

HOUSE BILL 580

J3

(8lr0724)

ENROLLED BILL

—Health and Government Operations/Finance—

Introduced 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**

Read and Examined by Proofreaders:

Proofreader.

Proofreader.

Sealed with the Great Seal and presented to the Governor, for his approval this

_____ day of _____ at _____ o'clock, _____ M.

Speaker.

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; *authorizing the Maryland Insurance*
12 *Commissioner to adopt certain regulations;* making certain provisions of law

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.

Italics indicate opposite chamber / conference committee amendments.



1 applicable to health maintenance organizations; defining certain terms; and
2 generally relating to regulation of pharmacy benefits managers.

3 BY adding to

4 Article – Insurance

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

7 Annotated Code of Maryland

8 (2006 Replacement Volume and 2007 Supplement)

9 BY adding to

10 Article – Health – General

11 Section 19–706(ppp)

12 Annotated Code of Maryland

13 (2005 Replacement Volume and 2007 Supplement)

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

16 **Article – Insurance**

17 **SUBTITLE 16. PHARMACY BENEFITS MANAGERS.**

18 ~~15–1601.~~

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

21 ~~(2) (i) “PHARMACY BENEFITS MANAGEMENT SERVICES”~~
22 ~~MEANS THE ADMINISTRATION OR MANAGEMENT OF PRESCRIPTION DRUG~~
23 ~~BENEFITS.~~

24 ~~(ii) “PHARMACY BENEFITS MANAGEMENT SERVICES”~~
25 ~~INCLUDES:~~

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

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

29 ~~3. ADMINISTRATION OF PAYMENTS RELATED TO~~
30 ~~PRESCRIPTION DRUG CLAIMS; AND~~

31 ~~4. NEGOTIATING OR ENTERING INTO CONTRACTUAL~~
32 ~~ARRANGEMENTS WITH PHARMACY PROVIDERS.~~

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

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

6 ~~(C) THE PROVISIONS OF THIS SECTION DO NOT APPLY TO AN INSURER,~~
7 ~~NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION,~~
8 ~~OR AN AFFILIATE, SUBSIDIARY, OR OTHER RELATED ENTITY OF AN INSURER,~~
9 ~~NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE ORGANIZATION~~
10 ~~ACTING OR REPRESENTING ITSELF AS A PHARMACY BENEFITS MANAGER IF:~~

11 ~~(1) THE INSURER, NONPROFIT HEALTH SERVICE PLAN, OR~~
12 ~~HEALTH MAINTENANCE ORGANIZATION OR THE AFFILIATE, SUBSIDIARY, OR~~
13 ~~OTHER RELATED ENTITY OF THE INSURER, NONPROFIT HEALTH SERVICE PLAN,~~
14 ~~OR HEALTH MAINTENANCE ORGANIZATION DIRECTLY OFFERS OR PROVIDES~~
15 ~~PHARMACY BENEFITS MANAGEMENT SERVICES; AND~~

16 ~~(2) THE PHARMACY BENEFITS MANAGEMENT SERVICES ARE~~
17 ~~OFFERED OR PROVIDED ONLY TO ENROLLEES, SUBSCRIBERS, OR INSUREDS~~
18 ~~WHO ALSO ARE COVERED BY HEALTH BENEFITS OFFERED OR PROVIDED BY THE~~
19 ~~INSURER, NONPROFIT HEALTH SERVICE PLAN, OR HEALTH MAINTENANCE~~
20 ~~ORGANIZATION.~~

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

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

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

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

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

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

31 ~~(2) HAVE A FINANCIAL INTEREST IN A PHARMACEUTICAL~~
32 ~~MANUFACTURER, OTHER THAN OWNERSHIP OF A NOMINAL NUMBER OF SHARES~~

~~1 OF THE PHARMACEUTICAL MANUFACTURER'S STOCK, PURCHASED ON A
2 NATIONAL SECURITIES EXCHANGE.~~

~~3 (F) (1) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A
4 PHARMACY TO PARTICIPATE IN A PHARMACY AND THERAPEUTICS COMMITTEE.~~

~~5 (2) IF A PHARMACY AGREES TO PARTICIPATE IN A PHARMACY
6 AND THERAPEUTICS COMMITTEE, THE PHARMACY BENEFITS MANAGER SHALL
7 REIMBURSE ANY EXPENSES INCURRED BY THE PHARMACY AS A RESULT OF ITS
8 PARTICIPATION.~~

9 15-1601.

