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

Introduced and read first time: February 3, 2014 Assigned to: Health and Government Operations

Committee Report: Favorable with amendments House action: Adopted Read second time: March 12, 2014

## CHAPTER \_\_\_\_\_

1 AN ACT concerning

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### **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  $\mathbf{5}$ requirement on a covered specialty drug that exceeds a certain dollar amount; 6 providing for an annual increase to the copayment or coinsurance requirement  $\overline{7}$ 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 12maintenance organization under certain conditions; authorizing a pharmacy registered under a certain provision of federal law to apply to be a designated 13 pharmacy for a certain purpose, under certain conditions; prohibiting an 1415insurer, nonprofit health service plan, or health maintenance organization from 16 unreasonably withholding certain approval; authorizing certain insurers, 17nonprofit health service plans, and health maintenance organizations to provide 18 coverage for specialty drugs through a managed care system; providing that a certain determination is considered a coverage decision under certain provisions 19 of law; authorizing the Maryland Insurance Commissioner to seek advice from 2021certain persons relating to certain complaints filed with the Commissioner; 22requiring the expenses for the advice to be paid for as provided under certain

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.



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$1 \\ 2 \\ 3$	<u>provisions of law</u> ; 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.
4	BY adding to
<b>5</b>	Article – Insurance
6	Section 15–847
$\overline{7}$	Annotated Code of Maryland
8	(2011 Replacement Volume and 2013 Supplement)
9	BY adding to
10	Article – Health – General
11	Section 19–706(0000)
12	Annotated Code of Maryland
13	(2009 Replacement Volume and 2013 Supplement)
14	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
15	MARYLAND, That the Laws of Maryland read as follows:
16	Article – Insurance
17	15-847.
18	(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
19	MEANINGS INDICATED.
20	(2) (I) "COMPLEX OR CHRONIC MEDICAL CONDITION" MEANS
21	A PHYSICAL, BEHAVIORAL, OR DEVELOPMENTAL CONDITION THAT:
22	1. MAY HAVE NO KNOWN CURE;
23	2. IS PROGRESSIVE; OR
24	<b>3.</b> CAN BE DEBILITATING OR FATAL IF LEFT
25	UNTREATED OR UNDERTREATED.
26	(II) "COMPLEX OR CHRONIC MEDICAL CONDITION"
27	INCLUDES:
28	1. MULTIPLE SCLEROSIS;
29	2. HEPATITIS C; AND
30	<b>3.</b> RHEUMATOID ARTHRITIS.

1	(3) "MANAGED CARE SYSTEM" MEANS A SYSTEM OF COST
2	CONTAINMENT METHODS THAT AN INSURER, A NONPROFIT HEALTH SERVICE
3	PLAN, OR A HEALTH MAINTENANCE ORGANIZATION USES TO REVIEW AND
4	PREAUTHORIZE DRUGS PRESCRIBED BY A HEALTH CARE PROVIDER FOR A
<b>5</b>	COVERED INDIVIDUAL TO CONTROL UTILIZATION, QUALITY, AND CLAIMS.
6	(4) (I) "RARE MEDICAL CONDITION" MEANS A DISEASE OR
7	CONDITION THAT AFFECTS FEWER THAN:
8	1. 200,000 INDIVIDUALS IN THE UNITED STATES; OR
9	2. APPROXIMATELY 1 IN 1,500 INDIVIDUALS
10	WORLDWIDE.
11	(II) <b>"RARE MEDICAL CONDITION" INCLUDES:</b>
12	1. CYSTIC FIBROSIS;
13	2. HEMOPHILIA; AND
14	<b>3.</b> MULTIPLE MYELOMA.
15	(5) "SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG THAT:
16	(I) IS PRESCRIBED FOR AN INDIVIDUAL WITH A COMPLEX
10 $17$	OR CHRONIC MEDICAL CONDITION OR A RARE MEDICAL CONDITION;
18	(II) COSTS \$600 OR MORE FOR UP TO A 30–DAY SUPPLY;
19	(III) IS NOT TYPICALLY STOCKED AT RETAIL PHARMACIES;
20	AND
21	(IV) 1. REQUIRES A DIFFICULT OR UNUSUAL PROCESS OF
22	DELIVERY TO THE PATIENT IN THE PREPARATION, HANDLING, STORAGE,
23	INVENTORY, OR DISTRIBUTION OF THE DRUG; OR
24	2. REQUIRES ENHANCED PATIENT EDUCATION,
25	MANAGEMENT, OR SUPPORT, BEYOND THOSE REQUIRED FOR TRADITIONAL
26	DISPENSING, BEFORE OR AFTER ADMINISTRATION OF THE DRUG.
27	(B) THIS SECTION APPLIES TO:

1 (1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT 2 PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER HEALTH INSURANCE 3 POLICIES OR CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE; AND

4 (2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE 5 COVERAGE FOR PRESCRIPTION DRUGS UNDER CONTRACTS THAT ARE ISSUED 6 OR DELIVERED IN THE STATE.

7 (C) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, AN
8 ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A COPAYMENT OR
9 COINSURANCE REQUIREMENT ON A COVERED SPECIALTY DRUG THAT EXCEEDS
10 \$150 FOR UP TO A 30-DAY SUPPLY OF THE SPECIALTY DRUG.

