

HOUSE BILL 580

J3

8lr0724

By: **Delegates Oaks, Costa, Davis, Elliott, Hammen, Hubbard, Kipke, ~~and Rudolph~~ Rudolph, Benson, Bromwell, Donoghue, Kach, McDonough, Mizeur, Montgomery, Morhaim, Nathan-Pulliam, Pena-Melnyk, Pendergrass, Reznik, Riley, V. Turner, and Weldon**

Introduced and read first time: January 31, 2008

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 16, 2008

CHAPTER _____

1 AN ACT concerning

2 **Pharmacy Benefits Managers – Pharmacy and Therapeutics ~~Committee~~**
3 **Committees**

4 FOR the purpose of establishing certain requirements for ~~members of~~ a pharmacy and
5 therapeutics committee of a pharmacy benefits manager; requiring a pharmacy
6 benefits manager to ensure that its pharmacy and therapeutics committee has
7 certain policies and procedures; requiring a pharmacy benefits manager to
8 disclose information about the composition of its pharmacy and therapeutics
9 committee to a certain person under certain circumstances; prohibiting a
10 pharmacy benefits manager from requiring a pharmacist to participate on its
11 pharmacy and therapeutics committee; making certain provisions of law
12 applicable to health maintenance organizations; defining certain terms; and
13 generally relating to regulation of pharmacy benefits managers.

14 BY adding to

15 Article – Insurance

16 Section 15–1601 and 15–1602 to be under the new subtitle “Subtitle 16.
17 Pharmacy Benefits Managers”

18 Annotated Code of Maryland

19 (2006 Replacement Volume and 2007 Supplement)

20 BY adding to

21 Article – Health – General

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike-out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 Section 19-706(ppp)
 2 Annotated Code of Maryland
 3 (2005 Replacement Volume and 2007 Supplement)

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

6 **Article - Insurance**

7 **SUBTITLE 16. PHARMACY BENEFITS MANAGERS.**

8 ~~15-1601.~~

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

11 ~~(2) (i) "PHARMACY BENEFITS MANAGEMENT SERVICES"~~
 12 ~~MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG~~
 13 ~~BENEFITS.~~

14 ~~(H) "PHARMACY BENEFITS MANAGEMENT SERVICES"~~
 15 ~~INCLUDES:~~

16 ~~1. PROCUREMENT OF PRESCRIPTION DRUGS AT A~~
 17 ~~NEGOTIATED RATE FOR DISPENSATION WITHIN THE STATE;~~

18 ~~2. PROCESSING OF PRESCRIPTION DRUG CLAIMS;~~

19 ~~3. ADMINISTRATION OF PAYMENTS RELATED TO~~
 20 ~~PRESCRIPTION DRUG CLAIMS; AND~~

21 ~~4. NEGOTIATING OR ENTERING INTO CONTRACTUAL~~
 22 ~~ARRANGEMENTS WITH PHARMACY PROVIDERS.~~

23 ~~(3) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT~~
 24 ~~PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.~~

25 ~~(B) THE PROVISIONS OF THIS SECTION DO NOT APPLY TO A MANAGED~~
 26 ~~CARE ORGANIZATION AUTHORIZED BY TITLE 15, SUBTITLE 1 OF THE HEALTH-~~
 27 ~~GENERAL ARTICLE.~~

28 ~~(C) THE PROVISIONS OF THIS SECTION DO NOT APPLY TO AN INSURER,~~
 29 ~~NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION,~~
 30 ~~OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF AN INSURER,~~

~~1 NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION
2 ACTING OR REPRESENTING ITSELF AS A PHARMACY BENEFITS MANAGER IF:~~

~~3 (1) THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR
4 HEALTH MAINTENANCE ORGANIZATION OR THE AFFILIATE, SUBSIDIARY, OR
5 OTHER RELATED ENTITY OF THE INSURER, NONPROFIT HEALTH SERVICE PLAN,
6 OR HEALTH MAINTENANCE ORGANIZATION DIRECTLY OFFERS OR PROVIDES
7 PHARMACY BENEFITS MANAGEMENT SERVICES; AND~~

~~8 (2) THE PHARMACY BENEFITS MANAGEMENT SERVICES ARE
9 OFFERED OR PROVIDED ONLY TO ENROLLEES, SUBSCRIBERS, OR INSUREDS
10 WHO ALSO ARE COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE
11 INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE
12 ORGANIZATION.~~

~~13 (D) (1) EACH MEMBER OF A PHARMACY AND THERAPEUTICS
14 COMMITTEE OF A PHARMACY BENEFITS MANAGER SHALL BE:~~

~~15 (I) A PHYSICIAN OR OTHER AUTHORIZED PRESCRIBER, A
16 PHARMACIST, OR A FACULTY MEMBER OF AN ACADEMIC MEDICAL CENTER; AND~~

