

HOUSE BILL 875

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CF SB 825

By: **Delegates Kipke, Bromwell, Kach, A. Kelly, McComas, Ready, and Tarrant**
Introduced and read first time: February 5, 2014
Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Pharmacy Benefits Managers – Specialty Drugs**

3 FOR the purpose of requiring a pharmacy benefits manager to designate on a certain
4 formulary the prescription drugs that are Tier I specialty drugs and Tier II
5 specialty drugs; requiring a pharmacy benefits manager to submit a list of
6 certain drugs to the Maryland Insurance Commissioner and to update the list
7 with a certain frequency; requiring a pharmacy benefits manager to allow
8 certain pharmacies and pharmacists to dispense certain specialty drugs if the
9 pharmacist or pharmacy meets certain requirements; prohibiting a pharmacy
10 benefits manager from requiring certain specialty drugs to be dispensed by mail
11 order; prohibiting a pharmacy benefits manager from imposing certain
12 payments or other conditions on beneficiaries under certain circumstances;
13 authorizing a pharmacist or pharmacy to request a certain determination from
14 the Commissioner under certain circumstances; requiring the Commissioner to
15 make a determination on a request in consultation with certain entities and
16 within a certain time period; requiring a pharmacy benefits manager to change
17 its designation of a certain specialty drug in accordance with the determination
18 of the Commissioner; requiring a pharmacy benefits manager to reimburse a
19 retail pharmacy for certain specialty drugs at a certain reimbursement rate;
20 prohibiting a pharmacy benefits manager from imposing a copayment or
21 coinsurance requirement that exceeds a certain amount for a certain supply of a
22 certain drug; defining certain terms; and generally relating to pharmacy
23 benefits managers and specialty drugs.

24 BY adding to
25 Article – Insurance
26 Section 15–1632
27 Annotated Code of Maryland
28 (2011 Replacement Volume and 2013 Supplement)

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



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

3 **Article – Insurance**

4 **15-1632.**

5 (A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE
6 MEANINGS INDICATED.

7 (2) “TIER I SPECIALTY DRUG” MEANS A PRESCRIPTION DRUG
8 THAT:

9 (I) IS NOT ROUTINELY DISPENSED AT A MAJORITY OF
10 RETAIL PHARMACIES DUE TO PHYSICAL OR ADMINISTRATIVE REQUIREMENTS
11 THAT LIMIT THE PREPARATION OR DELIVERY OF THE PRESCRIPTION DRUG IN A
12 RETAIL PHARMACY ENVIRONMENT;

13 (II) INCLUDES NONORAL CHEMOTHERAPY DRUGS,
14 NONORAL RADIATION DRUGS, INTRAVENOUS THERAPY DRUGS, OR OTHER
15 DRUGS THAT REQUIRE PHYSICAL FACILITIES, SUCH AS A VENTILATION HOOD
16 FOR PREPARATION, THAT ARE NOT TYPICALLY FOUND IN A RETAIL PHARMACY
17 ENVIRONMENT;

18 (III) IS USED TO TREAT COMPLEX, CHRONIC, OR RARE
19 MEDICAL CONDITIONS:

20 1. THAT CAN BE PROGRESSIVE;

21 2. THAT CAN BE DEBILITATING OR FATAL IF LEFT
22 UNTREATED OR UNDERTREATED; OR

23 3. FOR WHICH THERE IS NO KNOWN CURE;

24 (IV) 1. REQUIRES SPECIAL HANDLING OR STORAGE; OR

25 2. HAS DISTRIBUTION OR INVENTORY LIMITATIONS;

26 (V) HAS A COMPLEX DOSING REGIMEN OR REQUIRES
27 SPECIALIZED ADMINISTRATION;

28 (VI) IS CONSIDERED BY THE U.S. FOOD AND DRUG
29 ADMINISTRATION TO HAVE RESTRICTED DISTRIBUTION;

1 (VII) REQUIRES:

- 2 1. COMPLEX AND EXTENDED PATIENT EDUCATION
3 OR COUNSELING;
4 2. INTENSIVE MONITORING; OR
5 3. CLINICAL OVERSIGHT; AND

6 (VIII) HAS SIGNIFICANT SIDE EFFECTS OR A SIGNIFICANT
7 RISK PROFILE.

8 (3) "TIER II SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG
9 THAT REQUIRES:

- 10 (I) SPECIAL HANDLING;
11 (II) SPECIAL ADMINISTRATION;
12 (III) UNIQUE INVENTORY MANAGEMENT;
13 (IV) A HIGH LEVEL OF PATIENT MONITORING; OR
14 (V) MORE INTENSE PATIENT SUPPORT THAN
15 CONVENTIONAL THERAPIES.

