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4lr3065 CF HB 761

By: Senator Klausmeier Senators Klausmeier, Astle, Feldman, Glassman, Kelley, Kittleman, Mathias, Middleton, Pugh, and Ramirez

Introduced and read first time: January 31, 2014 Assigned to: Finance

Committee Report: Favorable with amendments Senate action: Adopted Read second time: March 13, 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 7limit; providing that, under certain circumstances, certain provisions of law or certain regulations do not preclude certain insurers, nonprofit health service 8 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 provider network of the insurer, nonprofit health service plan, or health 11 12maintenance organization under certain conditions; authorizing a pharmacy registered under a certain provision of federal law to apply to be a designated 13 14 pharmacy for a certain purpose, under certain conditions; prohibiting an insurer, nonprofit health service plan, or health maintenance organization from 15unreasonably withholding certain approval; authorizing certain insurers, 16 17nonprofit health service plans, and health maintenance organizations to provide 18 coverage for specialty drugs through a managed care system; providing that a 19 certain determination is considered a coverage decision under certain provisions 20of law; authorizing the Maryland Insurance Commissioner to seek advice from certain persons relating to certain complaints filed with the Commissioner; 2122requiring the expenses for the advice to be paid for as provided under certain 23provisions of law; defining certain terms; making the provisions of this Act

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

<u>Underlining</u> 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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$\frac{1}{2}$	applicable to health maintenance organizations; providing for the application of this Act; and generally relating to specialty drugs.
$3 \\ 4 \\ 5 \\ 6 \\ 7$	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(0000) Annotated Code of Maryland (2009 Replacement Volume and 2013 Supplement)
13 14	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
15	Article – Insurance
16	15-847.
17 18	(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS INDICATED.
19 20	(2) (I) "COMPLEX OR CHRONIC MEDICAL CONDITION" MEANS A PHYSICAL, BEHAVIORAL, OR DEVELOPMENTAL CONDITION THAT:
21	1. MAY HAVE NO KNOWN CURE;
22	2. IS PROGRESSIVE; OR
23	3. CAN BE DEBILITATING OR FATAL IF LEFT
24	UNTREATED OR UNDERTREATED.
$\frac{25}{26}$	(II) "COMPLEX OR CHRONIC MEDICAL CONDITION" INCLUDES:
27	1. MULTIPLE SCLEROSIS;
28	2. HEPATITIS C; AND
29	3. RHEUMATOID ARTHRITIS.
30	(3) "MANAGED CARE SYSTEM" MEANS A SYSTEM OF COST
31	CONTAINMENT METHODS THAT AN INSURER, A NONPROFIT HEALTH SERVICE

PLAN, OR A HEALTH MAINTENANCE ORGANIZATION USES TO REVIEW AND 1 $\mathbf{2}$ PREAUTHORIZE DRUGS PRESCRIBED BY A HEALTH CARE PROVIDER FOR A 3 COVERED INDIVIDUAL TO CONTROL UTILIZATION, QUALITY, AND CLAIMS. "RARE MEDICAL CONDITION" MEANS A DISEASE OR 4 (4) **(I)** $\mathbf{5}$ CONDITION THAT AFFECTS FEWER THAN: 6 **200,000** INDIVIDUALS IN THE UNITED STATES; OR 1. 7 2. **APPROXIMATELY** 1 IN 1,500 **INDIVIDUALS** 8 WORLDWIDE. "RARE MEDICAL CONDITION" INCLUDES: 9 **(II)** 10 1. **CYSTIC FIBROSIS;** 2. 11 **HEMOPHILIA; AND** 3. 12**MULTIPLE MYELOMA.** 13 (5) "SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG THAT: 14**(I)** IS PRESCRIBED FOR AN INDIVIDUAL WITH A COMPLEX OR CHRONIC MEDICAL CONDITION OR A RARE MEDICAL CONDITION; 1516 **(II)** COSTS \$600 OR MORE FOR UP TO A 30-DAY SUPPLY; 17(III) IS NOT TYPICALLY STOCKED AT RETAIL PHARMACIES; 18 AND 19 (IV) 1. **REQUIRES A DIFFICULT OR UNUSUAL PROCESS OF** 20DELIVERY TO THE PATIENT IN THE PREPARATION, HANDLING, STORAGE, INVENTORY, OR DISTRIBUTION OF THE DRUG; OR 21222. **REQUIRES ENHANCED PATIENT** EDUCATION, 23MANAGEMENT, OR SUPPORT, BEYOND THOSE REQUIRED FOR TRADITIONAL DISPENSING, BEFORE OR AFTER ADMINISTRATION OF THE DRUG. 2425THIS SECTION APPLIES TO: **(B)** 26(1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT 27PROVIDE COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL, GROUP, 28OR BLANKET HEALTH INSURANCE POLICIES OR CONTRACTS THAT ARE ISSUED

29 OR DELIVERED IN THE STATE; AND

1(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE2COVERAGE FOR PRESCRIPTION DRUGS UNDER INDIVIDUAL OR GROUP3CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.