~~17 (II) DISCLOSED BY NAME TO THE PURCHASER ON REQUEST.~~

~~18 (2) A MAJORITY OF COMMITTEE MEMBERS MAY NOT BE
19 EMPLOYED BY THE PHARMACY BENEFITS MANAGER.~~

~~20 (E) A PHARMACY AND THERAPEUTICS COMMITTEE MEMBER MAY NOT:~~

~~21 (1) BE AN OFFICER, EMPLOYEE, DIRECTOR, OR AGENT OF A
22 PHARMACEUTICAL MANUFACTURER; OR~~

~~23 (2) HAVE A FINANCIAL INTEREST IN A PHARMACEUTICAL
24 MANUFACTURER, OTHER THAN OWNERSHIP OF A NOMINAL NUMBER OF SHARES
25 OF THE PHARMACEUTICAL MANUFACTURER'S STOCK, PURCHASED ON A
26 NATIONAL SECURITIES EXCHANGE.~~

~~27 (F) (1) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A
28 PHARMACY TO PARTICIPATE IN A PHARMACY AND THERAPEUTICS COMMITTEE.~~

~~29 (2) IF A PHARMACY AGREES TO PARTICIPATE IN A PHARMACY
30 AND THERAPEUTICS COMMITTEE, THE PHARMACY BENEFITS MANAGER SHALL
31 REIMBURSE ANY EXPENSES INCURRED BY THE PHARMACY AS A RESULT OF ITS
32 PARTICIPATION.~~

33 15-1601.

1 **(A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS**
2 **INDICATED.**

3 **(B) “BENEFICIARY” MEANS AN INDIVIDUAL WHO RECEIVES**
4 **PRESCRIPTION DRUG COVERAGE OR BENEFITS FROM A PURCHASER.**

5 **(C) “ERISA” HAS THE MEANING STATED IN § 8-301 OF THIS ARTICLE.**

6 **(D) “FORMULARY” MEANS A LIST OF PRESCRIPTION DRUGS USED BY A**
7 **PURCHASER.**

8 **(E) “NONPROFIT HEALTH MAINTENANCE ORGANIZATION” HAS THE**
9 **MEANING STATED IN § 6-121(A) OF THIS ARTICLE.**

10 **(F) (1) “PHARMACY BENEFITS MANAGEMENT SERVICES” MEANS:**

11 **(I) THE PROCUREMENT OF PRESCRIPTION DRUGS AT A**
12 **NEGOTIATED RATE FOR DISPENSATION WITHIN THE STATE TO BENEFICIARIES;**

13 **(II) THE ADMINISTRATION OR MANAGEMENT OF**
14 **PRESCRIPTION DRUG COVERAGE PROVIDED BY A PURCHASER FOR**
15 **BENEFICIARIES; AND**

16 **(III) ANY OF THE FOLLOWING SERVICES PROVIDED WITH**
17 **REGARD TO THE ADMINISTRATION OF PRESCRIPTION DRUG COVERAGE:**

18 **1. MAIL SERVICE PHARMACY;**

19 **2. CLAIMS PROCESSING, RETAIL NETWORK**
20 **MANAGEMENT AND PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION**
21 **DRUGS DISPENSED TO BENEFICIARIES;**

22 **3. CLINICAL FORMULARY DEVELOPMENT AND**
23 **MANAGEMENT SERVICES;**

24 **4. REBATE CONTRACTING AND ADMINISTRATION;**

25 **5. PATIENT COMPLIANCE, THERAPEUTIC**
26 **INTERVENTION, AND GENERIC SUBSTITUTION PROGRAMS; OR**

27 **6. DISEASE MANAGEMENT PROGRAMS.**

28 **(2) “PHARMACY BENEFITS MANAGEMENT SERVICES” DOES NOT**
29 **INCLUDE ANY SERVICE PROVIDED BY A NONPROFIT HEALTH MAINTENANCE**

1 ORGANIZATION THAT OPERATES AS A GROUP MODEL, PROVIDED THAT THE
2 SERVICE:

3 (I) IS PROVIDED SOLELY TO A MEMBER OF THE NONPROFIT
4 HEALTH MAINTENANCE ORGANIZATION; AND

5 (II) IS FURNISHED THROUGH THE INTERNAL PHARMACY
6 OPERATIONS OF THE NONPROFIT HEALTH MAINTENANCE ORGANIZATION.

7 (G) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT
8 PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.

9 (H) "PHARMACY AND THERAPEUTICS COMMITTEE" MEANS A
10 COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER TO:

11 (1) OBJECTIVELY APPRAISE AND EVALUATE PRESCRIPTION
12 DRUGS; AND

13 (2) MAKE RECOMMENDATIONS TO A PURCHASER REGARDING THE
14 SELECTION OF DRUGS FOR THE PURCHASER'S FORMULARY.

15 (I) (1) "PURCHASER" MEANS THE STATE EMPLOYEE AND RETIREE
16 HEALTH AND WELFARE BENEFITS PROGRAM, AN INSURER, A NONPROFIT
17 HEALTH SERVICE PLAN, OR A HEALTH MAINTENANCE ORGANIZATION THAT:

18 (I) PROVIDES PRESCRIPTION DRUG COVERAGE OR
19 BENEFITS IN THE STATE; AND

20 (II) ENTERS INTO AN AGREEMENT WITH A PHARMACY
21 BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS
22 MANAGEMENT SERVICES.

