HOUSE BILL 875

C3 4lr1815
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

AN ACT concerning

Pharmacy Benefits Managers – Specialty Drugs

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

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

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

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

Article – Insurance

15–1632.

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

(2) "TIER I SPECIALTY DRUG" MEANS A PRESCRIPTION DRUG THAT:

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

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

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

1. THAT CAN BE PROGRESSIVE;

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

3. FOR WHICH THERE IS NO KNOWN CURE;

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

2. HAS DISTRIBUTION OR INVENTORY LIMITATIONS;

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

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

(VII) REQUIRES:

1. COMPLEX AND EXTENDED PATIENT EDUCATION OR COUNSELING;

2. INTENSIVE MONITORING; OR

3. CLINICAL OVERSIGHT; AND

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

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

(I) SPECIAL HANDLING;

(II) SPECIAL ADMINISTRATION;

(III) UNIQUE INVENTORY MANAGEMENT;

(IV) A HIGH LEVEL OF PATIENT MONITORING; OR

(V) MORE INTENSE PATIENT SUPPORT THAN CONVENTIONAL THERAPIES.

(B) A PHARMACY BENEFITS MANAGER SHALL:

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

(I) TIER I SPECIALTY DRUGS; AND

(II) TIER II SPECIALTY DRUGS;

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

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

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

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

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

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

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

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

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

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

(E) A PHARMACY BENEFITS MANAGER MAY NOT:

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

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

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

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

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

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

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

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

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