

HOUSE BILL 1183

C3

8lr2878
CF 8lr3424

By: **Delegate Kipke**

Introduced and read first time: February 8, 2018

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Access to and Coverage of Specialty Drugs – Definition**

3 FOR the purpose of altering the definition of “specialty drug” for purposes of certain
4 provisions of law governing access to specialty drugs through certain pharmacies;
5 making conforming changes; providing for the application of this Act; providing for
6 a delayed effective date; and generally relating to insurance carriers and access to
7 and coverage of specialty drugs.

8 BY repealing and reenacting, with amendments,

9 Article – Insurance

10 Section 15–847

11 Annotated Code of Maryland

12 (2017 Replacement Volume)

13 BY adding to

14 Article – Insurance

15 Section 15–847.1

16 Annotated Code of Maryland

17 (2017 Replacement Volume)

18 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND,

19 That the Laws of Maryland read as follows:

20 **Article – Insurance**

21 15–847.

22 (a) (1) In this section the following words have the meanings indicated.

23 [(2) (i) “Complex or chronic medical condition” means a physical,

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 behavioral, or developmental condition that:

- 2 1. may have no known cure;
- 3 2. is progressive; or
- 4 3. can be debilitating or fatal if left untreated or
- 5 undertreated.

6 (ii) “Complex or chronic medical condition” includes:

- 7 1. multiple sclerosis;
- 8 2. hepatitis C; and
- 9 3. rheumatoid arthritis.]

10 **[(3)] (2)** “Managed care system” means a system of cost containment
11 methods that an insurer, a nonprofit health service plan, or a health maintenance
12 organization uses to review and preauthorize drugs prescribed by a health care provider
13 for a covered individual to control utilization, quality, and claims.

14 **[(4)] (i)** “Rare medical condition” means a disease or condition that
15 affects fewer than:

- 16 1. 200,000 individuals in the United States; or
- 17 2. approximately 1 in 1,500 individuals worldwide.

18 (ii) “Rare medical condition” includes:

- 19 1. cystic fibrosis;
- 20 2. hemophilia; and
- 21 3. multiple myeloma.]

22 **[(5)] (3)** “Specialty drug” means a prescription drug that:

23 **[(i)]** is prescribed for an individual with a complex or chronic medical
24 condition or a rare medical condition;

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

26 **[(iii)]** is not typically stocked at retail pharmacies; and

1 (iv) 1. requires a difficult or unusual process of delivery to the
2 patient in the preparation, handling, storage, inventory, or distribution of the drug; or

3 2. requires enhanced patient education, management, or
4 support, beyond those required for traditional dispensing, before or after administration of
5 the drug]

6 (I) IS DESIGNATED A LIMITED DISTRIBUTION DRUG BY THE
7 U.S. FOOD AND DRUG ADMINISTRATION;

8 (II) IS NOT AVAILABLE IN AN ORAL OR SELF-ADMINISTERED
9 FORMULATION; OR

10 (III) REQUIRES SPECIAL HANDLING ABOVE AND BEYOND
11 REFRIGERATION OR PATIENT COUNSELING.

12 (b) This section applies to:

13 (1) insurers and nonprofit health service plans that provide coverage for
14 prescription drugs under individual, group, or blanket health insurance policies or
15 contracts that are issued or delivered in the State; and

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

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

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

27 [(d)] (C) Subject to § 15-805 of this subtitle and notwithstanding § 15-806 of
28 this subtitle, nothing in this article or regulations adopted under this article precludes an
29 entity subject to this section from requiring a covered specialty drug to be obtained through:

30 (1) a designated pharmacy or other source authorized under the Health
31 Occupations Article to dispense or administer prescription drugs; or

32 (2) a pharmacy participating in the entity's provider network, if the entity
33 determines that the pharmacy:

1 (i) meets the entity's performance standards; and

2 (ii) accepts the entity's network reimbursement rates.

3 **[(e)] (D)** (1) A pharmacy registered under § 340B of the federal Public Health
4 Services Act may apply to an entity subject to this section to be a designated pharmacy
5 under subsection **[(d)(1)] (C)(1)** of this section for the purpose of enabling the pharmacy's
6 patients with HIV, AIDS, or hepatitis C to receive the copayment or coinsurance maximum
7 provided for in **[subsection (c) of this section] § 15-847.1(C) OF THIS SUBTITLE** if:

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

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

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

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

17 **[(f)] (E)** An entity subject to this section may provide coverage for specialty
18 drugs through a managed care system.

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

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

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

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

31 **15-847.1.**

32 **(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE MEANINGS**
33 **INDICATED.**

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

- 3 **1. MAY HAVE NO KNOWN CURE;**
4 **2. IS PROGRESSIVE; OR**
5 **3. CAN BE DEBILITATING OR FATAL IF LEFT UNTREATED**
6 **OR UNDERTREATED.**

7 **(II) “COMPLEX OR CHRONIC MEDICAL CONDITION” INCLUDES:**

- 8 **1. MULTIPLE SCLEROSIS;**
9 **2. HEPATITIS C; AND**
10 **3. RHEUMATOID ARTHRITIS.**

11 **(3) (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 **(4) “SPECIALTY DRUG” MEANS A PRESCRIPTION DRUG THAT:**

21 **(I) IS PRESCRIBED FOR AN INDIVIDUAL WITH A COMPLEX OR**
22 **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; AND**

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

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

7 (B) THIS SECTION APPLIES TO:

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

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

15 (C) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, AN ENTITY
16 SUBJECT TO THIS SECTION MAY NOT IMPOSE A COPAYMENT OR COINSURANCE
17 REQUIREMENT ON A COVERED SPECIALTY DRUG THAT EXCEEDS \$150 FOR UP TO A
18 30-DAY SUPPLY OF THE SPECIALTY DRUG.

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

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

28 (2) FOR COMPLAINTS FILED WITH THE COMMISSIONER UNDER THIS
29 SUBSECTION, IF THE ENTITY MADE ITS DETERMINATION THAT A PRESCRIPTION
30 DRUG IS NOT A SPECIALTY DRUG ON THE BASIS THAT THE PRESCRIPTION DRUG DID
31 NOT MEET THE CRITERIA LISTED IN SUBSECTION (A)(4)(I) OF THIS SECTION:

32 (I) THE COMMISSIONER MAY SEEK ADVICE FROM AN
33 INDEPENDENT REVIEW ORGANIZATION OR MEDICAL EXPERT ON THE LIST

1 COMPILED UNDER § 15-10A-05(B) OF THIS TITLE; AND

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

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 on or
7 after January 1, 2019.

8 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
9 January 1, 2019.