23 (2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES
24 PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO
25 ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS
26 THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER
27 WELFARE ASSOCIATION AS DEFINED IN § 514(B)(6)(A)(II) OF ERISA.

28 15-1602.

29 (A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A
30 PHARMACY BENEFITS MANAGER SHALL MEET THE REQUIREMENTS OF THIS
31 SECTION.

32 (B) (1) A PHARMACY AND THERAPEUTICS COMMITTEE SHALL:

1 (I) INCLUDE CLINICAL SPECIALISTS THAT REPRESENT THE
2 NEEDS OF A PURCHASER'S BENEFICIARIES; AND

3 (II) INCLUDE AT LEAST ONE PRACTICING PHARMACIST AND
4 ONE PRACTICING PHYSICIAN WHO ARE INDEPENDENT OF ANY DEVELOPER OR
5 MANUFACTURER OF PRESCRIPTION DRUGS.

6 (2) EACH MEMBER OF A PHARMACY AND THERAPEUTICS
7 COMMITTEE SHALL SIGN A CONFLICT OF INTEREST STATEMENT UPDATED AT
8 LEAST ANNUALLY DISCLOSING ANY ECONOMIC INTEREST OR RELATIONSHIP
9 THAT COULD INFLUENCE THE PHARMACY AND THERAPEUTICS COMMITTEE'S
10 DECISIONS.

11 (3) A MAJORITY OF THE MEMBERS OF A PHARMACY AND
12 THERAPEUTICS COMMITTEE SHALL BE PRACTICING PHYSICIANS OR
13 PRACTICING PHARMACISTS.

14 (C) A PHARMACY BENEFITS MANAGER SHALL ENSURE THAT ITS
15 PHARMACY AND THERAPEUTICS COMMITTEE HAS:

16 (1) POLICIES AND PROCEDURES, INCLUDING DISCLOSURE
17 REQUIREMENTS, TO ADDRESS POTENTIAL CONFLICTS OF INTEREST THAT
18 MEMBERS OF THE PHARMACY AND THERAPEUTICS COMMITTEE MAY HAVE WITH
19 DEVELOPERS OR MANUFACTURERS OF PRESCRIPTION DRUGS;

20 (2) A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC
21 EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION
22 DRUGS, INCLUDING AVAILABLE COMPARATIVE INFORMATION ON CLINICALLY
23 SIMILAR PRESCRIPTION DRUGS, WHEN DECIDING WHAT PRESCRIPTION DRUGS
24 TO RECOMMEND TO INCLUDE ON A FORMULARY;

25 (3) A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC
26 EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION
27 DRUGS WHEN RECOMMENDING UTILIZATION REVIEW REQUIREMENTS, DOSE
28 RESTRICTIONS, AND STEP THERAPY REQUIREMENTS; AND

29 (4) A PROCESS TO ENABLE THE PHARMACY AND THERAPEUTICS
30 COMMITTEE TO CONSIDER THE NEED TO RECOMMEND A FORMULARY CHANGE
31 TO A PURCHASER IN A TIMELY MANNER BUT AT LEAST ANNUALLY.

32 (D) THE COMMISSIONER MAY CONSIDER A PHARMACY AND
33 THERAPEUTICS COMMITTEE OF A PHARMACY BENEFITS MANAGER AS HAVING
34 MET THE REQUIREMENTS OF SUBSECTIONS (B) AND (C) OF THIS SECTION IF THE

1 PHARMACY BENEFITS MANAGER HAS OBTAINED ACCREDITATION FROM AN
2 ACCREDITING ORGANIZATION APPROVED BY THE COMMISSIONER.

3 (E) ON REQUEST OF A PURCHASER FOR WHICH THE PHARMACY AND
4 THERAPEUTICS COMMITTEE MAKES RECOMMENDATIONS, A PHARMACY
5 BENEFITS MANAGER SHALL DISCLOSE INFORMATION ABOUT THE COMPOSITION
6 OF ITS PHARMACY AND THERAPEUTICS COMMITTEE TO THE PURCHASER.

7 (F) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A
8 PHARMACIST TO PARTICIPATE ON ITS PHARMACY AND THERAPEUTICS
9 COMMITTEE.

10 (G) ON OR BEFORE APRIL 1, 2009, THE COMMISSIONER SHALL ADOPT
11 REGULATIONS TO IMPLEMENT THIS SECTION.

12 (H) THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING
13 \$5,000 FOR EACH VIOLATION OF THIS SECTION.

14 **Article - Health - General**

15 19-706.

16 (PPP) THE PROVISIONS OF § 15-1601 OF THE INSURANCE ARTICLE APPLY
17 TO HEALTH MAINTENANCE ORGANIZATIONS.

18 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
19 October 1, 2008.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.