

# HOUSE BILL 1383

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CF 6lr3708

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By: **Delegates Kipke, Bromwell, Angel, Cullison, Hayes, Kelly, Krebs, McDonough, Miele, Morgan, Morhaim, Oaks, Rose, Saab, Sample–Hughes, Szeliga, West, and K. Young**

Introduced and read first time: February 12, 2016

Assigned to: Health and Government Operations

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## A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Specialty Drugs – Participating Pharmacies**

3 FOR the purpose of altering the conditions under which certain insurers, nonprofit health  
4 service plans, or health maintenance organizations may require a covered specialty  
5 drug to be obtained through a pharmacy participating in the provider network of the  
6 insurer, nonprofit health service plan, or health maintenance organization;  
7 providing that certain provisions of law do not prohibit a manufacturer from  
8 establishing a certain network; altering the definition of “specialty drug”; providing  
9 for the application of this Act; providing for a delayed effective date; and generally  
10 relating to specialty drugs.

11 BY repealing and reenacting, with amendments,  
12 Article – Insurance  
13 Section 15–847  
14 Annotated Code of Maryland  
15 (2011 Replacement Volume and 2015 Supplement)

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

18 **Article – Insurance**

19 15–847.

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

21 (2) (i) “Complex or chronic medical condition” means a physical,  
22 behavioral, or developmental condition that:

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EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

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

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

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

13 (4) (i) “Rare medical condition” means a disease or condition that  
14 affects fewer than:

- 15 1. 200,000 individuals in the United States; or
- 16 2. approximately 1 in 1,500 individuals worldwide.

17 (ii) “Rare medical condition” includes:

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

21 (5) “Specialty drug” means a prescription drug that:

22 (i) is prescribed for an individual with a complex or chronic medical  
23 condition or a rare medical condition;

24 (ii) costs \$600 or more for up to a 30-day supply; AND

25 (iii) [is not typically stocked at retail pharmacies; and

26 (iv)] **AS DOCUMENTED OR IDENTIFIED BY THE MANUFACTURER**  
27 **OF THE PRESCRIPTION DRUG;**

1                   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           (b)       This section applies to:

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

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

13           (c)       (1)       Subject to paragraph (2) of this subsection, an entity subject to this  
14 section may not impose a copayment or coinsurance requirement on a covered specialty  
15 drug that exceeds \$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 coinsurance  
17 requirement on a covered specialty drug shall increase by a percentage equal to the  
18 percentage change from the preceding year in the medical care component of the March  
19 Consumer Price Index for All Urban Consumers, Washington-Baltimore, from the U.S.  
20 Department of Labor, Bureau of Labor Statistics.

21           (d)       **(1)**       Subject to § 15-805 of this subtitle and notwithstanding § 15-806 of  
22 this subtitle, nothing in this article or regulations adopted under this article precludes an  
23 entity subject to this section from requiring a covered specialty drug to be obtained through:

24                   [(1)]   **(I)**       a designated pharmacy or other source authorized under the  
25 Health Occupations Article to dispense or administer prescription drugs; or

26                   [(2)]   **(II)**       a pharmacy participating in the entity's provider network, if [the  
27 entity determines that] the pharmacy:

28                           [(i)   meets the entity's performance standards; and]

29                                   **1.     IS LICENSED;**

30                                   **2.     HAS IN INVENTORY OR READILY IS ABLE TO OBTAIN**  
31 **THE COVERED SPECIALTY DRUG FROM THE MANUFACTURER; AND**

32                                   [(ii)] **3.     accepts the entity's network reimbursement rates.**

1           **(2) THIS SUBSECTION DOES NOT PROHIBIT A MANUFACTURER FROM**  
2 **ESTABLISHING A LIMITED DISTRIBUTION NETWORK FOR ONE OR MORE OF THE**  
3 **MANUFACTURER'S PRODUCTS.**

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

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

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

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

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

18           (f) An entity subject to this section may provide coverage for specialty drugs  
19 through a managed care system.

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

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

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

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

32           SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all  
33 policies, contracts, and health benefit plans issued, delivered, or renewed in the State on or  
34 after January 1, 2017.

1           SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect  
2   January 1, 2017.