10 (A) IN THIS SUBTITLE THE FOLLOWING WORDS HAVE THE MEANINGS
11 INDICATED.

12 (B) "BENEFICIARY" MEANS AN INDIVIDUAL WHO RECEIVES
13 PRESCRIPTION DRUG COVERAGE OR BENEFITS FROM A PURCHASER.

14 (C) "ERISA" HAS THE MEANING STATED IN § 8-301 OF THIS ARTICLE.

15 (D) "FORMULARY" MEANS A LIST OF PRESCRIPTION DRUGS USED BY A
16 PURCHASER.

17 (E) "NONPROFIT HEALTH MAINTENANCE ORGANIZATION" HAS THE
18 MEANING STATED IN § 6-121(A) OF THIS ARTICLE.

19 (F) (1) "PHARMACY BENEFITS MANAGEMENT SERVICES" MEANS:

20 (I) THE PROCUREMENT OF PRESCRIPTION DRUGS AT A
21 NEGOTIATED RATE FOR DISPENSATION WITHIN THE STATE TO BENEFICIARIES;

22 (II) THE ADMINISTRATION OR MANAGEMENT OF
23 PRESCRIPTION DRUG COVERAGE PROVIDED BY A PURCHASER FOR
24 BENEFICIARIES; AND

25 (III) ANY OF THE FOLLOWING SERVICES PROVIDED WITH
26 REGARD TO THE ADMINISTRATION OF PRESCRIPTION DRUG COVERAGE:

27 1. MAIL SERVICE PHARMACY;

28 2. CLAIMS PROCESSING, RETAIL NETWORK
29 MANAGEMENT AND PAYMENT OF CLAIMS TO PHARMACIES FOR PRESCRIPTION
30 DRUGS DISPENSED TO BENEFICIARIES;

1 **3. CLINICAL FORMULARY DEVELOPMENT AND**
2 **MANAGEMENT SERVICES;**

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

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

6 **6. DISEASE MANAGEMENT PROGRAMS.**

7 **(2) "PHARMACY BENEFITS MANAGEMENT SERVICES" DOES NOT**
8 **INCLUDE ANY SERVICE PROVIDED BY A NONPROFIT HEALTH MAINTENANCE**
9 **ORGANIZATION THAT OPERATES AS A GROUP MODEL, PROVIDED THAT THE**
10 **SERVICE:**

11 **(I) IS PROVIDED SOLELY TO A MEMBER OF THE NONPROFIT**
12 **HEALTH MAINTENANCE ORGANIZATION; AND**

13 **(II) IS FURNISHED THROUGH THE INTERNAL PHARMACY**
14 **OPERATIONS OF THE NONPROFIT HEALTH MAINTENANCE ORGANIZATION.**

15 **(G) "PHARMACY BENEFITS MANAGER" MEANS A PERSON THAT**
16 **PERFORMS PHARMACY BENEFITS MANAGEMENT SERVICES.**

17 **(H) "PHARMACY AND THERAPEUTICS COMMITTEE" MEANS A**
18 **COMMITTEE ESTABLISHED BY A PHARMACY BENEFITS MANAGER TO:**

19 **(1) OBJECTIVELY APPRAISE AND EVALUATE PRESCRIPTION**
20 **DRUGS; AND**

21 **(2) MAKE RECOMMENDATIONS TO A PURCHASER REGARDING THE**
22 **SELECTION OF DRUGS FOR THE PURCHASER'S FORMULARY.**

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

26 **(I) PROVIDES PRESCRIPTION DRUG COVERAGE OR**
27 **BENEFITS IN THE STATE; AND**

28 **(II) ENTERS INTO AN AGREEMENT WITH A PHARMACY**
29 **BENEFITS MANAGER FOR THE PROVISION OF PHARMACY BENEFITS**
30 **MANAGEMENT SERVICES.**

1 **(2) "PURCHASER" DOES NOT INCLUDE A PERSON THAT PROVIDES**
2 **PRESCRIPTION DRUG COVERAGE OR BENEFITS THROUGH PLANS SUBJECT TO**
3 **ERISA AND DOES NOT PROVIDE PRESCRIPTION DRUG COVERAGE OR BENEFITS**
4 **THROUGH INSURANCE, UNLESS THE PERSON IS A MULTIPLE EMPLOYER**
5 **WELFARE ~~ASSOCIATION~~ ARRANGEMENT AS DEFINED IN § 514(B)(6)(A)(II) OF**
6 **ERISA.**