4 (C) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, AN 5 ENTITY SUBJECT TO THIS SECTION MAY NOT IMPOSE A COPAYMENT OR 6 COINSURANCE REQUIREMENT ON A COVERED SPECIALTY DRUG THAT EXCEEDS 7 \$150 FOR UP TO A 30-DAY SUPPLY OF THE SPECIALTY DRUG.

8 (2) ON JULY 1 OF EACH YEAR, THE LIMIT ON THE COPAYMENT OR COINSURANCE REQUIREMENT ON A COVERED SPECIALTY DRUG SHALL 9 INCREASE BY A PERCENTAGE EQUAL TO THE PERCENTAGE CHANGE FROM THE 10 11 PRECEDING YEAR IN THE MEDICAL CARE COMPONENT OF THE PRICE INDEX FOR ALL 12MARCH CONSUMER Urban CONSUMERS. WASHINGTON-BALTIMORE, FROM THE U.S. DEPARTMENT OF LABOR, BUREAU 13**OF LABOR STATISTICS.** 14

15 (D) SUBJECT TO § 15-805 OF THIS SUBTITLE AND NOTWITHSTANDING § 16 15-806 OF THIS SUBTITLE, NOTHING IN THIS ARTICLE OR REGULATIONS 17 ADOPTED UNDER THIS ARTICLE PRECLUDES AN ENTITY SUBJECT TO THIS 18 SECTION FROM REQUIRING A COVERED SPECIALTY DRUG TO BE OBTAINED 19 THROUGH:

20(1)A DESIGNATED PHARMACY OR OTHER SOURCE AUTHORIZED21UNDER THE HEALTH OCCUPATIONS ARTICLE TO DISPENSE OR ADMINISTER22PRESCRIPTION DRUGS; OR

23(2)A PHARMACY PARTICIPATING IN THE ENTITY'S PROVIDER24NETWORK, IF THE ENTITY DETERMINES THAT THE PHARMACY:

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- (I) MEETS THE ENTITY'S PERFORMANCE STANDARDS; AND
- 26(II)ACCEPTS THE ENTITY'S NETWORK REIMBURSEMENT27RATES.

(E) (1) <u>A PHARMACY REGISTERED UNDER § 340B OF THE FEDERAL</u>
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:

34(I)THE PHARMACY IS OWNED BY A FEDERALLY QUALIFIED35HEALTH CENTER, AS DEFINED IN 42 U.S.C. § 254B;

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$egin{array}{c} 1 \\ 2 \\ 3 \end{array}$	(II) <u>THE FEDERALLY QUALIFIED HEALTH CENTER PROVIDES</u> INTEGRATED AND COORDINATED MEDICAL AND PHARMACEUTICAL SERVICES TO HIV POSITIVE, AIDS, AND HEPATITIS C PATIENTS; AND
4 5	(III) THE PRESCRIPTION DRUGS ARE COVERED SPECIALTY DRUGS FOR THE TREATMENT OF HIV, AIDS, OR HEPATITIS C.
6 7 8	(2) AN ENTITY SUBJECT TO THIS SECTION MAY NOT UNREASONABLY WITHHOLD APPROVAL OF A PHARMACY'S APPLICATION UNDER PARAGRAPH (1) OF THIS SUBSECTION.
9 10	(<u>f)</u> An entity subject to this section may provide coverage for specialty drugs through a managed care system.
$11 \\ 12 \\ 13$	(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.
14 15 16 17 18	(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:
19 20 21	(I) <u>THE COMMISSIONER MAY SEEK ADVICE FROM AN</u> <u>INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT ON THE LIST</u> <u>COMPILED UNDER § 15–10A–05(B) OF THIS TITLE; AND</u>
$22 \\ 23 \\ 24$	(II) <u>THE EXPENSES FOR ANY ADVICE PROVIDED BY AN</u> <u>INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT SHALL BE PAID</u> <u>FOR AS PROVIDED UNDER § 15–10A–05(H) OF THIS TITLE.</u>
25	Article – Health – General
26	19–706.
$\frac{27}{28}$	(0000) THE PROVISIONS OF § 15–847 OF THE INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.
29 30	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

31 on or after January 1, 2016.

- SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect 1 $\mathbf{2}$
- October 1, 2014.

Approved:

Governor.

President of the Senate.

Speaker of the House of Delegates.