16 (B) A PHARMACY BENEFITS MANAGER SHALL:

17 (1) DESIGNATE ON THE FORMULARY OF THE PHARMACY
18 BENEFITS MANAGER THE PRESCRIPTION DRUGS THAT ARE:

- 19 (I) TIER I SPECIALTY DRUGS; AND
20 (II) TIER II SPECIALTY DRUGS;

21 (2) SUBMIT TO THE COMMISSIONER A LIST OF PRESCRIPTION
22 DRUGS THAT HAVE BEEN DESIGNATED BY THE PHARMACY BENEFITS MANAGER
23 AS TIER I SPECIALTY DRUGS;

24 (3) UPDATE THE LIST OF TIER I SPECIALTY DRUGS EVERY 90
25 DAYS; AND

1 **(4) SUBMIT THE UPDATED LIST OF TIER I SPECIALTY DRUGS TO**
2 **THE COMMISSIONER.**

3 **(C) A PHARMACY BENEFITS MANAGER SHALL ALLOW ANY PHARMACY**
4 **TO DISPENSE A TIER I SPECIALTY DRUG TO THE BENEFICIARIES OF THE**
5 **PHARMACY BENEFITS MANAGER IF THE PHARMACY:**

6 **(1) HOLDS A PHARMACY PERMIT IN THE STATE; AND**

7 **(2) IS AUTHORIZED BY A WHOLESALE DISTRIBUTOR TO**
8 **PURCHASE THE TIER I SPECIALTY DRUG.**

9 **(D) A PHARMACY BENEFITS MANAGER SHALL ALLOW ANY LICENSED**
10 **PHARMACIST OR ANY PHARMACY THAT HOLDS A PHARMACY PERMIT IN THE**
11 **STATE TO DISPENSE A PRESCRIPTION FOR A TIER II SPECIALTY DRUG IF THE**
12 **PHARMACIST OR PHARMACY:**

13 **(1) HOLDS A CONTRACT WITH THE PHARMACY BENEFITS**
14 **MANAGER;**

15 **(2) HAS THE TIER II SPECIALTY DRUG IN INVENTORY OR HAS**
16 **READY ACCESS TO THE TIER II SPECIALTY DRUG; AND**

17 **(3) IS CAPABLE OF COMPLYING WITH ANY SPECIAL HANDLING,**
18 **SPECIAL ADMINISTRATION, UNIQUE INVENTORY MANAGEMENT, HIGH LEVEL OF**
19 **PATIENT MONITORING, OR MORE INTENSE PATIENT SUPPORT REQUIREMENTS**
20 **FOR THE TIER II SPECIALTY DRUG.**

21 **(E) A PHARMACY BENEFITS MANAGER MAY NOT:**

22 **(1) REQUIRE A TIER I SPECIALTY DRUG OR A TIER II SPECIALTY**
23 **DRUG TO BE DISPENSED BY MAIL ORDER; OR**

24 **(2) IMPOSE A COPAYMENT, A DEDUCTIBLE, OR ANY OTHER**
25 **CONDITION ON A BENEFICIARY WHO USES THE SERVICE OF A NONCOMMUNITY**
26 **PHARMACY FOR A TIER I SPECIALTY DRUG OR A TIER II SPECIALTY DRUG THAT**
27 **IS NOT IMPOSED WHEN THE BENEFICIARY USES THE SERVICES OF A COMMUNITY**
28 **PHARMACY FOR A TIER I SPECIALTY DRUG OR A TIER II SPECIALTY DRUG IF**
29 **THE BENEFITS ARE PROVIDED UNDER THE SAME PROGRAM, POLICY, OR**
30 **CONTRACT.**

31 **(F) (1) IF A PHARMACIST OR PHARMACY DISPUTES THE**
32 **DESIGNATION BY A PHARMACY BENEFITS MANAGER OF A PRESCRIPTION DRUG**

1 AS A TIER I SPECIALTY DRUG OR A TIER II SPECIALTY DRUG, THE PHARMACIST
2 OR PHARMACY MAY REQUEST A DETERMINATION FROM THE COMMISSIONER AS
3 TO WHETHER THE PRESCRIPTION DRUG IS A TIER I SPECIALTY DRUG OR A TIER
4 II SPECIALTY DRUG.

5 (2) IF THE COMMISSIONER RECEIVES A REQUEST FROM A
6 PHARMACIST OR A PHARMACY UNDER PARAGRAPH (1) OF THIS SUBSECTION,
7 THE ADMINISTRATION, IN CONSULTATION WITH THE STATE BOARD OF
8 PHARMACY AND THE UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY,
9 SHALL MAKE A DETERMINATION ON THE REQUEST WITHIN 30 DAYS AFTER
10 RECEIPT.

11 (3) A PHARMACY BENEFITS MANAGER SHALL CHANGE THE
12 DESIGNATION OF A TIER I SPECIALTY DRUG OR A TIER II SPECIALTY DRUG IN
13 ACCORDANCE WITH THE DETERMINATION OF THE COMMISSIONER.

14 (G) A PHARMACY BENEFITS MANAGER SHALL REIMBURSE A RETAIL
15 PHARMACY FOR A TIER I SPECIALTY DRUG AND A TIER II SPECIALTY DRUG ON
16 THE FORMULARY OF THE PHARMACY BENEFITS MANAGER AND DISPENSED BY
17 THE RETAIL PHARMACY AT THE CURRENT PREFERRED BRAND TIER
18 REIMBURSEMENT RATE SPECIFIED IN THE CONTRACT BETWEEN THE PHARMACY
19 BENEFITS MANAGER AND THE RETAIL PHARMACY.

20 (H) A PHARMACY BENEFITS MANAGER MAY NOT IMPOSE A COPAYMENT
21 OR COINSURANCE REQUIREMENT THAT EXCEEDS \$150 FOR UP TO A 30-DAY
22 SUPPLY OF A COVERED TIER I SPECIALTY DRUG OR TIER II SPECIALTY DRUG.

23 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
24 October 1, 2014.