11 (2) ON JULY 1 OF EACH YEAR, THE LIMIT ON THE COPAYMENT OR 12COINSURANCE REQUIREMENT ON A COVERED SPECIALTY DRUG SHALL 13INCREASE BY A PERCENTAGE EQUAL TO THE PERCENTAGE CHANGE FROM THE 14MEDICAL CARE COMPONENT PRECEDING YEAR IN THE OF THE PRICE INDEX FOR ALL URBAN CONSUMERS. 15MARCH CONSUMER WASHINGTON-BALTIMORE, FROM THE U.S. DEPARTMENT OF LABOR, BUREAU 16 **OF LABOR STATISTICS.** 17

18 (D) SUBJECT TO § 15–805 OF THIS SUBTITLE AND NOTWITHSTANDING § 19 15–806 OF THIS SUBTITLE, NOTHING IN THIS ARTICLE OR REGULATIONS 20 ADOPTED UNDER THIS ARTICLE PRECLUDES AN ENTITY SUBJECT TO THIS 21 SECTION FROM REQUIRING A COVERED SPECIALTY DRUG TO BE OBTAINED 22 THROUGH:

23 (1) A DESIGNATED PHARMACY OR OTHER SOURCE AUTHORIZED
 24 UNDER THE HEALTH OCCUPATIONS ARTICLE TO DISPENSE OR ADMINISTER
 25 PRESCRIPTION DRUGS; OR

26(2)A PHARMACY PARTICIPATING IN THE ENTITY'S PROVIDER27NETWORK, IF THE ENTITY DETERMINES THAT THE PHARMACY:

28

(I) MEETS THE ENTITY'S PERFORMANCE STANDARDS; AND

29(II) ACCEPTS THE ENTITY'S NETWORK REIMBURSEMENT30RATES.

31(E)(1)A PHARMACY REGISTERED UNDER § 340B OF THE FEDERAL32PUBLIC HEALTH SERVICES ACT MAY APPLY TO AN ENTITY SUBJECT TO THIS33SECTION TO BE A DESIGNATED PHARMACY UNDER SUBSECTION (D)(1) OF THIS34SECTION FOR THE PURPOSE OF ENABLING THE PHARMACY'S PATIENTS WITH

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1	HIV, AIDS, OR HEPATITIS C TO RECEIVE THE COPAYMENT OR COINSURANCE
2	MAXIMUM PROVIDED FOR IN SUBSECTION (C) OF THIS SECTION IF:
3	(I) THE PHARMACY IS OWNED BY A FEDERALLY QUALIFIED
4	HEALTH CENTER, AS DEFINED IN 42 U.S.C. § 254B;
<b>5</b>	(II) THE FEDERALLY QUALIFIED HEALTH CENTER PROVIDES
6	INTEGRATED AND COORDINATED MEDICAL AND PHARMACEUTICAL SERVICES
7	TO HIV POSITIVE, AIDS, AND HEPATITIS C PATIENTS; AND
•	
8	(III) THE PRESCRIPTION DRUGS ARE COVERED SPECIALTY
9	DRUGS FOR THE TREATMENT OF HIV, AIDS, OR HEPATITIS C.
U	
10	(2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT
11	UNREASONABLY WITHHOLD APPROVAL OF A PHARMACY'S APPLICATION UNDER
11	PARAGRAPH (1) OF THIS SUBSECTION.
14	<u>FARAGRAFH (1) OF THIS SUBSECTION</u> .
13	(E) (F) AN ENTITY SUBJECT TO THIS SECTION MAY PROVIDE
14	COVERAGE FOR SPECIALTY DRUGS THROUGH A MANAGED CARE SYSTEM.
14	COVERAGE FOR STECIALIT DROUGS THROUGH A MANAGED CARE STSTEM.
15	(G) (1) A DETERMINATION BY AN ENTITY SUBJECT TO THIS SECTION
16	THAT A PRESCRIPTION DRUG IS NOT A SPECIALTY DRUG IS CONSIDERED A
17	COVERAGE DECISION UNDER § 15–10D–01 OF THIS TITLE.
18	(2) FOR COMPLAINTS FILED WITH THE COMMISSIONER UNDER
19	THIS SUBSECTION, IF THE ENTITY MADE ITS DETERMINATION THAT A
1 <i>5</i> 20	PRESCRIPTION DRUG IS NOT A SPECIALTY DRUG ON THE BASIS THAT THE
20 21	
	PRESCRIPTION DRUG DID NOT MEET THE CRITERIA LISTED IN SUBSECTION
22	(A)(5)(I) OF THIS SECTION:
23	(I) THE COMMISSIONER MAY SEEK ADVICE FROM AN
24	INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT ON THE LIST
25	COMPILED UNDER § 15–10A–05(B) OF THIS TITLE; AND
90	
26	(II) THE EXPENSES FOR ANY ADVICE PROVIDED BY AN
27	INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT SHALL BE PAID
28	FOR AS PROVIDED UNDER § 15–10A–05(H) OF THIS TITLE.
90	Article – Health – General
29	Article – Health – General
30	19–706.
50	10 100.
31	(0000) The provisions of § 15–847 of the Insurance Article
32	APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

1 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all 2 policies, contracts, and health benefit plans issued, delivered, or renewed in the State 3 on or after January 1, 2016.

4 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect 5 October 1, 2014.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.