7 **15-1602.**

8 **(A) A PHARMACY AND THERAPEUTICS COMMITTEE ESTABLISHED BY A**
9 **PHARMACY BENEFITS MANAGER SHALL MEET THE REQUIREMENTS OF THIS**
10 **SECTION.**

11 **(B) (1) A PHARMACY AND THERAPEUTICS COMMITTEE SHALL:**

12 **(I) INCLUDE CLINICAL SPECIALISTS THAT REPRESENT THE**
13 **NEEDS OF A PURCHASER'S BENEFICIARIES; AND**

14 **(II) INCLUDE AT LEAST ONE PRACTICING PHARMACIST AND**
15 **ONE PRACTICING PHYSICIAN WHO ARE INDEPENDENT OF ANY DEVELOPER OR**
16 **MANUFACTURER OF PRESCRIPTION DRUGS.**

17 **(2) EACH MEMBER OF A PHARMACY AND THERAPEUTICS**
18 **COMMITTEE SHALL SIGN A CONFLICT OF INTEREST STATEMENT UPDATED AT**
19 **LEAST ANNUALLY DISCLOSING ANY ECONOMIC INTEREST OR RELATIONSHIP**
20 **THAT COULD INFLUENCE THE PHARMACY AND THERAPEUTICS COMMITTEE'S**
21 **DECISIONS.**

22 **(3) A MAJORITY OF THE MEMBERS OF A PHARMACY AND**
23 **THERAPEUTICS COMMITTEE SHALL BE PRACTICING PHYSICIANS OR**
24 **PRACTICING PHARMACISTS.**

25 **(C) A PHARMACY BENEFITS MANAGER SHALL ENSURE THAT ITS**
26 **PHARMACY AND THERAPEUTICS COMMITTEE HAS:**

27 **(1) POLICIES AND PROCEDURES, INCLUDING DISCLOSURE**
28 **REQUIREMENTS, TO ADDRESS POTENTIAL CONFLICTS OF INTEREST THAT**
29 **MEMBERS OF THE PHARMACY AND THERAPEUTICS COMMITTEE MAY HAVE WITH**
30 **DEVELOPERS OR MANUFACTURERS OF PRESCRIPTION DRUGS;**

31 **(2) A PROCESS TO EVALUATE MEDICAL AND SCIENTIFIC**
32 **EVIDENCE CONCERNING THE SAFETY AND EFFECTIVENESS OF PRESCRIPTION**
33 **DRUGS, INCLUDING AVAILABLE COMPARATIVE INFORMATION ON CLINICALLY**

1 SIMILAR PRESCRIPTION DRUGS, WHEN DECIDING WHAT PRESCRIPTION DRUGS
2 TO RECOMMEND TO INCLUDE ON A FORMULARY;

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

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

10 (D) THE COMMISSIONER MAY CONSIDER A PHARMACY AND
11 THERAPEUTICS COMMITTEE OF A PHARMACY BENEFITS MANAGER AS HAVING
12 MET THE REQUIREMENTS OF SUBSECTIONS (B) AND (C) OF THIS SECTION IF THE
13 PHARMACY BENEFITS MANAGER HAS OBTAINED ACCREDITATION FROM AN
14 ACCREDITING ORGANIZATION APPROVED BY THE COMMISSIONER.

15 (E) ON REQUEST OF A PURCHASER FOR WHICH THE PHARMACY AND
16 THERAPEUTICS COMMITTEE MAKES RECOMMENDATIONS, A PHARMACY
17 BENEFITS MANAGER SHALL DISCLOSE INFORMATION ABOUT THE COMPOSITION
18 OF ITS PHARMACY AND THERAPEUTICS COMMITTEE TO THE PURCHASER.

19 (F) A PHARMACY BENEFITS MANAGER MAY NOT REQUIRE A
20 PHARMACIST TO PARTICIPATE ON ITS PHARMACY AND THERAPEUTICS
21 COMMITTEE.

22 ~~(G) ON OR BEFORE APRIL 1, 2009, THE~~ THE ~~COMMISSIONER SHALL~~
23 ~~MAY~~ ADOPT REGULATIONS TO IMPLEMENT THIS SECTION SUBTITLE.

24 ~~(H) THE COMMISSIONER MAY ASSESS A CIVIL PENALTY NOT EXCEEDING~~
25 ~~\$5,000 FOR EACH VIOLATION OF THIS SECTION.~~

26 **Article - Health - General**

27 19-706.

28 (PPP) ~~THE PROVISIONS OF § 15-1601~~ TITLE 15, SUBTITLE 16 OF THE
29 INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

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