDERTREATED.**

1 (II) "COMPLEX OR CHRONIC MEDICAL CONDITION"
2 INCLUDES:

- 3 1. MULTIPLE SCLEROSIS;
- 4 2. HEPATITIS C; AND
- 5 3. RHEUMATOID ARTHRITIS.

6 (3) "MANAGED CARE SYSTEM" MEANS A SYSTEM OF COST
7 CONTAINMENT METHODS THAT AN INSURER, A NONPROFIT HEALTH SERVICE
8 PLAN, OR A HEALTH MAINTENANCE ORGANIZATION USES TO REVIEW AND
9 PREAUTHORIZE DRUGS PRESCRIBED BY A HEALTH CARE PROVIDER FOR A
10 COVERED INDIVIDUAL TO CONTROL UTILIZATION, QUALITY, AND CLAIMS.

11 (4) (I) "RARE MEDICAL CONDITION" MEANS A DISEASE OR
12 CONDITION THAT AFFECTS FEWER THAN:

- 13 1. 200,000 INDIVIDUALS IN THE UNITED STATES; OR
- 14 2. APPROXIMATELY 1 IN 1,500 INDIVIDUALS
15 WORLDWIDE.

16 (II) "RARE MEDICAL CONDITION" INCLUDES:

- 17 1. CYSTIC FIBROSIS;
- 18 2. HEMOPHILIA; AND
- 19 3. MULTIPLE MYELOMA.

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

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

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

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

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

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

4 (b) THIS SECTION APPLIES TO:

5 (1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT
6 PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL, GROUP,
7 OR BLANKET HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED
8 OR DELIVERED IN THE STATE; AND

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

12 (c) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, AN
13 ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A COPAYMENT OR
14 COINSURANCE REQUIREMENT ON A COVERED SPECIALTY DRUG THAT EXCEEDS
15 \$150 FOR UP TO A 30-DAY SUPPLY OF THE SPECIALTY DRUG.

16 (2) ON JULY 1 OF EACH YEAR, THE LIMIT ON THE COPAYMENT OR
17 COINSURANCE REQUIREMENT ON A COVERED SPECIALTY DRUG SHALL
18 INCREASE BY A PERCENTAGE EQUAL TO THE PERCENTAGE CHANGE FROM THE
19 PRECEDING YEAR IN THE MEDICAL CARE COMPONENT OF THE
20 MARCH CONSUMER PRICE INDEX FOR ALL URBAN CONSUMERS,
21 WASHINGTON-BALTIMORE, FROM THE U.S. DEPARTMENT OF LABOR, BUREAU
22 OF LABOR STATISTICS.

23 (d) SUBJECT TO § 15-805 OF THIS SUBTITLE AND NOTWITHSTANDING §
24 15-806 OF THIS SUBTITLE, NOTHING IN THIS ARTICLE OR REGULATIONS
25 ADOPTED UNDER THIS ARTICLE PRECLUDES AN ENTITY SUBJECT TO THIS
26 SECTION FROM REQUIRING A COVERED SPECIALTY DRUG TO BE OBTAINED
27 THROUGH:

28 (1) A DESIGNATED PHARMACY OR OTHER SOURCE AUTHORIZED
29 UNDER THE HEALTH OCCUPATIONS ARTICLE TO DISPENSE OR ADMINISTER
30 PRESCRIPTION DRUGS; OR

31 (2) A PHARMACY PARTICIPATING IN THE ENTITY'S PROVIDER
32 NETWORK, IF THE ENTITY DETERMINES THAT THE PHARMACY:

33 (1) MEETS THE ENTITY'S PERFORMANCE STANDARDS; AND

1 (II) ACCEPTS THE ENTITY'S NETWORK REIMBURSEMENT
2 RATES.

3 (E) (1) A PHARMACY REGISTERED UNDER § 340B OF THE FEDERAL
4 PUBLIC HEALTH SERVICES ACT MAY APPLY TO AN ENTITY SUBJECT TO THIS
5 SECTION TO BE A DESIGNATED PHARMACY UNDER SUBSECTION (D)(1) OF THIS
6 SECTION FOR THE PURPOSE OF ENABLING THE PHARMACY'S PATIENTS WITH
7 HIV, AIDS, OR HEPATITIS C TO RECEIVE THE COPAYMENT OR COINSURANCE
8 MAXIMUM PROVIDED FOR IN SUBSECTION (C) OF THIS SECTION IF:

9 (I) THE PHARMACY IS OWNED BY A FEDERALLY QUALIFIED
10 HEALTH CENTER, AS DEFINED IN 42 U.S.C. § 254B;

11 (II) THE FEDERALLY QUALIFIED HEALTH CENTER PROVIDES
12 INTEGRATED AND COORDINATED MEDICAL AND PHARMACEUTICAL SERVICES
13 TO HIV POSITIVE, AIDS, AND HEPATITIS C PATIENTS; AND

14 (III) THE PRESCRIPTION DRUGS ARE COVERED SPECIALTY
15 DRUGS FOR THE TREATMENT OF HIV, AIDS, OR HEPATITIS C.

16 (2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT
17 UNREASONABLY WITHHOLD APPROVAL OF A PHARMACY'S APPLICATION UNDER
18 PARAGRAPH (1) OF THIS SUBSECTION.

19 ~~(E)~~ (F) AN ENTITY SUBJECT TO THIS SECTION MAY PROVIDE
20 COVERAGE FOR SPECIALTY DRUGS THROUGH A MANAGED CARE SYSTEM.

21 (G) (1) A DETERMINATION BY AN ENTITY SUBJECT TO THIS SECTION
22 THAT A PRESCRIPTION DRUG IS NOT A SPECIALTY DRUG IS CONSIDERED A
23 COVERAGE DECISION UNDER § 15-10D-01 OF THIS TITLE.

24 (2) FOR COMPLAINTS FILED WITH THE COMMISSIONER UNDER
25 THIS SUBSECTION, IF THE ENTITY MADE ITS DETERMINATION THAT A
26 PRESCRIPTION DRUG IS NOT A SPECIALTY DRUG ON THE BASIS THAT THE
27 PRESCRIPTION DRUG DID NOT MEET THE CRITERIA LISTED IN SUBSECTION
28 (A)(5)(I) OF THIS SECTION:

29 (I) THE COMMISSIONER MAY SEEK ADVICE FROM AN
30 INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT ON THE LIST
31 COMPILED UNDER § 15-10A-05(B) OF THIS TITLE; AND

32 (II) THE EXPENSES FOR ANY ADVICE PROVIDED BY AN
33 INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT SHALL BE PAID
34 FOR AS PROVIDED UNDER § 15-10A-05(H) OF THIS TITLE.

1 **Article – Health – General**

2 19–706.

3 **(0000) THE PROVISIONS OF § 15–847 OF THE INSURANCE ARTICLE**
4 **APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.**

5 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all
6 policies, contracts, and health benefit plans issued, delivered, or renewed in the State
7 on or after January 1, 2016.

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

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.